Use these links to rapidly review the document
TABLE OF CONTENTS
INDEX TO FINANCIAL STATEMENTS EAGLE PHARMACEUTICALS, INC.

Table of Contents

As confidentially submitted to the Securities and Exchange Commission on December 17, 2013. This draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Eagle Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**2834**	**20-8179278**
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

50 Tice Boulevard, Suite 315
Woodcliff Lake, NJ 07677
(201) 326-5300
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Scott Tarriff
Chief Executive Officer
Eagle Pharmaceuticals, Inc.
50 Tice Boulevard, Suite 315
Woodcliff Lake, NJ 07677
(201) 326-5300
(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

Copies to:

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Approximate date of commencement of proposed sale to the public:
As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (the "Securities Act"), check the following box. o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer o	Non-accelerated filer ☒	Smaller reporting company o

(Do not check if a
smaller reporting company)

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price[(1)]	Amount of registration fee
Common Stock, $0.001 par value per share	$	$

(1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act. Includes the offering price of shares that the underwriters have the option to purchase to cover over-allotments, if any.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

Table of Contents

The information in this prospectus is not complete and may be changed. We may not sell these securities until the Securities and Exchange Commission declares our registration statement effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

**Subject to completion, dated , **

Shares

EAGLE PHARMACEUTICALS, INC.

Common Stock

$ per share

- Eagle Pharmaceuticals, Inc. is offering shares.
- We anticipate that the initial public offering price will be between $ and $ per share.
- This is our initial public offering and no public market exists for our shares.
- Proposed trading symbol: EGRX

This investment involves risk. See "Risk Factors" beginning on page 10.

We are an "emerging growth company" as defined by the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

	Per Share	Total
Public offering price	$	$
Underwriting discount[(1)]	$	$
Proceeds, before expenses, to Eagle Pharmaceuticals, Inc.	$	$

(1) We refer you to "Underwriting" beginning on page 158 of this prospectus for additional information regarding underwriting compensation.

The underwriters have a 30-day option to purchase up to additional shares of common stock from us.

Neither the Securities and Exchange Commission nor any state securities commission has approved of anyone's investment in these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Piper Jaffray **William Blair**

Cantor Fitzgerald

The date of this prospectus is , .

TABLE OF CONTENTS

	Page
Prospectus Summary	1
Risk Factors	10
Special Note Regarding Forward-Looking Statements	51
Use of Proceeds	53
Dividend Policy	54
Capitalization	55
Dilution	57
Selected Financial Data	59
Management's Discussion and Analysis of Financial Condition and Results of Operations	60
Business	72
Management	112
Executive and Director Compensation	121
Certain Relationships and Related Party Transactions	139
Principal Stockholders	143
Description of Capital Stock	146
Shares Eligible for Future Sale	152
Material U.S. Federal Income and Estate Tax Consequences to Non-U.S. Holders of Our Common Stock	154
Underwriting	158
Legal Matters	166
Experts	166
Where You Can Find More Information	166
Index to the Consolidated Financial Statements	F-1

We have not authorized anyone to provide you with different information, and we take no responsibility for any other information others may give you. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the front of this prospectus.

Dealer Prospectus Delivery Obligation

Through and including , 2014 (25 days after the commencement of this offering), all dealers that buy, sell or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus. Because it is only a summary, it does not contain all of the information that you should consider before investing in shares of our common stock and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in this prospectus. You should read the entire prospectus carefully, especially "Risk Factors" and our financial statements and the related notes, before deciding to buy shares of our common stock. Unless the context requires otherwise, references in this prospectus to "Eagle," "Eagle Pharmaceuticals," "we," "us" and "our" refer to Eagle Pharmaceuticals, Inc.

Overview

We are a specialty pharmaceutical company focused on developing and commercializing injectable products utilizing the FDA's 505(b)(2) regulatory pathway. We develop products that address the shortcomings, as identified by physicians, pharmacists and other stakeholders, of existing commercially successful injectable products. Our currently disclosed product portfolio includes two approved products and six advanced product candidates that together account for approximately $4 billion in peak U.S. branded reference drug sales. For each of our products, we intend to enter the market no later than the first generic drug, allowing us to substantially convert the market to our product while maintaining attractive pricing. We believe we can further extend the commercial duration of our products through new intellectual property protection and/or orphan drug exclusivity and three years of regulatory exclusivity as provided under the Hatch-Waxman Act, as applicable. We believe our strategy has been validated with the approval of our first product, EP-1101, a proprietary version of argatroban, which was approved by the FDA in June 2011. EP-1101 entered the market prior to the first generic version of argatroban and has captured a 28%, and growing, share of the overall argatroban market while maintaining attractive pricing.

Two of our most advanced product candidates are proprietary presentations of bendamustine, which is currently marketed by Teva Pharmaceuticals, or Teva, under the brand name Treanda and indicated for the treatment of certain hematologic cancers. Bendamustine had 2012 U.S. branded sales of over $600 million, and based on recent market research we anticipate sales to continue to grow substantially in 2013 and 2014, and we estimate that sales could reach $800 million in 2015. We believe our proprietary bendamustine products, EP-3101 and EP-3102, are improved products compared to Teva's Treanda because they are ready to dilute, or RTD, liquids with longer stability and also offer the potential for shorter infusion time. These attributes result in added benefits to nurses, patients and pharmacists, and improved economics to physicians and other stakeholders. Our NDA for EP-3101 was filed with the FDA on September 6, 2013 and we believe EP-3101 will enter the market prior to generic competition and will capture a significant portion of the bendamustine market, as has been the case for our argatroban product.

Our currently disclosed product portfolio also includes proprietary innovations of Alimta, Angiomax, and Dantrium (dantrolene), which together represent $3.4 billion in U.S. peak branded drug sales. Our orphan drug designated version of dantrolene (Ryanodex) is formulated to require substantially less volume and shorter reconstitution time when treating malignant hyperthermia, a hyperacute situation where time to treatment is of critical importance. We believe these formulation characteristics afford us

the unique ability to treat exertional heat stroke, for which there are no currently approved drugs, and therefore represents a major unmet market opportunity.

Product	U.S. Branded Reference Drug	2012 U.S. Branded Sales[(1)]	Status
EP-3101 (bendamustine RTD)	Treanda	$608 million	NDA submitted
EP-3102 (bendamustine short infusion time)	Treanda	$608 million	In pivotal clinical trials
Ryanodex (dantrolene)	Dantrium/ Revonto	$20 million	NDA submission expected by end of 2013; orphan drug designation received
EP-4104 (dantrolene)	No drug currently approved	N/A	Orphan drug designation received for heat stroke
EP-6101 (bivalirudin)	Angiomax	$502 million	Type C meeting with the FDA completed in the fourth quarter of 2013
EP-5101 (pemetrexed)	Alimta	$1,122 million	Formulation work complete
EP-1101 (argatroban)	Argatroban	$99 million	Approved (US); marketed by The Medicines Company and Sandoz
EP-2101 (topotecan)	Hycamtin	$25 million	Approved (EU); not marketed; no current plans to commercialize in the U.S.

(1) Based on publicly filed reports with the SEC, independent market research and management's estimates extrapolated therefrom.

Our Strengths

We believe our competitive strengths include our:

- currently disclosed portfolio which includes two approved products and six distinct product candidates in development that target an overall U.S. market of approximately $4 billion in peak annual branded reference drug revenue;
- knowledge of the industry, including our ability to optimize products' ease and safety of use for healthcare providers, produce less drug waste and lower cost to stakeholders; and our experience with the 505(b)(2) regulatory pathway, and our ability to navigate paragraph IV challenges;
- differentiated business model as compared to generic and branded specialty pharmaceutical drug companies, which we believe has been validated by our first approval and commercial launch in the United States of our novel formulation of argatroban, EP-1101, utilizing the 505(b)(2) pathway;
- patent estate of eight owned or exclusively licensed U.S. issued patents and eleven filed U.S. patent applications, as well as several patent applications that have been filed in various worldwide territories, that protect or will protect, as applicable the market value of our current portfolio of products;

- ability to leverage our formulation and development expertise to avoid infringing existing patents; and

- senior management team, which has over 100 years of combined experience in building and running leading pharmaceutical companies including our President and Chief Executive Officer, Scott Tarriff, who spearheaded the most successful product introductions in Par Pharmaceuticals' history.

Our Strategy

- **Take advantage of the 505(b)(2) regulatory pathway in order to enter the market no later than the first generic drug.** We intend to enter the market no later than the first generic of the branded reference drug. During this period, the number of competitors is lowest and branded drugs are generally at peak or near peak value. This will allow us to influence usage patterns and market our products as improved versions in terms of potential for longer stability, shorter infusion time, less waste and/or ease and safety of use for healthcare professionals, thereby achieving favorable pricing. Even if we enter the market simultaneously with, or after, the first generic drug, as a 505(b)(2) applicant, we would be able to enter the market without regard to any generic drug's 180-day exclusivity period.

- **Retain commercial rights in the United States and selectively partner outside of the United States.** We believe that we can cost-effectively commercialize our products in the United States and thereby retain full commercial value of these products. We plan to establish a small, specialty sales force that will focus on group purchasing organizations, hospital systems and key stakeholders in acute care settings, primarily hospitals and infusion centers.

- **Strengthen our product portfolio.** We intend to continue to strengthen our product portfolio in the areas of oncology, critical care and orphan diseases. We will continue to develop our current product portfolio and leverage our expertise to identify new products with suboptimal characteristics that present us with significant opportunity for revenue generation. In addition to our internal efforts, we will opportunistically in-license or acquire product candidates that fit our therapeutic areas of focus and meet our rigorous evaluation process.

- **Continue to build our robust intellectual property portfolio.** We are the owner or exclusive licensee of a patent estate consisting primarily of formulation and method-of-use patents. We intend to continue to build our patent portfolio by filing for patent protection on new developments with respect to product candidates that will not infringe patents that cover the branded reference drugs. We expect these patents will, if issued, allow us to list our own patents in the Orange Book, which will offer us the potential to trigger our own 30-month stay under the Hatch-Waxman Act against future 505(b)(2) and ANDA filers that reference our drugs, if approved.

Our Market Opportunity

We believe there is a large and unmet market need for improved injectable drugs that address the specific needs of patients, physicians, nurses, and pharmacists to simplify their use, reduce waste, increase shelf life and lower healthcare costs.

Based on market data, we estimate that the U.S. generic injectable industry reported approximately $7.0 billion in sales in 2012 and grew at a compound annual growth rate of 17% over the last five

years. Based on industry data, we believe that the U.S. generic injectable market will continue to grow at a compound annual growth rate of 11.6% due to several factors, including (i) label expansion for approved products increasing the patient pool for such products, (ii) a pipeline of injectable medications at various stages of clinical development, and (iii) the increasing incidence of certain diseases that necessarily utilize injectable medications such as cancer and autoimmune disorders.

Selected Risk Factors

Risks Associated with Our Business

Our business is subject to numerous risks, as more fully described in the section entitled "Risk Factors" immediately following this prospectus summary. You should read these risks before you invest in our common stock. We may be unable, for many reasons, including those that are beyond our control, to implement our business strategy.

These risks include, but are not limited to, the following:

- we have incurred significant losses in the past and may not be able to achieve or sustain profitability in the future;
- our independent registered public accounting firms have expressed substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing;
- we are heavily dependent on the success of our lead product candidates EP-3101 (bendamustine RTD), EP-3102 (bendamustine short infusion time), Ryanodex (dantrolene for malignant hyperthermia, or MH) and EP-4104 (dantrolene for exertional heat stroke, or EHS);
- if the FDA does not conclude that our product candidates satisfy the requirements for the 505(b)(2) regulatory approval pathway, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in any case may not be successful;
- the regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed;
- an NDA submitted under Section 505(b)(2) subjects us to the risk that we may be subject to a patent infringement lawsuit that would delay or prevent the review or approval of our product candidate;
- a competitor may obtain, or may have obtained as in the case of bendamustine, orphan drug exclusivity, thereby precluding us from commercializing our product for the same indication for up to seven years, plus an additional six months for pediatric exclusivity, as applicable, unless we show superior safety or efficacy, or qualify under certain other limited exceptions;
- if we are unable to achieve and maintain adequate levels of coverage and reimbursement for our products or product candidates, if approved, their commercial success may be severely hindered;

- we rely on third parties to conduct preclinical studies and manufacture commercial supplies and any disruptions in those relationships could have a material adverse effect on our business;
- we operate in a very competitive business environment and if we are unable to compete successfully against our existing or potential competitors, our sales and operating results may be negatively affected and we may not grow;
- if we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue;
- if we or our sales representatives fail to comply with U.S. federal and state fraud and abuse laws, we could be subject to civil and criminal penalties, which could adversely impact our reputation and business operations; and
- if we are unable to protect our intellectual property rights, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.

Corporate Information

We were incorporated in Delaware in January 2007. Our principal executive offices are located at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677, and our telephone number is (201) 326-5300. Our corporate website address is www.eagleus.com. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

This prospectus contains references to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenue of at least $1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeded $700.0 million as of the prior March 31st, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We refer to the Jumpstart Our Business Startups Act of 2012 herein as the "JOBS Act" and references herein to "emerging growth company" shall have the meaning associated with it in the JOBS Act.

THE OFFERING

Shares of common stock offered by us	shares
Shares of common stock to be outstanding after this offering	shares (of which % will be held by non-affiliates)
Option to purchase additional shares	shares
Use of proceeds	We intend to use the net proceeds from this offering for research and development expenses, to expand U.S. and international sales and marketing efforts, for working capital and other general corporate purposes, including for costs and expenses associated with being a public company. See "Use of Proceeds."
Proposed Nasdaq Global Market symbol	"EGRX"
Risk factors	You should read the "Risk Factors" section of this prospectus for a discussion of certain of the factors to consider carefully before deciding to purchase any shares of our common stock.

The number of shares of our common stock to be outstanding after this offering is based on 67,536,286 shares of common stock outstanding as of September 30, 2013 excluding:

- 5,213,133 shares of common stock issuable upon the exercise of outstanding stock options as of September 30, 2013, under our 2007 Incentive Compensation Plan, or 2007 Plan, at a weighted average exercise price of $0.87 per share;
- 1,756,701 shares of common stock reserved for future grant or issuance under the 2007 Plan as of September 30, 2013; provided however, that in connection with this offering, the 2007 Plan will be terminated so that no further awards may be granted under the 2007 Plan;
- An estimated shares of common stock issuable upon conversion of the preferred stock issuable upon the net exercise of preferred stock warrants that were outstanding as of September 30, 2013, at a weighted-average exercise price of $1.82 per share, assuming an initial public offering price of $ per share, (the midpoint of the price range set forth on the cover page of this prospectus);
- shares of common stock reserved for future issuance under our 2014 Equity Incentive Plan, or the 2014 Plan, which will become effective as of the date of the effectiveness of this registration statement; and
- shares of common stock reserved for future issuance under our 2014 Employee Stock Purchase Plan, or the ESPP, which will become effective as of the date of the effectiveness of this registration statement.

Unless otherwise indicated, all information contained in this prospectus assumes:

- the conversion of all our outstanding preferred stock into an aggregate of 47,997,673 shares of common stock in connection with the closing of this offering;

- no exercise by the underwriters of their option to purchase up to an additional shares of our common stock;
- the filing of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws immediately prior to the closing of this offering; and
- a one-for- reverse stock split of our common stock to be effected prior to the closing of this offering.

We refer to our Series A, Series B, Series B-1 and Series C preferred stock collectively as "preferred stock" in this prospectus, as well as for financial reporting purposes and in the financial tables included in this prospectus. We refer to our outstanding warrants to purchase shares of our Series C preferred stock issued in August and September of 2012 as "preferred stock warrants" in this prospectus.

SUMMARY FINANCIAL DATA

The following table summarizes certain of our financial data. We derived the summary statement of operations data for the fiscal years ended September 30, 2013 and 2012 from our audited financial statements and related notes appearing elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future. The summary financial data should be read together with our financial statements and related notes, "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this prospectus.

	Fiscal Year ended September 30,	
	2013	2012
Total revenue	$ 13,678,903	$ 2,539,402
Operating expenses:		
Cost of revenue	7,380,825	3,166,593
Research and development	9,795,542	12,804,684
Marketing, general and administrative	4,957,660	6,398,863
Total operating expenses	22,134,027	22,370,140
Loss from operations	(8,455,124)	(19,830,738)
Total other income/(expense), net	1,507,948	(333,164)
Loss before income tax benefit	(6,947,176)	(20,163,902)
Income tax benefit	898,703	781,261
Net loss	$ (6,048,473)	$ (19,382,641)
Less dividends to Series A, B, B-1 and C		
Convertible Preferred Stock	(3,836,777)	(3,933,425)
Net loss attributable to common stockholders	$ (9,885,250)	$ (23,316,066)
Basic and diluted net loss per common share[1]	$ (0.51)	$ (2.20)
Basic and diluted weighted average shares of common stock outstanding[1]	19,514,110	10,595,166

(1) See Note 3 of our Notes to Financial Statements appearing elsewhere in this prospectus for an explanation of the method used to calculate the basic and diluted net loss per common share and the number of shares used in the computation of the per share amounts.

	As of September 30, 2013		
	Actual	Pro Forma[1]	Pro Forma as Adjusted[2][3]
Balance Sheet Data			
Cash and cash equivalents	$ 10,455,565		
Working capital (deficit)	$ 3,140,602		
Total assets	$ 18,102,620		
Convertible Preferred Stock	$ 89,983,000		
Accumulated deficit	$ (102,136,057)		
Total stockholders' deficit	$ (87,929,014)		

(1) Pro forma amounts reflect the conversion of (i) all our outstanding shares of preferred stock as of September 30, 2013 into an aggregate of 47,997,673 shares of our common stock and (ii) the issuance of shares of common stock upon conversion of the preferred shares issuable upon the net exercise of outstanding warrants that would otherwise expire upon the completion of this offering assuming an initial offering price of $ per share (the midpoint of the price range set forth on the cover page of this prospectus).

(2) Pro forma as adjusted amounts reflect the pro forma conversion adjustments described in footnote (1) above, as well as the sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share (the mid-point of the range set forth on the cover page of this prospectus), and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(3) A $1.00 increase (decrease) in the assumed initial public offering price would increase (decrease) each of the cash, cash equivalents and marketable securities, working capital, total assets and total stockholders' deficit by $, $, $ and $, respectively, assuming the number of shares offered by us as stated on the cover page of this prospectus remains unchanged and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, a share increase (decrease) in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) each of cash, cash equivalents and marketable securities, working capital, total assets and total stockholders' deficit by $, $, $ and $, respectively, assuming the assumed initial public offering price of $ per share (the mid-point of the price range set forth on the cover page of this prospectus) remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

RISK FACTORS

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this prospectus, before deciding to invest in our common stock. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future growth prospects. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Financial Condition and Need for Additional Capital

We have incurred significant losses since our inception and we will continue to incur significant losses for the foreseeable future and may never be profitable.

We have a limited operating history. To date, we have focused primarily on developing a broad product portfolio and have obtained regulatory approval for two products. Some of our product candidates will require substantial additional development time and resources before we would be able to receive regulatory approvals, implement commercialization strategies and begin generating revenue from product sales. We may not generate significant revenue from sales of our product candidates in the near-term, if ever. We have incurred significant net losses of $6.0 million and $19.4 million for the years ended September 30, 2013 and 2012, respectively. As of September 30, 2013, we had an accumulated deficit of $102.1 million.

We have devoted most of our financial resources to product development. To date, we have financed our operations primarily through the sale of equity and debt securities. The size of our future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenue. To date, only EP-1101 (argatroban) has been commercialized, and if our product candidates are not successfully developed or commercialized, or if revenue is insufficient following marketing approval, we will not achieve profitability and our business may fail. Even if we successfully obtain regulatory approval to market our product candidates in the United States, our revenue is also dependent upon the size of the markets outside of the United States, as well as our ability to obtain market approval and achieve commercial success in those jurisdictions.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to fully predict the timing or amount of our expenses, but we expect to continue to incur substantial expenses, which we expect to increase as we expand our development activities and product portfolio. As a result of the foregoing, we expect to continue to incur significant and increasing losses and negative cash flows for the foreseeable future, which may increase compared to past periods. We believe that the net proceeds from this offering and our existing cash and cash equivalents, together with interest thereon, may only be sufficient to fund our operations through the third quarter of fiscal year 2015.

If we fail to obtain additional financing, we would be forced to delay, reduce or eliminate our product development programs.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect our development expenses to substantially increase in connection with our ongoing activities, particularly as we advance our clinical programs.

We estimate that the net proceeds from this offering will be approximately $ million, assuming an initial public offering price of $ per share (the mid-point of the price range set forth on the cover page of this prospectus) and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Regardless of our expectations as to how long our net proceeds from this offering will fund our operations, changing circumstances beyond our control may

cause us to consume capital more rapidly than we currently anticipate. For example, our product development efforts could encounter technical or other difficulties that could increase our development costs more than we expect. In any event, we may require additional capital prior to obtaining regulatory approval for, or commercializing, any of our product candidates.

In addition, attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back or discontinue the development or commercialization of our product candidates;
- seek corporate partners for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- relinquish or license on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves; or
- significantly curtail, or cease, operations.

The occurence of any of these factors could have a material adverse effect on our business, operating results and prospects.

We may sell additional equity or incur debt to fund our operations, which may result in dilution to our stockholders and impose restrictions on our business.

In order to raise additional funds to support our operations, we may sell additional equity or incur debt, which could adversely impact our stockholders, as well as our business. The sale of additional equity or convertible debt securities would result in the issuance of additional shares of our capital stock and dilution to all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

We may not have enough available cash or be able to raise additional funds on satisfactory terms, if at all, through equity or debt financings to repay our indebtedness at the time any such repayment is required (causing a default under such indebtedness), which could have a material adverse effect on our business, financial condition and results of operations.

Our short operating history makes it difficult to evaluate our business and prospects.

We were incorporated in and have only been conducting operations since 2007. Our operations to date have been limited to developing and bringing to market a limited number of products and developing our other product candidates. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing a significant number of pharmaceutical products.

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.

Our independent registered public accounting firm stated that our financial statements for the fiscal years ended September 30, 2013 and 2012 were prepared assuming that we would continue as a going

concern, and that certain matters raise substantial doubt about our ability to continue as a going concern. Such doubts are based on our recurring net losses, accumulated deficit and deficiency in working capital. We continue to experience losses. Our ability to continue as a going concern is subject to our ability to generate a profit and/or obtain necessary funding from outside sources, including by the sale of common stock in this offering, or obtaining loans from financial institutions or other financing arrangements. Our continued losses and "going concern" audit reports increase the difficulty of our meeting such goals and our efforts to continue as a going concern may not prove successful notwithstanding this offering.

Risks Related to Regulatory Approval

We are heavily dependent on the success of our lead product candidates EP-3101 (bendamustine RTD), EP-3102 (bendamustine short infusion time), Ryanodex (dantrolene for MH) and EP-4104 (dantrolene for EHS). We cannot give any assurance that we will receive regulatory approval for such product candidates, which is necessary before they can be commercialized.

Our business and future success are substantially dependent on our ability to successfully and timely develop, obtain regulatory approval for, and commercialize our lead product candidates EP-3101 (bendamustine RTD), EP-3102 (bendamustine short infusion time), Ryanodex (dantrolene for MH) and EP-4104 (dantrolene for EHS). Any delay or setback in the development of any of these product candidates could adversely affect our business. Our planned development, approval and commercialization of these product candidates may fail to be completed in a timely manner or at all. Our other product candidates, EP-6101 (bivalirudin) and EP-5101 (pemetrexed), are at an earlier development stage and it will require additional time and resources to develop and seek regulatory approval for such product candidates and, if we are successful, to proceed with commercialization. We cannot provide assurance that we will be able to obtain approval for any of our product candidates from the FDA or any foreign regulatory authority or that we will obtain such approval in a timely manner. For example, in August 2009, we submitted our product EP-2101 (topotecan) for approval in the United States under the 505(b)(2) regulatory pathway, referencing the brand product, Hycamtin. Ultimately, the FDA determined that it could not approve the application as submitted due to the amount of active drug per vial in our product and the potential for unintentional overdose. Based on the FDA's feedback and our determination that the market for topotecan had become overly competitive with multiple players, we decided not to continue to pursue product approval and we do not currently have plans to commercialize EP-2101 (topotecan) in the United States.

If the FDA does not conclude that our product candidates satisfy the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of any of our product candidates under Section 505(b)(2) are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.

We intend to seek FDA approval through the 505(b)(2) regulatory pathway for each of our product candidates described in this prospectus. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act, or FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant.

If the FDA does not allow us to pursue the 505(b)(2) regulatory pathway for our product candidates as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates would likely substantially increase. Moreover, the inability to pursue the 505(b)(2) regulatory pathway could result

in new competitive products reaching the market faster than our product candidates, which could materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the 505(b)(2) regulatory pathway for a product candidate, we cannot assure you that we will receive the requisite or timely approvals for commercialization of such product candidate.

In addition, we expect that our competitors will file citizens' petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development.

Clinical testing, even when utilizing the 505(b)(2) pathway, is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process, even with active ingredients that have previously been approved by the FDA as safe and effective. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later stage clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

Our product candidates are in various stages of development, from early stage to late stage. Clinical trial failures may occur at any stage and may result from a multitude of factors both within and outside our control, including flaws in formulation, adverse safety or efficacy profile and flaws in trial design, among others. If the trials result in negative or inconclusive results, we or our collaborators may decide, or regulators may require us, to discontinue trials of the product candidates or conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. For these reasons, our future clinical trials may not be successful.

We do not know whether any future clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If any product candidate for which we are conducting clinical trials is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it. If we are unable to bring any of our current or future product candidates to market, our business would be materially harmed and our ability to create long-term stockholder value will be limited.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and could jeopardize or delay our ability to obtain regulatory approval and commence product sales. We may also find it difficult to enroll patients in our clinical trials, which could delay or prevent development of our product candidates.

We may experience delays in clinical trials of our product candidates. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including:

- inability to raise or delays in raising funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;

- imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, or failure by such CROs to carry out the clinical trial at each site in accordance with the terms of our agreements with them;
- delays in obtaining required institutional review board, or IRB, approval at each site;
- difficulties or delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites electing to terminate their participation in one of our clinical trials, which would likely have a detrimental effect on subject enrollment;
- time required to add new clinical sites; or
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

If initiation or completion of our planned clinical trials is delayed for any of the above reasons or other reasons, our development costs may increase, our regulatory approval process could be delayed and our ability to commercialize and commence sales of our product candidates could be materially harmed, which could have a material adverse effect on our business.

In addition, identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates as well as completion of required follow-up periods. We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics or to complete our clinical trials in a timely manner. Patient enrollment is and completion of the trials is affected by factors including:

- severity of the disease under investigation;
- design of the trial protocol;
- size of the patient population;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under trial;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

Our products or product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance, or result in significant negative consequences following marketing approval, if any.

As with many pharmaceutical and biological products, treatment with our products or product candidates may produce undesirable side effects or adverse reactions or events. Although the nature of our products or product candidates as containing active ingredients that have already been approved means that the side effects arising from the use of the active ingredient or class of drug in our products or product candidates is generally known, our products or product candidates may still cause

undesireable side effects. These could be attributed to the active ingredient or class of drug or to our unique formulation of such products or product candidates, or other potentially harmful characteristics. Such characteristics could cause us, our IRBs, clinical trial sites, the FDA or other regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay, denial or withdrawal of regulatory approval, which may harm our business, financial condition and prospects significantly.

Further, if any of our products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution;
- the FDA may require implementation of a Risk Evaluation and Mitigation Strategy, or REMS;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical studies;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or product candidate and could substantially increase the costs of commercializing our products and product candidates.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. To date we have obtained regulatory approval for one product in the United States and one product in Europe, but it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval in the United States or other jurisdictions.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree that our changes to branded reference drugs meet the criteria for the 505(b)(2) regulatory pathway or foreign regulatory pathways;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective or comparable to its branded reference product for its proposed indication;

- the results of any clinical trials we conduct may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change significantly in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would harm our business, results of operations and prospects significantly.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could harm the commercial prospects for our product candidates.

We have limited experience using the 505(b)(2) regulatory pathway to submit an NDA or any similar drug approval filing to the FDA, and we cannot be certain that any of our product candidates will receive regulatory approval. For example, we obtained FDA approval for our product EP-1101 (argatroban) using the 505(b)(2) regulatory pathway, but, after discussions with the FDA, we decided not to continue pursuing FDA approval of our product EP-2101 (topotecan). The FDA determined that it could not approve the application as submitted due to the amount of active drug per vial in our product and the potential for unintentional overdose. Based on the FDA's feedback and our determination that the market for topotecan had become overly competitive with multiple players, we decided not to continue to pursue product approval and we do not currently have plans to commercialize EP-2101 (topotecan) in the United States. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such products, if approved.

An NDA submitted under Section 505(b)(2) subjects us to the risk that we may be subject to a patent infringement lawsuit that would delay or prevent the review or approval of our product candidate.

Our product candidates will be submitted to the FDA for approval under Section 505(b)(2) of the FDCA. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies that were not conducted by, or for, the applicant and on which the applicant has not obtained a right of reference. The 505(b)(2) application would enable us to reference published literature and/or the FDA's previous findings of safety and effectiveness for the branded reference drug. For NDAs submitted under Section 505(b)(2) of the FDCA, the patent certification and related provisions of the Hatch-Waxman Act apply. In accordance with the Hatch-Waxman Act, such NDAs may be required to include certifications, known as paragraph IV

certifications, that certify that any patents listed in the Patent and Exclusivity Information Addendum of the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, with respect to any product referenced in the 505(b)(2) application, are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505(b)(2) NDA.

Under the Hatch-Waxman Act, the holder of patents that the 505(b)(2) application references may file a patent infringement lawsuit after receiving notice of the paragraph IV certification. Filing of a patent infringement lawsuit against the filer of the 505(b)(2) applicant within 45 days of the patent owner's receipt of notice triggers a one-time, automatic, 30-month stay of the FDA's ability to approve the 505(b)(2) NDA, unless patent litigation is resolved in the favor of the paragraph IV filer or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all. In addition, a 505(b)(2) application will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, or NCE, listed in the Orange Book for the referenced product has expired. The FDA may also require us to perform one or more additional clinical studies or measurements to support the change from the branded reference drug, which could be time consuming and could substantially delay our achievement of regulatory approvals for such product candidates. The FDA may also reject our future 505(b)(2) submissions and require us to file such submissions under Section 505(b)(1) of the FDCA, which would require us to provide extensive data to establish safety and effectiveness of the drug for the proposed use and could cause delay and be considerably more expensive and time consuming. These factors, among others, may limit our ability to successfully commercialize our product candidates.

Companies that produce branded reference drugs routinely bring litigation against abbreviated new drug application, or ANDA, or 505(b)(2) applicants that seek regulatory approval to manufacture and market generic and reformulated forms of their branded products. These companies often allege patent infringement or other violations of intellectual property rights as the basis for filing suit against an ANDA or 505(b)(2) applicant. Likewise, patent holders may bring patent infringement suits against companies that are currently marketing and selling their approved generic or reformulated products. We filed an application with the FDA for our EP-3101 (bendamustine RTD) product candidate through the 505(b)(2) regulatory pathway on September 6, 2013, referencing Teva's Treanda product, including a paragraph IV certification stating our belief that our bendamustine product will not infringe Teva's patents on Treanda. We notified Teva of our 505(b)(2) filing and paragraph IV certification, and Teva filed a patent infringement lawsuit against us in the United States District Court for the District of Delaware on October 21, 2013. Teva's filing of the lawsuit invoked a 30-month stay of FDA approval of our bendamustine product, which will delay the FDA from approving EP-3101 (bendamustine RTD) until the earlier of the March 2016 expiration of the 30-month stay imposed by the Hatch-Waxman Act, or such time as the district court enters judgment in our favor or otherwise acts to shorten the stay. Moreover, regardless of when the 30-month stay is resolved or expires, the FDA may still be prohibited from approving our 505(b)(2) NDA due to Teva's unexpired orphan drug and related pediatric exclusivities for Treanda. Specifically, Teva has received orphan drug and pediatric exclusivity expiring in September 2015 and May 2016 for the CLL and NHL indications (as defined in "Business—Our Products and Product Portfolio"), respectively. When a drug, such as Treanda, has orphan drug exclusivity, the FDA may not approve any other application to market the same drug for the same indication for a period of up to seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. In the United States, pediatric exclusivity adds six months to any existing exclusivity period. If we cannot demonstrate that EP-3101 is clinically superior to Treanda, or qualify under certain other limited exceptions, we will not

be able to enter the market for the CLL indication until September 2015 (assuming the 30-month stay is resolved by that time) or the NHL indication until May 2016.

Litigation to enforce or defend intellectual property rights is often complex and often involves significant expense and can delay or prevent introduction or sale of our product candidates. If patents are held to be valid and infringed by our product candidates in a particular jurisdiction, we would, unless we could obtain a license from the patent holder, be required to cease selling in that jurisdiction and may need to relinquish or destroy existing stock in that jurisdiction. There may also be situations where we use our business judgment and decide to market and sell our approved products, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts, which is known as an "at-risk launch." The risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement may include, among other things, damages measured by the profits lost by the patent owner and not necessarily by the profits earned by the infringer. In the case of a willful infringement, the definition of which is subjective, such damages may be increased up to three times. Moreover, because of the discount pricing typically involved with bioequivalent and, to a lesser extent, 505(b)(2), products, patented branded products generally realize a substantially higher profit margin than bioequivalent and, to a lesser extent, 505(b)(2), products, resulting in disproportionate damages compared to any profits earned by the infringer. An adverse decision in patent litigation could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If we are found to have improperly promoted off-label uses of our products or product candidates, if approved, we may become subject to significant liability. Such enforcement has become more common in the industry. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for our product candidates for our proposed indications, physicians may nevertheless use our products for their patients in a manner that is inconsistent with the approved label, if the physicians personally believe in their professional medical judgment it could be used in such manner. However, if we are found to have promoted our products for any off-label uses, the federal government could levy civil, criminal and/or administrative penalties, and seek fines against us. The FDA or other regulatory authorities could also request that we enter into a consent decree or a corporate integrity agreement, or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Our business is subject to extensive regulatory requirements and our approved product and product candidates that obtain regulatory approval will be subject to ongoing and continued regulatory review, which may result in significant expense and limit our ability to commercialize such products.

Even after a product is approved, we will remain subject to ongoing FDA and other regulatory requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, import, export, record-keeping and reporting of safety and other post-market information. The holder of an approved NDA is obligated to monitor and report adverse events, or AEs, and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the

approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. In addition, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. For example, a product's approval may contain requirements for potentially costly post-approval studies and surveillance to monitor the safety and efficacy of the product, or the imposition of a REMS program.

Manufacturers of drug products and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, and adherence to commitments made in the NDA. If we or a regulatory agency discovers previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring product recall, notice to physicians, withdrawal of the product from the market or suspension of manufacturing.

If we or our products or product candidates or our manufacturing facilities fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters asserting that we are in violation of the law;
- impose restrictions on the marketing or manufacturing of the product;
- seek an injunction or impose civil, criminal and/or administrative penalties, damages, assess monetary fines, require disgorgement, consider exclusion from participation in Medicare, Medicaid and other federal healthcare programs and require curtailment or restructuring of our operations;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA submitted by us;
- seize product; or
- refuse to allow us to enter into government contracts.

Similar postmarket requirements may apply in foreign jurisdictions in which we may seek approval of our products. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenues.

In addition, the FDA's regulations, policies or guidance may change and new or additional statutes or government regulations in the United States and other jurisdictions may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. For example, the Food and Drug Administration Safety and Innovation Act, or FDASIA, requires the FDA to issue new guidance on permissible forms of internet and social media promotion of regulated medical products, and the FDA may soon specify new restrictions on this type of promotion. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our products and/or product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct that violates (1) the laws of the United States FDA and similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulatory bodies; (2) healthcare fraud and abuse laws of the United States and similar foreign fraudulent misconduct laws; and (3) laws requiring the reporting of financial information or data accurately. Specifically, the promotion, sales and marketing of health care items and services, as well as certain business arrangements in the healthcare industry are subject to extensive laws designed to prevent misconduct, including fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. It is not always possible to identify and deter employee and other third-party misconduct. The precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws. If any such actions are instituted against us, and we are not successful in defending ourselves, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Any relationships with healthcare professionals, principal investigators, consultants, customers (actual and potential) and third party payors are and will continue to be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, marketing expenditure tracking and disclosure, or sunshine laws, government price reporting and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face penalties, including, without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations.

Our business operations and activities may be directly, or indirectly, subject to various federal, state and local fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as proposed and future sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by the federal government, state governments and foreign jurisdictions in which we conduct our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in

whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other third party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;

- the federal Physician Payment Sunshine Act, created under Section 6002 of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, ACA, and its implementing regulations requires manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members, with data collection required beginning August 1, 2013 and reporting to the Centers for Medicare & Medicaid Services required by March 31, 2014 and by the 90th day of each subsequent calendar year;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- federal government price reporting laws, changed by ACA to, among other things, increase the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program and offer such rebates to additional populations, that require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on our marketed drugs. Participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs and potentially limit our ability to offer certain marketplace discounts;

- the Foreign Corrupt Practices Act, a United States law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals); and

- state law equivalents of each of the above federal laws, such as anti-kickback, false claims, consumer protection and unfair competition laws which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third party payors, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers; state laws that require drug manufacturers to file reports with states regarding marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative effect on our business and/or increase enforcement scrutiny of our activities); and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, with differing effects.

In addition, any sales of our products or product candidates once commercialized outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to, without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

We are required to obtain regulatory approval for each of our products in each jurisdiction in which we intend to market such products, and the inability to obtain such approvals would limit our ability to realize their full market potential.

In order to market products outside of the United States, we must comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. However, the failure to obtain regulatory approval in one jurisdiction may adversely impact our ability to obtain regulatory approval in another jurisdiction. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional non-clinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. If we fail to comply with regulatory requirements in international

markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

If we fail to develop, acquire or in-license other product candidates or products, our business and prospects will be limited.

Our long-term growth strategy is to develop and commercialize a portfolio of product candidates in addition to our existing product candidates. We may also acquire or in-license such product candidates. Although we have internal research and development capacity that we believe will enable us to make improvements to existing compounds or active ingredients, we do not have internal drug discovery capabilities to identify and develop entirely new chemical entities or compounds. As a result, our primary means of expanding our pipeline of product candidates is to develop improved formulations and delivery methods for existing FDA-approved products and/or select and acquire or in-license product candidates for the treatment of therapeutic indications that complement or augment our current targets, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Developing new formulations of existing products or identifying, selecting and acquiring or in-licensing promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual development, acquisition or in-license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. If we are unable to add additional product candidates to our pipeline, our long-term business and prospects will be limited.

Risks Related to Commercialization of Our Products and Product Candidates

Our commercial success depends upon attaining significant market acceptance of our products and product candidates, if approved, among physicians, nurses, pharmacists, patients and the medical community.

Even if we obtain regulatory approval for our product candidates, our product candidates may not gain market acceptance among physicians, nurses, pharmacists, patients, the medical community or third party payors, which is critical to commercial success. Market acceptance of our products and any product candidate for which we receive approval depends on a number of factors, including:

- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- the convenience and ease of administration to patients of the product candidate;
- the potential and perceived advantages of such product candidate over alternative treatments;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- the availability of coverage and adequate reimbursement and pricing by third party payors and government authorities;
- relative convenience and ease of administration;
- any negative publicity related to our or our competitors' products that include the same active ingredient;

- the prevalence and severity of adverse side effects, including limitations or warnings contained in a product's FDA-approved labeling; and
- the effectiveness of sales and marketing efforts.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be known until after it is launched. If our products or product candidates, if approved, fail to achieve an adequate level of acceptance by physicians, nurses, pharmacists, patients and the medical community, we will be unable to generate significant revenues, and we may not become or remain profitable.

Guidelines and recommendations published by government agencies can reduce the use of our product candidates.

Government agencies promulgate regulations and guidelines applicable to certain drug classes which may include our products and product candidates that we are developing. Recommendations of government agencies may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Regulations or guidelines suggesting the reduced use of certain drug classes which may include our products and product candidates that we are developing or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of our product candidates or negatively impact our ability to gain market acceptance and market share.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

Although we intend to establish a small, focused, specialty sales and marketing organization to promote any approved products in the United States, we currently have no such organization or capabilities, and the cost of establishing and maintaining such an organization may exceed the benefit of doing so. Eagle has no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We also intend to enter into strategic partnerships with third parties to commercialize our product candidates outside of the United States. We may have difficulty establishing relationships with third parties on terms that are acceptable to us, or in all of the regions where we wish to commercialize our products, or at all. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If any of our product candidates are approved for commercialization, we may enter into agreements with third parties to market these products, as well as argatroban, outside the United States. We expect that we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;

- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

If we are unable to differentiate our product candidates from branded reference drugs or existing generic therapies for the similar treatments, or if the FDA or other applicable regulatory authorities approve generic products that compete with any of our product candidates, the ability to successfully commercialize our product candidates would be adversely affected.

Our strategy is to have our drugs enter the market no later than the first generic to the applicable branded reference drug. We expect to compete against branded reference drugs and to compete with their generic counterparts that will be sold for a lower price. Although we believe that our product candidates will be clinically differentiated from branded reference drugs and their generic counterparts, if any, it is possible that such differentiation will not impact our market position. If we are unable to achieve significant differentiation for our product candidates against other drugs, the opportunity for our product candidates to achieve premium pricing and be commercialized successfully would be adversely affected.

In addition to existing branded reference drugs and the related generic products, the FDA or other applicable regulatory authorities may approve generic products that compete directly with our product candidates, if approved. Once an NDA, including a 505(b)(2) application, is approved, the product covered thereby becomes a "listed drug" which can, in turn, be cited by potential competitors in support of approval of an ANDA. The FDCA, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as our product candidate and that the generic product is bioequivalent to ours, meaning it is absorbed in the body at the same rate and to the same extent as our product candidate. These generic equivalents, which must meet the same quality standards as branded pharmaceuticals, would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product is typically lost to the generic product. Accordingly, competition from generic equivalents of our product candidates would materially adversely impact our ability to successfully commercialize our product candidates.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We expect to have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. For example, argatroban is currently marketed in the United States by, among others, GlaxoSmithKline, or GSK, and West-Ward Pharmaceuticals, or West-Ward, under the brand name Argatroban and bendamustine is marketed in the United States by Teva Pharmaceuticals under the brand name Treanda. Further, makers of branded reference drugs could also enhance their own formulations in a manner that competes with our enhancements of these drugs. Teva has obtained approval for a ready to dilute, or RTD, version of Treanda which will compete with our EP-3101 (bendamustine RTD) product. We expect the Treanda RTD product to enter the market before December 31, 2013. We filed a submission for our EP-3101 (bendamustine RTD) product with the FDA on September 6, 2013, including a paragraph IV certification of non-infringement of Teva's patents covering its Treanda product. We notified Teva of our 505(b)(2) filing and paragraph IV certification, and Teva filed a patent infringement lawsuit against us in the United States District Court for the District of Delaware on October 21, 2013. Teva's filing of the lawsuit invoked a 30-month stay of FDA approval of our bendamustine product, which will delay the FDA from approving EP-3101 (bendamustine RTD) until the earlier of the March 2016 expiration of the 30-month stay imposed by the Hatch-Waxman Act, or such time as the district court enters judgment in our favor or otherwise acts to shorten the stay. Moreover, regardless of when the 30-month stay is resolved or expires, the FDA may still be prohibited from approving our 505(b)(2) NDA due to Teva's unexpired orphan drug and related pediatric exclusivities for Treanda. Specifically, Teva has received orphan drug and pediatric exclusivity expiring in September 2015 and May 2016 for the CLL and NHL indications (as defined in "Business—Our Products and Product Portfolio"), respectively. When a drug, such as Treanda, has orphan drug exclusivity, the FDA may not approve any other application to market the same drug for the same indication for a period of up to seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. In the United States, pediatric exclusivity adds six months to any existing exclusivity period. If we cannot demonstrate that EP-3101 is clinically superior to Treanda, or qualify under certain other limited exceptions, we will not be able to enter the market for the CLL indication until September 2015 (assuming the 30-month stay is resolved by that time) or the NHL indication until May 2016.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products or drug delivery technologies that are more effective or less costly than argatroban or any product candidate that we are currently developing or that we may develop. In addition, our competitors may file citizens' petitions with the FDA in an attempt to pursuade the FDA that our products, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

We believe that our ability to successfully compete will depend on, among other things:

- the efficacy and safety of our products and product candidates, including as relative to marketed products and product candidates in development by third parties;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- the ability to maintain a good relationship with regulatory authorities;
- the ability to commercialize and market any of our product candidates that receive regulatory approval;
- the price of our products, including in comparison to branded or generic competitors;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;
- the ability to protect intellectual property rights related to our products and product candidates;
- the ability to manufacture on a cost-effective basis and sell commercial quantities of our products and product candidates that receive regulatory approval; and
- acceptance of any of our products and product candidates that receive regulatory approval by physicians and other healthcare providers.

If our competitors market products that are more effective, safer or less expensive than our product candidates, if any, or that reach the market sooner than our product candidates, if any, we may enter the market too late in the cycle and may not achieve commercial success. In addition, the biopharmaceutical industry is characterized by rapid technological change. Because we have limited research and development capabilities, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

We could incur substantial costs and disruption to our business and delays in the launch of our product candidates if our competitors and/or collaborators bring legal actions against us, which could harm our business and operating results.

We cannot predict whether our competitors or potential competitors, some of whom we collaborate with, may bring legal actions against us based on our research, development and commercialization activities, as well as any product candidates or products resulting from these activities, claiming, among other things, infringement of their intellectual property rights, breach of contract or other legal theories. If we are forced to defend any such lawsuits, whether they are with or without merit or are ultimately determined in our favor, we may face costly litigation and diversion of technical and management personnel. These lawsuits could hinder our ability to enter the market early with our product candidates and thereby hinder our ability to influence usage patterns when fewer, if any, of our potential competitors have entered such market, which could adversely impact our potential revenue from such product candidates. Some of our competitors have substantially greater resources than we do and could be able to sustain the cost of litigation to a greater extent and for longer periods of time than we could. Furthermore, an adverse outcome of a dispute may require us: to pay damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed a party's patent or other intellectual property rights; to cease making, licensing or using products that are alleged to incorporate or make use of the intellectual property of others; to expend additional development resources to reformulate our products or prevent us from marketing a certain

drug; and to enter into potentially unfavorable royalty or license agreements in order to obtain the rights to use necessary technologies. Royalty or licensing agreements, if required, may be unavailable on terms acceptable to us, or at all.

If we are unable to achieve and maintain adequate levels of coverage and reimbursement for our products or product candidates, if approved, their commercial success may be severely hindered.

Successful sales of our products and any other approved product candidates depend on the availability of adequate coverage and reimbursement from third party payors. Patients who are prescribed medications for the treatment of their conditions generally rely on third party payors to reimburse all or part of the costs associated with their prescription drugs. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Assuming we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for EP-1101 (argatroban) and our product candidates will depend significantly on access to third party payors' drug formularies, or lists of medications for which third party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access through formulary controls or otherwise to a branded drug when a less costly generic equivalent or other alternative is available.

Third party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy requirement for coverage and reimbursement for drug products exists among third party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third party coverage and reimbursement for our product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Recently enacted and future legislation may increase the difficulty and cost for us to commercialize our product candidates and affect the prices we may obtain.

The United States and some foreign jurisdictions are considering, or have enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products and our product candidates profitably, once they are approved for sale. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs,

improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

In March 2010, the ACA was enacted, which includes measures that have or will significantly change the way healthcare is financed by both governmental and private insurers. Among the ACA provisions of importance to the pharmaceutical industry are the following:

- an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs that began in 2011;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- new methodologies by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and for drugs that are line extensions;
- changes to the Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing manufacturers' Medicaid rebate liability;
- new requirements under the federal Physician Payment Sunshine Act for reporting by manufacturers of drugs, devices, biologicals and medical supplies of information related to payments or other transfers of value made or distributed to physicians and teaching hospitals, as well as certain investment interests;
- a new requirement to annually report drug samples that manufacturers and distributors provide to licensed practitioners or to pharmacies of hospitals or other health care entities, effective April 1, 2012;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute changes, new government investigative powers and enhanced penalties for noncompliance;
- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and

- creation of the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs.

In addition, other legislative changes have been proposed and adopted since ACA was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals for spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The full impact of these new laws, as well as laws and other reform measures that may be proposed and adopted in the future remains uncertain, but may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and, accordingly, our financial operations.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third party CROs to monitor and manage data for our preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with FDA laws and regulations regarding current good clinical practice, or GCP, which are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Conference on Harmonization, or ICH, guidelines for all of our products in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. While we have agreements governing activities of our CROs, we have limited influence over their actual performance. In addition, portions of the clinical trials for our product candidates are expected to be conducted outside of the United States, which will make it more difficult for us to monitor CROs and perform visits of our clinical trial sites and will force us to rely heavily on CROs to ensure the proper and timely conduct of our clinical trials and compliance with applicable regulations, including GCP. Failure to comply with applicable regulations in the conduct of the clinical trials for our product candidates may require us to repeat clinical trials, which would delay the regulatory approval process.

Some of our CROs have an ability to terminate their respective agreements with us if, among other reasons, it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely on third parties to manufacture commercial supplies of argatroban and clinical supplies of our product candidates, and we intend to rely on third parties to manufacture commercial supplies of any other approved products. The commercialization of any of our products could be stopped, delayed or made less profitable if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices or fail to maintain or achieve satisfactory regulatory compliance.

We do not own any manufacturing facilities, and we do not currently, and do not expect in the future, to independently conduct any aspects of our product manufacturing and testing, or other activities related to the clinical development and commercialization of our product candidates. We currently rely, and expect to continue to rely, on third parties with respect to these items, and control only certain aspects of their activities.

Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it could delay our product candidate development and commercialization activities. Our reliance on these third parties reduces our control over these activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards and any applicable trial protocols. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we will not be able to complete, or may be delayed in completing, clinical trials required to support future regulatory submissions and approval of our product candidates.

Our products and product candidates are highly reliant on very complex sterile techniques and personnel aseptic techniques. The facilities used by our third-party manufacturers to manufacture our products and product candidates must be approved by the applicable regulatory authorities pursuant to inspections that will be conducted after we submit our NDA to the FDA. If any of our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the

applicable regulatory authorities' strict regulatory requirements, or pass regulatory inspection, they will not be able to secure or maintain regulatory approval for the manufacturing facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Quality problems in manufacturing are linked to a majority of shortages of sterile injectable drugs. Some of the largest manufacturers of sterile injectable drugs have had serious quality problems leading to the temporary voluntary closure or renovations of major production facilities. Further, as we scale up manufacturing of our product candidates and conduct required stability testing, product, packaging, equipment and process-related issues may require refinement or resolution in order for us to proceed with our planned clinical trials and obtain regulatory approval for commercialization of our product candidates. In the future, for example, we may identify impurities in the product manufactured for us for commercial supply, which could result in increased scrutiny by the regulatory agencies, delays in our clinical program and regulatory approval, increases in our operating expenses, or failure to obtain or maintain approval for our product candidates. If the FDA or any other applicable regulatory authority does not approve these facilities for the manufacture of our products or if they withdraw any such approval in the future, or if our suppliers or third-party manufacturers decide they no longer want to manufacture our products, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our products or product candidates.

More generally, manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to make product candidates available for clinical trials and development purposes or to further commercialize argatroban or commercialize any of our other product candidates in the United States would be jeopardized. Any delay or interruption in our ability to meet commercial demand may result in the loss of potential revenues and could adversely affect our ability to gain market acceptance for approved products. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. Regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

The occurence of any of these factors could have a material adverse effect on our business, results of operations, financial condition and prospects.

The design, development, manufacture, supply, and distribution of our product candidates is highly regulated and technically complex.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP and equivalent foreign standards. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational

products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. The development, manufacture, supply, and distribution of EP-1101 (argatroban), as well as our other product candidates, is highly regulated and technically complex. We, along with our third-party providers, must comply with all applicable regulatory requirements of the FDA and foreign authorities.

We, or our contract manufacturers, must supply all necessary documentation in support of our regulatory filings for our product candidates on a timely basis and must adhere to the FDA's good laboratory practices, or GLP, and cGMP regulations enforced by the FDA through its facilities inspection program, and the equivalent standards of the regulatory authorities in other countries. Any failure by our third-party manufacturers to comply with cGMP or failure to scale-up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must also pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities in any country may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities and quality systems do not pass a pre-approval plant inspection, FDA approval of our product candidates, or the equivalent approvals in other jurisdictions, will not be granted.

Regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or biological product or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be materially harmed.

We rely on limited sources of supply for argatroban and for our product candidates, and any disruption in the chain of supply may impact production and sales of argatroban and cause delay in developing and commercializing our product candidates.

We currently have relationships with only one third party for the manufacture of each of our most advanced product candidates and for our commercial supply of argatroban. These include development relationships with Zydus BSV Pharma Pvt. Ltd. for our EP-3101 (bendamustine RTD) product and AAIPharma Services Corp. for our dantrolene product and a supply agreement with Cipla Limited for supply of argatroban product to The Medicines Company and Sandoz under their agreements with us for commercialization of argatroban. Because of the unique equipment and process for manufacturing argatroban, transferring manufacturing activities for argatroban to an alternate supplier would be a time-consuming and costly endeavor, and there are only a limited number of manufacturers that we believe are capable of performing this function for us. Switching finished drug suppliers may involve substantial cost and could result in a delay in our desired clinical and commercial timelines. If any of

these single-source manufacturers breaches or terminates their agreements with us, we would need to identify an alternative source for the manufacture and supply of product candidates to us for the purposes of our development and commercialization of the applicable products. Identifying an appropriately qualified source of alternative supply for any one or more of these product candidates could be time consuming, and we may not be able to do so without incurring material delays in the development and commercialization of our product candidates, which could harm our financial position and commercial potential for our products. Any alternative vendor would also need to be qualified through an NDA supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if we appoint a new manufacturer for supply of our product candidates that differs from the manufacturer used for clinical development of such product candidates. For our other product candidates, we expect that only one supplier will initially be qualified as a vendor with the FDA. If supply from the approved vendor is interrupted, there could be a significant disruption in commercial supply.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of components and active pharmaceutical ingredient on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

We may not be successful in establishing development and commercialization collaborations which could adversely affect, and potentially prohibit, our ability to develop our product candidates.

Because developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products are expensive, we are exploring collaborations with third parties outside of the United States that have more resources and experience. For example, we are exploring selective partnerships with third parties for development and commercialization of our product candidates outside of the United States. We may, however, be unable to advance the development of our product candidates in territories outside of the United States, which may limit the market potential for this product candidate.

In situations where we enter into a development and commercial collaboration arrangement for a product candidate, we may also seek to establish additional collaborations for development and commercialization in territories outside of those addressed by the first collaboration arrangement for such product candidate. There are a limited number of potential partners, and we expect to face competition in seeking appropriate partners. If we are unable to enter into any development and commercial collaborations and/or sales and marketing arrangements on acceptable terms, if at all, we may be unable to successfully develop and seek regulatory approval for our product candidates and/or effectively market and sell future approved products, if any, in all of the territories outside of the United States where it may otherwise be valuable to do so.

We may not be successful in maintaining development and commercialization collaborations, and any partner may not devote sufficient resources to the development or commercialization of our product candidates or may otherwise fail in development or commercialization efforts, which could adversely affect our ability to develop certain of our product candidates and our financial condition and operating results.

Even if we are able to establish collaboration arrangements, any such collaboration may not ultimately be successful, which could have a negative impact on our business, results of operations, financial condition and prospects. If we partner with a third party for development and commercialization of a

product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. It is possible that a partner may not devote sufficient resources to the development or commercialization of our product candidate or may otherwise fail in development or commercialization efforts, in which event the development and commercialization of such product candidate could be delayed or terminated and our business could be substantially harmed. In addition, the terms of any collaboration or other arrangement that we establish may not prove to be favorable to us or may not be perceived as favorable, which may negatively impact the trading price of our common stock. In some cases, we may be responsible for continuing development of a product candidate or research program under a collaboration, and the payment we receive from our partner may be insufficient to cover the cost of this development. Moreover, collaborations and sales and marketing arrangements are complex and time consuming to negotiate, document and implement, and they may require substantial resources to maintain.

We are subject to a number of additional risks associated with our dependence on collaborations with third parties, the occurrence of which could cause our collaboration arrangements to fail. Conflicts may arise between us and our partners, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. If any such conflicts arise, a partner could act in its own self-interest, which may be adverse to our interests. Any such disagreement between us and a partner could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates and harm our business:

- reductions in the payment of royalties or other payments we believe are due pursuant to the applicable collaboration arrangement;
- actions taken by a partner inside or outside our collaboration which could negatively impact our rights or benefits under our collaboration; and
- unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities.

If we are unable to maintain our group purchasing organization, or GPO, relationships, our revenues could decline and future profitability could be jeopardized.

Most of the end-users of injectable pharmaceutical products have relationships with GPOs whereby such GPOs provide such end-users access to a broad range of pharmaceutical products from multiple suppliers at competitive prices and, in certain cases, exercise considerable influence over the drug purchasing decisions of such end-users. Hospitals and other end-users contract with the GPO of their choice for their purchasing needs. We currently derive, and expect to continue to derive, a large percentage of our revenue from end-user customers that are members of a small number of GPOs. Maintaining strong relationships with these GPOs will require us to continue to be a reliable supplier, remain price competitive and comply with FDA regulations. The GPOs with whom we have relationships may have relationships with companies that sell competing products, and such GPOs may earn higher margins from these products or combinations of competing products or may prefer products other than ours for other reasons. If we are unable to maintain our GPO relationships, sales of our products and revenue could decline.

We rely on a limited number of pharmaceutical wholesalers to distribute our products.

As is typical in the pharmaceutical industry, we rely upon pharmaceutical wholesalers in connection with the distribution of our products. A significant amount of our products are sold to end-users under GPO pricing arrangements through a limited number of pharmaceutical wholesalers. If we are

unable to maintain our business relationships with these pharmaceutical wholesalers on commercially acceptable terms, it could have a material adverse effect on our sales and may prevent us from achieving profitability.

Risks Related to Our Business Operations and Industry

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the principal members of our executive team listed under "Management" located elsewhere in this prospectus, the loss of whose services may adversely impact the achievement of our objectives. Any of our executive officers could leave our employment at any time, as all of our employees are "at will" employees. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit key executives or the loss of the services of any executive or key employee might impede the progress of our development and commercialization objectives.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of September 30, 2013, we had a total of 18 full-time employees in the US, two part time employees in the US, and one full time consultant in India. As our company matures, we expect to expand our employee base to increase our managerial, scientific and engineering, operational, sales, marketing, financial and other resources and to hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to sell argatroban and commercialize our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage any future growth.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability.

The use of our product candidates in clinical trials (if any), and the sale of EP-1101 (argatroban) and any product candidates for which we obtain marketing approval, exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with EP-1101 (argatroban), other approved future products and our product candidates. If we cannot successfully

defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical study participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for EP-1101 (argatroban) and our product candidates, if approved for commercial sale.

Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our product development and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of product development or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs and the development of our product candidates could be delayed.

Business interruptions could delay us in the process of developing our product candidates and could disrupt our sales of EP-1101(argatroban).

Our headquarters are located in Woodcliff Lake, New Jersey. If we encounter any disruptions to our operations at this building or if it were to shut down for any reason, including by fire, natural disaster, such as a hurricane, tornado or severe storm, power outage, systems failure, labor dispute or other unforseen disruption, then we may be prevented from effectively operating our business. We do not carry insurance for natural disasters and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations.

We are involved in litigation in which Hikma has alleged breach of an asset purchase agreement entered into between us and Hikma and failure by us to disclose alleged manufacturing product defects. If Hikma prevails in this litigation, we could be required to pay substantial damages to Hikma.

In March 2012, Hikma purchased from us for $3.5 million certain assets relating to a generic drug, diclofenac/misoprostol tablets. That drug was the subject of an ANDA filed by us with the FDA. The ANDA is still pending before the FDA, and we continue to expect it to receive approval. The terms of the sale were set forth in a March, 2012 Asset Purchase Agreement, or Hikma APA. On June 24, 2013, Hikma Pharmaceutical Co., Ltd., or Hikma, filed a lawsuit against us in the United States District Court for the Southern District of New York alleging that we (a) breached the Hikma APA by failing to refund the purchase price following Hikma's purported termination of the Hikma APA as a result of us failing to receive timely ANDA approval, and (b) intentionally failed to disclose alleged manufacturing product defects to Hikma prior to the execution of the Hikma APA. On August 27, 2013, we filed an answer to Hikma's complaint, which denied Hikma's claims, and asserted a counterclaim alleging that Hikma by its actions had repudiated the Hikma APA.

Should Hikma prevail on its claims that we breached the APA or intentionally failed to disclose alleged product defects, we could be required to pay substantial damages, including, but not limited to, the return of the $3.5 million purchase price plus interest and other damages, Hikma's lost profits from being unable to market the drug, and punitive damages. This outcome could result in a material adverse effect on our cash resources. Even if we were to prevail, this litigation could be costly and time-consuming, divert the attention of our management and key personnel from our business operations, which would also materially harm our business. During the course of litigation, we anticipate announcements of the results of hearings and motions, and other interim developments related to the litigation. If securities analysts or investors regard these announcements as negative, the market price of our common stock may decline.

We are vigorously defending these claims and do not believe that Hikma is entitled to damages because Hikma's purported termination violated the terms of the Hikma APA and we believe that the claims of non-disclosure of manufacturing product defects are without merit. Given the early stage in the litigation, we are unable to predict the likelihood of success of Hikma's contract breach and fraud claims.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to any of our product candidates, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and our product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover the products in the U.S. or in foreign countries or territories. If this were to occur, early generic competition could be expected against our products and our product candidates in development. There may be relevant prior art relating to our patents and patent applications which could invalidate a patent or prevent a patent from issuing based on a pending patent application. In particular, because the active pharmaceutical ingredients in many of our product candidates have been on the market as separate products for many years, it is possible that these products have previously been used off-label in such a manner that such prior usage would affect the validity of our patents or our ability to obtain patents based on our patent applications.

Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Any adverse outcome in these types of matters could result in one or more generic versions of our products being launched before the expiration of the listed patents, which could adversely affect our ability to successfully execute our business strategy to increase sales of our products and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the patent applications we hold with respect to our products or product candidates fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop them and threaten our ability to commercialize our product candidates. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will be found not invalid and not unenforceable or will go unthreatened by third parties. Further, if we encounter delays in regulatory approvals, the period of time during which we could market our product candidates under patent protection could be reduced. If third parties have filed such patent applications, an interference proceeding in the United States can be provoked by a third party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug development and reformulation processes that involve proprietary know-how, information or technology that is not covered by patents. For example, we maintain trade secrets with respect to certain of the formulation and manufacturing techniques related to EP-1101 (argatroban) and our product candidates. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all.

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the U.S. and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. For example, on September 16, 2011, the Leahy-Smith

America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office, or USPTO, has developed new and untested regulations and procedures to govern the full implementation of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in March 2013. The Leahy-Smith Act has also introduced procedures making it easier for third-parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy-Smith Act contains new statutory provisions that still require the USPTO to issue new regulations for their implementation and it may take the courts years to interpret the provisions of the new statute. Accordingly, it is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. An inability to obtain, enforce and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance to us, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims in, or the written description or enablement in, a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Our drug development strategy relies heavily upon the 505(b)(2) regulatory pathway, which requires us to certify that we do not infringe upon third-party patents covering approved drugs. Such certifications typically result in third-party claims of intellectual property infringement, the defense of which will be costly and time consuming, and an unfavorable outcome in any litigation may prevent or delay our development and commercialization efforts which would harm our business.

Litigation or other proceedings to enforce or defend intellectual property rights are often complex in nature, may be very expensive and time-consuming, may divert our management's attention from other aspects of our business and may result in unfavorable outcomes that could adversely impact our ability to launch and market our product candidates, or to prevent third parties from competing with our products and product candidates.

There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party reexamination proceedings before the USPTO. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators

are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

In particular, our commercial success depends in large part on our avoiding infringement of the patents and proprietary rights of third parties for existing approved drug products. Because we utilize the 505(b)(2) regulatory pathway for the approval of our products and product candidates, we rely in whole or in part on studies conducted by third parties related to those approved drug products. As a result, upon filing with the FDA for approval of our product candidates, we will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of our proposed drug product. When we submit a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to the patent owner once our 505(b)(2) NDA is accepted for filing by the FDA. The third party may then initiate a lawsuit against us to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving our NDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in our favor. If the third party does not file a patent infringement lawsuit within the required 45-day period, our NDA will not be subject to the 30-month stay.

In addition to paragraph IV litigation noted above, third-party owners of patents may generally assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of EP-1101 (argatroban) and/or our product candidates. Because patent applications can take many years to issue, there may be currently pending or subsequently filed patent applications which may later result in issued patents that may be infringed by our products or product candidates. If any third-party patents were held by a court of competent jurisdiction to cover aspects of our product candidates, including the formulation, method of use, any method or process involved in the manufacture of any of our product candidates, any molecules or intermediates formed during such manufacturing process or any other attribute of the final product itself, the holders of any such patents may be able to block our ability to commercialize our product candidates unless we obtain a license under the applicable patents, or until such patents expire. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may request and/or obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates on a temporary or permanent basis. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products or manufacturing processes, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research, manufacture clinical trial supplies or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third party patents do not exist which might be

enforced against our products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

If we fail to comply with our obligations in the agreements under which we license rights to technology from third parties, or if the license agreements are terminated for other reasons, we could lose license rights that are important to our business.

We are a party to a number of technology licenses that are important to our business and expect to enter into additional licenses in the future. Our existing license agreements impose, and we expect that future license agreements will impose, on us, various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. Additionally, one of our existing license agreements is a sublicense from a third party who is not the original licensor of the intellectual property at issue. Under these agreements, we must rely on our licensor to comply with their obligations under the primary license agreements under which such third party obtained rights in the applicable intellectual property, where we may have no relationship with the original licensor of such rights. If our licensors fail to comply with their obligations under these upstream license agreements, the original third-party licensor may have the right to terminate the original license, which may terminate our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do at a reasonable cost or on reasonable terms, which may impact our ability to continue to develop and commercialize our product candidates and companion diagnostic incorporating the relevant intellectual property. If we fail to comply with our obligations under our license agreements, or we are subject to a bankruptcy or insolvency, the licensor may have the right to terminate the license. In the event that any of our important technology licenses were to be terminated by the licensor, we would likely cease further development of the related program or be required to spend significant time and resources to modify the program to not use the rights under the terminated license.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by

disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

The patents and the patent applications that we have covering our products are limited to specific formulations, methods of use and processes, and our market opportunity for EP-1101 (argatroban) and our product candidates may be limited by the lack of patent protection for the active ingredients and by competition from other formulations and delivery methods that may be developed by competitors.

Patent protection on the active ingredient in argatroban has expired, and there is therefore no composition of matter patent protection available for the active ingredient in EP-1101 (argatroban). This is also the case with respect to our other product candidates. We have obtained, and continue to seek to obtain patent protection of other aspects of EP-1101 (argatroban) and our product candidates, including specific formulations, methods of use and processes, which may not be as effective as composition of matter coverage in preventing work-arounds by competitors. As a result, generic products that do not infringe the claims of our issued patents covering formulations, methods of use and processes are, or may be, available while we are marketing our products. Competitors who obtain the requisite regulatory approval will be able to commercialize products with the same active ingredients as EP-1101 (argatroban) and such other product candidates so long as the competitors do not infringe any process, use or formulation patents that we have developed for our products, subject to any regulatory exclusivity we may be able to obtain for our products.

The number of patents and patent applications covering products containing the same active ingredient as EP-1101 (argatroban) and our product candidates indicates that competitors have sought to develop and may seek to commercialize competing formulations that may not be covered by our patents and patent applications. The commercial opportunity for EP-1101 (argatroban) and our product candidates could be significantly harmed if competitors are able to develop and commercialize alternative formulations of EP-1101 (argatroban) and our product candidates that are different from ours and do not infringe our issued patents covering our products.

EP-1101 (argatroban) has been approved by the FDA, and we anticipate that other product candidates will be approved by the FDA in the future. Once our products are on the market, one or more third parties may also challenge the patents that we control covering our products, which could result in the invalidation or unenforceability of some or all of the relevant patent claims of our issued patents covering our products. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

EP-1101 (argatroban) has been approved by the FDA, and we anticipate that other product candidates will be approved by the FDA in the future. Once our products are on the market, one or more third parties may also challenge the patents that we control covering our products in court or the US PTO, which could result in the invalidation or unenforceability of some or all of the relevant patent claims of our issued patents covering our products.

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering one of our products or product candidates, the defendant could counterclaim that the patent covering our product or product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are common,

and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors that control the prosecution and maintenance of our licensed patents fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates and companion diagnostic. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Risks Related to this Offering and Ownership of Our Common Stock

The market price of our common stock may be highly volatile, and you may not be able to resell your shares at or above the initial public offering price.

The trading price of our common stock is likely to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- any delay in filing an NDA for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA's review of that NDA;
- failure to successfully execute our commercialization strategy with respect to EP-1101 (argatroban) or any other approved product in the future;
- adverse results or delays in clinical trials, if any;
- significant lawsuits, including patent or stockholder litigation;
- inability to obtain additional funding;
- failure to successfully develop and commercialize our product candidates;
- changes in laws or regulations applicable to our product candidates;

- inability to obtain adequate product supply for our product candidates, or the inability to do so at acceptable prices;
- unanticipated serious safety concerns related to the use of EP-1101 (argatroban) or any of our product candidates;
- adverse regulatory decisions;
- introduction of new products or technologies by our competitors;
- failure to meet or exceed product development or financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future; and
- trading volume of our common stock.

In addition, the stock market in general, and The Nasdaq Stock Market, or Nasdaq, in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these listed companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

An active trading market for our common stock may not develop.

Prior to this offering, there has not been a public market for our common stock. Although we have applied to have our common stock listed on Nasdaq, an active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop, you may not be able to sell your shares quickly or at an acceptable price. The initial public offering price for the shares will be determined by negotiations between us and representatives of the underwriters and may not be indicative of prices that will prevail in the trading market.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of September 30, 2013, our executive officers, directors, 5% or greater stockholders and their affiliates beneficially own approximately 82.6% of our voting stock. Based upon the assumed number of shares to be sold in this offering as set forth on the cover page of this prospectus, upon the closing of this offering, that same group will beneficially own approximately % of our outstanding voting stock. Therefore, even after this offering these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of

assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenue of at least $1 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior March 31st, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC, and the Nasdaq have imposed various requirements on public companies. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that required the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the pro forma as adjusted book value (deficit) per share of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of $ per share, based on an assumed initial public offering price of $ per share (the mid-point of the price range set forth on the cover page of this prospectus) and our pro forma as adjusted net tangible book value (deficit) as of September 30, 2013. For more information on the dilution you may suffer as a result of investing in this offering, see "Dilution."

This dilution is due to the substantially lower price paid by our investors who purchased shares prior to this offering as compared to the price offered to the public in this offering and the exercise of stock options granted to our employees. The exercise of any of these options would result in additional dilution. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation.

Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to fall.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock.

Substantially all of our existing stockholders are subject to lock-up agreements with the underwriters of this offering that restrict the stockholders' ability to transfer shares of our common stock for at least 180 days after the date of this prospectus. The lock-up agreements limit the number of shares of common stock that may be sold immediately following the public offering. Subject to certain limitations, including sales volume limitations with respect to shares held by our affiliates, substantially

all of our outstanding shares prior to this offering will become eligible for sale upon expiration of the lock-up period, as calculated and described in more detail in the section of this prospectus entitled "Shares Eligible for Future Sale." In addition, shares issued or issuable upon exercise of options and warrants vested as of the expiration of the lock-up period will be eligible for sale at that time. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock.

Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended, or the Securities Act, subject to the 180-day lock-up arrangement described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Future issuances of our common stock or rights to purchase our common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We intend to register all shares of common stock that we may issue under our stock-based compensation plans. As of September 30, 2013, options to purchase 5,213,133 shares of our common stock at a weighted average exercise price of $0.87 per share were outstanding. Once we register these shares, they can be freely sold in the public market upon issuance, subject to the lock-up agreements and the restrictions imposed under Rule 144 under the Securities Act, which may cause our stockholders to experience additional dilution.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds, including for any of the purposes described in the section of this prospectus entitled "Use of Proceeds," and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three year period, the corporation's ability to use its pre-change net operating loss carryforwards and other prechange tax attributes, such as research tax credits, to offset its post-change income may be limited. We believe that, with our initial public offering, our most recent private placement and other transactions that have occurred over the past three years, we may have

triggered an "ownership change" limitation. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a classified board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. The forward-looking statements are contained principally in the sections entitled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the success, cost and timing of our product development activities and clinical trials;
- our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our ability to obtain funding for our operations;
- our plans to research, develop and commercialize our product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our ability to successfully commercialize our product candidates;
- the rate and degree of market acceptance of our product candidates;
- our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators;
- regulatory developments in the United States and foreign countries;
- the performance of our third-party suppliers and manufacturers;
- the success of competing drugs that are or become available;
- the loss of key scientific or management personnel;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act;
- our use of the proceeds from this offering;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates; and
- our ability to prevent or minimize the effects of paragraph IV patent litigation.

In some cases, you can identify these statements by terms such as "anticipate," "believe," "could," "estimate," "expects," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions. These forward-looking statements reflect our management's beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this prospectus and are subject to risks and uncertainties. We discuss

many of these risks in greater detail under the heading "Risk Factors." Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately $ million (or approximately $ million if the underwriters' option to purchase additional shares is exercised in full) from the sale of the shares of common stock offered by us in this offering, based on an assumed initial public offering price of $ per share (the mid-point of the price range set forth on the cover page of this prospectus), and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) the net proceeds to us from this offering by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, a share increase (decrease) in the number of shares offered by us, as set forth on the cover of this prospectus, would increase (decrease) the net proceeds to us by $, assuming the assumed initial public offering price of $ per share (the mid-point of the price range set forth on the cover of this prospectus) remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations, to create a public market for our common stock and to facilitate our future access to the public equity markets. We intend to use the net proceeds of this offering as follows:

- approximately $ million to continue to invest in our research and development program;
- approximately $ to $ million to continue to expand our U.S. and international sales and marketing efforts; and
- the balance for working capital and general corporate purposes.

We may also use a portion of the net proceeds from this offering to in-license, acquire, or invest in complementary businesses, technologies, products or assets. However we have no current plan, commitments or obligations to do so.

We believe that the net proceeds from this offering and our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations through at least the third quarter of fiscal year 2015.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering, or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors, including our ability to obtain additional financing, the progress, cost and results of our product candidate development programs, including our planned clinical trials, and whether we are able to enter into future collaboration arrangements. As a result, our management will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the net proceeds from this offering.

Pending their use, we plan to invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

CAPITALIZATION

The following table sets forth our cash, cash equivalents and marketable securities, and our capitalization as of September 30, 2013:

- on an actual basis;
- on a pro forma basis, giving effect to (i) the conversion of all our outstanding preferred stock into an aggregate of 47,997,673 shares of our common stock upon the closing of this offering and (ii) the issuance of shares of common stock upon the automatic net exercise of outstanding warrants that would otherwise expire upon the completion of this offering and the related mark-to-market adjustment that will be reflected in accumulated deficit;
- on a pro forma as adjusted basis, reflecting the pro forma adjustments discussed above and giving further effect to the sale by us of shares of our common stock at an assumed initial public offering price of $ per share (the mid-point of the range set forth on the cover of this prospectus), and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma information below is illustrative only and our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this table together with our audited consolidated financial statements and the related notes appearing at the end of this prospectus, the sections entitled "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other financial information contained in this prospectus.

	As of September 30, 2013		
	Actual	Pro Forma (unaudited)	Pro Forma As Adjusted[1]
Cash and cash equivalents	$ 10,455,565	$	$
Convertible preferred stock	89,983,000		
Common stock; $.001 par value: 80,000,000 shares authorized, 19,538,613 shares issued and outstanding, actual; 80,000,000 shares authorized, shares issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted	19,538		
Additional paid in capital	14,187,505		
Accumulated deficit	(102,136,057)		
Total stockholders' equity (deficit)	(87,929,014)		
Total capitalization	$ 2,053,986	$	$

(1) Each $1.00 increase or decrease in the assumed initial public offering price of $ per share would increase or decrease, respectively, the amount of cash, cash equivalents and short-term investments, additional paid-in capital and total capitalization by approximately $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering costs payable by us. Similarly, a share increase (decrease) in the number of shares offered by us, as set forth on the cover of this prospectus, would increase (decrease) the net proceeds to us by $, assuming the assumed initial public offering price of $ per share (the mid-point of the price range set forth on the cover of this prospectus) remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The number of common shares shown as issued and outstanding on a pro forma as adjusted basis in the table is based on the number of shares of our common stock outstanding as of September 30, 2013, and excludes:

- 5,213,133 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2013 under the 2007 Plan at a weighted average exercise price of $0.87 per share;
- 1,756,701 shares of common stock reserved for future grant or issuance under the 2007 Plan as of September 30, 2013; provided however, that in connection with this offering, the 2007 Plan will be terminated so that no further awards may be granted under the 2007 Plan;
- An estimated shares of common stock issuable upon conversion of the preferred stock issuable upon the net exercise of preferred stock warrants that were outstanding as of September 30, 2013, at a weighted-average exercise price of $1.82 per share, assuming an initial public offering price of $ per share (the midpoint of the price range set forth on the cover page of this prospectus);
- shares of common stock reserved for future issuance under the 2014 Plan, which will become effective as of the date of the effectiveness of this registration statement; and
- shares of common stock reserved for issuance under the ESPP, which will become effective as of the date of the effectiveness of this registration statement.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share and the pro forma net tangible book value per share of our common stock after this offering.

Our historical net tangible book value (deficit) as of September 30, 2013 was approximately $( ) million, or $ ( ) per share of common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our liabilities and preferred stock which is not included within equity. Net historical tangible book value (deficit) per share is our historical net tangible book value (deficit) divided by the number of shares of common stock outstanding as of September 30, 2013. Our pro forma net tangible book value (deficit) as of September 30, 2013 was $ million, or $ per share of common stock. Pro forma net tangible book value (deficit) gives effect to the conversion of all of our outstanding preferred stock into an aggregate of 47,997,673 shares of our common stock.

Pro forma as adjusted net tangible book value is our pro forma net tangible book value (deficit), plus the effect of the sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share (the mid-point of the range set forth on the cover of this prospectus), and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. This amount represents an immediate increase in pro forma as adjusted net tangible book value of $ per share to our existing stockholders, and an immediate dilution of $ per share to new investors participating in this offering.

The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share		$
Historical net tangible book value (deficit) per share as of September 30, 2013	$ ( )	
Pro forma increase in net tangible book value per share as of September 30, 2013 attributable to the conversion of preferred stock		
Pro forma net tangible book value per share as of September 30, 2013, before giving effect to this offering		
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution per share to new investors participating in this offering		$

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the mid-point of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value (deficit) per share after this offering by approximately $ per share and the dilution in pro forma per share to investors participating in this offering by approximately $ per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, a share increase (decrease) in the number of shares offered by us, as set forth on the cover of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value (deficit) per share after this offering by approximately $ and the dilution in pro forma per share to investors participating in this offering by approximately $, assuming the assumed initial public offering price of $ per share, which is the mid-point of the price range set forth on the cover of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option in full to purchase additional shares of our common stock in this offering, the pro forma as adjusted net tangible book value will increase to $ per share, representing an immediate increase to existing stockholders of $ per share and an immediate dilution of $ per share to new investors participating in this offering.

The foregoing discussion is based on 67,536,286 shares of common stock outstanding as of September 30, 2013, after giving effect to the conversion of our outstanding preferred shares into an aggregate of 47,997,673 shares of common stock, and excludes:

- 5,213,133 shares of common stock issuable upon the exercise of outstanding stock options under the 2007 Plan as of September 30, 2013 at a weighted average exercise price of $0.87 per share;
- 1,756,701 shares of common stock reserved for future grant or issuance under the 2007 Plan as of September 30, 2013; provided however, that in connection with this offering, the 2007 Plan will be terminated so that no further awards may be granted under the 2007 Plan;
- An estimated shares of common stock issuable upon conversion of the preferred stock issuable upon the net exercise of preferred stock warrants that were outstanding as of September 30, 2013, at a weighted-average exercise price of $1.82 per share, assuming an initial public offering price of $ per share (the midpoint of the price range set forth on the cover page of this prospectus);
- shares of common stock reserved for future issuance under the 2014 Plan, which will become effective as of the date of the effectiveness of this registration statement; and
- shares of common stock reserved for issuance under the ESPP, which will become effective as of the date of the effectiveness of this registration statement.

Effective immediately upon the closing of this offering, an aggregate of shares of our common stock will be reserved for issuance under the 2014 Plan (including shares of common stock reserved for issuance under our 2007 Plan, which shares will be added to the shares reserved under the 2014 Plan upon its effectiveness) and the ESPP. To the extent that any of these options are exercised, new options are issued under our equity incentive plans or we issue additional shares of common stock or other equity or convertible debt securities in the future, there will be further dilution to investors participating in this offering.

SELECTED FINANCIAL DATA

The following selected financial data should be read together with our financial statements and accompanying notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus. The selected financial data in this section is not intended to replace our financial statements and the accompanying notes. Our historical results are not necessarily indicative of our future results. The selected financial data as of September 30, 2013 and 2012 and for the years then ended have been derived from our financial statements included elsewhere in this prospectus.

	Fiscal Year ended September 30,	
Statement of Operations Data	**2013**	**2012**
Product sales	$ 5,314,610	$ 1,155,358
Royalty income	8,364,293	1,384,044
Total revenue	13,678,903	2,539,402
Cost of revenue	7,380,825	3,166,593
Research and development	9,795,542	12,804,684
Selling, general and administrative	4,957,660	6,398,863
Total operating expenses	22,134,027	22,370,140
Loss from operations	(8,455,124)	(19,830,738)
Total other income/(expense), net	1,507,948	(333,164)
Loss before income tax benefit	(6,947,176)	(20,163,902)
Income tax benefit	898,703	781,261
Net loss	$ (6,048,473)	$ (19,382,641)
Less dividends to Series A, B, B-1 and C		
Convertible Preferred Stock	(3,836,777)	(3,933,425)
Net loss attributable to common stockholders	$ (9,885,250)	$ (23,316,066)
Basic and diluted net loss per common share	$ (0.51)	$ (2.20)
Basic and diluted weighted average shares of common stock outstanding	19,514,110	10,595,166

	September 30,	
Balance Sheet Data	**2013**	**2012**
Cash and cash equivalents	$ 10,455,565	$ 5,066,886
Short term investments	$ —	$ 1,500,000
Working capital (deficit)	$ 3,140,602	$ (12,016,562)
Total assets	$ 18,102,620	$ 9,438,048
Convertible Preferred Stock	$ 89,983,000	$ 81,335,894
Accumulated deficit	$ (102,136,057)	$ (95,537,403)
Total stockholders' deficit	$ (87,929,014)	$ (93,433,932)

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes appearing at the end of this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read the "Risk Factors" section of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Business Overview

We are a specialty pharmaceutical company focused on developing and commercializing injectable products utilizing the FDA's 505(b)(2) regulatory pathway. Our business model is to develop proprietary innovations to FDA-approved, injectable drugs that offer longer commercial duration at attractive prices. For each of our products, we intend to enter the market no later than the first generic drug, allowing us to substantially convert the market to our product by addressing the needs of stakeholders who ultimately use our products. We believe we can further extend commercial duration through new intellectual property protection and/or orphan drug exclusivity and three years of regulatory exclusivity as provided under the Hatch-Waxman Act, as applicable.

Since our inception, we have focused on identifying attractive product candidates for our approach under the 505(b)(2) regulatory pathway. As a result, our disclosed product portfolio now includes two approved products and six advanced product candidates. We currently have one commercialized product, EP-1101 (argatroban). Due to limited financial resources, we initially decided to collaborate with a commercial partners in order to commercialize EP-1101 (argatroban)and it is now currently marketed by The Medicines Company and Sandoz Inc. pursuant to separate agreements. As a result of our commercialization strategy, we have been able to minimize certain expenses, but also are required to share revenues from EP-1101 (argatroban) with our commercial partners.

In the future, we intend to commercialize our products independently in the United States, while outside of the United States, we intend to utilize partners for the commercialization of our products. As part of this strategy, we intend to establish a small, specialty sales force that will target group purchasing organizations, hospital groups and key stakeholders in acute care settings, primarily hospitals and infusion centers. We expect the impact on our results of operations of this commercialization strategy will be that we will receive revenue from direct sales, and royalty income, and income from collaborative arrangement will be a less significant part of our revenues. This commercialization strategy will also result in higher infrastructure and selling expenses, along with greater working capital requirements to support this strategy.

For the year ended September 30, 2013, we had revenues of $13.7 million, an increase of $11.1 million as compared to the year ended September 30, 2012 and a net loss of $6.0 million, a reduction in losses of $13.4 million as compared to the year ended September 30, 2012. We expect our revenue to continue to grow over the long term due to the launch of new products.

Financial Operations Overview

Revenues

Revenues include product sales, royalty income and revenue from collaborative arrangements. Revenue results are difficult to predict, and any shortfall in revenue or delay in recognizing revenue could cause operating results to vary significantly from quarter to quarter and year to year.

Product Sales. We recognize revenues from product sales to our commercial partners. Such sales are typically made at little or no profit for resale by our commercial partners.

Royalty Income. We recognize revenue from royalties based on our commercial partners' net sales of products, typically calculated as a percentage of the net selling price, which is net of discounts, returns and allowances incurred by our commercial partners. Royalty Income is recognized as earned in accordance with contract terms when it can be reasonably estimated and collectability is reasonably assured.

Collaborative Arrangements. We recognize revenue from reimbursement received in connection with feasibility studies and development work for third parties. Our principal costs under these arrangements include our personnel conducting research and development, and our allocated overhead, as well as research and development performed by outside contractors or consultants.

Our revenues from collaborative arrangements may either be in the form of the recognition of deferred revenues upon milestone achievement for which cash has already been received or recognition of revenue upon milestone achievement, the payment for which is reasonably assured to be received in the future.

Currently, our product sales and royalty income are derived from the sale of EP-1101 (argatroban) to, and the resale by, two commercial partners, Sandoz Inc., or Sandoz, and The Medicines Company. The primary factors that determine our revenues derived from EP-1101 (argatroban) are:

- the level of orders submitted by our commercial partners — Sandoz, and The Medicines Company;
- the level of institutional demand for EP-1101 (argatroban);
- unit sales prices; and
- the amount of gross-to-net sales adjustments realized by our marketing partners.

We also have generated collaborative licensing and development revenue from our collaboration arrangements with third parties. Revenues have been generated from the achievement of milestones pursuant to, or other payments made under, arrangements related to the divestiture of non-core assets, namely diclofena/misoprostal tablets, a generic product candidate sold to Hikma, and EP-2101 (topotecan), which was licensed to Pfizer.

Cost of Revenue

Cost of revenue consists of the costs associated with producing our products for our commercial partners and providing research and development services to our collaboration partners. In particular, our cost of revenue includes production costs of EP-1101 (argatroban) paid to a contract manufacturing organization coupled with shipping and customs charges, as well as royalty expense associated with the license of EP-2101 (topotecan) to Pfizer. Cost of revenue may also include the effects of product recalls, if applicable.

Research and Development

Our research and development expenses consist of expenses incurred in developing, testing, manufacturing and seeking regulatory approval of our product candidates, including: expenses associated with regulatory submissions, clinical trials and manufacturing, including additional expenses to prepare for the commercial manufacture of products including EP-1101 (argatroban), Ryanodex (dantrolene for MH), EP-3101 (bendamustine RTD), EP-3102 (bendamustine short infusion time) and our other product candidates; payments made to third-party CROs, contract laboratories and independent contractors; payments made to consultants who perform research and development on our behalf and assist us in the preparation of regulatory filings; payments made to third-party investigators who perform research and development on our behalf and clinical sites where such research and development is conducted; expenses incurred to maintain technology licenses; and facility, maintenance, allocated rent, utilities, depreciation and amortization and other related expenses.

Clinical trial expenses for our product candidates are and will be a significant component of our research and development expenses. Product candidates in later stage clinical development generally have higher research and development expenses than those in earlier stages of development. We coordinate clinical trials through a number of contracted investigational sites and recognize the associated expense based on a number of factors, including actual and estimated subject enrollment and visits, direct pass-through costs and other clinical site fees.

We expect to incur additional research and development expenses as we accelerate the development of dantrolene in additional indications. These expenditures are subject to numerous uncertainties regarding timing and cost to completion. Completion of clinical trials may take several years or more and the length of time generally varies according to the type, complexity, novelty and intended use of a product candidate. We are currently unable to determine our future research and development expenses related to dantrolene because the timing and outcome of the Food and Drug Administration, or FDA, review of the New Drug Application, or NDA, for Ryanodex (dantrolene for MH) is not currently known and the requirements of any additional clinical trials of dantrolene for additional indications has yet to be determined. The cost of clinical development may vary significantly due to factors such as the scope, rate of progress, expense and outcome of our clinical trials and other development activities.

We could incur additional research and development expenses for EP-3101 (bendamustine RTD), for which an NDA was filed with the FDA on September 6, 2013. FDA review of NDAs is governed by the Prescription Drug User Fee Act, or PDUFA, regarding response time to the application. The PDUFA goal date for EP-3101 (bendamustine RTD) is July 6, 2014. Any further actions requested by the FDA may result in additional research and development expenses. For additional information regarding the PDUFA review process, see "Business—Government Regulation—FDA Approval Process."

Selling, General and Administrative

Selling, general and administrative costs consist primarily of salaries, benefits and other related costs, including stock-based compensation for executive, finance, selling and operations personnel. General and administrative expenses include facility and related costs, professional fees for legal, consulting, tax and accounting services, insurance, selling, market research, advisory board and key opinion leaders, depreciation and general corporate expenses. We expect that our selling, general and administrative expenses will increase with the continued development and potential commercialization of our product candidates particularly as we move to a business model in which we commercialize our own products in the United States, as well as increased expenses associated with us becoming a public company.

Other Income and Expense

Other income (expense) consists primarily of interest income, interest expense and changes in value of our warrant liability. Interest income consists of interest earned on our cash and cash equivalents and short-term investments. Interest expense consists primarily of cash and non-cash interest costs related to our issuance of convertible notes in the fourth quarter of fiscal 2012, including the amortization of debt discounts and deferred financing costs.

Income Tax Benefit

Income tax benefit primarily consists of proceeds from the sale of the Company's New Jersey state net operating losses which is net of any minimum state taxes paid.

Results of Operations

Comparison of Years Ended September 30, 2013 and 2012

Revenues

	Year ended September 30, 2013	2012	Increase/ (Decrease)
Product sales	$ 5,314,610	$ 1,155,358	$ 4,159,252
Royalty income	8,364,293	1,384,044	6,980,249
Total revenue	$ 13,678,903	$ 2,539,402	$ 11,139,501

Total revenue increased $11.1 million in the 2013 fiscal year to $13.7 million as compared to $2.5 million in fiscal 2012.

In fiscal 2013, total product sales increased $4.2 million to $5.3 million as compared to $1.2 million in fiscal 2012 due to the longer period of time during which EP-1101 (argatroban) was marketed in fiscal 2013 as compared to fiscal 2012 as well as greater market penetration by our marketing partners.

Royalty income increased $7.0 million in fiscal 2013 to $8.4 million in 2012 as compared to $1.4 million in fiscal 2012, as a result of the longer period of time during which EP-1101 (argatroban) was marketed in fiscal 2013 as well as greater market penetration by our marketing partners, which resulted in higher royalty revenues from the end use sales of EP-1101 (argatroban) by our commercial partners.

There were no revenues from collaborative arrangements in 2013 or 2012.

Cost of Revenue

	Year ended September 30, 2013	2012	Increase/ (Decrease)
Cost of revenue	$ 7,380,825	$ 3,166,593	$ 4,214,232

Cost of revenue increased $4.2 million in fiscal 2013 to $7.4 million as compared to $3.2 million in fiscal 2012 as a result of the increased product sales from the full launch of EP-1101 (argatroban). Included in fiscal 2012 are approximately $1.6 million in costs associated with an EP-1101 (argatroban) product recall and related inventory write-offs.

Research and Development

	Year ended September 30, 2013	2012	Increase/ (Decrease)
Ryanodex (dantrolene for MH)	$ 1,682,350	$ 2,931,892	$ (1,249,542)
EP-3101 (bendamustine RTD)	1,090,321	1,623,261	(532,940)
EP-4104 (dantrolene for EHS)	162,236	1,204,587	(1,042,351)
All other projects	3,552,996	2,973,585	579,411
Salary and other personnel related expenses	3,307,639	4,071,359	(763,720)
Total Research and Development	$ 9,795,542	$ 12,804,684	$ (3,009,142)

Research and development expenses decreased $3.0 million in fiscal 2013 to $9.8 million as compared to $12.8 million in fiscal 2012. Expenses in fiscal 2013 were lower than in fiscal 2012 as a result of decreased project spending specifically for the Ryanodex (dantrolene for MH), EP-4104 (dantrolene for EHS) and EP-3101 (bendamustine RTD) projects and lower personnel and related expenses, partially offset by higher spending in other completed projects.

Selling, General and Administrative

Selling general and administrative expenses decreased $1.4 million in fiscal 2013 to $5.0 million from $6.4 million in fiscal 2012. The decreased costs in fiscal 2013 over fiscal 2012 are primarily due to $0.9 million in costs related to The Medicines Company arbitration described elsewhere in this prospectus, $0.2 million in market research activities and $0.3 million in miscellaneous expenses.

Other Income and Expense

	Year ended September 30, 2013	2012	Increase/ (Decrease)
Interest income	$ 3,212	$ 34,530	$ (31,318)
Net proceeds from MDCO Arbitration	4,050,252	—	4,050,252
Interest expense	(309,121)	(90,718)	(218,403)
Deferred financing costs	(96,417)	(19,283)	(77,134)
Amortization of debt discount	(1,090,878)	(218,176)	(872,702)
Change in value of warrant liability	(1,052,302)	—	(1,052,302)
Loss on subscription loan settlement	—	(51,379)	51,379
Other income, net	3,202	11,862	(8,660)
Total other income/(expense), net	$ 1,507,948	$ (333,164)	$ 1,841,112

Other income and expense increased $1.8 million in fiscal 2013 to income of $1.5 million as compared to net other expense of $0.3 million in fiscal 2012. The fiscal 2013 other income and expense primarily includes interest expense and the amortization of deferred financing costs and debt discount related to the convertible notes that were issued in the fourth quarter of fiscal 2012, the recognition of the change in value of the warrant liability and the settlement related to the MDCO arbitration. The fiscal 2012 other income and expense primarily includes interest expense and the amortization of deferred financing costs and debt discount related to the convertible notes that were issued in the fourth quarter of fiscal 2012.

State Income Tax Benefit

In the fiscal years ended 2013 and 2012, we realized proceeds from the sale of our New Jersey state net operating losses of $0.9 million and $0.8 million, respectively.

Net Loss

Net loss for fiscal 2013 was $6.0 million as compared to net loss of $19.4 million in fiscal 2012, as a result of the factors described above.

Liquidity and Capital Resources

Our primary uses of cash are to fund working capital requirements, product development costs and operating expenses. Historically, we have funded our operations primarily through private placements of preferred stock and convertible notes and out-licensing product rights. Cash and cash equivalents were $10.5 million and $5.1 million at September 30, 2013 and 2012, respectively. Including short term investments, total cash, cash equivalents and short term investments were $10.5 million and $6.6 million at September 30, 2013 and 2012, respectively.

For the fiscal year ended September 30, 2013, we incurred a net loss of $6.0 million. We have sustained significant losses since our inception on January 2, 2007 and had accumulated a deficit of $102.3 million as of September 30, 2013. In addition, as of September 30, 2013, we had a surplus of working capital of $3.1 million. For the fiscal year ended September 30, 2012, we incurred a net loss of $19.4 million. We had an accumulated a deficit of $95.5 million as of September 30, 2012. In addition, as of September 30, 2012, we had a deficiency of working capital of $12.0 million. The financial statements have been prepared on a going concern basis, assuming we had the ability to satisfy our obligations in the normal course of business. The financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern. Our auditors included an explanatory paragraph in their audit report expressing substantial doubt about our ability to continue as a going concern.

We believe that future cash flows from operations, together with proceeds from this initial public offering will be sufficient to fund our currently anticipated working capital requirements through the third quarter of fiscal year 2015. No assurance can be given that operating results will improve, out-licensing of products will be successful or that additional financing could be obtained on terms acceptable to us.

Operating Activities:

Net cash used in operating activities for the year ended September 30, 2013 was $5.9 million and resulted primarily from $6.0 million of net loss for the period. Non-cash adjustments amounted to $3.0 million in depreciation, amortization, interest, stock-based compensation expense and the change in value of warrant liability. Net changes in working capital decreased cash from operating activities by approximately $2.8 million, primarily due to an increase in accounts receivable of $3.5 million from the higher product revenues of EP-1101 (argatroban), an increase in prepaid expenses of $1.4 million ($0.7 million for prepaid product costs and $0.8 million for FDA user fees, offset by decreases of $0.1 in other prepaid expenses) and a decrease in accounts payable of $0.3 million offset by an increase of $1.7 million in accrued expenses ($2.2 million in royalties due to The Medicines Company and SciDose offset by $0.5 million of reductions in other accrued expenses) and an increase in deferred revenue of $0.5 million.

Net cash used in operating activities for the year ended September 30, 2012 was $15.5 million and resulted primarily from $19.4 million of net loss for the period. Non-cash adjustments amounted to

approximately $1.0 million in depreciation and amortization and stock-based compensation expense. Net changes in working capital increased cash from operating activities by approximately $2.8 million, primarily due to an increase in accounts receivable of $1.3 million from the higher product revenues of EP-1101 (argatroban), a decrease in inventories of $1.1 million, an increase in deferred revenue of $3.5 million related to the divestiture of diclofenac- misoprostol tablets and related assets to Hikma and a decrease in accounts payable and accrued expenses of approximately of $0.6 million.

Investing Activities:

In the years ended September 30, 2013 and 2012, we invested $40 thousand and $33 thousand, respectively, for the purchase of property and equipment. In the years ended September 30, 2013 and 2012, we redeemed $1.5 million and $3.0 million, respectively of short term investments.

Financing Activities:

Net cash provided by financing activities in fiscal 2013 and 2012 was $9.8 million and $9.6 million resulting from the issuance of Series C Preferred Stock in fiscal 2013 and the issuance of convertible notes and warrants in fiscal 2012.

Contractual Obligations

Our future material contractual obligations include the following:

		Fiscal Years Ended September 30,					
	Total	2014	2015	2016	2017	2018	Beyond
Operating lease obligations	$ 454,025	$ 272,415	$ 181,610	$ —	$ —	$ —	$ —

Quantitative and Qualitative Disclosures about Market Risk

The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. Our exposure to market risk is confined to our cash and cash equivalents. As of September 30, 2013, we had cash and cash equivalents of $10.5 million. We do not engage in any hedging activities against changes in interest rates. Because of the short-term maturities of our cash and cash equivalents and short-term investments, we do not believe that an increase in market rates would have any significant impact on the realized value of our investments.

Recent Accounting Pronouncements

No accounting standards or interpretations issued recently are expected to have a material impact on our financial position, operation or cash flow.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future material effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources.

Impact of Inflation

While it is difficult to accurately measure the impact of inflation due to the imprecise nature of the estimates required, we believe the effects of inflation, if any, on our results of operations and financial condition have been immaterial.

Critical Accounting Policies and Estimates

We have based our management's discussion and analysis of our financial condition and results of operations on our financial statements that have been prepared in accordance with generally accepted accounting principles, or GAAP, in the United States. The preparation of these financial statements requires us to make estimates that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to clinical trial expenses and stock-based compensation. We base our estimates on historical experience and on various other factors we believe to be appropriate under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully discussed in Note 3 to our audited financial statements included in this prospectus, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements. We have reviewed these critical accounting policies and estimates with the audit committee of our board of directors.

Revenue recognition

Revenue recognition determines the timing of certain expenses, such as commissions and royalties. Revenue results are difficult to predict, and any shortfall in revenue or delay in recognizing revenue could cause operating results to vary significantly from quarter to quarter and year to year. Royalty revenues, based on net sales by licensees, are recorded as revenue for the period in which those sales are made by the licensees. License fees are recorded over the life of the license. Deferred revenue is recognized upon the achievement of milestones. Other deferred revenue is amortized over the life of the underlying agreement.

We recognize revenue in accordance with SEC Staff Accounting Bulletin, or SAB, No. 104, *Revenue Recognition*, and Statement of Financial Accounting Standards, or ASC 605, *Revenue Recognition*.

Product sales. We recognize net revenues from products manufactured and supplied to our commercial partners, when the following four basic revenue recognition criteria under the related accounting guidance are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. Prior to the shipment of our manufactured products, we conduct initial product release and stability testing in accordance with current good manufacturing practices, or cGMP. Our commercial partners can return the products within contracted specified timeframes if the products do not meet the applicable inspection tests. We estimate our return reserves based on our experience with historical return rates. Historically, our product returns have not been material.

Royalty income. We recognize revenue from royalties based on our commercial partners' net sales of products. Royalties are recognized as earned in accordance with contract terms when they can be reasonably estimated and collectability is reasonably assured. Our commercial partners are obligated to report their net product sales and the resulting royalty due to us within 60 days from the end of each quarter. Based on historical product sales, royalty receipts and other relevant information, we accrue royalty revenue each quarter and subsequently true-up when we receive royalty reports from our commercial partners.

Collaborative arrangements. We recognize revenue from reimbursements received in connection with feasibility studies and development work for third parties when our contractual services are performed,

provided collectability is reasonably assured. Our principal costs under these arrangements include our personnel conducting research and development, and our allocated overhead, as well as research and development performed by outside contractors or consultants.

We recognize revenues from non-refundable up-front license fees received under collaboration arrangements ratably over the performance period as determined under the collaboration agreement (estimated development period in the case of development arrangements, and contract period or longest patent life in the case of supply and distribution arrangements). If the estimated performance period is subsequently modified, we will modify the period over which the up-front license fee is recognized accordingly on a prospective basis. Upon termination of a collaboration agreement, any remaining non-refundable license fees received by us, which had been deferred, are generally recognized in full. All such recognized revenues are included in collaborative licensing and development revenue in our statements of operations. We recognize revenue from milestone payments received under collaboration arrangements when earned, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, we have no further performance obligations relating to the event and collectability is reasonably assured. If these criteria are not met, we recognize milestone payments ratably over the remaining period of our performance obligations under the collaboration agreement.

Accounting for Fair Value for Warrant Liabilities. The estimated fair value of the common stock warrant liability and embedded derivative are determined by using the Black-Scholes option pricing model which is based on our stock price at measurement date, exercise price of this warrant, risk-free rate and historical volatility and are classified as a Level 3 measurement.

The guidance in ASC 815 requires that we mark the value of its warrant liability to market and recognize the change in valuation in its statement of operations each reporting period. These mark-to-market adjustments each reporting period could materially adversely affect our future operating results. Determining the warrant liability to be recorded requires us to develop estimates to be used in calculating the fair value of the warrant.

Since these preferred stock warrants do not trade in an active securities market, we recognize a warrant liability and estimate the fair value of these warrants using a Probability-Weighted Expected Returns valuation model. Therefore, the warrant liability is considered a Level 3 measurement.

Stock-based compensation. We account for stock-based compensation under ASC, 718 "*Accounting for Stock Based Compensation.* All stock-based awards granted to nonemployees are accounted for at their fair value in accordance with ASC 718, and ASC 505, "*Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*," under which compensation expense is generally recognized over the vesting period of the award. Determining the amount of stock-based compensation to be recorded requires us to develop estimates of fair values of stock options as of the grant date.

For the years ended September 30, 2013 and 2012, we recognized employee stock-based compensation expense pertaining to the issuance of stock options of $317,192 and $402,289, respectively.

We account for stock-based compensation by measuring and recognizing compensation expense for all stock-based payments made to employees and directors based on estimated grant date fair values. We use the straight-line method to allocate compensation cost to reporting periods over each optionee's requisite service period, which is generally the vesting period. We estimate the fair value of our stock-based awards to employees and directors using the Black-Scholes option valuation model, or Black-Scholes model. The Black-Scholes model requires the input of subjective assumptions, including the

expected stock price volatility, the calculation of expected term and the fair value of the underlying common stock on the date of grant, among other inputs. The risk-free interest rate was determined with the implied yield currently available for zero-coupon U.S. government issues with a remaining term approximating the expected life of the options.

Valuation of Common Stock

The fair market value of the common stock is determined on each grant date by our management and board of directors, and considers our most recently available valuation of common stock and our assessment of additional objective and subjective factors that we believe are relevant and which may change from the date of the most recent valuation through the date of the grant. In the absence of a public trading market for our common stock, our determination of the fair value of our common stock was performed using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants Audit and Accounting Practice Aid Series: *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. In addition, our board of directors considered various objective and subjective factors, along with input from management, to determine its best estimate of the fair value of our common stock as of each grant date, including the following:

- contemporaneous third-party valuations of our common stock;
- peer group trading multiples;
- the prices at which we sold shares of preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- our historical and forecasted performance and operating results;
- the status of our development programs;
- our stage of development and business strategy;
- the composition of, and changes to, our management team and board of directors;
- the lack of an active public market for our common and our preferred stock;
- the likelihood of achieving a liquidity event such as a sale of our company or an initial public offering given prevailing market conditions; and
- external market conditions affecting the pharmaceutical and healthcare industry.

Our common stock valuations have been prepared utilizing the probability-weighted expected return method, or PWERM. The value of common shares for this purpose was estimated using a probability weighted analysis of the present value of the returns afforded to shareholders under each of four possible future scenarios for us. Three of the scenarios assume a shareholder exit, either through initial public offering, sale, or dissolution. The fourth scenario assumes operations continue as a private company and no exit transaction occurs. The estimated values of common shares indicated under each scenario were probability weighted based upon management's estimate of the probabilities of occurrence of each of the scenarios, as of the valuation date. The discounted cash flow method was used with the assumptions and estimates provided by management. Further, discounts for lack of control and lack of marketability, to account for the illiquidity of the common stock, were applied to the indicated common stock value to estimate the fair market value of the common stock. The relative probability of each type of future event scenario was determined by management and our board of directors based on an analysis of market conditions at the time, including then-current IPO valuations of similarly situated companies, and expectations as to the timing and likely prospects of the future event scenarios.

An enterprise value at the valuation date was not determined. For each of the PWERM scenarios, as of a future liquidity event date (5 years subsequent to the valuation date), the hypothetical sale proceeds were added to the cumulative operating cash flows, and the total was allocated first to the preferred claims (including accrued dividends) and the remainder was allocated to the common shares. The common share proceeds were then discounted to present value using the applicable discount rate. To derive the value of the common stock for each scenario using the PWERM, the proceeds to the common stockholders were calculated based on the preferences and priorities of the preferred and common stock.

The estimated values of common shares indicated under each scenario were probability weighted based upon management's estimate of the probabilities of occurrence of each of the scenarios, as of the valuation date.

The tables below include the following estimated probabilities under the PWERM:

Options granted on July 12, 2012 assumed probabilities for an initial public offering, merger / acquisition, no exit / private company, or dissolution, of 10%, 50%, 30%, and 10%, respectively. Prior to July 2012 we were party to a licensing deal which opened dialogue between us and a potential licensee for a possible merger or acquisition. As such, the estimated probability for a merger / acquisition was greater than in subsequent valuation dates. The licensing deal closed and assumed probabilities for a merger / acquisition were reduced in the next two valuations. In calculating the value of future cash flows after the terminal year of the forecast, we used the Gordon Growth Model and the estimates for risk free rate of return 3.61%, equity risk premium 15.35% and specific company premium 23.0% to develop an estimated cost of equity of 42.0% and a long term growth rate estimate of 5.0%, which was selected based on our analysis of national economic and industry trends and forecasts. To assist in quantifying the lack of control and marketability discounts, we reviewed numerous authoritative tests and studies of empirical market data. The control, marketable value of common stock indicated by the PWERM was reduced by a 25.0% discount for lack of control and 35.0% discount for lack of marketability.

Options granted on April 19, 2013 assumed probabilities for an initial public offering, merger / acquisition, no exit / private company, or dissolution, of 0%, 35%, 60%, and 5%, respectively. In calculating the value of future cash flows after the terminal year of the forecast, we used the Gordon Growth Model and the estimates for risk free rate of return 2.5%, equity risk premium 14.38% and specific company premium 24.0% to develop an estimated cost of equity of 41.0% and a long term growth rate estimate of 5.0%, which was selected based on our analysis of national economic and industry trends and forecasts. To assist in quantifying the lack of control and marketability discounts, we reviewed numerous authoritative tests and studies of empirical market data. The control, marketable value of common stock indicated by the PWERM was reduced by a 25.0% discount for lack of control and 35.0% discount for lack of marketability.

Options granted on November 21, 2013 assumed probabilities for an initial public offering, merger / acquisition, no exit / private company, or dissolution, of 15%, 20%, 60%, and 5%, respectively. The exercise price for grant date July 12, 2012 included assumptions weighted heavily toward a merger / acquisition. A merger / acquisition liquidity event did not take place and the estimated probabilities were normalized. Prior to the April 19, 2013 grant date, we closed on a Series C financing, which included further dilution, hence lowering the exercise price in combination with the normalized estimated probability. The November 21, 2013 grant date exercise price increased, when compared to April 19, 2013's grant date, which included a higher estimated probability for an initial public offering. In calculating the value of future cash flows after the terminal year of the forecast, we used the Gordon Growth Model and the estimates for risk free rate of return 4.58%, equity risk premium

14.93% and specific company premium 14.52% to develop an estimated cost of equity of 34.03% and a long term growth rate estimate of 5.0%, which was selected based on our analysis of national economic and industry trends and forecasts. To assist in quantifying the lack of control and marketability discounts, we reviewed numerous authoritative tests and studies of empirical market data. The control, marketable value of common stock indicated by the PWERM was reduced by a 25.0% discount for lack of control and a 35.0% discount for lack of marketability.

The following table details stock options granted from July 1, 2012 to September 30, 2013:

Grant Date	Exercise Price	Number of Shares Granted	Black-Scholes
7/12/2012	$ 1.37	1,253,000	$ 0.53
4/19/2013	$ 0.69	1,243,991	$ 0.27

On November 21, 2013, additional options were granted.

Grant Date	Exercise Price	Number of Shares Granted	Black-Scholes
11/21/2013	$ 0.77	420,000	$ 0.41

The guideline public companies selected for the purpose of deriving a valuation multiple as an input to the PWERM are relatively large capitalization companies with diversified product lines that produce relatively stable positive earnings. The guideline public companies include the following:

- Actavis, Inc.
- Allergan, Inc.
- AstraZeneca PLC
- Bristol-Meyers Squibb Company
- Forest Laboratories, Inc.
- Hospira, Inc.
- Momenta Pharmaceuticals, Inc.
- Mylan, Inc.
- Sanofi SA
- Teva

These guideline public companies all have similar characteristics to the company in one or all of the characteristics listed. The portfolios of these guideline public companies focus on in-licensing products or technology and developing, marketing and distributing branded generic and specialty pharmaceuticals either directly to customers or through wholesalers. Each of the companies has product approvals in more than one country outside the United States. The companies listed may compete with the company in more than one setting, e.g., hospital settings or infusion centers. To account for differences in the number of products, types of products, size, working capital, liquidity, etc., a quantitative adjustment factor was calculated and applied to each multiple for the selected earnings measures to arrive at an adjusted multiple.

BUSINESS

Company Overview

We are a specialty pharmaceutical company focused on developing and commercializing injectable products, primarily in the critical care and oncology areas, using the FDA's 505(b)(2) NDA regulatory pathway. Our business model is to develop proprietary innovations to FDA-approved, injectable drugs, which we refer to as branded reference drugs, that offer longer commercial duration at attractive prices compared to generic competitors. We intend to enter the market no later than the first generic drug and substantially convert the market by addressing the needs of stakeholders who ultimately use our products. We believe we can further extend commercial duration through new intellectual property protection and/or orphan drug exclusivity and three years of non-patent regulatory exclusivity for future product candidates, as provided under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, as applicable. Through our senior management team's extensive knowledge of the marketplace, we strive to enhance branded reference drugs to optimize their ease and safety of use for healthcare providers, produce less drug waste, lower cost to stakeholders, and create the opportunity for label expansion to additional indications. Our regulatory and commercial strategy is to introduce our products no later than the first generic competitor of the branded reference product, which provides us with the potential for superior pricing and helps diminish competition from impending generic products to the branded reference drug. Our model has been validated by the approval and successful launch of our novel formulation of EP-1101 (argatroban).

Our broad and diverse disclosed product portfolio includes two approved products and six distinct product candidates in late-stage development, which we plan to register globally. Our two most advanced product candidates are EP-3101 (bendamustine RTD), a proprietary intravenous version of the chemotherapeutic agent that is marketed by Teva under the brand name Treanda, and Ryanodex (dantrolene for MH), a proprietary intravenous version of an approved treatment for malignant hyperthermia. Our NDA for EP-3101 (bendamustine RTD) was submitted to the FDA on September 6, 2013, and we have a PDUFA goal date of July 6, 2014. We believe that bendamustine represents a

branded peak annual sales opportunity in the United States of $608 million. We expect to submit an NDA for Ryanodex by the end of 2013. Our currently disclosed product portfolio consists of:

Product	U.S. Brand Reference Drug	Description	Indication	2012 U.S. Branded Sales	Status
EP-3101 (bendamustine ready to dilute, or RTD)	Treanda	Chemotherapeutic agent	Chronic lymphocytic leukemia; Indolent non-Hodgkin's lymphoma	$608 million[1]	NDA submitted
EP-3102 (bendamustine short infusion time)	Treanda	Chemotherapeutic agent	Chronic lymphocytic leukemia; Indolent non-Hodgkin's lymphoma	$608 million[1]	In pivotal clinical trials
Ryanodex (dantrolene for MH)	Dantrium/ Revonto	Muscle relaxant	Malignant hyperthermia	$20 million[2]	NDA submission expected by end of 2013; orphan drug designation received
EP-4104 (dantrolene for EHS)	No drug currently approved	Muscle relaxant	Exertional heat stroke	N/A	Orphan drug designation received for heat stroke
EP-6101 (bivalirudin)	Angiomax	Anti-Coagulant; thrombin inhibitor	Percutaneous transluminal angioplasty	$502 million[1]	Type C meeting with the FDA completed in the fourth quarter of 2013
EP-5101 (pemetrexed)	Alimta	Chemotherapeutic agent	Lung cancer and mesothelioma	$1,122 million[1]	Formulation work complete
EP-1101 (argatroban)	Argatroban	Anti-coagulant; thrombin inhibitor	Heparin-induced thrombocytopenia	$99 million[2]	Approved (US); marketed by The Medicines Company and Sandoz
EP-2101 (topotecan)	Hycamtin	Chemotherapeutic agent	Ovarian, cervical and small-cell lung cancer	$25 million[3]	Approved (EU); not marketed; no current plans to commercialize in the U.S.

(1) Based on publicly filed reports with the SEC.

(2) Based on independent market research and management's estimates extrapolated therefrom.

(3) Based on independent market research.

Based on market data, we estimate that the U.S. generic injectable industry reported approximately $7.0 billion in sales in 2012 and grew at a compound annual growth rate of 17% over the last five years. Based on industry data, we believe that the U.S. generic injectable market will continue to grow at a compound annual growth rate of 11.6% due to several factors, including (i) label expansion for approved products increasing the patient pool for such products, (ii) a pipeline of injectable medications at various stages of clinical development, and (iii) the increasing incidence of certain diseases that necessarily utilize injectable medications such as cancer and autoimmune disorders. Further, we estimate that the current worlwide market for the branded reference drugs addressed by our disclosed product portfolio is approximately $4 billion and we have begun development of several additional products that could capture an additional share of the overall injectable market. We believe that, if our product candidates are approved, we can cost-effectively commercialize our product portfolio with our own specialty sales force in the United States, thereby maximizing our economics. Our targeted, specialty sales force will focus on GPOs, hospital groups and key stakeholders in acute care settings. Outside of the United States, we intend to utilize partners for the commercialization of our products.

In general, our goal is to launch our proprietary products no later than the first generic to the branded reference drug. This allows us to take advantage of the market opportunity during its most profitable cycle where price is higher and fewer, if any, generic competitors exist. In addition, we benefit from meaningful barriers to entry that are not inherent to generic drugs under the ANDA regulatory pathway, including a robust patent portfolio and the potential for three years of marketing exclusivity for our future product candidates as a result of the 505(b)(2) regulatory pathway of the Hatch-Waxman Act.

A generic drug company must either (i) wait for the innovator's patents to expire or to be proven invalid to gain market entry or (ii) choose to enter the market at risk of patent infringement. Patent invalidity challenges are time consuming and complex, and outcomes are uncertain. Compared to the ANDA regulatory pathway, which is only available for generic drugs that are the same as, and bioequivalent to, the branded reference drug, the 505(b)(2) regulatory pathway enables us to more broadly modify our drugs while still relying on the safety and efficacy data supporting approval of the branded reference drug. We are therefore able to design our products in an effort to avoid infringing existing patents covering the branded reference drug, which, we believe, in many cases will allow us to enter the existing market earlier than applicable generic drugs. In addition, our drugs that we expect to be approved under the 505(b)(2) regulatory pathway are not precluded from marketing during the 180-day exclusivity period that the first ANDA holder(s) may enjoy under the Hatch-Waxman Act.

We are managed by a team with significant executive experience in branded and generic pharmaceuticals. Our senior management team has over 100 years of combined experience at leading pharmaceutical companies. We have developed company-wide knowledge in the key disciplines required for success of our model, including: the ability to choose product candidates, product development and formulation, the 505(b)(2) regulatory pathway and patent infringement and related patent litigation. Our senior management team includes Scott Tarriff, our President and Chief Executive Officer, David Riggs, our Chief Financial Officer, and other experienced executives. Prior to forming Eagle, Mr. Tarriff was President and Chief Executive Officer of Par Pharmaceutical Companies, Inc. from 1998 to 2006. Mr. Tarriff spearheaded the most successful product introductions in Par's history, including generic versions of Prozac, Paxil, Megace O/S, Ultracet and Par's first branded pharmaceutical product, Megace ES. David Riggs, our Chief Financial Officer, was previously the Chief Executive Officer of eXegenics Inc., a publicly-traded pharmaceutical company that is now OPKO Health Inc., and has served as the Chief Financial Officer of various private and publicly-traded and private pharmaceutical companies. Ken Degen, our Senior Vice President, Hospital Sales and Marketing, spent over 20 years with Schering-Plough Pharmaceuticals where he served in a variety of

roles. Mr. Degen built a sales team that was involved in the promotion of multiple Schering-Plough brands with annual sales ranging from $50 million to approximately $1 billion. Dr. Peter Grebow, our Executive Vice President of Research and Development, held several key positions with Cephalon, Inc. (now Teva Pharmaceuticals), including Senior Vice President, Worldwide Business Development and Senior Vice President, Drug Development. Dr. Paul Bruinenberg, our Chief Medical Officer, has more than 28 years of experience in clinical operations and development.

Industry Background

Injection is a common drug delivery route for biopharmaceuticals due to the lower bioavailability of alternative administration routes. Based on market data provided by Markets and Markets, the global market for injectable products was estimated to be approximately $12.3 billion in 2012. The data project that the United States generic injectable market will continue to grow at a compound annual growth rate of 16.3% due to several factors, including (i) label expansion for approved products increasing the patient pool for such products, (ii) a pipeline of injectable medications at various stages of clinical development, and (iii) the increasing incidence of certain diseases that necessarily utilize injectable medications such as cancer and autoimmune disorders.

Limitations of Existing Drug Products and Generics

We believe that many currently available critical care and oncology injectable products have suboptimal characteristics that do not meet the needs of patients, physicians, nurses or pharmacists. These characteristics can impact safety, shelf life, convenience, waste, cost, and ease of use by practitioners and pharmacy staff. For instance, existing drugs may be packaged inefficiently or come in formulations that require reconstitution or dilution, or which are otherwise difficult or inconvenient to prepare, and which expose workers to cytotoxic compounds and can result in dosing errors. This can also lead to wasted quantities of drug, inefficiencies in staff time and constrained work flow, reduced shelf life and the need for multiple dosing of individual patients to complete treatment.

Market Opportunity

We believe there is a large and unmet market for developing injectable drugs that address the specific needs of patients, physicians, nurses and pharmacists to simplify their use, reduce waste and lower healthcare costs. Such improvements could also reduce infusion times, reduce dosing errors, remove unnecessary exposure to toxic materials and potentially improve the safety of the product.

Hatch-Waxman Act. Section 505 of the FDCA describes three types of NDAs that may be submitted to request marketing authorization for a new drug. A 505(b)(1) NDA is an application that contains full reports of investigations of safety and effectiveness. The Hatch-Waxman Act created two additional marketing pathways under Sections 505(j) and 505(b)(2) of the FDCA. Section 505(j) establishes an abbreviated approval process for generic versions of approved drug products through the submission of an ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. ANDA applicants are required to conduct bioequivalence testing to confirm chemical and therapeutic equivalence to the branded reference drug. Generic versions of drugs can often be substituted by pharmacists under prescriptions written for the branded reference drug.

A 505(b)(2) NDA is an application that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant. This alternate regulatory pathway enables the applicant to rely, in part, on the FDA's findings of safety and efficacy for an existing product, or published literature, in support of its application. The FDA may then approve the new product candidate for all or some of

the labeled indications for which the referenced product has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

Upon submission of an ANDA or a 505(b)(2) NDA, an applicant must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. If the paragraph IV certification is challenged by an NDA holder or patent owner(s) asserts a patent challenge to the paragraph IV certification, the FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

The Hatch-Waxman Act establishes periods of regulatory exclusivity for certain approved drug products, during which the FDA cannot approve (or in some cases accept) an ANDA or 505(b)(2) application that relies on the branded reference drug. For example, the holder of an NDA may obtain five years of exclusivity upon approval of a new drug containing a new chemical entity, or NCE, that has not been previously approved by the FDA. The Hatch-Waxman Act also provides three years of marketing exclusivity to the holder of an NDA (including a 505(b)(2) NDA) for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. This three-year exclusivity period protects against FDA approval of ANDAs and 505(b)(2) NDA for drugs that include the innovation that required the new clinical data.

Orphan Drug Act. In addition, the Orphan Drug Act provides incentives for the development of products intended to treat rare diseases or conditions. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation provides manufacturers with research grants, tax credits, and eligibility for orphan drug exclusivity. If a product that has orphan drug designation subsequently receives the first FDA approval of the active moiety for the treatment of that disease or condition for which it has such designation, the product may be entitled to orphan drug exclusivity, which for seven years would prohibit the FDA from approving another product with the same active ingredient for the same indication, except in limited circumstances such as when a subsequent product demonstrates clinical superiority.

The following table provides a description of general similarities and differences between the various regulatory pathways:

	ANDA	505(b)(2) NDA	Traditional NDA
Clinical Trials/Testing Required	Only to show bioequivalence	Yes, to address potential differences between the branded reference product and the 505(b)(2) product.	Yes
Results in Orange Book Listed Patents	No	Yes, for novel formulations, other enhancements and new indications	Yes
Exclusivity	Potential for 180 days against other generic filers if first generic to file	Potential for three years for new clinical investigations (other than bioavailability and bioequivelance studies) that are essential to approval of the application Potential for 30-month stay for Orange Book-listed patents	Potential for five years for a new chemical entity, or three years for new clinical investigations
Paragraph IV Certification Required	Yes	Yes	No
Potential Orphan Drug Status	No	Yes	Yes

Our Competitive Strengths

We believe that our management's unique knowledge of the industry, including its ability to identify products for enhancement, its experience with the 505(b)(2) regulatory pathway, and its ability to navigate paragraph IV challenges, combined with our portfolio of attractive assets, enables us to compete effectively in the market for injectable therapeutics.

Attractive portfolio of injectable assets that address a large market opportunity. Our product portfolio is focused on oncology, critical care, and orphan diseases and includes two approved products and six distinct product candidates in advanced development. Together, our disclosed portfolio targets an overall U.S. market of approximately $4 billion in annual branded reference drug revenue. We believe that we can leverage our formulation and development expertise to achieve improved product attributes in terms of potential for longer stability, shorter infusion times, less waste and/or ease and safety of use for healthcare professionals and achieve longer commercial duration compared to generic competitors. We believe that our products may offer certain benefits as compared to existing injectable drugs which may include one or more of the following:

- improved safety through elimination of reconstitution in the pharmacy or in the acute care setting;
- reduction in the number of injections required;

- reduction in the volume of drug needed to be injected, potentially expanding the application to additional medical situations;
- reduction in drug waste;
- reduction in drug infusion time; and
- potential label expansion to include additional indications.

Validated business model. We believe that our differentiated business model as compared to generic and branded specialty pharmaceutical drug companies has been validated with our first approval and commercial launch in the United States of a novel version of argatroban, for which we received approval of a 505(b)(2) NDA in June 2011. Our version of argatroban was formulated in a manner designed to avoid the infringement of related Orange Book patents for the branded reference product, and we were successful in doing so without triggering a patent infringement suit by the innovator of the branded reference drug. We therefore entered the market prior to the first generic version of argatroban and our version of the drug has captured 28% of the total argatroban market. Our competitors' undifferentiated ANDAs referencing the branded drug remain tentatively approved by FDA and, because they have not been able to prove invalidity or noninfringement of the applicable patents, must await patent expiration on June 30, 2014 before full approval and commercialization. When these generic competitors do enter the market, our market share and product price could decline. The extent of the decline will depend upon such factors as the pricing for these generic products, the number of generic competitors, and our customer's willingness to use a product that does not provide the benefits provided by our version of argatroban.

Unique insight into limitations of existing products. We believe that many injectable products for use in acute care settings have suboptimal characteristics that do not meet the needs of patients, physicians, nurses or pharmacists. These characteristics can impact safety, shelf life, convenience, waste, cost, and ease of use by practitioners and pharmacy staff. Because generic drugs are essentially copies of the branded reference drugs, these suboptimal characteristics are shared by the generic versions. We have and continue to engage physicians, nurses, pharmacists and key opinion leaders, or KOL's, to indentify specific products where the characteristics described above present opportunities for product improvement. We evaluate the product opportunities presented by the stakeholders and determine whether or not they conform to our research and development planning. A key aspect of our evaluation is the intellectual property landscape for each product opportunity, including our ability to avoid infringing existing patents and the potential patentability of our modified version of the drug. We utilize our experienced team of formulators with extensive experience in branded and generic pharmaceuticals, including significant experience with injectable pharmaceuticals, and a track record of success in product development, regulatory relations, and quality assurance to develop improved products. Our President and Chief Executive Officer, Scott Tarriff, who spearheaded the most successful product introductions in Par Pharmaceuticals' history, leads our management team in selecting drug candidates with significant branded product sales that can be optimized by creating new formulations of branded reference drugs and seeking approval via the 505(b)(2) pathway.

Barriers to entry and intellectual property. Because our products are differentiated from the branded reference drugs, we believe we are able to avoid infringing existing patents covering the branded reference drug allowing us to enter the existing market no later than applicable generic drugs, which may be subject to protracted patent litigation delaying market entry. Protracted litigation is a significant barrier to entry for competitors seeking approval of an ANDA referencing the branded reference product, and our early entry into the market leads to less price erosion due to constrained competition. Our patent estate includes nine owned or exclusively-licensed U.S. issued patents and ten filed U.S. patent applications, as well as several patent applications that have been filed in various

worldwide territories, that protect or will protect, as applicable the market value of our current portfolio products. We believe that other potential barriers to entry consist of one or more of the following:

- our own patents, which could prevent competition from generic versions of our products. In addition, we expect to be able to list our patents in the Orange Book, which will offer us the potential to trigger our own 30-month stay under the Hatch-Waxman Act against future 505(b)(2) and ANDA filers that reference our drugs;

- our early entry into the market allows us to influence usage patterns when fewer, if any, competitors exist and allows us to market our products as improved versions of the branded reference drug prior to or concurrent with any generic entry, thereby giving us the opportunity to capture significant market share at this early stage. We believe that such early entry into the market will limit later conversions into generic versions of the branded reference drugs, deterring competition and allowing us to maintain market share and favorable pricing;

- the potential for seven years of exclusivity upon approval of a 505(b)(2) NDA that receives orphan drug status; and

- the potential for three years of regulatory exclusivity for our future product candidates upon approval, if any, of a 505(b)(2) NDA supported by new clinical investigations (other than bioequivalence and bioavailability studies) essential to approval of the application.

Our Strategy

Our goal is to be a leading specialty pharmaceutical company focused on the development and commercialization of injectable pharmaceutical products for use in acute care settings. Our strategy to achieve this goal includes:

Enter the market no later than the first generic drug. We intend to enter the market no later than the first generic of the branded reference drug. During this period, the number of competitors is lowest and branded drugs are generally at peak or near peak value. This will allow us to influence usage patterns and market our products as improved versions, thereby achieving favorable pricing. Even if we enter the market simultaneously with, or after, the first generic drug, as a 505(b)(2) applicant, we would be able to enter the market without regard to any generic drug's 180-day exclusivity period.

Retain commercial rights in the United States and selectively partner outside of the United States. We believe that we can cost-effectively commercialize our products in the United States, and thereby retain full commercial value of these products. We plan to establish a small, specialty sales force that will focus on GPOs, hospital systems and key stakeholders in acute care settings, primarily hospitals and infusion centers. Because we focus on proprietary versions of already well established branded products, we generally believe we will not need to focus our commercial resources on marketing our products directly to physicians, thereby substantially limiting our commercial expense. Outside of the United States, we intend to utilize partners for the commercialization of our products.

Strengthen our product portfolio. We intend to continue to strengthen our product portfolio in the areas of oncology, critical care and orphan diseases. We will continue to develop our current product portfolio and leverage our expertise to identify new products with suboptimal characteristics that present us with significant opportunity for revenue generation. In addition to our internal efforts, we will opportunistically in-license or acquire product candidates that fit our therapeutic areas of focus and meet our rigorous evaluation process.

Continue to build a robust intellectual property portfolio. Our patent estate includes nine owned or exclusively-licensed U.S. issued patents and ten filed U.S. patent applications, as well as several that have been filed in various worldwide territories, that protect or will protect, as applicable the market value of our approved and pipeline products, consisting primarily of formulation and method-of-use patents. We intend to continue to build our patent portfolio by filing for patent protection on new developments with respect to our product candidates that will not infringe patents that cover the branded reference drugs. We expect that these will, if issued, allow us to list our own patents in the Orange Book, to which potential competitors will be required to certify upon submission of their applications referencing our products, if approved.

Our Products and Product Portfolio

EP-3101 (bendamustine RTD) and EP-3102 (bendamustine short infusion time) for Chronic Lymphocytic Leukemia and Non-Hodgkin's Lymphoma

Bendamustine is an alkylating agent approved for use in chronic lymphocytic leukemia, or CLL, and indolent B-cell non-Hodgkin's lymphoma, or NHL, that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen (which we refer to herein as the NHL indication). We are developing a ready to dilute, or RTD, liquid formulation of bendamustine in two presentations:

- Our first-generation product, EP-3101 (bendamustine RTD), is an RTD, multi-dose liquid with extended drug stability for use with a 500mL intravenous, or IV, infusion bag, for which we recently submitted a 505(b)(2) NDA and were assigned a July 6, 2014 PDUFA goal date; and

- Our second-generation product, EP-3102 (bendamustine short infusion time), is an RTD liquid that can be administered in a shorter time-frame than current drugs on the market.

Both EP-3101 (bendamustine RTD) and EP-3102 (bendamustine short infusion time), if approved, will treat the same indications as the branded form of bendamustine, but will not require reconstitution prior to administration, which we believe is a significant advantage.

Currently-Marketed Bendamustine Product

Teva currently markets its bendamustine product under the trade name Treanda. Treanda is currently available in two presentations: 25mg and 100mg single-use vials, both containing lyophilized powder that requires reconstitution with sterile water prior to administration. Both presentations, once reconstituted, are infused from a 500mL IV infusion bag for 30 minutes to patients with CLL and for 60 minutes to patients with NHL, on days one and two of a 28-day chemotherapy treatment cycle. Treanda was recently approved in a new RTD formulation, expected to be commercialized beginning in the fourth quarter of 2013. We expect that the commercialization of Teva's Treanda RTD formulation will successfully convert a large portion of the existing lyophilized market to a liquid RTD market. Upon launch of EP-3101 (bendamustine RTD), we believe that we will be able to effectively compete with Treanda RTD based on various factors, including price, without the added burden of transitioning customers from a lyophilized product. U.S. sales of Treanda in 2012 were $608 million. Due to Treanda's orphan drug and pediatric exclusivities for both the CLL and NHL indications, the FDA may be precluded from approving EP-3101 (bendamustine RTD) for those same indications until September 2015 (assuming resolution of the 30-month stay prior to that time) and May 2016, respectively.

Limitations of Treanda

There are currently several drawbacks with reconstituting a lyophilized oncology drug, such as Treanda. First, there is potential for dosing errors to occur when mixing Treanda with sterile water.

The pharmacist or pharmacy technician may add too much or too little of the diluent, or even use the wrong diluent. When mixing the Treanda lyophilized powder with the diluent, there is also the potential for exposure of the healthcare professional to cytotoxic vapors. Many oncologists do not allow pregnant nurses to mix oncology drugs because of concern for fetal exposure to cytotoxic drugs. For these and other reasons, the Joint Commission on Accreditation of Healthcare Organizations, known as the Joint Commission, the premier, independent, non-profit organization that accredits hospitals in the United States, encourages the use of RTU and RTD presentations over products that require reconstitution. In addition, the reconstitution of drugs such as Treanda is time consuming resulting in an inefficient work flow. Further, Treanda has limited vial stability of 30 minutes at room temperature after the vial stopper has been punctured, potentially resulting in significant waste if the product is not used within that period of time.

Eagle's Solution: EP-3101 (bendamustine RTD) and EP-3102 (bendamustine short infusion time) Presentations

Both generations of our bendamustine product are liquid formulations, eliminating the need to reconstitute the drug prior to use. As a result, we believe there is less potential for dosing errors, less exposure to cytotoxic vapors and a more efficient work flow. EP-3101 (bendamustine RTD) and EP-3102 (bendamustine short infusion time) are both RTD formulations, as preferred by the Joint Commission. Also, because both EP-3101 (bendamustine RTD) and EP-3102 (bendamustine short infusion time) will be available in a multi-dose vial with extended vial stability of 28 days, they will reduce the amount of drug waste that typically occurs in oncology settings.

The following chart illustrates certain potential benefits of EP-3101 (bendamustine RTD) and EP-3102 (bendamustine short infusion time) over the currently marketed branded drug, Treanda:

Key Product Characteristics	Treanda	EP-3101/EP-3102	EP-3101/EP-3102 Potential Benefits
RTD	No, must be reconstituted	Yes, liquid formulation	Reduced risk of dosing errors, less exposure to cytotoxic vapors and time savings; Joint Commission—preferred
Stability after first use	30 minutes in vial	28 days in vial	Reduced product waste
Infusion Time	30-60 minutes	Less than 30 minutes (EP-3102)	Less time in infusion chair for patient; greater office efficiencies due to less nursing time with each patient
Fluid Volume	500mL	Less than 500mL (EP-3102)	Less potential for patient fluid load and edema

We engaged two market research firms, Phoenix Marketing International and Healogix, to conduct market research with healthcare stakeholders regarding the value of our proposed bendamustine presentations. We commissioned three studies with over 100 oncologists and oncology nurses in total, the research objectives of which were to explore experiences and attitudes within oncology practices regarding the currently marketed lyophilized Treanda product, investigate the benefits and drawbacks of such product, and gauge reactions to both of our proposed bendamustine presentations. Based on the feedback received, there was a preference for both of our liquid bendamustine presentations. Specifically, oncologists and oncology nurses who regularly prepare and use the currently marketed lyophilized Treanda product appreciated the ease-of-use, increased safety profile of a liquid RTD product candidate (from both a drug exposure and a dosing error perspective), as well as the time savings associated with administering an RTD formulation. Also noted were the benefits of longer drug stability of EP-3101's (bendamustine RTD) and EP-3102's (bendamustine short infusion time) multi-dose vial.

In addition, with respect to EP-3102's (bendamustine short infusion time) infusion bag administration, physicians and nurses were asked to compare the value of our short infusion RTD product candidate with the lyophilized Treanda product. On a scale of 1 to 10 (with 10 being the best), comparing the attributes of each product, oncologists rated the lyophilized Treanda product a 6.0 on average and our product candidate an 8.5 on average. Oncology nurses rated Treanda a 6.2 on average and our product candidate an 8.5 on average. We believe that this demonstrates the incremental value associated with our product candidate.

Finally, respondents noted that the additional benefits of administering EP-3102 (bendamustine short infusion time) in a RTD smaller infusion bag include: less time in the infusion chair for patients, improved workflow and increased productivity for oncology practices, less likelihood of weight gain and edema for all patients because of the smaller volume of liquid administered to patients, and the potential to treat elderly patients who suffer from renal impairment and who cannot handle 500mL of 0.9% sodium chloride typically infused during Treanda drug administration.

EP-3101 (bendamustine RTD) and EP-3102 (bendamustine short infusion time) Clinical Development and Regulatory Status

We have submitted a 505(b)(2) NDA for our first generation bendamustine product, EP-3101 (bendamustine RTD), and received a PDUFA goal date of July 6, 2014. We notified Teva of our 505(b)(2) filing and paragraph IV certification, and Teva filed a patent infringement lawsuit against us in the United States District Court for the District of Delaware on October 21, 2013. Teva's filing of the lawsuit invoked a 30-month stay of FDA approval of our bendamustine product, which will delay the FDA from approving EP-3101 (bendamustine RTD) until the earlier of the March 2016 expiration of the 30-month stay imposed by the Hatch-Waxman Act, or such time as the district court enters judgment in our favor or otherwise acts to shorten the stay. Moreover, Teva has received orphan drug and related pediatric exclusivity expiring in September 2015 and May 2016 for the CLL and NHL indications, respectively. When a drug, such as Treanda, has orphan drug exclusivity, the FDA may not approve any other application to market the same drug for the same indication for a period of up to seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. In the United States, pediatric exclusivity adds six months to any existing exclusivity period. If we cannot demonstrate that EP-3101 is clinically superior to Treanda, or qualify under certain other limited exceptions, we will not be able to enter the market for the CLL indication until September 2015 (assuming the 30-month stay is resolved by that time) or the NHL indication until May 2016.

After numerous discussions with the FDA, we have developed a regulatory strategy for our second generation product candidate, EP-3102 (bendamustine short infusion time). We are currently dosing patients in our Phase 1 pivotal clinical trial for that product presentation.

Our bendamustine product candidates, if approved, will be reimbursed using a "J-code" assigned for injectable drugs. If we can demonstrate that EP-3102 (bendamustine short infusion time) for administration in a smaller infusion bag is clinically significantly different than the other drugs that share the J-code, such as Treanda, the Center for Medicare & Medicaid Services, or CMS, may assign a unique reimbursement J-code allowing more pricing flexibility.

Ryanodex (dantrolene) for Malignant Hyperthermia

Dantrolene was first introduced to the U.S. market in 1979 and is currently the only drug approved to treat a rare genetic disorder called malignant hyperthermia, or MH. There are only 500 to 800 cases of MH in the United States each year, qualifying dantrolene for orphan drug designation. This disease is triggered when a patient with this genetic predisposition has a surgical procedure and is exposed to

certain inhaled anesthetics or the muscle relaxant, succinylcholine. When this exposure occurs, a metabolic response can be triggered in the patient resulting in an episode of MH that can be fatal if not treated immediately. Because dantrolene is the only approved drug available to treat MH, the Joint Commission requires that all hospitals stock vials of this product at all times, generally in the operating room area.

Currently-Marketed Dantrolene Products for MH

The two current dantrolene drugs on the market for the treatment of MH, Dantrium and Revonto, are offered in a vial containing 20mg of lyophilized powder that requires mixing with 60mL of sterile water. We estimate that the worldwide market for MH drugs is approximately $40 million per year.

Limitations of Dantrium and Revonto

When an MH crisis occurs during surgery, the surgical procedure is immediately discontinued and the anesthesiologist and others in the operating room quickly begin reconstituting dantrolene, often at the same time as performing other resuscitative efforts, in order to administer the drug to the patient as an IV push. Based on recommendations from the Malignant Hyperthermia Association of the United States, or MHAUS, the recognized authority on treating MH in the United States, the recommended dose is 2.5mg/kg or higher. It is critically important that the drug be administered as rapidly as possible, as MH symptoms include tachycardia, elevated blood pressure, raised CO_2 levels and very high body temperature levels. If not treated immediately, the disease can be fatal.

Because of the dosing required to reverse the MH symptoms and the current formulations of Dantrium and Revonto, it is often necessary to reconstitute 10 to 20 vials of dantrolene. As the current formulations are also poorly water soluble, this process generally takes up to 15 to 20 minutes at a point when time is critical and the patient is extremely unstable. Furthermore, the volume of diluent required to reconstitute Dantrium and Revonto means that the patient receives a significant volume of fluid (600mL to 1,200mL) as an IV infusion, which on occasion can result in detrimental secondary physiological consequences for the patient, such as pulmonary edema and extravasation, which can lead to tissue necrosis.

Eagle's Solution: Ryanodex (dantrolene for MH)

Eagle is developing a differentiated formulation that, if approved, will be sold under the brand name, Ryanodex, for the treatment of MH. The presentation will be a 5mL vial containing 250mg of dantrolene in lyophilized powder form.

We believe that the immediate benefits of our Ryanodex formulation will be clinically significant in critical care situations. Specifically, we expect Ryanodex (dantrolene for MH) will reduce the amount of time to reconstitute and administer dantrolene from the current 15 to 20 minutes, to one minute, as the anesthesiologist will be able to mix and administer a dose of 250mg from a single vial of Ryanodex (dantrolene for MH) in contrast to the current need to mix and administer up to 12 or more vials. A recent retrospective study conducted by MHAUS demonstrated that every 15-minute delay in treating MH resulted in a 7.8% increase in patient complications. Additionally, fluid volume to the patient will also be reduced from up to 720mL or more with Dantrium and Revonto to only 5mL with Ryanodex (dantrolene for MH), potentially further reducing secondary physiological complications for the patient.

We engaged Phoenix Marketing International, Healogix and BAL Consulting to conduct three independent market research studies with approximately 30 anesthesiologists and other doctors, hospital pharmacists and payors to assess the value of our Ryanodex (dantrolene for MH) product. All

of these groups of healthcare professionals agreed that rapid administration of dantrolene is critical in averting a serious negative outcome in MH. Anesthesiologists also stated that the greatest drawback to the existing dantrolene products is the time required to administer this drug in a life or death situation. Many of these physicians also noted their substantial concern over encountering a patient with MH because of the risks of mortality, the challenges in diagnosing its onset, and their lack of experience in treating this rare disease. They confirmed that time to administration is the greatest concern when they encounter an MH crisis. When asked to rate the value of Eagle's Ryanodex product candidate on a scale of 1 to 10 (10 being the best), anesthesiologists and pharmacists rated Ryanodex (dantrolene for MH) a 9 on average and stated that they would use this product as their drug of choice. The most-mentioned reason for this very high rating is the faster time to mix Ryanodex (dantrolene for MH) and administer it to their patients.

Ryanodex Clinical Development and Regulatory Status

A pharmacokinetic study was completed on August 2013 after which we had a pre-NDA meeting with the FDA. At this meeting, the FDA asked us to provide additional clinical/nonclinical information to further evaluate the size of the safety database necessary at the time of NDA filing. A response to the requested information was submitted to the FDA in October 2013. We intend to submit our 505(b)(2) application for Ryanodex (dantrolene for MH) during the fourth quarter of 2013. Our 505(b)(2) NDA will be based, in part, on efficacy data derived from animal studies in accordance with the FDA's "Animal Rule."

We also completed a pilot study that was designed to test whether Ryanodex would have a beneficial effect on treatment outcomes of a metabolic crisis. In the study, MH susceptible swine were anesthetized (using a non-MH triggering protocol) and their core temperatures were gradually increased to approximately 41.5°C from a baseline of approximately 38-39°C. At this point, all animals were removed from the warming blankets and assigned to one of three different treatment scenarios. One animal received no treatment and data from this animal showed a continued increase in core and skeletal muscle temperature, with a worsening of the pathophysiologic parameters, until the animal died of a cardiac arrest in under an hour. Three animals were provided with the current standard of care for EHS, which involved external cooling and IV hydration. This cooling technique was successful in reducing their core and skeletal muscle temperature, but only nominally. All three animals subsequently died or were euthanized within one hour. Five animals were provided with the same cooling techniques as the second group but were also given a 2.5 mg/kg dose of Ryanodex. In each of the five animals, a notable reversal in the pathophysiologic signs of the hypermetabolic crisis was observed within ten minutes of Ryanodex administration. The return of these parameters to baseline was accompanied with a more rapid cooling of both core and skeletal muscle temperature. All five animals were adjudged to be out of the metabolic crisis within one hour of Ryanodex administration. All five animals were taken off of mechanical ventilation once the anesthesia had worn off but one animal subsequently died as a result of post-extubation complications (which was not considered to be a direct consequence of the hypermetabolic crisis and not considered a reflection of failure to resolve the hypermetabolic crisis). The prompt administration of 2.5 mg/kg of Ryanodex, combined with the standard of care for EHS, produced dramatic improvement, if not full resolution, of the heat stroke and hypermetabolic crisis within one hour of Ryanodex administration.

EP-4104 (dantrolene) for Exertional Heat Stroke

Exertional heat stroke, or EHS, is a rare, emergency and serious medical condition that is potentially life-threatening. Its symptoms and effects are closely correlated to MH and our research and development efforts have suggested dantrolene's efficacy for treating EHS. Based on the clinical relationship that exists between MH and EHS, we also are developing a dantrolene formulation for EHS.

EHS is one of the top three causes of sudden death in athletes and, we believe, most likely is the leading cause of death during the months of July and August in this group. We believe it is also a leading cause of non-combat death in the military. EHS is a state of extreme hyperthermia (above 104°F) that occurs when heat that is generated by muscular exercise exceeds the body's ability to dissipate it at the same rate. EHS typically affects young, seemingly healthy individuals during exercise and manifests within a few minutes to hours of such activity and is characterized by an increased core body temperature and central nervous system dysfunction including delirium, convulsions, and coma. Although well-known, predisposing factors to EHS include a lack of heat acclimatization, poor physical fitness, dehydration, recent infection, exercising in warm and humid conditions and concurrent illness. There is also a genetic component related to those who suffer from MH. The pathogenesis of EHS is multifactorial and complex and not completely understood, but it is believed that a defect in the calcium transport in skeletal muscle sarcoplasmic reticulum is a key component of both EHS and MH. This link suggests that the genetic variant which predisposes patients to MH also puts those patients at an increased susceptibility to EHS.

Currently Marketed Dantrolene Products for EHS

There are currently no FDA-approved products that treat EHS, and patients continue to die or suffer significant morbidity from the condition. Independent market research commissioned by us suggests that the worldwide peak revenue for EHS could exceed $150 million.

Limitations of Current EHS Therapies

The current treatment regimen for EHS is not directed at the underlying cause of the disease, but is essentially symptomatic therapy, which in some cases results in mortality or permanent organ damage. Currently, to treat EHS, the standard treatment includes immediate surface cooling with ice and support of organ system function with a goal of accelerating the transfer of heat from the skin to the environment without compromising the flow of blood to the skin. Even if these cooling techniques are properly implemented patients are still subject to risk of brain damage, irreversible organ damage and death.

Eagle's Solution: EP-4104 (dantrolene) for EHS

EP-4104's (dantrolene for EHS) presentation will be identical to Eagle's presentation of Ryanodex (dantrolene for MH) — a 5mL vial containing 250mg of dantrolene in lyophilized powder form requiring reconstitution. Like Ryanodex, only one 5mL injection of EP-4104 (dantrolene for EHS) will be required to initially treat EHS, avoiding the potential need to reconstitute up to 12 or more vials of drug in a short time, as is the current treatment for the related condition of MH. Additionally, because our formulation of EP-4104 (dantrolene for EHS) could be carried by emergency responders (currently impractical with marketed dantrolene products due to the IV volume of up to 720 mL or more required under current dosing guidelines), we believe that administering EP-4104 (dantrolene for EHS) in the field, prior to arriving at the hospital, would be possible. Given that immediate treatment for EHS is crucial for improving outcomes, we believe that our formulation will provide significant benefits over the current standard of care.

EP-4104 (dantrolene for EHS) Clinical Development and Regulatory Status

EP-4104 (dantrolene for EHS) has completed a Phase 1 clinical study in human volunteers and we are currently designing a pivotal clinical study to support our NDA submission that we anticipate will start in mid-2014. Additionally, we were granted Orphan Drug designation for EP-4104 (dantrolene for EHS) in September 2012.

EP-5101 (pemetrexed) for Lung Cancer

Pemetrexed is an IV-administered cancer agent indicated for locally advanced or metastatic non-small cell lung cancer and mesothelioma. We are developing EP-5101 (pemetrexed) as an RTD liquid form of pemetrexed that will be available in a 500mg multi-dose vial with extended stability. We are currently performing pre-clinical formulation and toxicology studies on EP-5101 (pemetrexed). Because our product will be available in liquid form, product reconstitution will not be required, making EP-5101 a preferred formulation under the Joint Commission guidelines.

Currently-Marketed Pemetrexed Product

The branded form of pemetrexed is marketed by Lilly Pharmaceuticals as Alimta. Alimta is approved for use to treat non-small cell lung cancer and mesothelioma. The product presentations for Alimta are 100mg and 500mg single use vials containing lyophilized power that must be reconstituted before patient administration. Once mixed, Alimta must be used within 24 hours due to product stability concerns. According to Lilly Pharmaceuticals, worldwide sales of Alimta in 2012 were approximately $2.6 billion.

Limitations of Alimta

Alimta requires reconstitution, which adds significant time to administration, presents cytotoxic safety issues for healthcare professionals administering the drug and the potential for dosing errors. Because reconstitution of Alimta is generally not performed until the patient has cleared all tests necessary to receive the drug, this process contributes to a significant amount of time spent by such patients in infusion clinics. Additionally, this method of administration limits the number of patients that may be treated on any given day by such clinics. Additionally, as with any oncology drug, cytotoxic vapors released through reconstitution can be potentially harmful to pharmacists, physicians and nurses. Moreover, dosing errors may occur during reconstitution, as incorrect amounts of diluent may be used. As a result, this lyophilized formulation is less preferred by the Joint Commission as compared to an RTD product.

Eagle's Solution: EP-5101 (Pemetrexed)

EP-5101 (pemetrexed) is an RTD liquid form of pemetrexed that we are designing as a 500mg multi-dose vial with extended stability. As an RTD liquid formulation, EP-5101 (pemetrexed) will not require additional time for reconstitution and will avoid certain safety concerns to healthcare professionals and potential dosing errors during mixing. This allows for a more efficient work flow within the infusion clinic, may result in more patients being seen each day and reduces exposure to the drug's cytotoxic vapors during reconstitution by healthcare providers.

We engaged Phoenix Marketing International to conduct independent market research with pharmacists and oncology nurses to study our proposed formulation of EP-5101 (pemetrexed). When subjects were asked to describe the ideal product profile for Alimta, many respondents indicated a desire for an RTD liquid formulation in a multi-dose vial. Extended stability was also described as an improvement to the existing drug.

The benefits of our proposed formulation identified by our research included a reduction in dosing errors as no reconstitution is required, as well as more flexibility in patient scheduling, possibly allowing a greater number of patients to be seen each day. Also mentioned was a possible opportunity to reduce office staff due to a more efficient work flow within the infusion clinic.

EP-5101 (pemetrexed) Clinical Development and Regulatory Status

We are currently performing pre-clinical formulation and toxicology studies on EP-5101 (pemetrexed). We plan to seek EU and U.S. approval of EP-5101 (pemetrexed) for use in non-small cell lung cancer and mesothelioma. We are anticipating a hybrid application filing in 2015 to the European Medicines Agency, or EMA, closely followed by a 505(b)(2) NDA filing in the United States.

EP-6101 (bivalirudin) for Percutaneous Transluminal Angioplasty

Bivalirudin is a direct thrombin inhibitor, administered as an IV infusion and indicated for use as an anticoagulant during coronary surgical procedures. We are developing EP-6101 (bivalirudin) as a ready-to-use, or, RTU, liquid formulation of bivalirudin in a 250mL vial that can be administered to patients without having to reconstitute the drug. As a result, EP-6101 (bivalirudin) will be Joint Commission-preferred.

Currently-Marketed Bivalirudin Product

Bivalirudin is marketed by The Medicines Company in the United States under the brand name Angiomax. The approved product's presentation is a vial containing 250mg of lyophilized powder which requires reconstitution. Worldwide sales of Angiomax were approximately $548 million in 2012.

Limitations of Angiomax

The powder form of Angiomax must be reconstituted before administration at the beginning of a catheter laboratory, or cath lab, procedure then further diluted into an IV bag. As with any drug requiring reconstitution, mixing can result in dosing errors if, for example, the wrong diluent or incorrect amount of diluent is added to the product. Additionally, reconstitution takes time, which results in slower work flows. Finally, Angiomax is limited in that the Joint Commission guidelines encourage the use of RTU presentations over products that require reconstitution. Additionally, U.S. Pharmacopeia, the scientific nonprofit organization that sets standards for medicines manufactured, distributed and consumed worldwide and whose drug standards are enforceable in the United States by the FDA, has issued USP 797, a far-reaching regulation that governs any pharmacy that prepares compounded sterile preparations and, among other things, requires that drug compounding be done in a clean room environment by a licensed pharmacist. In many situations where no licensed pharmacist is available (for example, during late-night shifts), nurses and other healthcare providers are required to mix the drug themselves.

Eagle's Solution: EP-6101 RTU Bivalirudin

We are developing EP-6101, a bivalirudin RTU liquid formulation to resolve each of the current limitations of Angiomax. If approved, our product formulation would be available for immediate patient administration with no reconstitution required. This would save time and reduce risks of dosing errors during reconstitution. Additionally, because no mixing of our drug is required, compliance with regulations such as USP 797 can be achieved regardless of the situation in which our drug is required to be administered.

We engaged Phoenix Marketing International to perform market research on our behalf for EP-6101 (bivalirudin) to determine how receptive hospital stakeholders would be to this new formulation. Phoenix worked with both hospital pharmacists and cath lab nurses in conducting this research. We believe these two groups of clinicians are the most important within an institution in terms of evaluating the opportunity for an RTU formulation of Angiomax, as they have extensive experience with the existing lyophilized powder product.

Hospital nurses and pharmacists provided feedback regarding EP-6101 (bivalirudin) stating that they believe this product will offer several benefits to both the staff and the patient, including more efficient work flows and the ability to more quickly and flexibly administer the drug in a variety of settings.

EP-6101 (bivalirudin) Clinical Development and Regulatory Status

We completed a Type C meeting with the FDA in November 2013 at which we discussed the expected product attributes of EP-6101. We anticipate submitting 505(b)(2) NDA in the first half of 2015.

EP-1101 (argatroban) for Heparin-Induced Thrombocytopenia

Argatroban is an anti-coagulant originally developed for the treatment of heparin-induced thrombocytopenia, or HIT. Our formulation of argatroban, EP-1101, is our first product approved by the FDA, and marketed by The Medicines Company and Sandoz under agreements with us. Through our agreement with The Medicines Company, we granted The Medicines Company exclusive rights to commercialize argatroban in the United States and Canada and a right of first negotiation to commercialize argatroban in other countries (except China). Through our settlement agreement and related supply and distribution agreement with Sandoz, we granted Sandoz the right to distribute an unbranded (generic) version of argatroban in 50mg/50mL vials in the United States. Through our contract manufacturer we supply The Medicines Company with argatroban in 50mg/50mL vials and we supply Sandoz with an unbranded (generic) version of argatroban in 50mg/50mL vials. Sandoz also markets argatroban in 125mg/125mL vials and pursuant to our agreements with Sandoz, Sandoz is obligated to pay us a majority of the net profits Sandoz receives for sales of such product in the United States. For more information regarding these agreements, see below under "— License Agreements."

Currently-Marketed Argatroban Product

Argatroban is currently sold by GSK, West-ward, The Medicines Company and Sandoz. It is sold in 250mL (GSK and West-ward), 125mL (Sandoz) and 50mL (The Medicines Company and Sandoz) presentations. According to IMS Health, argatroban had U.S. annual sales of $99 million in 2012.

Limitations of Argatroban

The branded form of argatroban from GSK and West-ward is supplied in a 2.5 mL vial with 100 mg/mL of active pharmaceutical ingredient. In this formulation, the current product requires 100-fold dilution for infusion, requiring the use of a 250 mL intravenous bag, typically resulting in approximately 30% waste primarily driven by prophylactic administration while waiting for HIT testing results, common infection control policies requiring change of intravenous bags every 24 hours and patient release from hospital prior to complete administration.

Eagle's Solution: EP-1101 (argatroban) Injection

Our formulation of argatroban is supplied in a single-use vial, containing 50mg of drug in a 50mL aqueous solution, where only 1% of the drug is wasted. EP-1101 (argatroban) is ready to use and the vial label contains a ring sling for convenient IV pole administration. It was approved by the FDA on June 29, 2011 for treatment of HIT in patients. Based on the expected expiration date of patents covering GSK's branded reference product, generic formulations of the drug may not enter the market until mid-2014, unless they succeed in invalidating or proving non-infringement of Sandoz's patents in paragraph IV litigation.

We believe that the development, approval and commercialization of EP-1101 (argatroban) provides validation of our business model and strategy because it has resulted in a product that improves upon the formulation of the branded reference product in terms of ease of use, reduced waste and lower

overall cost of treatment. Further, our argatroban product obtained meaningful exclusivity with respect to any generic versions of the branded reference products, given that it launched for commercial sale in September 2011, nearly three years prior to the anticipated June 2014 market entry for generic versions of the branded reference products, and only shortly after Sandoz obtained approval in May 2011 for its RTU 125mL presentation of argatroban and prior to West-ward's approval of its 250mL presentation of argatroban in January 2012. Our argatroban product is currently demonstrating a strong pricing position relative to the branded price, and according to recent monthly IMS Health data, has a market share of 28% that we expect to continue to grow.

EP-2101 (topotecan) for Ovarian, Cervical and Small-Cell Lung Cancers

Topotecan is a chemotherapeutic agent for use in ovarian, cervical and small-cell lung cancers. GlaxoSmithKline currently markets Hycamtin in the United States as the branded approved formulation of topotecan. The current market for Hycamtin is approximately $65 million per year. We currently own all rights to EP-2101, our proprietary formulation of topotecan, pursuant to an agreement with SciDose wherein we were assigned the rights to all intellectual property related to our formulation of topotecan. EP-2101 (topotecan) was approved by the EMA in December 2011 for use in Europe and is our second approved product. We have not yet launched EP-2101 (topotecan) in Europe and we cannot anticipate at this point in time when we will enter the European market. In August 2009, we submitted for approval in the United States under the 505(b)(2) regulatory pathway, referencing the brand product, Hycamtin. Ultimately, the FDA determined that it could not approve the application as submitted due to the amount of active drug per vial in our product and the potential for unintentional overdose. Based on the FDA's feedback and our determination that the market for topotecan had become overly competitive with multiple players, we decided not to continue to pursue product approval and we do not currently have plans to commercialize EP-2101 (topotecan) in the United States. However, like EP-1101 (argatroban), we believe that the development, approval and commercialization of EP-2101 (topotecan) provides validation of our drug development expertise, regulatory strategy and business model.

Additional Products in our Portfolio

In addition to our disclosed products pipeline, we are pursuing a number of potential products that address broad indications such as oncology, infectious diseases and others. We intend to use our novel and well-developed methods to identify ideal development candidates and to commercialize improved formulations of widely prescribed therapeutics.

Product Commercialization

Historically, we have chosen to out-license the commercial rights for products we have developed, such as EP-1101 (argatroban) which launched in the United States in 2011 and is sold by The Medicines Company as argatroban in the United States and Canada under an exclusive license from us. This arrangement allowed our management to focus our financial resources on research and development of other products in our portfolio. Additionally, in 2013 our management decided to also license certain rights to commercialize argatroban in the United States to Sandoz as part of a settlement of a paragraph IV dispute between the parties. Sandoz has developed strong relationships with the pharmaceutical group purchasing organizations and wholesalers, providing stronger commercial terms for EP-1101 (argatroban) with these important customers. For more information regarding this arrangement, see below under "— License Agreements."

In the future, however, we intend to develop and commercialize our product portfolio in the United States on our own while out-licensing commercialization rights for other territories. Our goal is to retain significant control over the development process and commercial execution for our product

portfolio, while participating in a meaningful way in the global economics of all drugs that we bring to the market. We believe that a small, focused specialty sales force will generally be sufficient to successfully commercialize our products because the nature of our products means that the majority of detailing points for our sales force are likely to be medium and large healthcare systems that operate multiple hospitals and purchase through group purchasing organizations, as well as hospital-based physicians and hospital pharmacists. We expect these contained detailing points will allow the sales team to be more efficient than traditional pharmaceutical sales forces, as the important clinical customers are located in a smaller number of key locations as opposed to the need to call on multiple physicians across a broad sales territory.

In addition to the above commercial execution strategy, following this offering, and assuming approval of Ryanodex on or about our scheduled PDUFA goal date in July 2014, we intend to launch Ryanodex (dantrolene for MH) into the U.S. market in 2014. The primary target audience for Ryanodex (dantrolene for MH) will be anesthesiologists and hospital pharmacists. Additionally, our sales representatives will call on nurse anesthetists, operating room nurses and also the purchasing department within these institutions. The sales team will be supported by a group of marketing individuals that will be providing materials to support product messaging.

Manufacturing

We do not own any manufacturing facilities. The manufacture of sterile injectables is highly reliant on very complex sterile techniques and personnel aseptic techniques which present significant challenges and requires specialized expertise. Further, sterile processes have a high level of scrutiny by regulatory agencies. Consequently, we utilize a network of third party manufacturers for production of our products. All manufacturers are monitored and evaluated by our quality department to assess compliance with regulatory requirements and our internal quality standards and benchmarks.

Historically, sterile injectable manufacturers have, from time to time, had quality control difficulties. If non-conformances occur, remediation, such as temporary voluntary closure or renovations of major production facilities, could be costly and time consuming, resulting in cascading and persistent shortages. Moreover, high rates of capacity utilization may also limit the ability of manufacturers to perform routine maintenance and keep facilities in state of compliance which can lead to product recalls or other supply disruptions.

We have a highly experienced quality group that works with and regularly inspects or meets with our manufacturers to review the manufacturing process for our products and to provide input on quality issues. We have recognized the risk of such supply chain disruptions and approached the situation through risk management strategies designed to mitigate the effects of such disruptions. These include having our products and product candidates manufactured at more than one site around the world. While this creates additional effort and requires maintaining dialogue and traveling to and overseeing production at a number of facilities, we believe our manufacturing risks are better managed by utilizing a range of third party manufacturers at diverse locations. We seek to minimize the risk of catastrophic events that could occur if our products were manufactured in a single location. Currently, with the exception of one site, no contract manufacturer produces more than one product for us. We currently utilize two manufacturing sites in India and one manufacturing site in the United States. We plan to manufacture the additional products in our portfolio in two additional sites, one in the United States and the other in Italy.

Given the range of difficulties we may encounter in manufacturing our sterile injectable product candidates, we plan to seek FDA approval to manufacture our disclosed product candidates in an additional location for each product. Due to FDA guidelines, we will not submit for the approval of

an additional manufacturing location until after the final FDA approval for a given product. Therefore, we expect to be dependent upon the single initial manufacturing site for approximately one year after approval. Upon approval of additional manufacturing locations, we will have back-up manufacturing sites for each product in the event that a given plant has difficulties. Where possible over time, we plan to add additional products to our back-up locations, although it may not be economically practical to follow this strategy for all of our product candidates.

Intellectual Property and Exclusivity

We strive to protect and enhance the proprietary technologies that we believe are important to our business. We seek to obtain and maintain patents for any patentable aspects of our products or product candidates, their methods of use and any other inventions that are important to our business model and maintaining a competitive advantage over generic competitors. Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, maintain our licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in the fields targeted by our products and product candidates.

Patents and Patent Applications

We are the exclusive licensee under our license with Lyotropic to a family of patents and applications that relate to low volume formulations of dantrolene, and methods of treatment using dantrolene. There are two issued US patents, and two pending US patent applications, along with foreign counterparts that include both issued patents and pending applications. The issued US patents (US 8,110,225, and US 7,758,890) cover low volume formulations of dantrolene in reconstitutable and in ready to use liquid form. We expect that the issued patents will expire no later than July 1, 2025, and the applications, if issued, will expire no later than June 13, 2022.

We are the sole owner of five pending US patent applications, and six corresponding foreign filings for patent applications in a number of jurisdictions covering various formulations and methods of use of bendamustine. We are currently prosecuting these applications, which, if issued, would expire no later than March 15, 2033.

We are the co-owner, with The Medicines Company, of two issued US patents (US 7,713,928 and US 7,803,762) that cover ready to use formulations and methods of treatment of bivalirudin, and there are no pending applications or foreign filings. We expect that our issued patents will expire no later than August 20, 2029.

We are the sole owner of a portfolio of issued US patents and pending applications (including US patents US 7,589,106 and US 7,687,516), and corresponding issued foreign patents and patent applications in a range of countries that cover various formulations and methods of use of argatroban. We expect that our issued patents in the US will expire no later than September 26, 2027, and our applications, if issued, will expire no later than October 9, 2027.

Trade Secrets and Proprietary Information

Trade secrets play an important role in protecting our products and provide protection beyond patents and regulatory exclusivity. The scale-up and commercial manufacture of our products involves processes, custom equipment, and in-process and release analytical techniques that we believe are

unique to us. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these security measures, individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our proprietary technology and processes may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, scientific advisors, contractors or any future collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. We seek to protect our proprietary information, including our trade secrets and proprietary know-how, by requiring third parties with whom we contract for services related to our products, including manufacturing services to agree to terms in our agreements with such third parties that protect our confidential and trade secret information. We also require our employees, consultants and other advisors to execute proprietary information and confidentiality agreements upon the commencement of their employment or engagement. These agreements generally provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not be disclosed to third parties except in specific circumstances. In the case of our employees, the agreements also typically provide that all inventions resulting from work performed for us, utilizing our property or relating to our business and conceived or completed during employment shall be our exclusive property to the extent permitted by law. Where appropriate, agreements we obtain with our consultants also typically contain similar assignment of invention obligations. Further, we require confidentiality agreements from entities that receive our confidential data or materials.

License Agreements

License Agreement with Lyotropic Therapeutics, Inc.

In October 2008, we entered into a license and sublicense agreement with Lyotropic Therapeutics, Inc., or Lyotropic, under which we were granted an exclusive license under Lyotropic's intellectual property rights relating to dantrolene, and an exclusive worldwide sublicense under certain nanocrystal technology relating to a formulation of dantrolene licensed by Alkermes, Inc. (as successor in interest to Elan Pharma International Limited), or Alkermes, to Lyotropic under an August 2004 license agreement between Alkermes and Lyotropic.

Under the terms of this license agreement with Lyotropic, we are responsible for the prosecution and maintenance of all of the licensed patents that solely or predominantly cover the dantrolene product. We are also required to use commercially reasonable efforts to progress the development of our dantrolene product in the United States, and after completion of required clinical trials, to file a 505(b)(2) application in the United States for such product. We are also required to use commercially reasonable efforts to obtain regulatory approval and make commercial sales of our dantrolene product in at least two countries in Europe, in Japan and in at least one of Korea, Australia, Canada or Brazil within certain specified time periods, or to enter into a bona fide sublicense agreement under which a third party would progress commercialization of the product in such country or countries. These time periods may be extended if additional clinical trials are required in any such country in order to obtain regulatory approval in such country. Each of Europe, Japan and the rest of the countries in the world, including Korea, Australia, Canada or Brazil are considered to be separate Ex-US Regions for the purpose of our license with Lyotropic. If we fail to comply with these commercial and regulatory diligence obligations in, each of the Ex-US Regions, our license in the applicable Ex-US Region will be revoked, and we will be required to discontinue operations in relation to the product in the applicable countries, and to transfer to Lyotropic all materials and information developed by us in relation to our dantrolene product in the Ex-US Regions.

Under our license agreement with Lyotropic, we are not required to make any milestone payments but we are required to pay royalties on a country-by-country basis at a percentage in the mid-teens on net sales of our dantrolene product until the earlier of (i) the later of ten years from the date of first commercial sale of our dantrolene product in such country and expiration of the last valid claim covering such product in such country and (ii) with respect to any country in which we or our affiliates (but not our sublicensees) are selling the dantrolene product, as of the beginning of the first fiscal quarter following the date of the first commercial sale of a generic version of our dantrolene product that results in a decrease in our net profits in such country by a specified percentage based on our average quarterly net profits for sales of our dantrolene product in such country over the 18 months immediately preceding the launch of such generic product.

Our agreement with Lyotropic will continue in force until terminated. The agreement may be terminated by either party for the other party's insolvency or material uncured breach, and we have the right to terminate the agreement upon 90 days written notice if, in our sole discretion, commercial development of the dantrolene product is no longer commercially reasonable.

License and Development Agreement with The Medicines Company

In September 2009, we entered into a license and development agreement with The Medicines Company under which we granted The Medicines Company an exclusive license under our patent and other intellectual property rights in argatroban to commercialize argatroban products in the United States and Canada, and a right of first negotiation to commercialize argatroban in other countries (except the right of first negotiation does not apply to China unless and until we regain rights to exploit argatroban products in China).

Under this agreement, we are responsible for development and obtaining regulatory approvals for argatroban in the United States, at our cost, and are required to use commercially reasonable efforts with respect to such activities. The Medicines Company is required to use commercially reasonable efforts to commercialize such argatroban products. We are also responsible, at our cost, for prosecution and maintenance of the licensed patents that cover the argatroban products, although The Medicines Company is required to reimburse us for half of our costs.

Under this agreement, we received an upfront lump sum payment of $5,000,000. Additionally, we are obligated to share equally gross profits we receive from Sandoz pursuant to the Sandoz Supply and Distribution Agreement with The Medicines Company and The Medicines Company is obligated to share equally with us the gross profits it receives from sales of argatroban product in the United States.

Our agreement with The Medicines Company will continue in force until terminated. The agreement may be terminated by either party for the other party's material uncured breach, and The Medicines Company has the right to terminate the agreement in its entirety or on a product-by-product basis upon 60 days written notice to us. In November 2011, we initiated a voluntary product recall of the argatroban product which was reintroduced on the market in May 2012. Under a 2012 amendment to this agreement we agreed to and received net payment of $471,077 from The Medicines Company under the agreement. In 2009, we and The Medicines Company also entered into a related supply agreement under which we are the exclusive supplier of argatroban product to The Medicines Company for sales in the United States and Canada. This agreement will remain in force for a period of ten years, unless our license to The Medicines Company is terminated, in which case the supply agreement will automatically terminate. Either we or The Medicines Company may also terminate this supply agreement for uncured material breach.

Settlement Agreement and Related Supply and Distribution Agreement with Sandoz

In January 2013, we entered into a settlement agreement with Sandoz Inc., or Sandoz, to resolve the suit we brought against Sandoz claiming infringement of our issued U.S. patents 7,589,106 and 7,687,516, based on Sandoz's filing of ANDA No. 203743, in which Sandoz requested approval from the FDA for distribution of argatroban prior to the expiration of such patents. In connection with, and at the same time as the settlement agreement, we also entered into a Supply and Distribution Agreement with Sandoz, under which we agreed to supply unbranded (generic) argatroban in 50mg/50mL vials, which we define as an Authorized Generic Product, to Sandoz through our contract manufacturer for exclusive distribution to Sandoz's customers in the United States.

Under the terms of the Supply and Distribution Agreement, Sandoz is obligated to pay us a percentage in the range of 85 to 95 percent of the net profits for all Authorized Generic Product sold by Sandoz. Also, under the terms of the Supply and Distribution Agreement, Sandoz will continue to market argatroban in 125mg/125mL vials, which we define as a Sandoz Product, and Sandoz is obligated to pay us a percentage in the range of 60 to 70 percent of the net profits of all Sandoz Product sold by Sandoz.

Sandoz was authorized to begin commercial sales of our argatroban 50mg/50mL product in the United States upon execution of this agreement and the agreement will continue in force for three years from the date of signing. The agreement will automatically renew for additional one year periods unless either party gives notice to the other of non-renewal at least six months prior to each renewal date. Either we or Sandoz may terminate this agreement earlier for the other party's uncured material breach, insolvency or force majeure. In addition, either we or Sandoz may terminate the agreement earlier if the agreement violates or could violate applicable laws, or if a party is subjected to increased risk due to a change in laws or regulations after the effective date of the agreement, in each case based on the opinion of governmental agencies and/or the advice of legal counsel, or if it is no longer commercially viable to continue sales of argatroban in the 50mg/50mL preparation in the United States, which is defined as the point at which net sales fall below a specified percentage of the cost argatroban product is sold to Sandoz under the agreement.

Development and License Agreement with SciDose (argatroban and bivalirudin).

In June 2007 we entered into a development and license agreement with SciDose, LLC, or SciDose, in which SciDose assigned us certain patents relating to argatroban, bivalirudin, and two additional products under development, or the SciDose Subject Products, and granted us an exclusive, sublicensable, worldwide (excluding China for all products except those containing bivalirudin), license under SciDose's intellectual property rights to develop, make, use, sell and import parenteral formulations of the SciDose Subject Products (and including all other formulations for one of the additional products under development).

Our collaboration with SciDose is guided by a joint development committee. SciDose is responsible, at its cost, for prosecuting and maintaining the licensed patents that cover the SciDose Subject Products. We are required to use commercially reasonable efforts to develop, obtain marketing authorization for and commercialize the SciDose Subject Products under this agreement.

Under the terms of this Agreement no further milestone payments are due to SciDose. We are required to make royalty payments based on gross profits of sales of the SciDose Subject Products by us and our affiliates at a percentage in the range of 45 to 55 percent for SciDose Subject Products that achieve regulatory approval and are commercialized on the basis of a 505(b)(2) application, and at a percentage in the range of 20 to 30 percent with respect to SciDose Subject Products that are commercialized on the basis of an ANDA application. Our royalty obligations continue on a product-by-product basis until the later of ten years after the first commercial sale of each SciDose Subject Product and the expiration of the last valid claim covering such SciDose Subject Product, subject to certain customary reductions in the event that there is no valid patent claim covering the manufacture, use, import or sale of such SciDose Subject Product in a country in the territory. In the event we grant a license to any third party under the patents assigned to us or the intellectual property rights licensed to us with respect to any SciDose Subject Product, we are required to pay to SciDose 100% of all milestone payments we receive with respect to commercialization of any such SciDose Subject Products outside the United States, and a percentage in the range of 45 to 55 percent of any milestone payments we receive with respect to commercialization of any such SciDose Subject Products in the United States.

This agreement expires upon the expiration of our royalty obligations. The agreement may be terminated earlier by either us or SciDose, for the other party's material uncured breach and we may terminate this agreement on a product-by-product basis if the costs and expenses related to clinical trials for a SciDose Subject Product exceed a specified threshold.

Development and License Agreement with Robert One, LLC (bendamustine)

In March 2008 we entered into a development and license agreement with Robert One, LLC, or Robert One, in which Robert One assigned to us certain patents relating to bendamustine and four additional 505(b)(2) products and/or ANDA products under development, or the Robert One (bendamustine) Subject Products, and granted us an exclusive, sublicensable, license under Robert One's intellectual property rights to develop make, use, sell and import Robert One (bendamustine) Subject Products worldwide (excluding China) with respect to bendamustine and other 505(b)(2) product applications and in North America with respect to ANDA product applications.

Our collaboration with Robert One is guided by a joint development committee. If the joint development committee is not able to make a decision by consensus then the dispute will be escalated to specified senior executive officers of the parties. Robert One is responsible, at its cost, for prosecuting and maintaining the licensed patents that cover the Robert One (bendamustine) Subject Products. We are required to use commercially reasonable efforts to develop the Robert One (bendamustine) Subject Products and obtain marketing authorization for the Robert One (bendamustine) Subject Products in the Territory and, upon receipt of marketing authorization, commercialize the Robert One (bendamustine) Subject Products under this agreement.

Under the terms of this Agreement no further milestone payments are due to Robert One. We are required to make royalty payments based on gross profits of sales of the Robert One (bendamustine) Subject Products by us and our affiliates in the Territory at a percentage in the range of 5 to 15 percent for bendamustine products and at a percentage in the range of 45 to 55 percent for products, other than bendamustine products, that achieve regulatory approval and are commercialized on the basis of a 505(b)(2) application, and at a percentage in the range of 20 to 30 percent with respect to products, other than bendamustine products, are commercialized on the basis of an ANDA application. Our royalty obligations continue on a product-by-product basis until the later of ten years after the first commercial sale of each Robert One (bendamustine) Subject Product and the expiration of the last valid claim covering such Robert One (bendamustine) Subject Product, subject to certain reductions in the event that there is no valid patent claim covering the manufacture, use, import or

sale of such Robert One (bendamustine) Subject Product in a country in the territory. In the event we grant a license to any third party under the patents assigned to us or the intellectual property rights licensed to us with respect to any Robert One (bendamustine) Subject Product, we are required to pay to Robert One 100% of all milestone payments we receive with respect to commercialization of any such Robert One (bendamustine) Subject Products outside the United States, and a percentage in the range of 45 to 55 percent of any milestone payments we receive with respect to commercialization of any such Robert One (bendamustine) Subject Products commercialized in the United States.

This agreement expires upon the expiration of our royalty obligations. The agreement may be terminated earlier by either us or Robert One, for the other party's material uncured breach and we may terminate this agreement on a product-by-product basis if the costs and expenses related to clinical trials for a Robert One (bendamustine) Subject Product exceed a specified threshold and either party may terminate the agreement if the ANDA or 505(b)(2) applications, as applicable, for the formulation of the Robert One (bendamustine) Subject Product has not been accepted by the FDA or if the ANDA or 505(b)(2), as applicable, is not approved by the FDA.

Development and License Agreement with Robert One, LLC (pemetrexed)

In February 2009 we entered into a development and license agreement with Robert One, in which Robert One assigned to us certain patents relating to pemetrexed and four additional 505(b)(2) products and/or ANDA products under development, or the Robert One (pemetrexed) Subject Product and granted us an exclusive, sublicensable, license under Robert One's intellectual property rights to develop make, use, sell and import Robert One (pemetrexed) Subject Products worldwide (excluding China) with respect to pemetrexed and other 505(b)(2) product applications and in North America with respect to ANDA product applications.

Our collaboration with Robert One is guided by a joint development committee. If the joint development committee is not able to make a decision by consensus then the dispute will be escalated to specified senior executive officers of the parties. Robert One is responsible, at its cost, for prosecuting and maintaining the licensed patents that cover the Robert One (pemetrexed) Subject Products. We are required to use commercially reasonable efforts to develop the Robert One (pemetrexed) Subject Products and obtain marketing authorization for the Robert One (pemetrexed) Subject Products in the United States and, upon receipt of marketing authorization, commercialize the Robert One (pemetrexed) Subject Products under this agreement.

Under the terms of this Agreement no further milestone payments are due to Robert One. We are required to make royalty payments based on gross profits of sales of the Robert One (pemetrexed) Subject Product by us and our affiliates in the Territory at a percentage in the range of 45 to 55 percent for Robert One (pemetrexed) Subject Products that achieve regulatory approval and are commercialized on the basis of a 505(b)(2) application, and at a percentage in the range of 20 to 30 percent with respect to Robert One (pemetrexed) Subject Products that are commercialized on the basis of an ANDA application. Our royalty obligations continue on a product-by-product basis until the later of ten years after the first commercial sale of each Robert One (pemetrexed) Subject Product and the expiration of the last valid claim covering such Robert One (pemetrexed) Subject Product, subject to certain reductions in the event that there is no valid patent claim covering the manufacture, use, import or sale of such Robert One (pemetrexed) Subject Product in a country in the territory. In the event we grant a license to any third party under the patents assigned to us or the intellectual property rights licensed to us with respect to any Robert One (pemetrexed) Subject Product, we are required to pay to Robert One 100% of all milestone payments we receive with respect to commercialization of any such Robert One (pemetrexed) Subject Products outside the United States and a percentage in the range of 45 to 55 percent of any milestone payments we receive with respect

to commercialization of any such Robert One (permetrexed) Subject Products commercialized in the United States.

This agreement expires upon the expiration of our royalty obligations. The agreement may be terminated earlier by either us or Robert One, for the other party's material uncured breach and we may terminate this agreement on a product-by-product basis if the costs and expenses related to clinical trials for a Robert One (pemetrexed) Subject Product exceed a specified threshold and either party may terminate this agreement if the ANDA or 505(b)(2) applications, as applicable, for the formulation of the Robert One (pemetrexed) Subject Product has not been accepted by the FDA in each case if the ANDA or 505(b)(2), as applicable, is not approved by the FDA and the joint development committee has not selected a replacement product within the specified timeframe.

Supply Agreement with Cipla Limited

In December of 2012 we entered into a non-exclusive supply agreement with Cipla Limited, or Cipla, pursuant to which Cipla agreed to supply argatroban product to us for sale in the United States and topotecan product to us for sale in the European Union. Under the terms of this agreement we are obligated to use commercially reasonable efforts to affect a transfer of the manufacture of argatroban to an alternate manufacturer by a specified date.

This agreement expires with respect to argatroban upon the later of (i) receipt by us of approval from the FDA for manufacture of argatroban for sale in the United States at a third party manufacturing site or (ii) December 31, 2014. This agreement expires with respect to topotecan upon the earlier of (i) receipt by us of approval for the manufacture of topotecan product for sale in the European Union at a third party manufacturing site or (ii) December 31, 2014, unless the parties agree in writing to extend this agreement beyond such date. The agreement may be terminated earlier by either us or Cipla, for the other party's uncured failure to pay an amount due under the agreement, for the other party's material uncured breach of the agreement, or if the other party becomes subject to specified bankruptcy, insolvency or similar circumstances.

Competition

The pharmaceutical and biotechnology industries are intensely competitive and subject to rapid and significant technological change. Our competitors include organizations such as major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and generic drug companies. Many of our competitors have greater financial and other resources than we have, such as more commercial resources, larger research and development staffs and more extensive marketing and manufacturing organizations. As a result, these companies may obtain marketing approval more rapidly than we are able and may be more effective in selling and marketing their products. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Our competitors may succeed in developing, acquiring or licensing on an exclusive basis technologies and drug products that are more effective or less costly than products that we are currently selling through partners or developing or that we may develop, which could render our products obsolete and noncompetitive. We expect any products that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price and the availability of reimbursement from government and other third-party payers. We also expect to face competition in our efforts to identify appropriate collaborators or partners to help commercialize our product portfolio in our target commercial markets.

Government Regulation

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The FDCA and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable FDA or other requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending applications, clinical holds, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, withdrawal of product from the market, injunctions, fines, civil penalties and criminal prosecution.

FDA approval is required before any new unapproved drug or dosage form, including a new use of a previously approved drug, can be marketed in the United States. The process required by the FDA before a new drug may be marketed in the United States generally involves:

- completion of pre-clinical laboratory and animal testing and formulation studies in compliance with the FDA's current good laboratory practice, or cGLP, regulations;
- submission to the FDA of an Investigational New Drug, or IND, application for human clinical testing which must become effective before human clinical trials may begin in the United States;
- approval by an independent institutional review board, or IRB, at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with current good clinical practices, or cGCP, to establish the safety and efficacy of the proposed drug product for each intended use;
- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is manufactured to assess compliance with the FDA's cGMP regulations to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- submission to the FDA of an NDA;
- satisfactory completion of a potential review by an FDA advisory committee, if applicable; and
- FDA review and approval of the NDA.

The preclinical and clinical testing and approval process takes many years and the actual time required to obtain approval, if any, may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including cGLPs. The results of preclinical testing are submitted to the FDA as part of an IND application along with other information, including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND application is submitted.

The IND application automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions relating to one or more proposed

clinical trials and places the clinical trial on a clinical hold, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. A separate submission to an existing IND application must also be made for each successive clinical trial conducted during product development. Further, an independent IRB, covering each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and informed consent information for subjects before the trial commences at that site and it must monitor the study until completed. The FDA, the IRB, or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk or for failure to comply with the IRB's requirements, or may impose other conditions. Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator in accordance with cGCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Sponsors of clinical trials generally must register and report, at the NIH-maintained website ClinicalTrials.gov, key parameters of certain clinical trials. For purposes of an NDA submission and approval, human clinical trials are typically conducted in the following sequential phases, which may overlap or be combined:

- *Phase 1:* In Phase 1, through the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness.

- *Phase 2:* Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks.

- *Phase3:* Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. Under federal law, the submission of most NDAs is subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment user fees.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information and is subject to payment of additional user fees. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. Under PDUFA the FDA has agreed to certain performance goals in the review of

NDAs through a two-tiered classification system, Standard Review and Priority Review. Priority Review designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. The FDA endeavors to review applications subject to Standard Review within ten to twelve months, whereas the FDA's goal is to review Priority Review applications within six to eight months, depending on whether the drug is a new molecular entity.

The FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions.

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCP requirements. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless it determines that the manufacturing process and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter to indicate that the review cycle for an application is complete and that the application is not ready for approval. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA may ultimately decide that an application does not satisfy the regulatory criteria for approval. If, or when, the deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

As a condition of NDA approval, the FDA may require a REMS to help ensure that the benefits of the drug outweigh the potential risks. If the FDA determines a REMS is necessary during review of the application, the drug sponsor must agree to the REMS plan at the time of approval. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate healthcare providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other elements to assure safe use, such as special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. In addition, the REMS must include a timetable to periodically assess the strategy. The requirement for a REMS can materially affect the potential market and profitability of a drug.

Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy, and the FDA has the authority to prevent or limit further marketing of a product based on the results of these post-marketing programs. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label, and, even if the FDA approves a product, it may limit the approved indications for use for the product or impose other conditions, including labeling or distribution restrictions or other risk-management mechanisms.

Further changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented, which may require us to develop additional data or conduct additional pre-clinical studies and clinical trials. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the similar procedures in reviewing NDA supplements as it does in reviewing NDAs.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to drug listing and registration, recordkeeping, periodic reporting, product sampling and distribution, adverse event reporting and advertising, marketing and promotion, including standards and regulations for direct to consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. While physicians may prescribe for off-label uses, manufacturers may only promote for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, quality-control, drug manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced and announced inspections by the FDA and these state agencies, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered. The FDA may also impose a REMS requirement on a drug already on the market if the FDA determines, based on new safety information, that a REMS is necessary to ensure that the drug's benefits outweigh its risks. In addition, regulatory authorities may take other enforcement action, including, among other things, warning letters, the seizure of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, refusal to approve pending applications or supplements to approved applications, civil penalties and criminal prosecution.

In addition, the distribution of prescription pharmaceuticals is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. A growing majority of states also impose certain drug pedigree requirements on the sale and distribution of prescription drugs.

The FDA may require post-approval studies and clinical trials if the FDA finds that scientific data, including information regarding related drugs, deem it appropriate. The purpose of such studies would be to assess a known serious risk or signals of serious risk related to the drug or to identify an unexpected serious risk when available data indicate the potential for a serious risk. The FDA may also require a labeling change if it becomes aware of new safety information that it believes should be included in the labeling of a drug.

The Hatch-Waxman Amendments

ANDA Approval Process

The Hatch-Waxman Act, established abbreviated FDA approval procedures for drugs that are shown to be equivalent to proprietary drugs previously approved by the FDA through its NDA process. Approval to market and distribute these drugs is obtained by filing an ANDA with the FDA. An ANDA is a comprehensive submission that contains, among other things, data and information

pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. Premarket applications for generic drugs are termed abbreviated because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, a generic applicant must demonstrate that its product is bioequivalent to the innovator drug. In certain situations, an applicant may obtain ANDA approval of a generic product with a strength or dosage form that differs from a referenced innovator drug pursuant to the filing and approval of an ANDA Suitability Petition. The FDA will approve the generic product as suitable for an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the innovator product. A product is not eligible for ANDA approval if the FDA determines that it is not equivalent to the referenced innovator drug, if it is intended for a different use, or if it is not subject to an approved Suitability Petition. However, such a product might be approved under an NDA, with supportive data from clinical trials.

505(b)(2) NDAs

As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments and permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant. If the 505(b)(2) applicant can establish that reliance on FDA's previous findings of safety and effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the approved branded reference drug. The FDA may then approve the new product candidate for all, or some, of the label indications for which the branded reference drug has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

Orange Book Listing

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent.

If the reference NDA holder and patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant.

The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired as described in further detail below.

Non-Patent Exclusivity

In addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non-patent exclusivity, during which the FDA cannot approve an ANDA or 505(b)(2) application that relies on the listed drug. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval of a new chemical entity, or NCE, which is a drug that contains an active moiety that has not been approved by FDA in any other NDA. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacologic action. During the five year exclusivity period, the FDA cannot accept for filing any ANDA seeking approval of a generic version of that drug or any 505(b)(2) NDA for the same active moiety and that relies on the FDA's findings regarding that drug, except that FDA may accept an application for filing after four years if the follow-on applicant makes a paragraph IV certification.

A drug, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA or 505(b)(2) application for the protected modification until after that three-year exclusivity period has run. However, unlike NCE exclusivity, the FDA can accept an application and begin the review process during the exclusivity period.

Orphan Drug Designation and Exclusivity

The Orphan Drug Act provides incentives for the development of products intended to treat rare diseases or conditions. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. If a sponsor demonstrates that a drug is intended to treat rare diseases or conditions, the FDA will grant orphan designation for that product for the orphan disease indication. Orphan designation must be requested before submitting an NDA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation, however, does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Orphan drug designation provides manufacturers with research grants, tax credits and eligibility for orphan drug exclusivity. If a product that has orphan drug designation subsequently receives the first FDA approval of the active moiety for that disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which for seven years prohibits the FDA from approving another product with the same active ingredient for the same indication, except in limited circumstances. If a drug designated as an orphan product receives marketing approval for an indication broader than the orphan indication for which it received the designation, it will not be entitled to orphan drug exclusivity. Orphan exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug

exclusivity is not able to meet market demand. Further, the FDA may approve more than one product for the same orphan indication or disease as long as the products contain different active ingredients. Moreover, competitors may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. As a result, even if one of our product candidates receives orphan exclusivity, we may still be subject to competition. Orphan exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug or if our product candidate is determined to be contained within the competitor's product for the same indication or disease.

The Animal Rule

In the case of product candidates that are intended to treat certain rare life-threatening diseases, conducting controlled clinical trials to determine efficacy may be unethical or unfeasible. Under regulations issued by the FDA in 2002, often referred to as the "Animal Rule," the approval of such products can be based on clinical data from trials in healthy human subjects that demonstrate adequate safety and efficacy data from adequate and well-controlled animal studies. Among other requirements, the animal studies must establish that the drug or biological product is reasonably likely to produce clinical benefits in humans. Because the FDA must agree that data derived from animal studies may be extrapolated to establish safety and effectiveness in humans, seeking approval under the Animal Rule may add significant time, complexity and uncertainty to the testing and approval process. In addition, products approved under the Animal Rule are subject to additional requirements including post-marketing study requirements, restrictions imposed on marketing or distribution or requirements to provide information to patients.

International Regulation

In addition to regulations in the United States, we are and will be subject to a variety of foreign regulations regarding development, approval, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional review periods, and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing, among other things, the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

In the European Union, or EU, we may seek marketing authorization under either the centralized authorization procedure or national authorization procedures.

- Centralized procedure. The European Medicines Agency, or EMA, implemented the centralized procedure for the approval of human medicines to facilitate marketing authorizations that are valid throughout the EU. This procedure results in a single marketing authorization issued by the European Commission following a favorable opinion by the EMA that is valid across the European Union, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human medicines that are: derived from biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer,

diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and officially designated orphan medicines. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

- National authorization procedures. There are also two other possible routes to authorize medicinal products in several European Union countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure: the decentralized procedure and the mutual recognition procedure. Under the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country for medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure. Under the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following a national authorization, the applicant may seek further marketing authorizations from other EU countries under a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

In the EU, medicinal products designated as orphan products benefit from financial incentives such as reductions in marketing authorization application fees or fee waivers and 10 years of marketing exclusivity following medicinal product approval. For a medicinal product to qualify as orphan: (i) it must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating; (ii) the prevalence of the condition in the EU must not be more than five in 10,000 or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development; and (iii) no satisfactory method of diagnosis, prevention or treatment of the condition concerned can be authorized, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

Other Healthcare Laws and Compliance Requirements

In the United States, the research, manufacturing, distribution, marketing, sale and promotion of drug products and medical devices are subject to numerous regulations by various federal, state and local authorities in addition to the FDA including, but not limited to, the U.S. Federal Communications Commission, the U.S. Department of Justice, HHS and its various enforcement divisions, such as CMS, the Office of Inspector General, or OIG, the Office for Human Research Protections, or OHRP, and the Office of Research Integrity, or ORI, state Attorneys General, state Medicaid Fraud Control Units, or MFCUs, and other state and local government agencies.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, including a prescription drug manufacturer, or a party acting on its behalf, from knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind in return for the purchase, recommendation, leasing, ordering or furnishing of an item or service, for which payment may be made in whole or in part under a federal healthcare program such as the Medicare and Medicaid programs. This statute has been interpreted broadly to apply to, among other things, arrangements between pharmaceutical manufacturers, on one hand, and prescribers, purchasers, and formulary managers, on the other. The term "remuneration" expressly includes kickbacks, bribes or rebates and also has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. There are a number of statutory exceptions and regulatory safe harbors protecting certain business

arrangements from prosecution. Failure to meet all of the requirements of a particular applicable statutory exception or safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not meet all of the criteria for safe harbor protection from federal Anti-Kickback Statute liability in all cases. Additionally, the ACA, among other things, amended the intent standard under the federal Anti-Kickback Statute to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The ACA also provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act (discussed below). Further, many states have adopted laws similar to the federal Anti-Kickback Statute, and some of these state laws may be broader in scope in that some of these state laws extend to all payors and may not contain safe harbors.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval by a federal healthcare program. The "*qui tam*" provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and potentially to share in any monetary recovery. In recent years, the number of suits brought by private individuals has increased dramatically. In addition, various states have enacted false claims laws analogous to the False Claims Act. Many of these state laws are broader in scope and apply to all payors, and therefore, are not limited to only those claims submitted to the federal government. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The False Claims Act has been used to assert liability on the basis of kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, and improper promotion of off-label uses not expressly approved by the FDA in a drug's label. Our future activities relating to the reporting of discount and rebate information and other information affecting federal, state and third party reimbursement of our products, and the sale and marketing of our products and our service arrangements or data purchases, among other activities, may be subject to scrutiny under these laws. Additionally, the civil monetary penalties statute, which, among other things, imposes fines against any person who is determined to have presented or caused to be presented claims to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

We are unable to predict whether we would be subject to actions under these laws or the impact of such actions. However, the cost of defending such claims, as well as any sanctions imposed, could adversely affect our financial performance.

Also, HIPAA created several new federal crimes, including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, we may be subject to, or our marketing activities may be limited by, data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA and its implementing regulations established uniform standards for certain "covered entities," which are healthcare providers, health plans and healthcare clearinghouses, as well as their business

associates, governing the conduct of specified electronic healthcare transactions and protecting the security and privacy of protected health information. The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included HITECH as an expansion of HIPAA's privacy and security standards. Among other things, HITECH makes HIPAA's security standards and certain privacy standards directly applicable to business associates. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

Additionally, federal transparency laws, including the federal Physician Payment Sunshine Act created under Section 6002 of the Affordable Care Act and its implementing regulations require that manufacturers of drugs for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to "payments or other transfers of value" made or distributed to physicians (defined to include doctors of medicine, dentists, optometrists, podiatrists and chiropractors), generally, with some exceptions, and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals. Additionally, applicable manufacturers and applicable group purchasing organizations are required to report annually to the CMS certain ownership and investment interests held by physicians (as defined above) and their immediate family members, with data collection required beginning August 1, 2013, and reporting to CMS is required by March 31, 2014 (and by the 90th day of each subsequent calendar year). Disclosure of such information is to be made on a publicly available website beginning in September 2014.

There are also an increasing number of analogous state laws that require manufacturers to file reports with states on pricing and marketing information, such as tracking and reporting of gifts, compensations, other remuneration and items of value provided to health care professionals and health care entities. Many of these laws contain ambiguities as to what is required to comply with the laws. For example, several states have enacted legislation requiring pharmaceutical companies to, among other things, establish and implement commercial compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities and/or register their sales representatives. Certain state laws also regulate manufacturers' use of prescriber-identifiable data. These laws may affect our sales, marketing and other promotional activities by imposing administrative and compliance burdens. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state and federal authorities.

If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private *qui tam* actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, the U.S. Foreign Corrupt Practices Act, the U.K. Anti-Bribery Act, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Third-Party Payor Coverage and Reimbursement

The commercial success of our product portfolio, if and when approved, will depend, in part, upon the availability of coverage and adequate reimbursement from third-party payors at the federal, state and private levels. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Sales of our product portfolio will therefore depend substantially, both domestically and abroad, on the extent to which the costs of our product portfolio will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or are reimbursed by government health administration authorities, such as Medicare and Medicaid, private health coverage insurers and other third-party payors. The market for our product portfolio will depend significantly on access to third-party payors' formularies, or lists of treatments for which third-party payors provide coverage and reimbursement.

Also, third-party payors are developing increasingly sophisticated methods of controlling healthcare costs and coverage and reimbursement for therapeutic products can differ significantly from payor to payor. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that adequate coverage and reimbursement will be obtained. The cost of pharmaceuticals and medical devices continues to generate substantial governmental and third-party payor scrutiny. We expect that the pharmaceutical industry will experience continued pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Our results of operations and business could be adversely affected by current and future third-party payor policies as well as healthcare legislative reforms.

Some third-party payors also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, these requirements or any announcement or adoption of such proposals could have a material adverse effect on our ability to obtain adequate prices for our product portfolio and to operate profitably.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. There can be no assurance that our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be available or that the third-party payors' reimbursement policies will not adversely affect our ability to sell our products profitably.

Healthcare Reform

In the United States and foreign jurisdictions, the legislative landscape continues to evolve. There have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs. In March 2010, the ACA was passed, which includes measures that have the potential to significantly change health care financing by both governmental and private insurers. The provisions of the Affordable Care Act of importance to the pharmaceutical and biotechnology industry are, among others, the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, that began in 2011;

- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;
- new methodologies by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and for drugs that are line extension products;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, unless the drug is subject to discounts under the 340B drug discount program;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a licensure framework for follow-on biologic products;
- new requirements under the federal Physician Payment Sunshine Act for drug manufacturers to report information related to payments and other transfers of value made to physicians and teaching hospitals as well as ownership or investment interests held by physicians and their immediate family members; and
- a new requirement to annually report certain drug samples that manufacturers and distributors provide to licensed practitioners, or to pharmacies of hospitals or other healthcare entities, effective April 1, 2012.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. In August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will

pay for healthcare products and services, which could result in reduced demand for our product portfolio or additional pricing pressures.

Other Regulatory Requirements

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the FDA and other government agencies have broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on us.

Employees

As of September 30, 2013, we had a total of 18 full-time employees in the US, two part time employees in the US, and one full time consultant in India, of which nine were in research and development, 4 were in regulatory affairs and quality control compliance, one was in Sales and marketing, one was in business development, four were in administration and two in finance. None of our employees are represented by a labor union or subject to a collective bargaining agreement. We have not experienced any work stoppage and consider our relations with our employees to be good.

Facilities

As of September 30, 2013 the Company conducted all of its non-outsourced operations at its 9,906 square foot leased office space located at 50 Tice Boulevard, Woodcliff Lake, NJ 07677. The term of the lease is for 24 months, expiring on May 30, 2015. Prior to May 31, 2013 the Company was located at 470 Chestnut Ridge Road, Woodcliff Lake, NJ 07677 since September 2007.

Legal Proceedings

In March 2012, Hikma purchased from us for $3.5 million certain assets relating to a generic drug, diclofenac/misoprostol tablets. That drug was the subject of an ANDA filed by us with the FDA. The ANDA is still pending before the FDA, and we continue to expect it to receive approval. The terms of the sale were set forth in a March 2012 Asset Purchase Agreement, or Hikma APA. On June 24, 2013, Hikma Pharmaceutical Co., Ltd., or Hikma, filed a lawsuit against us in the United States District Court for the Southern District of New York alleging that we (a) breached the Hikma APA by failing to refund the purchase price following Hikma's purported termination of the Hikma APA as a result of us failing to receive timely ANDA approval, and (b) intentionally failed to disclose alleged manufacturing product defects to Hikma. On August 27, 2013, we filed an answer to Hikma's complaint, which denied Hikma's claims, and asserted a counterclaim alleging that Hikma by its actions had repudiated the Hikma APA.

Should Hikma prevail on its claims that we breached the Hikma APA or intentionally failed to disclose alleged product defects, we could be required to pay substantial damages, including, but not limited to, the return of the $3.5 million purchase price plus interest and other damages.

We are vigorously defending these claims and we do not believe that Hikma is entitled to any damages because Hikma's purported termination violated the terms of the Hikma APA and believe that the claims of non-disclosure of manufacturing product defects are without merit. Given the early stage in the litigation, we are unable to predict the likelihood of success of Hikma's contract breach and fraud claims.

In addition to the matter described above, from time to time, third parties may assert patent infringement claims against us in the form of letters, litigation, or other forms of communication; we may be subject to other legal proceedings and claims in the ordinary course of business, including claims of alleged infringement of trademarks, copyrights and other intellectual property rights; employment claims; and general contract or other claims. We may, from time to time, also be subject to various legal or government claims, disputes, or investigations. Such matters may include, but not be limited to, claims, disputes, or investigations related to breach of contract, employment, intellectual property, government regulation, or compliance or other matters.

MANAGEMENT

Executive Officers, Directors and Key Employees

The following table sets forth certain information regarding our executive officers, directors and key employees as of September 30, 2013:

Name	Age	Position(s)
Executive Officers and Key Employees		
Scott Tarriff	54	President and Chief Executive Officer, Director
David E. Riggs	61	Chief Financial Officer
Paul Bruinenberg, M.D.	54	Chief Medical Officer
Steven L. Krill, Ph.D	54	Chief Scientific Officer
Daniel O'Connor	33	Finance Director
Ken Degen	55	Senior Vice President, Hospital Sales and Marketing
Peter Grebow, Ph.D.	67	Executive Vice President of Research and Development
Non-Employee Directors		
Jay Moorin(2)	62	Director
Steven Ratoff(1)	71	Director
Sander Flaum(1)	76	Director
Michael Graves(2)	51	Director
Alain Schreiber, M.D.	58	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

Executive Officers and Key Employees

Scott Tarriff is the founder and has served as our President and Chief Executive Officer and as a member of our board of directors since our inception in January 2007. Prior to joining Eagle, Mr. Tariff held various executive positions at Par Pharmaceutical Companies, Inc., a publicly-traded developer, manufacturer and marketer of specialty pharmaceuticals, including as president and chief executive officer from September 2003 to September 2006, after joining Par in 1998. Mr. Tarriff also served on Par's board of directors from 2002 to September 2006. Prior to that, Mr. Tarriff held various positions with Bristol-Meyers Squibb, a publicly-traded biopharmaceutical company, including senior director-marketing. Mr. Tarriff has served as a director of Synthetic Biologics, Inc., a publicly-traded biotechnology company, since February 2012 and previously served on the board of directors of Clinical Data, Inc., a publicly-traded pharmaceutical company, from September 2009 to April 2011 when Clinical Data was acquired by Forest Laboratories, Inc. Mr. Tarriff holds a B.S. in marketing from Pennsylvania State University and an M.B.A. from Rider College. The board of directors believes that Mr. Tarriff's extensive knowledge of our business, his management experience in the pharmaceutical industry, as well as his operational expertise, qualifies him to serve on our board of directors and as our President and Chief Executive Officer.

David E. Riggs has served as our Chief Financial Officer since November 2013. From May 2010 to October 2013, Mr. Riggs served as a healthcare consultant at various biotechnology and pharmaceutical companies. From March 2006 to May 2010, Mr. Riggs served as chief financial officer of Ferring Pharmaceuticals Inc., a private biopharmaceutical company devoted to isolating, developing and marketing innovative products in the fields of reproductive health, urology, gastroenterology, endocrinology and osteoarthritis. From January 2003 to September 2005, Mr. Riggs held various positions at eXegenics Inc., a publicly-traded pharmaceutical company that is now OPKO Health, Inc.,

including most recently as its chief executive officer. Mr. Riggs served as senior vice president and chief financial officer of Axys Pharmaceuticals, Inc., a publicly-traded pharmaceutical company, from March 2000 until it was acquired by Applera Corporation in November 2001. From February 1992 to February 2000, Mr. Riggs held various positions at Unimed Pharmaceuticals, Inc., a private company focused on developing and commercializing products in human immunodeficiency virus, oncology and urology specialty markets. Previously, Mr. Riggs held various positions at Fujisawa Pharmaceuticals, Inc., a private pharmaceutical company that was acquired by Astellas Pharma Inc., including treasurer and director of financial planning and analysis. Mr. Riggs holds a B.S. in accounting from the University of Illinois and an M.B.A. from DePaul University.

Paul Bruinenberg, M.D. has served as our Chief Medical Officer and Head of Research & Development since November 2011. From May 2007 to October 2011, Dr. Bruinenberg served as senior medical director of Aradigm Corporation, a publicly-traded pharmaceutical company developing and commercializing drugs delivered by inhalation for the treatment of severe respiratory disease, with responsibility for developing Aradigm's early stage respiratory compounds. From May 2006 to May 2007, Dr. Bruinenberg served as vice president of clinical research of Fulcrum Pharma Developments, Inc., a subsidiary of Fulcrum Pharma PLC that develops drugs, with responsibility for leading development teams. In April 2003, Dr. Bruinenberg founded Biotrack Consultancy, a provider of consulting and advising services in the areas of clinical research, development, regulatory compliance and clinical operating processes. Previously, Dr. Bruinenberg served as medical director Europe of Yamanouchi Pharmaceutical Co., Ltd., now part of Astellas Pharma Ltd., with responsibility for leading clinical teams in registering compounds worldwide. Beginning in 1995, Dr. Bruinenberg held several positions of increasing responsibility during a five-year tenure at F. Hoffmann-La Roche AG, a global healthcare company, including international medical manager in the areas of cystic fibrosis, asthma, chronic obstructive pulmonary disease and transplant and global business leader in the areas of respiratory and transplant. During this tenure at Roche, Dr. Bruinenberg played a pivotal role in bringing three products to the market, Pulmozyme®, Cellcept® and Zenapax®. Earlier in his career, Dr. Bruinenberg was a practicing physician and researcher for eight years and managed the Cardiac Care Unit in Amstelveen Hospital. Dr. Bruinenberg holds a medical degree from the medical school of the University of the Stellenbosch, South Africa, an M.B.A. from the University of Nijenrode in the Netherlands and an M.B.A. from Rochester University.

Steven L. Krill, Ph.D. has served as our Chief Scientific Officer since February, 2013. He held the position of Vice President of Pharmaceutical Development from October 2011 to February 2013. Dr. Krill served as the vice president of Scientific Affairs at Teva Parenteral Medicines from March 2009 to August 2011. Dr. Krill held the positions of Vice President Pharmaceutical Research and Development (December 2005 until March 2009) and Director of Pharmaceutics and Investigational Supplies (from May 2002 to December 2005) at Boehringer Ingelheim. Prior to that, Dr. Krill held various management positions at Lipocine Inc., Novartis Pharmaceuticals and Abbott Laboratories Dr. Krill is an author of over 30 publications and inventor of multiple patents in the area of drug delivery. Dr. Krill holds a B.S. in pharmacy and an M.S. in pharmaceutical sciences from the University of Cincinnati and a Ph.D. in Pharmaceutics from the University of Utah.

Daniel O'Connor joined our company in 2007 and served as our Finance Director since 2011. From May 2013 to November 2013 he also served as our Interim Chief Financial Officer. From January 2005 to October 2007, Mr. O'Connor held various management positions with Ethicon Inc., a Johnson & Johnson Company subsidiary that develops surgical products for laparoscopic and minimally invasive procedures, including senior analyst and analyst roles. During this time, Mr. O'Connor also acted as a lead finance liaison with Ethicon's joint venture with Omrix Biopharmaceuticals, Inc. From June 2002 to December 2004, Mr. O'Connor held several finance positions at Ranbaxy Pharmaceuticals Inc., a wholly-owned subsidiary of Ranbaxy Inc. that markets

generic products in the U.S., including most recently, financial analyst. Mr. O'Connor holds a B.S. in business administration from West Virginia University and an M.B.A. from Rutgers University.

Ken Degen has served as our Senior Vice President, Sales and Marketing since January 2009. Prior to Eagle, Mr. Degen held various management positions in the areas of sales, marketing and managed care during his over 20-year tenure at Schering-Plough Pharmaceuticals, a prescription pharmaceutical manufacturer and marketer that merged with Merck & Co. in 2009, including as director of sales and marketing in Schering-Plough's Global Diversified Products Group, a $2 billion business unit, and as a co-chair of a research institute team charged with evaluating product life cycle management opportunities. Mr. Degen holds a B.S. in business administration from George Mason University.

Peter Grebow, Ph.D. has served as our Executive Vice President of Research and Development since October 2013. From 1991 to March 2011, Dr. Grebow held several senior management positions at Cephalon Inc., a biopharmaceutical company that was acquired and became a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd. in 2011, including as executive vice president, Cephalon Ventures, executive vice president technical operations, senior vice president, worldwide business development and senior vice president, drug development. Dr. Grebow has served on the board of directors of Optimer Pharmaceuticals, a publicly-traded biopharmaceutical company, since February 2009, the board of directors of Q Therapeutics Holdings, Inc., a publicly-traded pharmaceutical company, since December 2011, the board of directors of GenSpera, Inc., a publicly-traded pharmaceutical company, since May 2012 and the board of directors of a private pharmaceutical company since December 2011. Dr. Grebow holds an A.B. degree in chemistry from Cornell University, an M.S. in chemistry from Rutgers University and a Ph.D. in physical biochemistry from the University of California, Santa Barbara.

Non-Employee Directors

Jay Moorin has served as a member of our board of directors since March 2007. In October 2013, our board of directors elected Mr. Moorin chairman of the board. Since 1998, Mr. Moorin has served as a founding general partner of ProQuest Investments, a healthcare venture capital firm. From 1991 to 1998, Mr. Moorin served as president and chief executive officer of Magainin Pharmaceuticals Inc., a publicly-traded biopharmaceutical company, and also served as chairman of its board of directors from 1996 to 1998. Previously, Mr. Moorin served as managing director of healthcare banking at Bear Stearns & Co. Inc. and vice president of marketing and business development at a division of the ER Squibb Pharmaceutical Company. Currently, Mr. Moorin serves on the board of directors of a private radiation therapy company, is an advisor to DPT Capital Management, LLC, an investment firm, and serves as a trustee of the Equinox Funds Trust. Mr. Moorin held the position of adjunct senior fellow of the Leonard Davis Institute of Health Economics at the University of Pennsylvania from 1997 to 2012. Previously, Mr. Moorin served on the board of directors of numerous public and private healthcare companies. Mr. Moorin holds a B.A. in economics from the University of Michigan. Our board of directors believes that Mr. Moorin's extensive senior management background and experience in the biotech, investment banking and pharmaceutical industries as well as his service on the board of directors of public and private companies qualifies him to serve on our board of directors.

Steven Ratoff has served as a member of our board of directors since March 2007. Since December 2004, Mr. Ratoff has served as a venture partner of ProQuest Investments. Since January 2010, Mr. Ratoff has served as president and chief executive officer of NovaDel Pharma Inc., a private specialty pharmaceutical company, and Mr. Ratoff has served in a number of interim executive positions since joining NovaDel's board of directors in May 2005. Mr. Ratoff has also served on NovaDel Pharma Inc.'s board of directors since May 2005 and currently serves as its chairman. Prior to NovaDel, Mr. Ratoff held various executive positions with Cima Labs, Inc., a publicly-traded

pharmaceutical company that was acquired by Cephalon in 2004, MacroMed, Inc., a private drug development and manufacturing company that was acquired by Protherics PLC in 2007, and Brown-Forman Corporation. Mr. Ratoff holds a B.S. in business administration from Boston University and an M.B.A. from the University of Michigan. Our board of directors believes that Mr. Ratoff's extensive executive experience and background in the global pharmaceutical and consumer products industries as well as his strong financial background qualifies him to serve on our board of directors.

Sander Flaum has served as a member of our board of directors since March 2007. Since January 2005, Mr. Flaum has served as a principal of Flaum Navigators, a healthcare consultancy firm that he founded. Mr. Flaum has also served as the chief executive officer of Flaum Partners, Inc., a healthcare consultancy firm he founded, since August 2004. From 1991 to 2002, Mr. Flaum served as chief executive officer of Robert A. Becker EURO/RSCG, a predecessor to Euro RSCG Life. Prior to that, Mr. Flaum held various positions during an 18-year career at Lederle Laboratories, a private vaccine manufacturer that is now Wyeth Pharmaceuticals, including as marketing director of prescription products, vaccines and generics. Mr. Flaum is a member of the Euro RSCG Healthcare Global Network, and he has served as its co-chairman since 1998. Mr. Flaum also serves on the board of directors of The Fisher College of Business at The Ohio State University, The James Cancer Center at the OSU Medical Center and the Fordham Graduate School of Business. Mr. Flaum is an adjunct professor of leadership at the Fordham University Graduate School of Business, where he chairs the Fordham Leadership Forum. Mr. Flaum holds a B.A. from The Ohio State University and an M.B.A. from Fairleigh Dickinson University. Our board of directors believes that Mr. Flaum's extensive experience in the pharmaceutical and biotech industries qualifies him to serve on our board of directors.

Michael Graves has served as a member of our board of directors since November 2013. In January 2012 Mr. Graves joined the board of directors of RiboCor, Inc. and in December 2011, Mr. Graves was appointed chairman of the board of directors of Nanocopoeia, Inc., both private pharmaceutical companies. From May 2007 to July 2011, Mr. Graves served as the chief executive officer and president of Paddock Laboratories, Inc., a pharmaceutical company engaged in the manufacture, distribution and marketing of bioequivalent generic pharmaceuticals. From September 2005 to November 2006, Mr. Graves served as president of the generic products division at Par Pharmaceutical Companies, Inc., a publicly-traded developer, manufacturer and marketer of specialty pharmaceuticals. While at Par, Mr. Graves oversaw the strategy development of Par's generic pharmaceutical business. Beginning in 1998, Mr. Graves served as director of marketing and sales operations of Par, and in 2004, Mr. Graves was promoted to senior vice president of corporate development and strategic planning. Mr. Graves served in this position until his promotion to president of the generic products division in September 2005. Mr. Graves holds a B.S. from State University College of New York at Buffalo. The board of directors believes that Mr. Graves' extensive experience in marketing, sales, business development and operations qualifies him to serve on our board of directors.

Alain Schreiber, M.D. has served as a member of our board of directors since September 2012. Since 2000, Dr. Schreiber has served as a general partner of ProQuest Investments. From 1992 to 2000, Dr. Schreiber served as president, chief executive officer and a director of Vical, Inc., a publicly-traded biopharmaceutical company. Prior to that, Dr. Schreiber held various management positions with Rhône-Poulenc Rorer Inc., a French chemical and pharmaceutical company that is now Sanofi-Aventis, including senior vice president of discovery research. Dr. Schreiber served on the board of directors of Cadence Pharmaceuticals, Inc., a publicly-traded biopharmaceutical company, from July 2004 to June 2007. Dr. Schreiber also served on the board of directors of Optimer Pharmaceuticals Inc., a publicly-traded biopharmaceutical company, from May 2001 to May 2010. Dr. Schreiber also currently serves on the board of directors of numerous private pharmaceutical companies. Dr. Schreiber holds a B.S. in chemistry and an M.D. from the Free University in Brussels, Belgium. Subsequently, he was a

postdoctoral fellow at the Weizmann Institute of Science in Israel. Our board believes that Dr. Schreiber's extensive industry experience and a depth of drug development expertise, as well as his service on the board of directors of public and private companies, qualifies him to serve on our board of directors.

Board Composition

Our business and affairs are organized under the direction of our board of directors, which currently consists of seven members. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Our board of directors has determined that all of our directors other than Scott Tarriff are independent directors, as defined by Rule 5605(a)(2) of the Nasdaq Listing Rules.

Effective upon the closing of this offering, we will divide our board of directors into three classes, as follows:

- Class I, which will consist of , and , whose terms will expire at our annual meeting of stockholders to be held in 2014;
- Class II, which will consist of , and , and whose terms will expire at our annual meeting of stockholders to be held in 2015; and
- Class III, which will consist of and , and whose terms will expire at our annual meeting of stockholders to be held in 2016.

At each annual meeting of stockholders to be held after the initial classification, the successors to directors whose terms then expire will serve until the third annual meeting following their election and until their successors are duly elected and qualified. The authorized size of our board of directors is currently seven members. The authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed between the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the board of directors may have the effect of delaying or preventing changes in our control or management. Our directors may be removed for cause by the affirmative vote of the holders of at least $66^{2}/_{3}\%$ of our voting stock.

Board Leadership Structure

Our board of directors is currently chaired by Jay Moorin. As a general policy, our board of directors believes that separation of the positions of Chairman and Chief Executive Officer reinforces the independence of the board of directors from management, creates an environment that encourages objective oversight of management's performance and enhances the effectiveness of the board of directors as a whole. As such, Mr. Tarriff serves as our President and Chief Executive Officer while Jay Moorin serves as our Chairman of the board of directors but is not an officer. We expect and intend the positions of Chairman of the board of directors and Chief Executive Officer to continue to be held by two individuals in the future.

Role of the Board in Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. The board of directors does not have a standing risk management committee, but rather administers this oversight function directly through the board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their

respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors compliance with legal and regulatory requirements. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

Board Committees

Our board of directors has established an audit committee and a compensation committee, and intends to form a nominating and corporate governance committee in connection with this offering, each of which has the composition and responsibilities described below. From time to time, the board may establish other committees to facilitate the management of our business.

Audit Committee

Our audit committee currently consists of Steven Ratoff and Sander Flaum. Immediately following the closing of this offering, our audit committee will consist of , and , each of whom our board of directors has determined satisfies the Nasdaq Stock Market and SEC independence requirements. The chairperson of our audit committee is currently Mr. Ratoff, and following the closing of this offering, Mr. Ratoff will continue to serve as the chair of our audit committee. The functions of this committee will include, among other things:

- evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors;
- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;
- monitoring the rotation of partners of our independent auditors on our engagement team as required by law;
- prior to engagement of any independent auditor, and at least annually thereafter, reviewing relationships that may reasonably be thought to bear on their independence, and assessing and otherwise taking the appropriate action to oversee the independence of our independent auditor;
- reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," and discussing the statements and reports with our independent auditors and management;
- reviewing with our independent auditors and management significant issues that arise regarding accounting principles and financial statement presentation and matters concerning the scope, adequacy and effectiveness of our financial controls;
- reviewing with management and our auditors any earnings announcements and other public announcements regarding material developments;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters and other matters;

- preparing the report that the SEC requires in our annual proxy statement;
- reviewing and providing oversight of any related-person transactions in accordance with our related person transaction policy and reviewing and monitoring compliance with legal and regulatory responsibilities, including our code of business conduct and ethics;
- reviewing our major financial risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management is implemented;
- reviewing on a periodic basis our investment policy; and
- reviewing and evaluating on an annual basis the performance of the audit committee, including compliance of the audit committee with its charter.

Our board of directors has determined that Steven Ratoff qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of the Nasdaq Listing Rules. In making this determination, our board has considered Mr. Ratoff's extensive financial experience and business background. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

Our audit committee will operate under a written charter, to be effective immediately prior to the completion of this offering, that satisfies the applicable rules of the Securities and Exchange Commission, or SEC, and the listing standards of the Nasdaq Stock Market.

Compensation Committee

Our compensation committee currently consists of Jay Moorin and Michael Graves. Immediately following the closing of this offering, our compensation committee will consist of three directors. The chairperson of our compensation committee is currently Jay Moorin, and following the closing of this offering, will serve as the chair of our compensation committee. Our board of directors has determined that each of the members of our compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Securities Exchange Act of 1934, as amended, or Exchange Act, is an outside director, as defined pursuant to Section 162(m) of the Code and satisfies the Nasdaq Stock Market independence requirements. The functions of this committee include, among other things:

- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) our overall compensation strategy and policies;
- reviewing and approving the compensation and other terms of employment of our executive officers;
- reviewing and approving performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;
- evaluating risks associated with our compensation policies and practices and assessing whether risks arising from our compensation policies and practices for our employees are reasonably likely to have a material adverse effect on us;

- reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) the type and amount of compensation to be paid or awarded to our non-employee board members;
- establishing policies with respect to votes by our stockholders to approve executive compensation as required by Section 14A of the Exchange Act and determining our recommendations regarding the frequency of advisory votes on executive compensation;
- reviewing and assessing the independence of compensation consultants, legal counsel and other advisors as required by Section 10C of the Exchange Act;
- administering our equity incentive plans;
- establishing policies with respect to equity compensation arrangements;
- reviewing the competitiveness of our executive compensation programs and evaluating the effectiveness of our compensation policy and strategy in achieving expected benefits to us;
- reviewing and approving the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;
- reviewing the adequacy of its charter on a periodic basis;
- reviewing with management and approving our disclosures under the caption "Compensation Discussion and Analysis" in our periodic reports or proxy statements to be filed with the SEC;
- preparing the report that the SEC requires in our annual proxy statement; and
- reviewing and assessing on an annual basis the performance of the compensation committee.

Our compensation committee will operate under a written charter, to be effective immediately prior to the completion of this offering, that satisfies the applicable rules of the SEC and the listing standards of the Nasdaq Stock Market.

Nominating and Corporate Governance Committee

Prior to the closing of this offering, we will form a nominating and corporate governance committee that will consist of three directors who our board will determine satisfy the Nasdaq Stock Market independence requirements. The functions of our nominating and corporate governance committee committee will include, among other things:

- identifying, reviewing and evaluating candidates to serve on our board of directors consistent with criteria approved by our board of directors;
- determining the minimum qualifications for service on our board of directors;
- evaluating director performance on the board and applicable committees of the board and determining whether continued service on our board is appropriate;
- evaluating, nominating and recommending individuals for membership on our board of directors;
- evaluating nominations by stockholders of candidates for election to our board of directors;
- considering and assessing the independence of members of our board of directors;

- developing a set of corporate governance policies and principles, including a code of business conduct and ethics, periodically reviewing and assessing these policies and principles and their application and recommending to our board of directors any changes to such policies and principles;
- considering questions of possible conflicts of interest of directors as such questions arise;
- reviewing the adequacy of its charter on an annual basis; and
- annually evaluating the performance of the nominating and corporate governance committee.

Our nominating and governance committee will operate under a written charter, to be effective immediately prior to the completion of this offering, that satisfies the applicable rules of the SEC and the listing standards of the Nasdaq Stock Market.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has ever been an executive officer or employee of ours. None of our executive officers currently serves, or has served during the last completed fiscal year, on the compensation committee or board of directors of any other entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

Code of Business Conduct and Ethics

In connection with this offering, we intend to adopt a Code of Business Conduct and Ethics, or the Code of Conduct, applicable to all of our employees, executive officers and directors. Following the completion of this offering, the Code of Conduct will be available on our website at *www.eagleus.com*. The nominating and corporate governance committee of our board of directors will be responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for employees, executive officers and directors. We expect that any amendments to the Code of Conduct, or any waivers of its requirements, will be disclosed on our website.

EXECUTIVE AND DIRECTOR COMPENSATION

Our named executive officers for the fiscal year ended September 30, 2013, which consist of our principal executive officer and the next two most highly compensated executive officers who were serving as executive officers as of September 30, 2013, are:

- Scott Tarriff, our President and Chief Executive Officer;
- Paul Bruinenberg, M.D., our Chief Medical Officer; and
- Steven L. Krill, Ph.D., our Chief Scientific Officer.

Summary Compensation Table

The following table provides information regarding the compensation provided to our named executive officers during the fiscal year ended September 30, 2013:

Name and Principal Position	Year	Salary ($)	Option Awards ($)[1]	All Other Compensation ($)[2]	Total ($)
Scott Tarriff. *President and Chief Executive Officer, Director*	2013	408,038	—	3,050	411,088
Paul Bruinenberg, M.D. *Chief Medical Officer*	2013	303,786	124,585	2,225	430,596
Steven L. Krill, Ph.D. *Chief Scientific Officer*	2013	272,592	116,547	3,050	392,189

(1) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the option awards granted during 2013 computed in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718 for stock-based compensation transactions (ASC 718). Assumptions used in the calculation of these amounts are included in Note 3 to our Financial Statements. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options.

(2) Amount consists of premiums paid by us for group life and long term disability insurance for each named executive officer. For more information regarding these benefits, see below under "— Perquisites, Health, Welfare and Retirement Benefits."

Annual Base Salary

The compensation of our named executive officers is generally determined and approved by our board of directors or our compensation committee of our board of directors (the Committee) effective as of April 1 of each year. The chart below reflects the base salaries approved by our board of directors and Committee for our named executive officers during fiscal year ended September 30, 2013.

Name	2013 Base Salary (effective from October 1, 2012 - March 31, 2013) ($)	2013 Base Salary ($) (effective from April 1, 2013 - September 30, 2013)
Scott Tarriff	424,360	424,360
Paul Bruinenberg, M.D.	310,000	322,369
Steven L. Krill, Ph.D.	260,000	298,700

We do not have a practice of providing, and we did not provide in fiscal year 2013, any bonuses or non-equity incentive based compensation to our named executive officers. We plan to adopt a performance-based bonus arrangement for our executive employees following the completion of this offering.

Equity-Based Incentive Awards

Our equity-based incentive awards are designed to align our interests with those of our employees and consultants, including our named executive officers. The board of directors or the Committee is responsible for approving equity grants. We have generally granted stock options to our executive officers, employees and consultants as incentive compensation, however we previously granted restricted stock awards to certain individuals other than our named executive officers, none of which remain outstanding. Vesting of equity awards is generally tied to continuous service with us and serves as an additional retention measure. We may grant equity awards to our employees and consultants from time to time, as determined appropriate by our board of directors or the Committee. In addition, our executives generally are awarded an initial option grant upon commencement of employment. Additional grants may occur periodically in order to specifically incentivize executives with respect to achieving certain corporate goals or to reward executives for exceptional performance.

Prior to this offering, we have granted all equity awards pursuant to the 2007 Incentive Compensation Plan, or the 2007 Plan, the terms of which are described below under "— Equity Benefit Plans." All options are granted with a per share exercise price equal to no less than the fair market value of a share of our common stock on the date of grant of each award. Generally our stock option awards vest over a four-year period and are granted with an early exercise feature allowing the holder to exercise and receive unvested shares of our stock which are subject to our right to repurchase in accordance with the vesting schedule. Stock options and shares acquired by early exercising stock options that are subject to our repurchase right accelerate vesting upon the occurrence of change in control transactions under certain circumstances, as further described below under "— Potential Payments Upon Termination or Change in Control" and "— Equity Benefit Plans."

On April 19, 2013, the board of directors granted an option to purchase 150,178 shares of common stock to Dr. Bruinenberg and an option to purchase 140,489 shares to Dr. Krill, each of which has a four year vesting schedule subject to the executive's continued service with us. The exercise prices and detailed vesting terms of the 2013 option grants are described in the footnotes to the "— Outstanding Equity Awards at Fiscal Year-End" table below.

Agreements with our Named Executive Officers

We entered into an employment agreement with Mr. Tarriff in March 2007 setting forth the terms of his employment. Pursuant to the agreement, Mr. Tarriff is entitled to an initial annual base salary of $280,000, subject to increase by the board of directors, and is eligible to receive an annual bonus if determined by the board of directors. Mr. Tarriff is additionally entitled to certain severance and change in control benefits pursuant to his agreement, the terms of which are described below under "— Potential Payments Upon Termination or Change in Control." During Mr. Tarriff's employment and for one year thereafter, Mr. Tarriff's may not solicit our employees or full-time consultants and he cannot be employed by or start a business that is in competition with us.

We entered into an offer letter agreement with Dr. Bruinenberg in September 2011 setting forth the terms of his employment. Pursuant to the agreement, Dr. Bruinenberg is entitled to an initial annual base salary of $310,000, a signing bonus of $30,000, which was paid to Dr. Bruinenberg in 2012, reimbursement up to $20,000 for relocation costs, which was paid to Dr. Bruinenberg in 2012, and an option to purchase 230,000 shares of our common stock which was granted to Dr. Buinenberg in October 2011. Such option vests over a four year period at 25% per year. As a condition to his employment, Dr. Bruinenberg was required to sign a standard Trade Secret, Non-Disclosure and Restrictive Covenant Agreement.

We entered into an offer letter agreement with Dr. Krill in September 2011 setting forth the terms of his employment. Pursuant to the agreement, Dr. Krill is entitled to an initial annual base salary of $260,000, reimbursement up to $20,000 for relocation costs, which was paid to Dr. Krill in 2011, and an option to purchase 50,000 shares of our common stock, which was granted to Dr. Krill in September 2011. Such option vests over a four year period at 25% per year. As a condition to his employment, Dr. Krill was required to sign a standard Trade Secret, Non-Disclosure and Restrictive Covenant Agreement.

Potential Payments Upon Termination or Change in Control

Pursuant to Mr. Tarriff's employment agreement, if he is terminated without cause (and other than as a result of his death or disability) or if he resigns for good reason, he is entitled to receive continued payments of his base salary for 12 months following the date of his termination, provided that he continues to comply with certain restrictive covenants set forth in his employment agreement.

For purposes of Mr. Tarriff's employment agreement, "cause" generally means (1) his neglect or failure to perform his substantial duties or obligations, including his material breach of his employment agreement, after receiving prior written notice and an opportunity to cure, if applicable; (2) his willful misconduct that materially injures our reputation, business or business relationships; (3) his conviction of or plea of guilty or *nolo contendere* to any crime or offense involving our money or other property; (4) his conviction of or plea of guilty or *nolo contendere* to or acceptance of deferred adjudication or judgment to any crime constituting a felony; (5) his breach of any fiduciary duty prohibiting his self-dealing to improperly secure any personal profit or gain in connection with our business; or (6) entry of an order of a court or securities regulatory or self-regulatory body which enjoins or otherwise sanctions, limits or restricts his performance under his employment agreement, due to his misconduct.

For purposes of Mr. Tarriff's employment agreement, "good reason" generally means his termination of employment with us for any of the following reasons unless cured within a specified period of notice by Mr. Tarriff: (1) our failure to promptly pay him any undisputed compensation owed under his employment agreement; (2) any reduction in his employee benefits or bonus opportunity, other than one made generally for all senior executives or as a result of our impaired finances; (3) our material diminution in his duties, title, authority or responsibilities; (4) our assignment to him of duties that are inconsistent with the duties stated in his employment agreement; (5) our material breach of any provision of his employment agreement; (6) a requirement that he relocate as a result of moving his offices outside the greater New York City metropolitan area; or (7) our delivery of a written notice electing not to extend the term of his employment under his employment agreement.

In addition, each of our named executive officers holds stock options under the 2007 Plan that provide for acceleration of vesting and lapse of our repurchase right with respect to shares acquired by early exercising such options upon certain change in control transactions or such named executive officer's subsequent termination. A detailed description of the change in control and termination provisions of the 2007 Plan and stock option agreements is provided below under "—Equity Benefit Plans."

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth certain information regarding outstanding equity awards granted to our named executive officers that remain outstanding as of September 30, 2013.

		Option awards[1]			
	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable[2]	Option Exercise Price Per Share ($)[3]	Option Expiration Date
Scott Tarriff	10/02/2008	725,000	—	0.63	10/01/2018
	04/02/2009	800,000	—	0.63	04/01/2019
	05/03/2011	200,000	—(4)	1.37	05/02/2021
Paul Bruinenberg, M.D.	10/31/2011	230,000	—(5)	1.37	10/30/2021
	07/12/2012	100,000	—(6)	1.37	07/11/2022
	04/19/2013	150,178	—(7)	0.69	04/18/2023
Steven L. Krill, Ph.D.	09/26/2011	50,000	—(8)	1.37	09/25/2021
	07/12/2012	35,000	—(9)	1.37	07/11/2022
	04/19/2013	140,489	—(7)	0.69	04/18/2023

(1) All of the option awards listed in the table above were granted under the 2007 Plan, the terms of which are described below under "— Equity Benefit Plans."

(2) All of the option awards listed in the table above are fully exercisable on the date of grant and vest with respect to 25% of the shares one year following the date of grant and with respect to 1/36th of the remaining shares on each monthly anniversary thereafter over the following three years, subject to the executive's continuous service with us through the vesting date.

(3) All of the option awards listed in the table above were granted with a per share exercise price equal to the fair market value of one share of our common stock on the date of grant, as determined in good faith by our board of directors with the assistance of a third-party valuation expert.

(4) As of September 30, 2013, 83,334 shares were unvested.

(5) As of September 30, 2013, 119,792 shares were unvested.

(6) As of September 30, 2013, 70,834 shares were unvested.

(7) As of September 30, 2013, all shares were unvested.

(8) As of September 30, 2013, 25,000 shares were unvested.

(9) As of September 30, 2013, 24,792 shares were unvested.

Option Repricings

We did not engage in any repricings or other modifications or cancellations with respect to the outstanding equity awards held by or granted to our named executive officers during the fiscal year ended September 30, 2013.

Perquisites, Health, Welfare and Retirement Benefits

Our named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, group life, disability and accidental death and dismemberment insurance plans, in each case on the same basis as all of our other employees. We provide the opportunity to participate in a 401(k) plan to our employees, including our named executive officers, as discussed in the section below entitled "— 401(k) Plan."

We generally do not provide perquisites or personal benefits to our named executive officers, except in certain limited circumstances such as providing relocation benefits in connection with hiring a new executive. We did not provide any such perquisites or personal benefits in fiscal year 2013. We do, however, pay the premiums for group term life insurance, long-term disability, dental and health insurance for all of our employees, including our named executive officers. None of our named executive officers participate in non-qualified deferred compensation plans or qualified defined benefit pension plans sponsored by us. Our board of directors may elect to adopt such plans in the future if it determines that doing so is in our best interests.

401(k) Plan

We maintain a 401(k) profit sharing plan, or 401(k) plan, for our employees. Our named executive officers are eligible to participate in the 401(k) plan on the same basis as our other employees. The 401(k) plan is intended to qualify as a tax-qualified plan under Section 401(k) of the Internal Revenue Code. The plan provides that each participant may contribute up to the lesser of 75% of his or her compensation or the statutory limit, which was $17,000 for calendar year 2012 and $17,500 for calendar year 2013. Participants who are 50 years or older can also make "catch-up" contributions, which in calendar year 2012 and 2013 was up to an additional $5,500 above the statutory limit. We did not make matching contributions or profit sharing contributions into the 401(k) plan on behalf of participants in fiscal year 2013. Participant contributions are held and invested, pursuant to the participant's instructions, by the plan's trustee.

Non-qualified Deferred Compensation

None of our named executive officers participate in or have account balances in non-qualified defined contribution plans or other non-qualified deferred compensation plans maintained by us. Our board of directors may elect to provide our officers and other employees with non-qualified defined contribution or other non-qualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

Limitations on Liability and Indemnification Agreements

As permitted by Delaware law, provisions in our amended and restated certificate of incorporation and amended and restated bylaws, both of which will become effective upon the consummation of this offering, limit or eliminate the personal liability of directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, a director exercise an informed business judgment based on all material information reasonably available to him or her. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any act related to unlawful stock repurchases, redemptions or other distributions or payments of dividends; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not limit or eliminate our rights or any stockholder's rights to seek nonmonetary relief, such as injunctive relief or rescission. These provisions will not alter a director's

liability under other laws, such as the federal securities laws or other state or federal laws. Our amended and restated certificate of incorporation that will become effective upon the completion of this offering also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Delaware law, our amended and restated bylaws to be effective upon the consummation of this offering will provide that:

- we will indemnify our directors, officers, employees and other agents to the fullest extent permitted by law;
- we must advance expenses to our directors and officers, and may advance expenses to our employees and other agents, in connection with a legal proceeding to the fullest extent permitted by law; and
- the rights provided in our amended and restated bylaws are not exclusive.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director or officer, then the liability of our directors or officers will be so eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to us, regardless of whether our bylaws permit such indemnification. We have obtained such insurance.

In addition to the indemnification that will be provided for in our amended and restated certificate of incorporation and amended and restated bylaws, we will enter into separate indemnification agreements with each of our directors and executive officers, which may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements may require us, among other things, to indemnify our directors and executive officers for some expenses, including attorneys' fees, expenses, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of his service as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. We believe that these provisions and agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers.

This description of the indemnification provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and our indemnification agreements is qualified in its entirety by reference to these documents, each of which is attached as an exhibit to the registration statement of which this prospectus forms a part.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought and we are not aware of any threatened litigation that may result in claims for indemnification.

Equity Benefit Plans

2014 Equity Incentive Plan

Our board of directors adopted the 2014 Plan in November 2013, and we expect our stockholders will approve the plan prior to this offering and that the 2014 Plan will become effective before and contingent upon the date of the underwriting agreement pursuant to which our common stock is priced for our initial public offering. Once the 2014 Plan is effective, no further grants will be made under the 2007 Plan.

Stock Awards. The 2014 Plan provides for the grant of incentive stock options (ISOs), non-statutory stock options (NSOs), stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards, and other forms of equity compensation (collectively, stock awards), all of which may be granted to employees, including officers, non-employee directors and consultants of us and our affiliates. Additionally, the 2014 Plan provides for the grant of performance cash awards. ISOs may be granted only to employees. All other awards may be granted to employees, including officers, and to non-employee directors and consultants.

Share Reserve. Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2014 Plan after the 2014 Plan becomes effective is the sum of (i) shares, plus (ii) the number of remaining shares reserved for issuance under our 2007 Plan at the time our 2014 Plan becomes effective, plus (iii) any shares subject to outstanding stock options or other stock awards that would have otherwise returned to our 2007 Plan (such as upon the expiration or termination of a stock award prior to vesting). Additionally, the number of shares of our common stock reserved for issuance under our 2014 Plan will automatically increase on October 1 of each year, beginning on October 1, 2014 (assuming the 2014 Plan becomes effective before such date) and continuing through and including October 1, 2024, by four percent (4%) % of the total number of shares of our capital stock outstanding on September 30 of the preceding fiscal year, or a lesser number of shares determined by our board of directors. The maximum number of shares that may be issued upon the exercise of ISOs under our 2014 Plan is shares.

No person may be granted stock awards covering more than 3,000,000 shares of our common stock under our 2014 Plan during any calendar year pursuant to stock options, stock appreciation rights and other stock awards whose value is determined by reference to an increase over an exercise or strike price of at least 100% of the fair market value on the date the stock award is granted. Additionally, no person may be granted in a calendar year a performance stock award covering more than 3,000,000 shares or a performance cash award having a maximum value in excess of $3,000,000. Such limitations are designed to help assure that any deductions to which we would otherwise be entitled with respect to such awards will not be subject to the $1,000,000 limitation on the income tax deductibility of compensation paid to any covered executive officer imposed by Section 162(m) of the Code. In addition, a maximum of the greater of 250,000 shares of our common stock or such number of shares of our common stock that has a fair market value on the grant date equal to $300,000 may be granted to any one non-employee director during any one calendar year pursuant to stock awards.

If a stock award granted under the 2014 Plan expires or otherwise terminates without being exercised in full, or is settled in cash, the shares of our common stock not acquired pursuant to the stock award again will become available for subsequent issuance under the 2014 Plan. In addition, the following types of shares under the 2014 Plan may become available for the grant of new stock awards under the 2014 Plan: (1) shares that are forfeited to or repurchased by us prior to becoming fully vested; (2) shares withheld to satisfy income or employment withholding taxes; or (3) shares used to pay the exercise or purchase price of a stock award. Shares issued under the 2014 Plan may be previously

unissued shares or reacquired shares bought by us on the open market. As of the date hereof, no awards have been granted and no shares of our common stock have been issued under the 2014 Plan.

Administration. Our board of directors, or a duly authorized committee thereof, has the authority to administer the 2014 Plan. Our board of directors may also delegate to one or more of our officers the authority to (1) designate employees (other than other officers) to be recipients of certain stock awards, and (2) determine the number of shares of common stock to be subject to such stock awards. Subject to the terms of the 2014 Plan, our board of directors or the authorized committee, referred to herein as the Plan administrator, determines recipients, dates of grant, the numbers and types of stock awards to be granted and the terms and conditions of the stock awards, including the period of their exercisability and vesting schedule applicable to a stock award. Subject to the limitations set forth below, the plan administrator will also determine the exercise price, strike price or purchase price of awards granted and the types of consideration to be paid for the award.

The plan administrator has the authority to modify outstanding awards under our 2014 Plan. Subject to the terms of our 2014 Plan, the plan administrator has the authority to reduce the exercise, purchase or strike price of any outstanding stock award, cancel any outstanding stock award in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any adversely affected participant.

Stock Options. Incentive and non-statutory stock options are granted pursuant to stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 2014 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2014 Plan vest at the rate specified by the plan administrator.

The plan administrator determines the term of stock options granted under the 2014 Plan, up to a maximum of 10 years. Unless the terms of an option holder's stock option agreement provide otherwise, if an option holder's service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, the option holder may generally exercise any vested options for a period of three months following the cessation of service. The option term may be extended in the event that exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder's service relationship with us or any of our affiliates ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. Additionally, options generally terminate immediately in the event that the option holder breaches certain restrictive covenants set forth in the option agreement. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of our common stock previously owned by the optionholder, (4) a net exercise of the option if it is an NSO, and (5) other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution, or pursuant to a domestic relations order. An optionholder may designate a beneficiary, however, who may exercise the option following the optionholder's death.

Tax Limitations On Incentive Stock Options. The aggregate fair market value, determined at the time of grant, of our common stock with respect to incentive stock options (ISOs) that are exercisable for the first time by an optionholder during any calendar year under all of our stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will generally be treated as non-statutory stock options (NSOs). No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant, and (2) the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Awards. Restricted stock awards are granted pursuant to restricted stock award agreements adopted by the plan administrator. Restricted stock awards may be granted in consideration for (1) cash, check, bank draft or money order, (2) services rendered to us or our affiliates, or (3) any other form of legal consideration. Common stock acquired under a restricted stock award may, but need not, be subject to a share repurchase option in our favor in accordance with a vesting schedule to be determined by the plan administrator. Rights to acquire shares under a restricted stock award may be transferred only upon such terms and conditions as set by the plan administrator. Except as otherwise provided in the applicable award agreement, restricted stock awards that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

Restricted Stock Unit Awards. Restricted stock unit awards are granted pursuant to restricted stock unit award agreements adopted by the plan administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, restricted stock units that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

Stock Appreciation Rights. Stock appreciation rights are granted pursuant to stock appreciation grant agreements adopted by the plan administrator. The plan administrator determines the strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Upon the exercise of a stock appreciation right, we will pay the participant an amount equal to the product of (1) the excess of the per share fair market value of our common stock on the date of exercise over the strike price, multiplied by (2) the number of shares of common stock with respect to which the stock appreciation right is exercised. A stock appreciation right granted under the 2014 Plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator.

The plan administrator determines the term of stock appreciation rights granted under the 2014 Plan, up to a maximum of ten years. Unless the terms of a participant's stock appreciation right agreement provides otherwise, if a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. The stock appreciation right term may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of

disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate immediately upon the occurrence of the event giving rise to the termination of the individual for cause. Additionally, stock appreciation rights generally terminate immediately in the event that the option holder breaches certain restrictive covenants set forth in the option agreement. In no event may a stock appreciation right be exercised beyond the expiration of its term.

Performance Awards. The 2014 Plan permits the grant of performance-based stock and cash awards that may qualify as performance-based compensation that is not subject to the $1,000,000 limitation on the income tax deductibility of compensation paid to a covered executive officer imposed by Section 162(m) of the Code. To help assure that the compensation attributable to performance-based awards will so qualify, our compensation committee can structure such awards so that stock or cash will be issued or paid pursuant to such award only after the achievement of certain pre-established performance goals during a designated performance period.

The performance goals that may be selected include one or more of the following: (i) earnings (including earnings per share and net earnings); (ii) earnings before interest, taxes and depreciation; (iii) earnings before interest, taxes, depreciation and amortization; (iv) earnings before interest, taxes, depreciation, amortization and legal settlements; (v) earnings before interest, taxes, depreciation, amortization, legal settlements and other income (expense); (vi) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense) and stock-based compensation; (vii) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense), stock-based compensation and changes in deferred revenue; (viii) total stockholder return; (ix) return on equity or average stockholder's equity; (x) return on assets, investment, or capital employed; (xi) stock price; (xii) margin (including gross margin); (xiii) income (before or after taxes); (xiv) operating income; (xv) operating income after taxes; (xvi) pre-tax profit; (xvii) operating cash flow; (xviii) sales or revenue targets; (xix) increases in revenue or product revenue; (xx) expenses and cost reduction goals; (xxi) improvement in or attainment of working capital levels; (xxii) economic value added (or an equivalent metric); (xxiii) market share; (xxiv) cash flow; (xxv) cash flow per share; (xxvi) share price performance; (xxvii) debt reduction; (xxviii) implementation or completion of projects or processes (including, without limitation, clinical trial initiation, clinical trial enrollment, clinical trial results, new and supplemental indications for existing products, regulatory filing submissions, regulatory filing acceptances, regulatory or advisory committee interactions, regulatory approvals, and product supply); (xxix) stockholders' equity; (xxx) capital expenditures; (xxxi) debt levels; (xxxii) operating profit or net operating profit; (xxxiii) workforce diversity; (xxxiv) growth of net income or operating income; (xxxv) billings; (xxxvi) bookings; (xxxvii) employee retention; (xxxviii) initiation of phases of clinical trials and/or studies by specific dates; (xxxix) patient enrollment rates; (xl) budget management; (xli) submission to, or approval by, a regulatory body (including, but not limited to the U.S. Food and Drug Administration) of an applicable filing or a product candidate; (xlii) regulatory milestones; (xliii) progress of internal research or clinical programs; (xliv) progress of partnered programs; (xlv) partner satisfaction; (xlvi) timely completion of clinical trials; (xlvii) submission of INDs and NDAs and other regulatory achievements; (xlviii) research progress, including the development of programs; (xlix) strategic partnerships or transactions (including in-licensing and out-licensing of intellectual property; (l) customer satisfaction; and (li) to the extent that an award is not intended to comply with Section 162(m) of the Code, other measures of performance selected by our board of directors.

The performance goals may be based on a company-wide basis, with respect to one or more business units, divisions, affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise (i) in the award agreement at the time the award is granted or (ii) in

such other document setting forth the performance goals at the time the goals are established, we will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (1) to exclude restructuring and/or other non-recurring charges; (2) to exclude exchange rate effects, as applicable, for non-U.S. dollar denominated goals; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of any "extraordinary items" as determined under generally accepted accounting principles and such other adjustments set forth in the 2014 Plan. In addition, we retain the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of the goals and to define the manner of calculating the performance goals selected. The performance goals may differ from participant to participant and from award to award.

Other Stock Awards. The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the stock award and all other terms and conditions of such awards.

Changes to Capital Structure. In the event that there is a specified type of change in our capital structure, such as a stock split or recapitalization, appropriate adjustments will be made to (a) the class and maximum number of shares reserved for issuance under the 2014 Plan, (b) the class and maximum number of shares by which the share reserve may increase automatically each year, (c) the class and maximum number of shares that may be issued upon the exercise of ISOs, (d) the class and maximum number of shares subject to stock awards that can be granted in a calendar year (as established under the 2014 Plan pursuant to Section 162(m) of the Code), (e) (iv) the class(es) and maximum number of securities that may be awarded to any Non-Employee Director and (f) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

Corporate Transactions. In the event of certain specified significant corporate transactions, the plan administrator has the discretion to take any of the following actions with respect to stock awards:

- arrange for the assumption, continuation or substitution of a stock award by a surviving or acquiring entity or parent company;
- arrange for the assignment of any reacquisition or repurchase rights held by us to the surviving or acquiring entity or parent company;
- accelerate the vesting of the stock award and provide for its termination prior to the effective time of the corporate transaction;
- arrange for the lapse of any reacquisition or repurchase right held by us;
- cancel or arrange for the cancellation of the stock award in exchange for such cash consideration, if any, as our board of directors may deem appropriate; or
- make a payment equal to the excess of (a) the value of the property the participant would have received upon exercise of the stock award over (b) the exercise price otherwise payable in connection with the stock award.

Our plan administrator is not obligated to treat all stock awards, even those that are of the same type, in the same manner.

Under the 2014 Plan, a corporate transaction is generally the consummation of (i) a sale or other disposition of all or substantially all of our consolidated assets, (ii) a sale or other disposition of at least 90% of our outstanding securities, (iii) a merger, consolidation or similar transaction following which we are not the surviving corporation, or (iv) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

Change in Control. The plan administrator may provide, in an individual award agreement or in any other written agreement between a participant and us that the stock award will be subject to additional acceleration of vesting and exercisability in the event of a change in control. Under the 2014 Plan, a change in control is generally (i) the acquisition by a person or entity of more than 50% of our combined voting power other than by merger, consolidation or similar transaction; (ii) a consummated merger, consolidation or similar transaction immediately after which our stockholders cease to own more than 50% of the combined voting power of the surviving entity; or (iii) a consummated sale, lease or exclusive license or other disposition of all or substantially of our consolidated assets.

Amendment and Termination. Our board of directors has the authority to amend, suspend, or terminate our 2014 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. No ISOs may be granted after the tenth anniversary of the date our board of directors adopted our 2014 Plan.

2007 Incentive Compensation Plan

Our board of directors and our stockholders approved the 2007 Plan, which became effective in August 2008. As of September 30, 2013, there were 1,756,701 shares remaining available for the grant of stock awards under the 2007 Plan and there were outstanding stock awards covering a total of 5,213,133 shares that were granted under the 2007 Plan, all of which were stock options.

After the effective date of the 2014 Plan, no additional awards will be granted under the 2007 Plan, and all awards granted under the 2007 Plan that are repurchased, forfeited, expire or are cancelled will become available for grant under the 2014 Plan in accordance with its terms.

Stock awards. The 2007 Plan provides for the grant of ISO, NSOs, stock appreciation rights, restricted stock awards, deferred stock awards, shares granted as a bonus or in lieu of another award under the 2007 Plan, dividend equivalents and other forms of stock-based awards and performance awards (collectively, stock awards), all of which may be granted to employees, including officers, non-employee directors, and consultants of us and our related entities. ISOs may be granted only to employees. All other stock awards may be granted to employees, including officers, and to non-employee directors and consultants.

Share Reserve. The aggregate number of shares of our common stock reserved for issuance pursuant to stock awards under the 2007 Plan is 8,800,000 shares. The maximum number of shares that may be issued upon the exercise of ISOs under the 2007 Plan is 4,301,445 shares.

If a stock award granted under the 2007 Plan is forfeited, expires or otherwise terminates without being exercised in full, or is settled in cash or otherwise does not result in an issuance of all or part of the common stock for a stock award, the shares of our common stock not issued pursuant to the stock award again will become available for subsequent issuance under the 2007 Plan. In addition, the following types of shares under the 2007 Plan may become available for the grant of new stock

awards under the 2007 Plan: (1) shares that are forfeited to or repurchased by us prior to becoming fully vested; (2) shares withheld to satisfy income or employment withholding taxes; or (3) shares used to pay the exercise or purchase price of a stock award. Shares issued under the 2007 Plan may consist, in whole or in part, of authorized and unissued shares or treasury shares.

Administration. The board of directors or the Committee has the authority to administer the 2007 Plan and may also delegate certain authority to one or more of our officers or managers. Subject to the terms of the 2007 Plan, our board of directors or the Committee, referred to herein as the plan administrator, determines recipients, dates of grant, the numbers and types of stock awards to be granted, and the terms and conditions of the stock awards, including the period of their exercisability and vesting schedule applicable to a stock award. Subject to the limitations set forth below, the plan administrator will also determine the exercise price, strike price or purchase price of awards granted, and the types of consideration to be paid for the award.

The plan administrator has the authority to modify outstanding awards under the 2007 Plan. However, subject to the terms of the 2007 Plan, the plan administrator has the authority, only with the approval of our stockholders, to reduce the exercise or strike price of any outstanding stock option or stock appreciation right, cancel any outstanding stock option or stock appreciation right with an exercise or strike price exceeding the fair market value of our common stock in exchange for other stock awards or take any other action with respect to stock options or stock appreciation rights that may be treated as a repricing.

Stock Options. Incentive and non-statutory stock options are granted pursuant to stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 2007 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2007 Plan vest at the rate specified by the plan administrator.

The plan administrator determines the term of stock options granted under the 2007 Plan, up to a maximum of 10 years. The terms of the stock option agreement provide for earlier termination upon certain circumstances. Generally, the stock option agreements provide that if an option holder's service relationship with us or any of our related entities ceases for any reason other than disability, death or cause, the option holder may generally exercise any vested options for a period of three months following the cessation of service. If an optionholder's service relationship with us or any of our affiliates ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 12 months. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. Additionally, options generally terminate immediately in the event that the option holder breaches certain restrictive covenants set forth in the option agreement. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option are determined by the plan administrator and generally include cash, check and shares of our common stock. Options will vest and become exercisable as determined by the plan administrator and set forth in the option agreement. Options granted under the 2007 Plan generally vest over a period of four years, subject to the option holder's continued service with us. Additionally, options generally may be exercised prior to vesting, and in such event, we have the right to repurchase any unvested shares upon the termination of the option holder's service with us for any reason other than death or disability at a price equal to the exercise price per share paid to purchase such shares.

Unless the plan administrator provides otherwise, options generally are not transferable except by will and the laws of descent and distribution. However, an optionholder may be permitted to designate a beneficiary who may exercise the option following the optionholder's death.

Tax Limitations on Incentive Stock Options. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an optionholder during any calendar year under all of our stock plans may not exceed $100,000. Options, or portions thereof, that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and (2) the option is not exercisable after the expiration of five years from the date of grant.

Changes to Capital Structure. In the event that there is a specified type of change in our capital structure, such as an extraordinary dividend or other distribution, recapitalization, stock split or other transaction that affects our common stock, appropriate adjustments will be made to (1) the class and maximum number of shares reserved for issuance under the 2007 Plan, (2) the class and maximum number of shares used to measure per person award limitations, (3) the class and maximum number of shares that may be issued upon the exercise of ISOs, and (3) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

Corporate Transactions. In the event of any merger, consolidation or other reorganization in which we do not survive or in the event of any change in control, outstanding stock awards may be dealt with in accordance with any of the following approaches as determined by the agreement effecting the transaction or if not so determined, as determined by the plan administrator (1) such stock awards may be continued by us if we are the surviving entity; (2) such stock awards may be assumed or substituted for outstanding awards by the surviving entity or its parent or subsidiary; (3) such stock awards may be subject to full exercisability or vesting and accelerated expiration; or (4) such stock awards may be settled based on their value, in cash or cash equivalents or other property followed by cancellation. The plan administrator must give written notice of any proposed transaction prior to the closing date of such transaction in order for holders of stock awards to have a reasonable period of time to exercise any stock awards. If provided in the terms of an individual stock award or another written agreement between us and the holder of a stock award, in the event of a change in control, all outstanding stock options and stock appreciation rights shall become immediately vested and exercisable. However, if the successor company in the change in control assumes or substitutes for outstanding stock awards, then each outstanding option or stock appreciation right shall not be accelerated.

The terms of our outstanding stock option agreements provide that the stock option will terminate immediately in the event of our liquidation or dissolution or any reorganization, merger, consolidation or other form of corporate transaction in which we do not survive or our common stock is exchanged for or converted into securities issued by another entity or affiliate of such successor or acquirer, unless the successor or acquirer or an affiliate assumes the stock option or substitutes and equivalent stock option or right for the stock option and the plan administrator may give written notice to cancel any outstanding unexercised stock option effective upon the consummation of any change in control. In addition, the stock option agreements provide that upon a change in control during the award holder's service to us, any shares acquired through early exercise of a stock option that are unvested and subject to our repurchase right will become fully and immediately vested and released from our repurchase right. However, if the company that retains or succeeds our business in connection with such change in control assumes or substitutes another award for such unvested shares or for such stock option, to the extent not exercised, then the vesting of 50% of the unvested shares shall not be

accelerated. Additionally, in the event the holder's employment with the successor company and its affiliates terminates for reasons other than by such successor for cause or by the holder without good reason within 24 months following such change in control, any unvested shares that did not vest in connection with the change in control will become immediately and fully vested and released from our repurchase right.

Under the 2007 Plan, a "change in control" is generally the occurrence of any of the following (1) the acquisition by a person or entity of a controlling interest in us, which means beneficial ownership of more than 50% of either our outstanding equity securities or combined voting power; (2) during any two consecutive years, individuals on our board of directors on the effective date of the 2007 Plan (or individuals whose election or nomination for election was approved by the vote of at least a majority of such directors) cease to constitute at least a majority of our board of directors; or (3) the consummation of a reorganization, merger, statutory share exchange, consolidation or similar transaction involving us, a sale or other disposition or all or substantially all of our assets or the acquisition of assets or equity of another entity by us, in each case unless following such transaction certain conditions are met.

Under the 2007 Plan, "good reason" has the same definition as set forth in any employment or other agreement for the performance of services between an award holder and us and if there is no such definition, generally means with respect to an award holder (1) assignment of duties inconsistent in any material respect with such holder's duties or responsibilities as assigned by us or any other action by us that results in a material diminution in such duties or responsibilities; (2) any material failure by us to comply with our obligations to the holder as agreed upon; or (3) our requiring the holder to be based at any office or location outside of 30 miles from the holder's location of employment or service.

Amendment and Termination. The 2007 Plan will terminate earliest of (1) no common stock remains for issuance under the 2007 Plan; (2) on March 7, 2017; or (3) our board of directors exercises its authority to amend, suspend, or terminate the 2007 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent.

As noted above, in connection with this offering, our 2007 Plan will be terminated and no further awards will be granted thereunder.

2014 Employee Stock Purchase Plan

Our board of directors adopted the ESPP in November 2013 and we expect our stockholders will approve the ESPP prior to the execution and delivery of the underwriting agreement for this offering. The ESPP will become effective contingent upon the date of the underwriting agreement pursuant to which our common stock is priced for our initial public offering. The purpose of the ESPP is to retain the services of new employees and secure the services of new and existing employees while providing incentives for such individuals to exert maximum efforts toward our success and that of our affiliates.

Share Reserve. Following this offering, the ESPP authorizes the issuance of shares of our common stock pursuant to purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase on October 1 of each fiscal year, from October 1, 2014 (assuming the ESPP becomes effective before such date) through October 1, 2024 by the least of (a) one percent (1%) of the total number of shares of our common stock outstanding on September 30 of the preceding fiscal year, (b) shares, or (c) a number determined by our board of directors that is less than (a) and (b). The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning

of Section 423 of the Code. As of the date hereof, no shares of our common stock have been purchased under the ESPP.

Administration. Our board of directors has delegated its authority to administer the ESPP to our compensation committee. The ESPP is implemented through a series of offerings of purchase rights to eligible employees. Under the ESPP, we may specify offerings with durations of not more than 24 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. An offering may be terminated under certain circumstances.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to 15% of their earnings for the purchase of our common stock under the ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for accounts of employees participating in the ESPP at a price per share equal to the lower of (a) 85% of the fair market value of a share of our common stock on the first date of an offering or (b) 85% of the fair market value of a share of our common stock on the date of purchase.

Limitations. Employees may have to satisfy one or more of the following service requirements before participating in the ESPP, as determined by our board of directors: (a) customarily employed for more than 20 hours per week, (b) customarily employed for more than five months per calendar year or (c) continuous employment with us or one of our affiliates for a period of time (not to exceed two years). No employee may purchase shares under the ESPP at a rate in excess of $25,000 worth of our common stock based on the fair market value per share of our common stock at the beginning of an offering for each year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value pursuant to Section 424(d) of the Code.

Changes to Capital Structure. In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large non-recurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or similar transaction, the board of directors will make appropriate adjustments to (a) the number of shares reserved under the ESPP, (b) the maximum number of shares by which the share reserve may increase automatically each year and (c) the number of shares and purchase price of all outstanding purchase rights.

Corporate Transactions. In the event of certain significant corporate transactions, including: (i) a sale of all or substantially all of our assets, (ii) the sale or disposition of 90% of our outstanding securities, (iii) the consummation of a merger or consolidation where we do not survive the transaction, and (iv) the consummation of a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction, any then-outstanding rights to purchase our stock under the ESPP may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within 10 business days prior to such corporate transaction, and such purchase rights will terminate immediately.

Plan Amendments, Termination. Our board of directors has the authority to amend or terminate our ESPP, provided that except in certain circumstances any such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

Director Compensation

Historically, we have not paid cash or equity compensation to directors who are also our employees for service on our board of directors. We have provided equity compensation generally in the form of stock option grants under the 2007 Plan to our non-employee members of our board of directors. We have reimbursed and will continue to reimburse all of our non-employee directors for their travel, lodging and other reasonable expenses incurred in attending meetings of our board of directors and committees of our board of directors. We do not maintain any agreements with our directors governing their services or compensation for their services on our board of directors.

On April 19, 2013 we granted an option under the 2007 Plan to purchase 15,000 shares to each of Mr. Flaum, Mr. Moorin, Mr. Nowak and Mr. Ratoff and an option to purchase 5,000 to Dr. Schreiber, each of which has an exercise price per share of $0.69, is fully exercisable on the date of grant and vests with respect to 25% of the underlying shares on each of the one, two, three and four years following the date of grant, subject to the director's continued service with us through such date.

The following table sets forth in summary form information concerning the compensation that we paid or awarded during the fiscal year ended September 30, 2013 to each of our non-employee directors:

Name[1]	Fees Earned or Paid in Cash ($)	Option Awards ($)[2]	Total ($)
Sander Flaum.	—	12,450	12,450
Jay Moorin	—	12,450	12,450
Reiner Nowak	—	12,450	12,450
Steven Ratoff	—	12,450	12,450
Alain Schreiber, M.D.	—	4,650	4,650
Hironori Hozoji	—	—	—

(1) Mr. Tarriff was an employee director during 2013 and his compensation is fully reflected in the "— Summary Compensation Table" above. Mr. Tarriff did not receive any compensation in 2013 for services provided as a member of our board of directors.

(2) Amounts listed in this column represent the aggregate grant date fair value of option awards granted during 2013 computed in accordance with ASC 718. Assumptions used in the calculation of these amounts are included in Note 3 to our Financial Statement. These amounts do not reflect the actual economic value that will be realized by our non-employee directors upon the vesting of the stock options, the exercise of the stock options or the sale of the common stock underlying such stock options. The aggregate number of shares subject to each non-employee director's outstanding option awards as of September 30, 2013 was as follows: Mr. Flaum: 90,000 outstanding and unexercised; Mr. Moorin: 90,000 outstanding and unexercised; Mr. Nowak: 90,000 outstanding and unexercised; Mr. Ratoff: 90,000 outstanding and unexercised; Dr. Schreiber: 5,000 outstanding and unexercised; Mr. Hozoji: 0 outstanding and unexercised.

Effective upon this offering, our board of directors adopted a new compensation policy that will be applicable to all of our non-employee directors. This compensation policy provides that each such non-employee director will receive the following compensation for service on our board of directors:

- an annual cash retainer of $25,000, paid quarterly for service (other than as chairman) on the board of directors;

- an additional annual cash retainer of $40,000, paid quarterly, for service as chairman of the board of directors;
- an additional annual cash retainer of $20,000, paid quarterly, for service as chairman of the audit committee;
- an additional annual cash retainer of $7,500, paid quarterly, for service as chairman of the compensation committee or the nominating and corporate governance committee;
- an additional annual cash retainer of $12,500, paid quarterly, for service (other than as chairman) on the audit committee;
- an additional annual cash retainer of $7,500, paid quarterly, for service on the executive committee;
- an additional annual cash retainer of $4,000, paid quarterly, for service (other than as chairman) on the compensation committee or the nominating and corporate governance committee;
- an annual option grant to purchase 30,000 shares (prior to any stock split) of our common stock vesting monthly over one year following the grant date;
- upon first joining our board of directors, an automatic initial grant of an option to purchase 60,000 shares (prior to any stock split) of our common stock vesting monthly over three years following the grant date.

Each of the option grants described above will vest in full upon a change in control (as defined under our 2014 Plan). The term of each option will be 10 years. The options will be granted under our 2014 Plan, the terms of which are described in more detail above under " — Equity Benefit Plans — 2014 Equity Incentive Plan."

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since October 1, 2010 to which we have been a party, in which the amount involved in the transaction exceeded $120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Compensation Discussion and Analysis."

Preferred Stock Financings

Series B-1 Preferred Stock Financing

In February 2011 and July 2011, we issued an aggregate of 10,177,085 shares of our Series B-1 preferred stock at a purchase price of $1.82 per share for aggregate consideration of $18.5 million to 17 accredited investors pursuant to a preferred stock purchase agreement. The following table sets forth the names of our directors, executive officers and holders of more than 5% of our capital stock, and entities affiliated with them, who participated in the Series B-1 preferred stock financing.

Related Party	Shares of Series B-1 Preferred Stock (#)	Aggregate Consideration Received ($)
Entities affiliated with ProQuest[1]	5,852,946	$ 10,652,362
General Electric Pension Trust	1,352,453	2,461,464
Prudential Jennison Health Sciences Fund, a series of Prudential Sector Funds, Inc.	1,200,000	2,184,000
Scott Tarriff	549,451	1,000,001
Entities affiliated with Jay Moorin[2]	274,731	500,010
Sander Flaum	54,945	100,000
Steven Ratoff	54,945	100,000

(1) Represents 5,451,834 shares purchased by ProQuest Investments IV, L.P., 243,753 shares purchased by ProQuest Management, LLC DBPP FBO Jay Moorin and 157,359 shares purchased by ProQuest Management, LLC Salary Savings Plan FBO of Jay Moorin and other individuals. ProQuest Investments IV, L.P., ProQuest Management, LLC DBPP FBO Jay Moorin and ProQuest Management, LLC Salary Savings Plan FBO of Jay Moorin and other individuals are collectively referred to as entities affiliated with ProQuest. Jay Moorin and Alain Schreiber, M.D, two of our directors, are managing members of ProQuest Management LLC and ProQuest Associates IV LLC, the General Partner of ProQuest Investments IV, L.P. Steven Ratoff, a member of our board of directors, is a venture partner of ProQuest Investments.

(2) Represents 243,753 shares purchased by ProQuest Management, LLC DBPP FBO Jay Moorin and 30,978 shares purchased by ProQuest Management, LLC Salary Savings Plan FBO of Jay Moorin. ProQuest Management, LLC DBPP FBO Jay Moorin and ProQuest Management, LLC Salary Savings Plan FBO of Jay Moorin are collectively referred to as entities affiliated with Jay Moorin.

Series C Preferred Stock Financing

In April 2013, we issued an aggregate of 5,494,506 shares of our series C preferred stock at a purchase price of $1.82 per share for aggregate consideration of $10,000,001 million to JAFCO Super V3 Investment Limited Partnership, a holder of more than 5% of our capital stock.

Bridge Debt Financing

In August 2012 and September 2012 we sold and issued convertible promissory notes to existing investors in an aggregate principal amount of $9.7 million and warrants to purchase shares of Series C preferred stock, pursuant to a note and warrant purchase agreement. The convertible promissory notes accrued interest at the rate of 6% per annum. In April 2013, the principal and accrued interest on the

convertible promissory notes were converted into an aggregate of 5,528,726 of our series C preferred stock at a conversion price of $1.82 per share and the warrants to purchase shares of preferred stock became exercisable to purchase an aggregate of 944,210 shares of series C preferred stock at exercise prices of $1.82 per share. The following table sets forth the names of our directors, executive officers and holders of more than 5% of our capital stock, and entities affiliated with them, who participated in this bridge debt financing.

Related Party	Aggregate Principal Amount of Notes ($)	Shares of Series C Preferred Stock Issued upon Conversion of Notes (#)	Shares of Series C Preferred Stock Issuable upon Exercise of Preferred Warrants (#)
Entities affiliated with ProQuest Investments IV, L.P.(1)	$ 6,482,375	3,710,742	641,112
Prudential Jennison Health Sciences Fund, a series of Prudential Sector Funds, Inc.	$ 888,543	508,633	87,877
General Electric Pension Trust	1,358,583	777,701	134,365
Scott Tarriff	286,635	162,662	22,048
Entities affiliated with Jay Moorin(2)	71,797	41,098	7,100
Sander Flaum	29,676	16,305	2,210
Steven Ratoff	14,359	8,148	1,104

(1) Represents 3,650,758 shares and 630,746 warrants acquired by ProQuest Investments IV, L.P., 36,464 shares and 6,300 warrants acquired by ProQuest Management, LLC DBPP FBO Jay Moorin and 23,540 shares and 4,066 warrants acquired by ProQuest Management, LLC Salary Savings Plan FBO of Jay Moorin and other individuals.

(2) Represents 36,464 shares and 6,300 warrants acquired by ProQuest Management, LLC DBPP FBO Jay Moorin and 4,634 shares and 800 warrants acquired by ProQuest Management, LLC Salary Savings Plan FBO of Jay Moorin.

Indebtedness of Management

In February 2011 and August 2011, we lent Mr. Tarriff an aggregate of $1.0 million to purchase shares of our series B-1 preferred stock. The original promissory notes evidencing this loan bore interest at a rate of 3.9% per annum, compounded annually, with payments due upon the earlier of the consummation of a debt financing or the second anniversary of the date of issuance of each promissory note. The promissory notes were secured by the 549,451 shares of our series B-1 preferred stock purchased by Mr. Tarriff. In August 2011, in connection with the bridge debt financing, we entered into a payoff and exchange agreement with Mr. Tarriff pursuant to which the aggregate principal amount and all accrued interest under the promissory notes was cancelled in exchange for Mr. Tarriff transferring the 549,451 shares of our series B-1 preferred stock held by Mr. Tarriff to us.

Stockholder Agreements

In connection with our preferred stock financings, we entered into a third amended and restated investor rights agreement, or the Investor Rights Agreement, a fourth amended and restated voting and drag-along agreement, or Voting Agreement, and a third amended and restated right of first refusal and co-sale agreement, or ROFR Agreement, to collectively provide for, among other things, registration rights, information rights, voting rights and obligations, and rights of first refusal with certain holders of our preferred stock and common stock, including JAFCO Super V3 Investment Limited Partnership, entities affiliated with ProQuest, Prudential Jennison Health Sciences Fund, a series of Prudential Sector Funds, Inc., Sander Flaum, entities affiliated with Jay Moorin, Steven Ratoff and Scott Tarriff. The ROFR Agreement, the Voting Agreement and portions of the Investor Rights Agreement will terminate in connection with the closing of this offering. The registration rights granted to certain holders of our preferred stock and common stock under our Investor Rights Agreement will

continue following the closing of this offering as more fully described below in "Description of Capital Stock — Registration Rights."

Employment Arrangements

We have entered into employment arrangements, with our executive officers, as more fully described in "Executive and Director Compensation — Agreements with our Named Executive Officers," "— Incentive Compensation" and "— Potential Payments upon Termination or Change in Control."

Stock Options Granted to Executive Officers and Directors

We have granted stock options to our executive officers and directors, as more fully described in "Executive and Director Compensation."

Indemnification Agreements

We have entered into, and intend to continue to enter into, indemnification agreements with each of our directors and executive officers, in addition to the indemnification provided for in our amended and restated bylaws and our amended and restated certificate of incorporation. These agreements, among other things, require us to indemnify our directors and executive officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. For more information regarding these agreements, see the section of this prospectus entitled "Executive Compensation — Limitations on liability and indemnification matters."

Policies and Procedures for Transactions with Related Persons

Prior to this offering, we have not had a formal policy regarding approval of transactions with related parties. We expect to adopt a related person transaction policy that will set forth our procedures for the identification, review, consideration and approval or ratification of related person transactions, which will become effective immediately prior to the completion of this offering. For purposes of our policy only, a "related-person transaction" will be defined as a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any "related person" are participants involving an amount that exceeds $120,000.

Transactions involving compensation for services provided to us as an employee, consultant or director will not be considered related-person transactions under this policy. A related person will be defined as any executive officer, director or a holder of more than 5% of our common stock, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-person transaction to our audit committee (or, where review by our audit committee would be inappropriate, to another independent body of our board of directors) for review. The presentation must include a description of, among other things, the material facts, the direct and indirect interests of the related persons, the benefits of the transaction to us and whether any alternative transactions are available. To identify related-person transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. In considering related-person transactions, our audit committee or other independent body of our board of directors will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;

- the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from our employees generally.

The policy will require that, in determining whether to approve, ratify or reject a related person transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion. In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval.

All of the transactions described above were entered into prior to the adoption of the written policy.

PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding beneficial ownership of our capital stock by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our current executive officers and directors as a group.

The percentage ownership information under the column entitled "Before offering" is based on 67,536,286 shares of common stock outstanding as of September 30, 2013, assuming conversion of all outstanding shares of our preferred stock into 47,997,673 shares of common stock. The percentage ownership information under the column entitled "After offering" is based on the sale of shares of common stock in this offering.

Information with respect to beneficial ownership has been furnished by each director, officer or beneficial owner of more than 5% of our common stock. We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options or warrants that are either immediately exercisable or exercisable on or before November 29, 2013 which is 60 days after September 30, 2013. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the address for each person or entity listed in the table is c/o Eagle Pharmaceuticals, Inc., 50 Tice Blvd. Suite 315, Woodcliff Lake, NJ 07677.

Name and address of beneficial owner	Number of shares beneficially owned	Percentage of shares beneficially owned	
		Before offering	After offering
5% or greater stockholders			
ProQuest and its affiliates[1]	29,519,100	43.3%	
General Electric Pension Trust[2]	6,110,673	9.0	
JAFCO Super V3 Investment Limited Partnership[3]	5,494,506	8.1	
Prudential Jennison Health Sciences Fund, a series of Prudential Sector Funds, Inc.[4]	3,996,510	5.9	
Directors and named executive officers			
Scott Tarriff[5]	12,369,442	17.9	
David E. Riggs	—	*	
Paul Bruinenberg, Ph.D[6]	146,250	*	
Steven L. Krill, M.D.[7]	35,937	*	
Sander Flaum[8]	240,960	*	
Michael Graves	—	*	
Jay Moorin[9]	29,519,100	43.3	
Steven Ratoff[10]	176,697	*	
Alain Schreiber, M.D.[11]	29,519,100	43.3	
All current executive officers and directors as a group (12 persons)[12]	42,784,948	60.7%	

*Represents beneficial ownership of less than one percent.

(1) Includes (a) 28,304,372 shares of common stock and 630,746 shares of common stock underlying a warrant that is exercisable within 60 days of September 30, 2013 held by ProQuest Investments IV, L.P., (b) 60,000 shares of common stock and 52,500 shares of common stock underlying options that are vested and exercisable within 60 days of September 30, 2013 held by ProQuest Management LLC, (c) 280,217 shares of common stock and 6,300 shares of common stock underlying a warrant that is exercisable within 60 days of September 30, 2013 held by ProQuest Management LLC DBPP FBO Jay Moorin, (d) 180,899 shares of common stock and 4,066 shares of common stock underlying a warrant that is exercisable within 60 days of September 30, 2013 held by ProQuest Management LLC Salary Savings Plan FBO Jay Moorin and for the benefit of certain other individuals. Jay Moorin and Alain Schreiber, M.D. two of our directors, are managing members of ProQuest Management LLC and ProQuest Associates IV, LLC, the General Partner of ProQuest Investments IV, L.P. and may be deemed to have shared voting, investment and dispositive power with respect to these shares. Pasquale DeAngelis and Messrs. Moorin and Schreiber are also trustees of ProQuest Management LLC DBPP FBO Jay Moorin and the ProQuest Management LLC Salary Savings Plan FBO Jay Moorin and for the benefit of certain other individuals and, as such, may be deemed to share voting and investment power with respect to all shares held by such entities. The principal address of each of the ProQuest entities is 90 Nassau Street, 4th Floor, Princeton, NJ 08542.

(2) Includes 134,365 shares of common stock underlying a warrant that is exercisable within 60 days of September 30, 2013. General Electric Pension Trust (GEPT) is an employee benefit plan trust for the benefit of the employees and retirees of General Electric Company and its subsidiaries. GE Asset Management Incorporated (GEAM) is a registered investment adviser and acts as Investment Manager for GEPT. GEAM may be deemed to beneficially share ownership of the shares owned by GEPT, but has no pecuniary interest in such shares. GEAM, acting alone, has the power to direct the voting and disposition of the Company securities held by GEPT. GEAM has delegated responsibility for exercising voting and dispositive power over such securities to three of its officers: Don W. Torey, Patrick J. McNeela and Tony Pantuso. These three officers act on a consensus basis in determining how and when to exercise voting and dispositive power with respect to these securities. Any such exercise requires the consent of at least two of these three persons. General Electric Company, Messrs. Torey, McNeela and Pantuso expressly disclaim beneficial ownership of all shares owned by GEPT. The principal address of General Electric Pension Trust is c/o GE Asset Management Incorporated, 1600 Summer Street, Stamford, CT 06905.

footnotes continued on following page

(3) Shinichi Fuki, Hiroshi Yamada, Yoshimitsu Oura, Tsunenori Kano, Shuichi Kinoshita and Naoki Sato, as members of the Investment Committee of JAFCO Co., Ltd., General Partner of JAFCO Super V3 Investment Limited Partnership, may be deemed to have shared voting, investment and dispositive power with respect to those shares. The principal address of JAFCO Super V3 Investment Limited Partnership is Otemachi First Square, West Tower 11F, 1-5-1, Otemachi, Chiyoda-ku, Tokyo, 100-0004 Japan.

(4) Jennison Associates LLC, or Jennison, serves as investment subadviser with power to direct investments and/or power to vote the shares owned by Prudential Jennison Health Sciences Fund, or Fund, a series of Prudential Sector Funds, Inc., and may be deemed to beneficially own the shares held by the Fund. Jennison expressly disclaims ownership of such shares. Jennison is a wholly-owned subsidiary of Prudential Financial, Inc., which is a publicly-traded financial services firm. The Fund is an investment company registered under the Investment Company Act of 1940. By virtue of their positions with Jennison, David Chan and Michael Del Balso, Managing Directors of Jennison and Portfolio Managers to the Fund, have authority to vote or dispose of the securities held by the Fund. Each of David Chan and Michael Del Balso will disclaim beneficial ownership of such securities, except to the extent of his pecuniary interest therein.

(5) Includes (a) 962,925 shares of common stock held by Janney Montgomery Scott LLC CUST FBO Scott Tarriff IRA and (b) 1,672,048 shares of common stock underlying options and a warrant that are vested and exercisable within 60 days of September 30, 2013. Mr. Tarriff is a trustee of Janney Scott LLC CUST FBO Scott Tarriff IRA and, as such, may be deemed to share voting and investment power with respect to all shares held by such entity.

(6) Includes 146,250 shares of common stock underlying options that are vested and exercisable within 60 days of September 30, 2013.

(7) Includes 35,937 shares of common stock underlying options that are vested and exercisable within 60 days of September 30, 2013.

(8) Includes 54,170 shares of common stock underlying options that are vested and exercisable within 60 days of September 30, 2013.

(9) Includes the shares of common stock held by the ProQuest entities referred to in footnote (1) above. Mr. Moorin is a managing member of ProQuest Management LLC and ProQuest Associates IV LLC, the General Partner of ProQuest Investments IV, L.P. and, as such, may be deemed to share voting and investment power with respect to all shares held by such entities. Mr. Moorin is also a trustee of ProQuest Management LLC DBPP FBO Jay Moorin and the ProQuest Management LLC Salary Savings Plan FBO Jay Moorin and for the benefit of certain other individuals and, as such, may be deemed to share voting and investment power with respect to all shares held by such entities. Mr. Moorin disclaims beneficial ownership of such shares except for 315,829 shares of common stock and 7,100 shares of common stock underlying warrants that held by ProQuest Management LLC DBPP FBO Jay Moorin and ProQuest Management LLC Salary Savings Plan FBO Jay Moorin, and otherwise except to the extent of his pecuniary interest therein.

(10) Includes 53,604 shares of common stock underlying options that are vested and exercisable within 60 days of September 30, 2013.

(11) Includes the shares of common stock held by the ProQuest entities referred to in footnote (1) above. Mr. Schreiber is a managing member of the ProQuest Management LLC and ProQuest Associates IV LLC, General Partner of ProQuest Investments IV, L.P. and, as such, may be deemed to share voting and investment power with respect to all shares held by such entities. Mr. Schreiber is also a trustee of ProQuest Management LLC DBPP FBO Jay Moorin and the ProQuest Management LLC Salary Savings Plan FBO Jay Moorin and for the benefit of certain other individuals and, as such, may be deemed to share voting and investment power with respect to all shares held by such entities. Mr. Schreiber disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein.

(12) Includes 39,857,225 shares of common stock held by all current executive officers and directors as a group and 2,927,723 shares of common stock that all current executive officers and directors as a group have the right to acquire from us pursuant to the exercise warrants and options that are vested and exercisable within 60 days of September 30, 2013.

DESCRIPTION OF CAPITAL STOCK

General

Upon the closing of this offering and the filing of our amended and restated certificate of incorporation, our authorized capital stock will consist of shares of common stock, par value $.001 per share, and shares of preferred stock, par value $.001 per share. All of our authorized preferred stock upon the closing of this offering will be undesignated. The following is a summary of the rights of our common and preferred stock and some of the provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective upon the closing of this offering and of the Delaware General Corporation Law. This summary is not complete. For more detailed information, please see our amended and restated certificate of incorporation and amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part, as well as the relevant provisions of the Delaware General Corporation Law.

Common Stock

Outstanding Shares

On September 30, 2013, there were 67,536,286 shares of common stock outstanding, held of record by 48 stockholders, which assumes the conversion of all outstanding shares of preferred stock into shares of common stock immediately prior to the closing of this offering. Based on this number, and assuming the issuance by us of shares of common stock in this offering, there will be shares of common stock outstanding upon the closing of this offering.

As of September 30, 2013, there were outstanding options to acquire 5,213,133 shares of common stock pursuant to our 2007 Incentive Compensation Plan, or 2007 Plan, and outstanding warrants to purchase 944,210 shares of common stock, assuming the conversion of all outstanding preferred stock into common stock immediately prior to the closing of this offering.

Voting

Our common stock is entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and does not have cumulative voting rights. Accordingly, the holders of a majority of the shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and

privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Fully Paid and Nonassessable

All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

Preferred Stock

On September 30, 2013, there were 47,997,673 shares of preferred stock outstanding, held of record by 19 stockholders. Upon the closing of this offering, all outstanding shares of preferred stock will have been converted into 47,997,673 shares of our common stock.

Upon the closing of this offering, our certificate of incorporation will be amended and restated to delete all references to such shares of preferred stock. Under the amended and restated certificate of incorporation, our board of directors will have the authority, without further action by the stockholders, to issue up to shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control that may otherwise benefit holders of our common stock and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock on the rights of holders of common stock until the board of directors determines the specific rights attached to that preferred stock. We have no current plans to issue any shares of preferred stock.

Options and Warrants

As of September 30, 2013, options to purchase an aggregate of 5,213,133 shares of common stock were outstanding under the 2007 Plan. For additional information regarding the terms of this plan, see the section of this prospectus titled "*Executive and Director Compensation — Equity Incentive Plans*."

As of September 30, 2013, warrants to purchase an aggregate of 944,210 shares of our Series C preferred stock at an exercise price of $1.82 per share were outstanding. These warrants have a net exercisable provision under which the holder may, in lieu of payment of the exercise price in cash, surrender the applicable warrant and receive a net amount of shares based on the fair market value of our stock at the time of exercise of the applicable warrant after deduction of the aggregate exercise price. Unless earlier exercised, these warrants will automatically net exercise in connection with this offering and the fair market value per warrant share will be the per share offering price of the common stock in this offering. The warrants also contain a provision for the adjustment of the exercise price and the number of shares issuable upon the exercise of the applicable warrant in the event of certain stock dividends, stock splits, reorganizations, reclassifications and consolidations.

Registration Rights

Following the closing of this offering, the holders of an aggregate of 66,610,330 shares of our common stock, which includes those shares of our common stock that will be issued upon conversion of our preferred stock in connection with this offering and those shares of our common stock that are issuable upon exercise of outstanding warrants, will be entitled to the registration rights set forth below with respect to registration of the resale of such shares under the Securities Act. These shares are collectively referred to herein as registrable securities. These rights are provided under the terms of a third amended and restated investor rights agreement, or investor rights agreement, by and among us and certain of our stockholders, which was entered into in connection with our preferred stock financings, and include demand, piggyback and S-3 registration rights as described more fully below. These registration rights are assignable, subject to certain conditions, including that the assignee be bound by the terms and conditions of the investor rights agreement.

Demand Registration Rights

At any time beginning six (6) months following the effective date of this registration statement, the holders of at least 30% of the outstanding registrable securities (but excluding for such purposes than shares of common stock held by Mr. Tarriff), have the right to make up to two demands that we effect a registration under the Securities Act covering the majority of registrable securities then outstanding (or a lesser portion if the anticipated aggregate offering price of securities requested to be sold under such registration statement would exceed $5.0 million, net of underwriting discounts and commissions). As of September 30, 2013, an aggregate of 58,135,330 registrable securities will be entitled to these demand registration rights. Additionally, as of September 30, 2013, Mr. Tarriff will be entitled to notice of any such demand registration with respect to the registrable securities held by him that are shares of common stock and will be entitled to include such shares of common stock in any such registration statement. These demand registration rights are subject to specified conditions and limitations, including the right of the underwriters, if any, to limit the number of shares included in any such registration under specified circumstances. Upon such a request, we will be required to use our reasonable best efforts to file the registration within 90 days.

Form S-3 Demand Registration Rights

If we are eligible to file a registration statement on Form S-3, holders of at least 10% of the outstanding registrable securities (but excluding for such purposes than shares of common stock held by Mr. Tarriff) have the right to demand that we file a registration statement on Form S-3 so long as the aggregate amount of securities to be sold under the registration statement on Form S-3 is at least $3.0 million and we have not already effected one registration on Form S-3 within the preceding 6-month period. As of September 30, 2013, an aggregate of 58,135,330 registrable securities will be entitled to these Form S-3 registration rights. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under specified circumstances. Upon such a request, we will be required to use our reasonable best efforts to file the registration within 90 days.

"Piggyback" Registration Rights

If we register any securities for public sale, holders of registration rights will each be entitled to notice of the registration and will have the right to include their shares in any such registration statement. These piggyback registration rights are subject to specified conditions and limitations, including the right of the underwriters of any underwritten offering to limit the number of shares having registration rights to be included in the registration statement, but not below 30% of the total number of shares requested by the holders to be included in the registration statement, except this offering in which the

holders have now waived any and all rights to have their shares included. As of September 30, 2013, an aggregate of 66,610,330 registrable securities will be entitled to these piggyback registration rights.

Expenses of Registration

Generally, we are required to bear all registration and selling expenses incurred in connection with the demand, piggyback and Form S-3 registrations described above, other than underwriting discounts and commissions.

Expiration of Registration Rights

The demand, piggyback and Form S-3 registration rights discussed above will terminate five (5) years following the closing of this offering or, as to a given holder of registrable securities, when such holder no longer holds any registrable securities.

Anti-Takeover Effects of Provisions of Our Amended and Restated Certificate of Incorporation, Our Bylaws and Delaware Law

Delaware Anti-Takeover Law

We are subject to Section 203 of the Delaware General Corporation Law, or Section 203. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years following the time that such stockholder became an interested stockholder, unless:

- prior to such time the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to such time the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least $66^{2}/_{3}\%$ of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a "business combination" to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an "interested stockholder" as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective upon the closing of this offering, may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose); and
- provide that special meetings of our stockholders may be called only by the chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least % of our then outstanding common stock.

Choice of Forum

Our certificate of incorporation to be in effect upon the completion of this offering will provide that a state or federal court located within the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty owed by and of our directors, officers or employees to us or our stockholders; any action asserting a

claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine.

Nasdaq Global Market Listing

We have applied for listing of our common stock on The Nasdaq Global Market under the symbol "EGRX."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is . The transfer agent and registrar's address is

SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of common stock in the public market could adversely affect prevailing market prices. Furthermore, since only a limited number of shares will be available for sale shortly after this offering because of contractual and legal restrictions on resale described below, sales of substantial amounts of common stock in the public market after the restrictions lapse could adversely affect the prevailing market price for our common stock as well as our ability to raise equity capital in the future.

Based on the number of shares of common stock outstanding as of September 30, 2013, upon the closing of this offering, shares of common stock will be outstanding, assuming no exercise of the underwriters' option to purchase additional shares and no exercise of options. All of the shares sold in this offering will be freely tradable unless held by an affiliate of ours. Except as set forth below, the remaining shares of common stock outstanding after this offering will be restricted as a result of securities laws or lock-up agreements. These remaining shares will generally become available for sale in the public market as follows:

- no restricted shares will be eligible for immediate sale upon the closing of this offering;
- up to restricted shares will be eligible for sale under Rule 144 or Rule 701 upon expiration of lock-up agreements at least 180 days after the date of this offering; and
- the remainder of the restricted shares will be eligible for sale, subject to restrictions under Rule 144 on affiliate sales, if applicable, from time to time thereafter upon expiration of their respective holding periods under Rule 144, as described below, but could be sold earlier if the holders exercise any available registration rights.

Rule 144

In general, under Rule 144 as currently in effect, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, any person who is not an affiliate of ours and has held their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell shares without restriction, provided current public information about us is available. In addition, under Rule 144, any person who is not an affiliate of ours and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available. Beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell a number of restricted shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering; or
- the average weekly trading volume of our common stock on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales of restricted shares under Rule 144 held by our affiliates are also subject to requirements regarding the manner of sale, notice and the availability of current public information about us. Rule 144 also provides that affiliates relying on Rule 144 to sell shares of our common stock that are

not restricted shares must nonetheless comply with the same restrictions applicable to restricted shares, other than the holding period requirement.

Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted shares have entered into lock-up agreements as described below and their restricted shares will become eligible for sale at the expiration of the restrictions set forth in those agreements.

Rule 701

Under Rule 701, shares of our common stock acquired upon the exercise of currently outstanding options or pursuant to other rights granted under our stock plans may be resold by:

- persons other than affiliates, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, subject only to the manner-of-sale provisions of Rule 144; and
- our affiliates, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, subject to the manner-of-sale and volume limitations, current public information and filing requirements of Rule 144, in each case, without compliance with the six-month holding period requirement of Rule 144.

As of September 30, 2013, options to purchase a total of 5,213,133 shares of common stock were outstanding, of which 3,273,394 were vested. Of the total number of shares of our common stock issuable under these options, all are subject to contractual lock-up agreements with us or the underwriters described below under "Underwriting" and will become eligible for sale at the expiration of those agreements unless held by an affiliate of ours.

Lock-Up Agreements

We, along with our directors, executive officers and substantially all of our other stockholders and optionholders, have agreed that for a period of 180 days after the date of this prospectus, subject to specified exceptions, we or they will not offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock without the consent of Piper Jaffray & Co. and William Blair & Company, L.L.C. Upon expiration of the "lock-up" period, certain of our stockholders will have the right to require us to register their shares under the Securities Act. See "Registration Rights" below.

Registration Rights

Upon the closing of this offering, the holders of shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up arrangement described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates, immediately upon the effectiveness of such registration statement. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. See "Description of Capital Stock — Registration Rights."

Equity Incentive Plans

We intend to file with the SEC a registration statement on Form S-8 under the Securities Act covering the shares of common stock subject to stock awards outstanding or reserved for issuance under the 2007 Plan, 2014 Plan and the ESPP. The registration statement is expected to be filed and become effective as soon as practicable after the closing of this offering. Accordingly, shares registered under the registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations and the lock-up agreements described above, if applicable.

MATERIAL U.S. FEDERAL INCOME AND ESTATE TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK

The following discussion describes the material U.S. federal income and estate tax consequences of the acquisition, ownership and disposition of our common stock acquired in this offering by Non-U.S. Holders (as defined below). This discussion does not address all aspects of U.S. federal income and estate taxes that may be relevant to Non-U.S. Holders in light of their particular circumstances, does not deal with state, local and non-U.S. tax consequences and does not address U.S. federal tax consequences other than income and estate taxes. Rules different from those described below may apply to certain Non-U.S. Holders that are subject to special treatment under the Code, such as financial institutions, insurance companies, tax-exempt organizations, broker-dealers and traders in securities, U.S. expatriates, "controlled foreign corporations," "passive foreign investment companies," corporations that accumulate earnings to avoid U.S. federal income tax, persons that hold our common stock as part of a "straddle," "hedge," "conversion transaction," "synthetic security" or integrated investment or other risk reduction strategy, partnerships and other pass-through entities, and investors in such pass-through entities or an entity that is treated as a disregarded entity for U.S. federal income tax purposes (regardless of its place of organization or formation). Such Non-U.S. Holders are urged to consult their own tax advisors to determine the U.S. federal, state, local and other tax consequences that may be relevant to them. Furthermore, the discussion below is based upon the provisions of the Code, and U.S. Treasury Regulations, rulings and judicial decisions thereunder in effect as of the date hereof, and such authorities may be repealed, revoked or modified, perhaps retroactively, so as to result in U.S. federal income and estate tax consequences different from those discussed below. We have not requested a ruling from the U.S. Internal Revenue Service, or IRS, with respect to the statements made and the conclusions reached in the following discussion, and there can be no assurance that the IRS will agree with such statements and conclusions. This discussion assumes that the Non-U.S. Holder holds our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment).

The following discussion is for general information only and is not tax advice. Persons considering the purchase of our common stock pursuant to this offering should consult their own tax advisors concerning the U.S. federal income and estate tax consequences of acquiring, owning and disposing of our common stock in light of their particular situations as well as any consequences arising under the laws of any other taxing jurisdiction, including any state, local and non-U.S. tax consequences and any U.S. federal non-income tax consequences.

For the purposes of this discussion, a "Non-U.S. Holder" is, for U.S. federal income tax purposes, a beneficial owner of common stock that has not been excluded from this discussion and is not a U.S. Holder. A "U.S. Holder" means a beneficial owner of our common stock that is for U.S. federal income tax purposes (a) an individual who is a citizen or resident of the United States, (b) a corporation or other entity treated as a corporation created or organized in or under the laws of the United States, any state thereof or the District of Columbia, (c) an estate the income of which is subject to U.S. federal income taxation regardless of its source or (d) a trust if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person for federal income tax purposes. Partnerships, or other entities that are treated as partnerships for U.S. federal income tax purposes (regardless of their place of organization or formation) and entities that are treated as disregarded entities for U.S. federal income tax purposes (regardless of their place of organization or formation) are not addressed by this discussion and are, therefore, not considered to be Non-U.S. Holders for the purposes of this discussion. If you are a partner of a partnership holding our common stock or the

owner of a disregarded entity holding our stock, you should consult your tax advisor regarding the tax consequences of the acquisition, ownership and disposition of our common stock.

Distributions

Subject to the discussion below, distributions, if any, made on our common stock to a Non-U.S. Holder of our common stock to the extent made out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles) generally will constitute dividends for U.S. tax purposes and will be subject to withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. To obtain a reduced rate of withholding under an applicable tax treaty, a Non-U.S. Holder generally will be required to provide us with a properly executed IRS Form W-8BEN certifying the Non-U.S. Holder's entitlement to benefits under that treaty. In the case of a Non-U.S. Holder that is an entity, U.S. Treasury Regulations and the relevant tax income treaty provide rules to determine whether, for purposes of determining the applicability of an income tax treaty, dividends will be treated as paid to the entity or to those holding an interest in that entity. If a Non-U.S. Holder holds stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to such agent. The holder's agent will then be required to provide certification to us or our paying agent, either directly or through other intermediaries. If you are eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty, you should consult with your own tax advisor to determine if you are able to obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS.

We generally are not required to withhold tax on dividends paid to a Non-U.S. Holder that are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment that such holder maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to us (or, if stock is held through a financial institution or other agent, to such agent). In general, such effectively connected dividends will be subject to U.S. federal income tax, on a net income basis at the regular graduated rates, unless a specific income tax treaty exemption applies. A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an additional "branch profits tax," which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable treaty) on the corporate Non-U.S. Holder's effectively connected earnings and profits, subject to certain adjustments.

To the extent distributions on our common stock, if any, exceed our current and accumulated earnings and profits, they will first constitute a non-taxable return of capital and will reduce your adjusted basis in our common stock, but not below zero, and then will be treated as gain and taxed in the same manner as gain realized from a sale or other disposition of common stock as described in the next section.

Gain on Disposition of Our Common Stock

Subject to the discussion below regarding backup withholding and foreign accounts, a Non-U.S. Holder generally will not be subject to U.S. federal income tax with respect to gain realized on a sale or other disposition of our common stock unless (a) the gain is effectively connected with a trade or business of such holder in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment that such holder maintains in the United States), (b) the Non-U.S. Holder is a nonresident alien individual and is present in the United States for 183 or more days in the taxable year of the disposition and certain other conditions are met, or (c) we are or have been a "United States real property holding corporation" ("USRPHC") within the meaning of Code

Section 897(c)(2) at any time within the shorter of the five-year period preceding such disposition or such holder's holding period. In general, we would be a United States real property holding corporation if interests in U.S. real estate comprised (by fair market value) at least half of our business assets. We believe that we are not, and do not anticipate becoming, a United States real property holding corporation, however, there can be no assurance that we will not become a U.S. real property holding corporation in the future. Even if we are or were to become a USRPHC, gain realized by a Non-U.S. Holder on a disposition of our common stock will not be subject to U.S. federal income tax so long as (1) the Non-U.S. Holder owned, directly, indirectly and constructively, no more than 5% of our common stock at all times within the shorter of (i) the five-year period preceding the disposition or (ii) the holder's holding period and (2) our common stock is regularly traded on an established securities market. There can be no assurance, however, that our common stock will qualify or continue to qualify as regularly traded on an established securities market.

If you are a Non-U.S. Holder described in (a) above, you will be required to pay tax on the net gain derived from the sale at regular graduated U.S. federal income tax rates, unless a specific treaty exemption applies, and corporate Non-U.S. Holders described in (a) above may be subject to the additional branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. If you are an individual Non-U.S. Holder described in (b) above, you will be required to pay a flat 30% tax on the gain derived from the sale, which gain may be offset by U.S. source capital losses (even though you are not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

Information Reporting Requirements and Backup Withholding

Generally, we or certain financial middlemen must report information to the IRS with respect to any dividends we pay on our common stock including the amount of any such dividends, the name and address of the recipient, and the amount, if any, of tax withheld. A similar report is sent to the holder to whom any such dividends are paid. Pursuant to tax treaties or certain other agreements, the IRS may make its reports available to tax authorities in the recipient's country of residence.

Dividends paid by us (or our paying agents) to a Non-U.S. Holder may also be subject to U.S. backup withholding. U.S. backup withholding generally will not apply to a Non-U.S. Holder who provides a properly executed IRS Form W-8BEN or otherwise establishes an exemption. The current backup withholding rate is 28%.

Under current U.S. federal income tax law, U.S. information reporting and backup withholding requirements generally will apply to the proceeds from a disposition of our common stock effected by or through a U.S. office of any broker, U.S. or non-U.S., except that information reporting and such requirements may be avoided if the holder provides a properly executed IRS Form W-8BEN or otherwise meets documentary evidence requirements for establishing Non-U.S. Holder status or otherwise establishes an exemption. Generally, U.S. information reporting and backup withholding requirements will not apply to a payment of disposition proceeds to a Non-U.S. Holder where the transaction is effected outside the United States through a non-U.S. office of a non-U.S. broker. Information reporting and backup withholding requirements may, however, apply to a payment of disposition proceeds if the broker has actual knowledge, or reason to know, that the holder is, in fact, a U.S. person. For information reporting purposes, certain brokers with substantial U.S. ownership or operations will generally be treated in a manner similar to U.S. brokers.

Backup withholding is not an additional tax. If backup withholding is applied to you, you should consult with your own tax advisor to determine if you are able to obtain a tax benefit or credit with respect to such backup withholding.

Foreign Accounts

A U.S. federal withholding tax of 30% may apply to dividends and the gross proceeds from a disposition of our common stock to a foreign financial institution (as specifically defined for this purpose), including when the foreign financial institution holds our common stock on behalf of a non-U.S. Holder, unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). This U.S. federal withholding tax of 30% will also apply to dividends and the gross proceeds from a disposition of our common stock to a non-financial foreign entity unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect U.S. owners or provides information regarding direct and indirect U.S. owners of the entity. The withholding tax described above will not apply if the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from the rules. Under certain circumstances, a Non-U.S. Holder might be eligible for refunds or credits of such taxes. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Holders are encouraged to consult with their own tax advisors regarding the possible implications of the legislation on their investment in our common stock.

The withholding provisions described above will generally apply to payments of dividends made on or after July 1, 2014 and to payments of gross proceeds from a sale or other disposition of common stock on or after January 1, 2017.

Federal Estate Tax

An individual Non-U.S. Holder who, at the time of death is not a citizen or resident of the United States and who is treated as the owner of, or has made certain lifetime transfers of, an interest in our common stock will be required to include the value thereof in his or her gross estate for U.S. federal estate tax purposes, and may be subject to U.S. federal estate tax unless an applicable estate tax treaty provides otherwise. The test for whether an individual is a resident of the United States for federal estate tax purposes differs from the test used for U.S. federal income tax purposes. Some individuals, therefore, may be "Non-U.S. Holders" for U.S. federal income tax purposes, but not for U.S. federal estate tax purposes, and vice versa.

THE PRECEDING DISCUSSION OF U.S. FEDERAL INCOME AND ESTATE TAX CONSIDERATIONS IS FOR GENERAL INFORMATION ONLY. IT IS NOT TAX ADVICE. EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAW.

UNDERWRITING

Piper Jaffray & Co. and William Blair & Company, L.L.C. are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of our common stock set forth opposite its name below.

Name	Number of Shares
Piper Jaffray & Co.	
William Blair & Company, L.L.C.	
Cantor Fitzgerald & Co.	
Total	

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act relating to losses or claims resulting from material misstatements in or omissions from this prospectus, the registration statement of which this prospectus is a part, certain free writing prospectuses that may be used in the offering and in any marketing materials used in connection with this offering and to contribute to payments the underwriters may be required to make in respect of those liabilities.

Commissions and Discounts

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of $ per share. After the initial offering, the public offering price, concession or any other term of this offering may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	Per Share	Without Option	With Option
Public offering price	$	$	$
Underwriting discount	$	$	$
Proceeds, before expenses, to us	$	$	$

The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' option to purchase additional shares described below. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters

may be increased. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase approximately the same percentage of the additional shares of common stock as the number listed next to the underwriter's name in the table above bears to the total number of shares of common stock listed next to the names of all underwriters in the above table.

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately $, which includes legal, accounting and printing costs and various other fees associated with the registration and listing of our common stock. We have also agreed to reimburse the underwriters for certain of their expenses in an amount up to $ as set forth in the underwriting agreement.

No Sales of Similar Securities

We have agreed not to sell or transfer any shares of our common stock or securities convertible into, exchangeable for, exercisable for, or repayable with shares of our common stock, for 180 days after the date of this prospectus without first obtaining the written consent of Piper Jaffray and William Blair & Company, L.L.C. Specifically, we have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, announce the intention to sell, sell or contract to sell any shares of our common stock;
- sell any option or contract to purchase any shares of our common stock;
- purchase any option or contract to sell any shares of our common stock;
- grant any option, right or warrant to purchase any shares of our common stock;
- otherwise transfer or dispose of, directly or indirectly, any shares of our common stock;
- enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of any shares of our common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise; or
- accelerate the vesting of any option or warrant or the lapse of any repurchase right.

Our executive officers and directors and our other existing stock holders have agreed not to sell or transfer any shares of our common stock or securities convertible into, exchangeable for, exercisable for, or repayable with shares of our common stock, for 180 days after the date of this prospectus without first obtaining the written consent of Piper Jaffray and William Blair & Company, L.L.C. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, announce the intention to sell, sell or contract to sell any shares of our common stock;
- sell any option or contract to purchase any shares of our common stock;
- purchase any option or contract to sell any shares of our common stock;

- grant any option, right or warrant to purchase any shares of our common stock;
- make any short sale or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock;
- enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of any shares of our common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise;
- make any demand for or exercise any right with respect to the registration of any shares of our common stock or any security convertible into or exercisable or exchangeable for shares of our common stock; or
- publically disclose the intention to do any of the foregoing.

Listing

We have applied to list our common stock on The NASDAQ Global Market under the symbol "EGRX." In order to meet the requirements for listing on that exchange, the underwriters have undertaken to sell a minimum number of shares to a minimum number of beneficial owners as required by that exchange.

Before this offering, there has been no public market for our common stock. The initial public offering price will be determined through negotiations among us and the representatives. In addition to prevailing market conditions, factors to be considered in determining the initial public offering price are

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us;
- our financial information;
- the history of, and the prospects for, our company and the industry in which we compete;
- an assessment of our management, its past and present operations and the prospects for, and timing of, our future revenues;
- the present state of our product development; and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares of our common stock may not develop. It is also possible that after this offering the shares of our common stock will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing shares of our common stock. However, the underwriters may engage in transactions that stabilize the price of our common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with this offering, the underwriters may purchase and sell shares of our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in this offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising this option or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through this option. "Naked" short sales are sales in excess of this option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering. Stabilizing transactions consist of various bids for or purchases of shares of our common stock made by the underwriters in the open market prior to the closing of this offering.

The underwriters may also impose penalty bids. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on The NASDAQ Global Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Offer, Sale and Distribution of Shares

In connection with this offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail. In addition, one or more of the underwriters may facilitate Internet distribution for this offering to certain of their internet subscription customers. Any such underwriter may allocate a limited number of shares for sale to its online brokerage customers. An electronic prospectus is available on the internet websites maintained by any such underwriter. Other than the prospectus in electronic format, the information on the websites of any such underwriter is not part of this prospectus.

Other Relationships

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with

us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of the issuer. The underwriters and their respective affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Selling Restrictions

European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State") an offer to the public of any shares of our common stock may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any shares of our common stock may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

(a) to any legal entity which is a qualified investor as defined in the Prospectus Directive;

(b) to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of shares of our common stock shall result in a requirement for the publication by us or any underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares of our common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of our common stock to be offered so as to enable an investor to decide to purchase any shares of our common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State, and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

United Kingdom

Each underwriter has represented and agreed that:

(a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 (the "FSMA")) received by it in connection with the issue or sale of the shares of our common stock in circumstances in which Section 21(1) of the FSMA does not apply to us; and

(b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares of our common stock in, from or otherwise involving the United Kingdom.

Canada

The common shares may be sold only to purchasers purchasing as principal that are both "accredited investors" as defined in National Instrument 45-106 Prospectus and Registration Exemptions and "permitted clients" as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the common shares must be made in accordance with an exemption from the prospectus requirements and in compliance with the registration requirements of applicable securities laws.

Hong Kong

The common shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), or (ii) to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong) and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to common shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the common shares may not be circulated or distributed, nor may the common shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to compliance with conditions set forth in the SFA.

Where the common shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six

months after that corporation or that trust has acquired the common shares pursuant to an offer made under Section 275 of the SFA except:

i) to an institutional investor (for corporations, under Section 274 of the SFA) or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such shares, debentures and units of shares and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than S$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions specified in Section 275 of the SFA;

ii) where no consideration is or will be given for the transfer; or

iii) where the transfer is by operation of law.

Switzerland

The common shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (the "SIX") or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the common shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, or the common shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of common shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of common shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ("CISA"). Accordingly, no public distribution, offering or advertising, as defined in CISA, its implementing ordinances and notices, and no distribution to any non-qualified investor, as defined in CISA, its implementing ordinances and notices, shall be undertaken in or from Switzerland, and the investor protection afforded to acquirers of interests in collective investment schemes under CISA does not extend to acquirers of common shares.

United Arab Emirates

This offering has not been approved or licensed by the Central Bank of the United Arab Emirates (the "UAE"), Securities and Commodities Authority of the UAE and/or any other relevant licensing authority in the UAE including any licensing authority incorporated under the laws and regulations of any of the free zones established and operating in the territory of the UAE, in particular the Dubai Financial Services Authority ("DFSA"), a regulatory authority of the Dubai International Financial Centre ("DIFC"). The offering does not constitute a public offer of securities in the UAE, DIFC and/or any other free zone in accordance with the Commercial Companies Law, Federal Law No 8 of 1984 (as amended), DFSA Offered Securities Rules and NASDAQ Dubai Listing Rules, accordingly, or otherwise. The common shares may not be offered to the public in the UAE and/or any of the free zones.

The common shares may be offered and issued only to a limited number of investors in the UAE or any of its free zones who qualify as sophisticated investors under the relevant laws and regulations of the UAE or the free zone concerned.

France

This prospectus (including any amendment, supplement or replacement thereto) is not being distributed in the context of a public offering in France within the meaning of Article L. 411-1 of the French Monetary and Financial Code (Code monétaire et financier).

This prospectus has not been and will not be submitted to the French Autorité des marchés financiers (the "AMF") for approval in France and accordingly may not and will not be distributed to the public in France.

Pursuant to Article 211-3 of the AMF General Regulation, French residents are hereby informed that:

1. the transaction does not require a prospectus to be submitted for approval to the AMF;

2. persons or entities referred to in Point 2°, Section II of Article L.411-2 of the Monetary and Financial Code may take part in the transaction solely for their own account, as provided in Articles D. 411-1, D. 734-1, D. 744-1, D. 754-1 and D. 764-1 of the Monetary and Financial Code; and

3. the financial instruments thus acquired cannot be distributed directly or indirectly to the public otherwise than in accordance with Articles L. 411-1, L. 411-2, L. 412-1 and L. 621-8 to L. 621-8-3 of the Monetary and Financial Code.

This prospectus is not to be further distributed or reproduced (in whole or in part) in France by the recipients of this prospectus. This prospectus has been distributed on the understanding that such recipients will only participate in the issue or sale of our common stock for their own account and undertake not to transfer, directly or indirectly, our common stock to the public in France, other than in compliance with all applicable laws and regulations and in particular with Articles L. 411-1 and L. 411-2 of the French Monetary and Financial Code.

LEGAL MATTERS

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Cooley LLP, Boston, Massachusetts. The underwriters are being represented by Latham & Watkins LLP, Chicago, Illinois.

EXPERTS

The financial statements as of September 30, 2013 and 2012, included in the prospectus and elsewhere in the registration statement have been so included in reliance on the report of BDO USA, LLP, an independent registered public accounting firm (the report on the financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern) appearing elsewhere herein and in the registration statement, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street, N.E., Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities. You may also request a copy of these filings, at no cost, by writing us at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677 or telephoning us at (201) 326-5300.

Upon the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and web site of the SEC referred to above. We also maintain a website at www.eagleus.com, at which, following the closing of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is incorporated by reference in, and is not part of, this prospectus.

INDEX TO FINANCIAL STATEMENTS

EAGLE PHARMACEUTICALS, INC.

	Page
Report of Independent Registered Public Accounting Firm	F-2
Balance Sheets	F-3
Statements of Operations	F-4
Statements of Changes in Stockholders' Deficit	F-5
Statements of Cash Flows	F-6
Notes to Financial Statements	F-7

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Eagle Pharmaceuticals, Inc.
Woodcliff Lake, NJ

We have audited the accompanying balance sheets of Eagle Pharmaceuticals, Inc. as of September 30, 2013 and 2012 and the related statements of operations, changes in stockholders' deficit, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Eagle Pharmaceuticals, Inc. at September 30, 2013 and 2012, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations since its inception and has a significant stockholders' deficit at September 30, 2013, that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ BDO USA, LLP

Woodbridge, NJ

November 25, 2013

EAGLE PHARMACEUTICALS, INC.

BALANCE SHEETS

	September 30, 2013	September 30, 2012
ASSETS		
Current assets		
Cash and cash equivalents	$ 10,455,565	$ 5,066,886
Short term investments	—	1,500,000
Accounts receivable, net of reserves of $0 and $25,891, respectively	5,124,182	1,580,845
Inventories	—	86,881
Deferred financing costs	—	96,417
Prepaid expenses and other current assets	1,902,660	533,968
Total current assets	17,482,407	8,864,997
Property and equipment, net	402,286	496,731
Other assets	46,320	76,320
Deferred IPO costs	171,607	—
Total assets	$ 18,102,620	$ 9,438,048
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 1,192,600	$ 1,443,838
Accrued expenses	3,129,552	1,340,339
Notes payable, net of discount	—	8,571,877
Deferred revenue	10,019,653	9,499,653
Other liabilities	—	25,852
Total current liabilities	14,341,805	20,881,559
Redeemable Series C preferred stock warrants	1,706,829	654,527
Shares subject to redemption:		
Series A convertible preferred stock, $0.001 par value;14,948,506 shares authorized, 14,948,506 and 20,237,911 issued and outstanding, subject to redemption, conversion or liquidation, as of September 30, 2013 and 2012, respectively (includes accumulated dividends)	20,056,790	26,035,170
Series B convertible preferred stock, $0.001 par value; 12,694,561 shares authorized, 12,694,561 and 16,052,343 shares, issued and outstanding, subject to redemption, conversion or liquidation, as of September 30, 2013 and 2012, respectively (includes accumulated dividends)	30,089,853	36,341,339
Series B-1 convertible preferred stock, $0.001 par value;9,331,374 shares authorized; 9,331,374 and 9,627,634 shares issued and outstanding, subject to redemption, conversion or liquidation, as of September 30, 2013 and 2012, respectively (includes accumulated dividends)	19,374,285	18,959,385
Series C convertible preferred stock, $0.001 par value;11,901,336 shares authorized; 11,023,232, and 0 shares issued and outstanding, subject to redemption, conversion or liquidation, as of September 30, 2013 and 2012, respectively (includes accumulated dividends)	20,462,072	—
Commitments and contingencies		
Stockholders' deficit:		
Common stock, $0.001 par value;80,000,000 shares authorized; 19,538,613 and 10,595,166 issued and outstanding as of September 30, 2013 and 2012, respectively	19,538	10,595
Additional paid in capital	14,187,505	2,092,876
Accumulated deficit	(102,136,057)	(95,537,403)
Total stockholders' deficit	(87,929,014)	(93,433,932)
Total liabilities and stockholders' deficit	$ 18,102,620	$ 9,438,048

See accompanying notes to financial statements.

EAGLE PHARMACEUTICALS, INC.

STATEMENTS OF OPERATIONS

	Year ended September 30,	
	2013	2012
Revenue:		
Product sales	$ 5,314,610	$ 1,155,358
Royalty income	8,364,293	1,384,044
Total revenue	**13,678,903**	**2,539,402**
Operating expenses:		
Cost of revenue	7,380,825	3,166,593
Research and development	9,795,542	12,804,684
Selling, general and administrative	4,957,660	6,398,863
Total operating expenses	**22,134,027**	**22,370,140**
Loss from operations	(8,455,124)	(19,830,738)
Interest income	3,212	34,530
Net proceeds from arbitration	4,050,252	—
Interest expense	(309,121)	(90,718)
Deferred financing costs	(96,417)	(19,283)
Amortization of debt discount	(1,090,878)	(218,176)
Change in value of warrant liability	(1,052,302)	—
Loss on subscription loan settlement	—	(51,379)
Other income/(expense), net	3,202	11,862
Total other income/(expense), net	1,507,948	(333,164)
Loss before income tax benefit	**(6,947,176)**	**(20,163,902)**
Income tax benefit	898,703	781,261
Net loss	**$ (6,048,473)**	**$ (19,382,641)**
Less dividends on Series A, B, B-1 and C Convertible Preferred Stock	(3,836,777)	(3,933,425)
Net loss attributable to common stockholders	**$ (9,885,250)**	**$ (23,316,066)**
Loss per share attributable to common stockholders Basic and diluted	$ (0.51)	$ (2.20)
Weighted average common shares outstanding Basic and diluted	19,514,110	10,595,166

See accompanying notes to financial statements.

EAGLE PHARMACEUTICALS, INC.

STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT

	Common Stock				
	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
Balance, September 30, 2011	**10,906,000**	**$ 10,906**	**$ 1,035,749**	**$ (72,221,337)**	**$ (71,174,682)**
Stock-based compensation expense	—	—	402,289	—	402,289
Beneficial conversion value of notes payable	—	—	654,527	—	654,527
Forfeitures of stock	(310,834)	(311)	311	—	—
Net loss	—	—	—	(19,382,641)	(19,382,641)
Dividends on Convertible Preferred Stock	—	—	—	(3,933,425)	(3,933,425)
Balance, September 30, 2012	**10,595,166**	**10,595**	**2,092,876**	**(95,537,403)**	**(93,433,932)**
Stock-based compensation expense	—	—	317,192	—	317,192
Conversion of Series A preferred to common stock	5,289,405	5,289	5,130,723	—	5,136,012
Conversion of Series B preferred to common stock	3,357,782	3,358	6,107,805	—	6,111,163
Conversion of Series B-1 preferred to common stock	296,260	296	538,909	—	539,205
Net loss	—	—	—	(6,048,473)	(6,048,473)
Dividends on Convertible Preferred Stock				(3,836,777)	(3,836,777)
Forfeitures of dividends on Convertible Preferred Stock	—	—	—	3,286,596	3,286,596
Balance, September 30, 2013	**19,538,613**	**$ 19,538**	**$ 14,187,505**	**$ (102,136,057)**	**$ (87,929,014)**

See accompanying notes to financial statements.

EAGLE PHARMACEUTICALS, INC.

STATEMENTS OF CASH FLOWS

	Year ended September 30, 2013	2012
Cash flows from operating activities:		
Net loss	**$ (6,048,473)**	**$ (19,382,641)**
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	134,994	240,193
Stock-based compensation	317,192	402,289
Non-cash interest expense	309,121	90,419
Amortization of deferred financing costs	96,417	19,283
Amortization of debt discount	1,090,878	218,176
Change in fair value of warrant liability	1,052,302	—
Loss on subscription loan settlement	—	51,379
Changes in operating assets and liabilities:	—	
Increase in accounts receivable	(3,543,337)	(1,320,836)
Decrease in inventories	86,881	1,052,055
(Increase) decrease in prepaid expenses and other current assets	(1,368,692)	197,285
Decrease in other assets	30,000	—
Decrease in accounts payable	(251,238)	(93,671)
Increase in deferred revenue	520,000	3,500,000
Increase (decrease) in accrued expenses and other liabilities	1,694,069	(521,446)
Net cash used for operating activities	**(5,879,886)**	**(15,547,515)**
Cash flows from investing activities:		
Purchase of property and equipment	(40,548)	(32,695)
Proceeds from short term investments	1,500,000	3,000,000
Net cash provided by investing activities	**1,459,452**	**2,967,305**
Cash flows from financing activities:		
Proceeds from Convertible Notes and Warrants	—	9,662,755
Proceeds from issuance of Series C Preferred Stock, net of offering costs of $167,465	9,828,737	—
Deferred Financing costs	—	(115,700)
Deferred IPO costs	(19,624)	—
Net cash provided by financing activities	**9,809,113**	**9,547,055**
Net increase (decrease) in cash	**5,388,679**	**(3,033,155)**
Cash and cash equivalents at beginning of year	**5,066,886**	**8,100,041**
Cash and cash equivalents at end of year	**$ 10,455,565**	**$ 5,066,886**
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Interest	$ —	$ 299
Financing costs	19,624	—
Franchise taxes	19,693	19,693
Non-cash financing activities		
Fair value of warrants issued with notes payable and the beneficial conversion feature	—	1,309,054
Conversion of note payable to Preferred Stock	10,062,296	—
Conversion of Preferred Stock and accumulated dividends to Common Stock	15,623,157	3,933,425
Accrued IPO costs	151,983	—

See accompanying notes to financial statements.

EAGLE PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS

1. Organization and Business Activities

Eagle Pharmaceuticals, Inc. (the "Company") is a pharmaceutical company focused on the development and commercialization of specialty and generic pharmaceutical products, primarily in the injectable arena within the hospital segment. The Company has agreements in place with development partners under which products will be jointly developed and profits from the sales of the products will be shared by the parties. The Company has a number of products currently under development and one currently being sold in the U.S..

2. Going Concern

These financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America applicable to a going concern, which assumes that the Company will be able to realize its assets and discharge its liabilities in the normal course of business.

For the fiscal year ended September 30, 2013, the Company incurred a net loss of $6,048,473. The Company has sustained significant losses since its inception on January 2, 2007 and has an accumulated deficit of $102,136,057 as of September 30, 2013.

Given the continuing significant losses, the Company's ability to realize its assets and discharge its liabilities depends on its ability to generate cash from capital financing, licensing activities and royalty revenues.

The Company plans to obtain funding to meet working capital needs for the foreseeable future. However, no assurances can be given that the financing will be completed within the next year. The Company continues its initiatives to increase revenues and generate cash in order to become cash-flow positive.

In light of the above, the financial statements have been prepared on a going concern basis, assuming the Company has the ability to satisfy its obligations in the normal course of business. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

The following is a summary of the key events that the Company has done in the past and are necessary in the future to attain profitability and obtain liquidity:

- The Company closed on a $10 million equity infusion in April 2013, See Note 9.
- The Company has opportunities to out-license products in its portfolio which can be utilized to generate near term cash and/or fund development activities for those products. Currently, the focus for out-licensing activities is concentrated outside the U.S.
- The Company has approximately fifteen products in various stages of development, including expanded indications. The Company has the ability to scale back or postpone development activities for certain products in order to conserve cash.
- Management continually identifies opportunities to streamline its research and development project spending and general and administrative costs.

EAGLE PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

2. Going Concern (Continued)

- The Company explores financing opportunities through debt or equity to sustain its operations.

Management believes these factors will contribute toward achieving working capital requirements.

The Company's principal source of funding, since inception, has been its Series A, Series B, Series B-1 and Series C financings, issuance of Convertible Notes, and revenues from product sales and the out-licensing of products. The Company has raised approximately $86 million from preferred stock offerings. Additionally, the Company has generated significant revenues from milestones in its portfolio. Since inception, the Company has generated $28 million in proceeds from such collaborative arrangements.

No assurance can be given that operating results will improve, out-licensing of products will be successful or that additional financing could be obtained on terms acceptable to the Company.

3. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the financial statements including disclosure of contingent assets and contingent liabilities, at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period and accompanying notes. The Company's critical accounting policies are those that are both most important to the Company's financial condition and results of operations and require the most difficult, subjective or complex judgments on the part of management in their application, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Because of the uncertainty of factors surrounding the estimates or judgments used in the preparation of the financial statements, actual results may materially vary from these estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. All cash and cash equivalents are held in United States financial institutions. The carrying amount of cash and cash equivalents approximates its fair value due to its short-term nature.

The Company, at times, maintains balances with financial institutions in excess of the FDIC limit.

Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable and notes payable. The carrying values of these financial instruments approximate their fair values due to their short term maturities.

EAGLE PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

3. Summary of Significant Accounting Policies (Continued)

Short Term Investments

Investments consisted of U.S. Treasury and agency securities that had an original maturity of greater than three months. The Company's investments were classified as Level 1 and available-for-sale and are recorded at fair value, based upon quoted market prices. No gains or losses on investments are realized until the sale occurs or a decline in fair value is determined to be other-than-temporary. If a decline in fair value is determined to be other-than-temporary, an impairment charge is recorded and a new cost basis in the investment is established.

Fair Value Measurements

GAAP establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes the following fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value:

- Level 1: Quoted prices in active markets for identical assets or liabilities.
- Level 2: Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The fair value of interest-bearing cash and cash equivalents and short term investments are classified as Level 1 at September 30, 2013 and 2012.

The Company is required by GAAP to record certain assets and liabilities at fair value on a recurring basis.

The guidance in ASC 815 requires that the Company mark the value of its warrant liability (See Note 7) to market and recognize the change in valuation in its statement of operations each reporting period. Determining the warrant liability to be recorded requires the Company to develop estimates to be used in calculating the fair value of the warrant.

Since these preferred stock warrants do not trade in an active securities market, the Company recognizes a warrant liability and estimates the fair value of these warrants using a Probability- Weighted Expected Returns valuation model. Therefore, the warrant liability is considered a level 3 measurement.

EAGLE PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

3. Summary of Significant Accounting Policies (Continued)

Concentration of Major Customers and Vendors

The Company's customers are its commercial and collaborative and licensing partners. The Company is dependent on these commercial partners to market and sell EP-1101 (argatroban), from which all of its revenues is currently derived; therefore, the Company's future revenues are highly dependent on these collaboration and distribution arrangements.

The total revenues and accounts receivables broken down by major customers as a percentage of the total are as follows:

	Year ended September 30,	
	2013	2012
Net revenues		
The Medicines Company	54%	100%
Sandoz, Inc.	46%	0%
	100%	100%

	September 30,	
	2013	2012
Accounts receivable, net		
The Medicines Company	58%	92%
Sandoz, Inc.	40%	0%
Other	2%	8%
	100%	100%

Currently, for EP-1101 (argatroban), the Company uses one vendor as its sole source of product. Because of the unique equipment and process for manufacturing EP-1101 (argatroban), transferring manufacturing activities for EP-1101 (argatroban) to an alternate supplier would be a time-consuming and costly endeavor, and there are only a limited number of manufacturers that are capable of performing this function for the Company.

Inventories

Inventories are recorded at the lower of cost or market, with cost determined on a first-in, first-out basis. Inventory consists of raw materials and finished product. The Company periodically reviews the composition of inventory in order to identify obsolete, slow-moving or otherwise non-saleable items. If non-saleable items are observed and there are no alternate uses for the inventory, the Company will record a write-down to net realizable value in the period that the decline in value is first recognized. In most instances, inventory is shipped from the Company's vendor directly to the Company's customers.

EAGLE PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

3. Summary of Significant Accounting Policies (Continued)

Property and Equipment

Property and equipment are stated at cost. Depreciation is computed over the estimated useful lives of the assets utilizing the straight-line method. Leasehold improvements are being amortized over the shorter of their useful lives or the lease term.

Research and Development Expense

Costs incurred for research and product development, including costs incurred for technology in the development stage, are expensed as incurred.

Deferred Financing Costs

Costs relating to obtaining Convertible Notes have been capitalized and amortized over the term of the related debt using the straight line method. Amortization of deferred financing costs charged to interest expense was $96,417 and $19,283 for the years ended September 30, 2013 and 2012, respectively. The unamortized balance was $0 and $96,417 at September 30, 2013, and 2012, respectively.

Deferred IPO Costs

Costs incurred related to an initial public offering of the Company's common stock, primarily professional fees, are deferred until either the completion of the offering at which time such costs will be netted against proceeds received and reclassified to Additional Paid In Capital or the determination to abandon the offering at which time such costs will be recorded as expense.

Advertising and Marketing

Advertising and marketing costs are expensed as incurred. Advertising and marketing costs were immaterial for the years ended September 30, 2013 and 2012.

Redeemable Convertible Preferred Stock

The carrying value of redeemable convertible preferred stock is increased by periodic accretions, using the interest method so that the carrying amount will equal the redemption amount at the earliest redemption date.

Accounting for Income Taxes

The Company accounts for deferred taxes using the asset and liability method as specified by ASC 740, *Income Taxes*. Deferred income tax assets and liabilities are determined based on differences between the financial statement reporting and the tax basis of assets and liabilities, operating losses and tax credit carry forwards. Deferred income taxes are measured using the enacted tax rates and laws that are anticipated to be in effect when the differences are expected to reverse. The measurement of deferred income tax assets is reduced, if necessary, by a valuation allowance for any tax benefits which are not expected to be realized. The effect on deferred income tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted.

EAGLE PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

3. Summary of Significant Accounting Policies (Continued)

Revenue Recognition

Product Revenue — The Company recognizes net revenue from products manufactured and supplied to its commercial partners, when the following four basic revenue recognition criteria under the related accounting guidance are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. Prior to the shipment of manufactured products, the Company conducts initial product release and stability testing in accordance with cGMP. The Company's commercial partners can return the products within contracted specified timeframes if the products do not meet the applicable inspection tests. The Company estimates its return reserves based on its experience with historical return rates. Historically, product returns have not been material.

Royalties — The Company recognizes revenue from royalties based on its commercial partners' net sales of products. Royalties are recognized as earned in accordance with contract terms when they can be reasonably estimated and collectability is reasonably assured. The Company's commercial partners are obligated to report their net product sales and the resulting royalty due to the Company within 60 days from the end of each quarter. Based on historical product sales, royalty receipts and other relevant information, the Company accrues royalty revenue each quarter and subsequently determines a true-up when it receives royalty reports from its commercial partners. Historically, these true-up adjustments have been immaterial.

Collaborative licensing and development revenue — The Company recognizes revenue from reimbursements received in connection with feasibility studies and development work for third parties when its contractual services are performed, provided collectability is reasonably assured. Its principal costs under these agreements include its personnel conducting research and development, and its allocated overhead, as the well as research and development performed by outside contractors or consultants.

The Company recognizes revenues from non-refundable up-front license fees received under collaboration agreements ratably over the performance period as determined under the collaboration agreement (estimated development period in the case of development agreements, and contract period or longest patent life in the case of supply and distribution agreements). If the estimated performance period is subsequently modified, the Company will modify the period over which the upfront license fee is recognized accordingly on a prospective basis. Upon termination of a collaboration agreement, any remaining non-refundable license fees received by us, which had been deferred, are generally recognized in full. All such recognized revenues are included in collaborative licensing and development revenue in its statements of operations. The Company recognizes revenue from milestone payments received under collaboration agreements when earned, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, the Company has no further performance obligations relating to the event, and collectability is reasonably assured. If these criteria are not met, the Company recognizes milestone payments ratably over the remaining period of its performance obligations under the collaboration agreement. No such revenue was recorded in 2013 or 2012.

EAGLE PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

3. Summary of Significant Accounting Policies (Continued)

Stock-Based Compensation

The Company accounts for stock-based compensation using the fair value provisions of ASC 718, *Compensation — Stock Compensation* that requires the recognition of compensation expense, using a fair-value based method, for costs related to all stock-based payments including stock options and restricted stock. This topic requires companies to estimate the fair value of the stock-based awards on the date of grant for options issued to employees and directors. The Company uses a Black-Scholes valuation model as the most appropriate valuation method for pricing these options. Awards for consultants are accounted for under ASC 505-50, *Equity Based Payments to Non-Employees*. Any compensation expense related to consultants is marked-to-market over the applicable vesting period as they vest. There are customary limitations on the sale or transfer of the stock.

The fair value of stock options granted to employees, directors, and consultants is estimated using the following assumptions:

	Year ended September 30,	
	2013	2012
Risk-free interest rate	.95 - 2.53%	.82 - 3.23%
Volatility	64%	34.34% - 39.38%
Expected term (in years)	6.07 - 10.00 years	6.07 - 10.00 years
Expected dividend yield	0.00%	0.00%

The risk-free rate assumption was based on U.S. Treasury instruments whose term was consistent with the expected term of the stock options. The expected stock price volatility was determined by examining the historical volatilities for industry peers as the Company did not have any trading history for its common stock. Industry peers consist of those companies in the pharmaceutical industry similar in size, stage of life-cycle and financial leverage. The expected term of stock options represents the average of the vesting period and the contractual life of the option for employees and the life of the option for consultants. The expected dividend assumption is based on the Company's history and expectation of future dividend payouts. Changes in the estimated forfeiture rates are reflected prospectively.

Net Loss Per Share

Basic loss per common share is computed based on the weighted average number of shares outstanding during the period. Diluted loss per share is computed in a manner similar to the basic loss per share, except that the weighted-average number of shares outstanding is increased to include all common shares, including those with the potential to be issued by virtue of warrants, options, convertible debt and other such convertible instruments. Diluted earnings per share contemplate a complete conversion to common shares of all convertible instruments only if they are dilutive in nature with regards to earnings per share. Since the Company has incurred net losses for all periods, basic loss per share and diluted loss per share are the same.

EAGLE PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

3. Summary of Significant Accounting Policies (Continued)

The anti-dilutive common shares equivalents outstanding at September 30, 2013 and 2012 were as follows:

	Year ended September 30,	
	2013	2012
Series A	14,948,506	20,237,911
Series B	12,694,561	16,052,343
Series B-1	9,331,374	9,627,634
Series C	11,023,232	—
Warrants	944,210	198,534
Options	5,213,133	4,742,300
Total	**54,155,016**	**50,858,722**

Reclassification

Certain previously reported amounts have been reclassified to conform to the presentation used in the September 30, 2013 financial statements.

4. Inventories

Inventories consist of the following at September 30, 2013, and 2012:

	September 30,	
	2013	2012
Raw materials	$ —	$ 86,881
	$ —	$ 86,881

As a result of the product recall in the first quarter of fiscal year 2012, the Company incurred losses in the aggregate amount of $1,643,913 during the fiscal year ended September 30, 2012. Of the total cost, $1,386,270 was attributable to cost of products returned, inventory write-offs and cost to administer the recall. The remaining expense of $257,643 pertained to commercial rebates not recovered by its commercial partner. These amounts were charged to Cost of Revenue. The Company re-launched the product in the third quarter of 2012.

EAGLE PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

5. Property and Equipment

Property and equipment at September 30, 2013 and 2012 consist of the following:

	September 30, 2013	September 30, 2012	Estimated useful life (years)
Furniture and equipment	$ 297,458	$ 297,458	7
Office equipment	292,864	292,864	3
Equipment	592,940	592,940	7
Leasehold improvements	40,548	480,003	2
	1,223,810	1,663,265	
Less accumulated depreciation	(821,524)	(1,166,534)	
Property and equipment, net	$ 402,286	$ 496,731	

Depreciation expense amounted to $134,994 and $240,193 for the years ended September 30, 2013 and 2012, respectively.

Included in equipment are assets held for future use which are not subject to depreciation. As of September 30, 2013 and 2012, this equipment amounted to approximately $270,000.

6. Balance Sheet Accounts

Prepaid and Other Current Assets

Prepaid and other current assets consist of the following:

	September 30, 2013	September 30, 2012
Prepaid Product Costs	$ 730,003	$ —
Prepaid FDA User Fee	1,023,291	273,705
Prepaid Insurance	117,510	122,213
All Other	31,856	138,050
Total Prepaid and Other Current Assets	$ 1,902,660	$ 533,968

EAGLE PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

6. Balance Sheet Accounts (Continued)

Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2013	September 30, 2012
Royalties Due to The Medicines Company	$ 1,724,061	$ —
Royalties Due to SciDose	546,756	—
Accrued R&D Expenses	282,682	573,800
Accrued Professional Fees	274,566	327,194
Accrued Salary Expenses.	169,568	—
Accrued Product Costs	62,737	219,915
All Other	69,182	219,430
Total Accrued Expenses	$ 3,129,552	$ 1,340,339

Deferred Revenue

Deferred revenue consists of the following:

	September 30, 2013	September 30, 2012
The Medicines Company	$ 519,653	$ (347)
Deferred Revenue for ongoing business	519,653	(347)
Hikma Pharmaceuticals, Co. Ltd.	3,500,000	3,500,000
Par Pharmaceuticals Companies, Inc.	5,500,000	5,500,000
Par Pharmaceuticals Companies, Inc./Tech Transfer	500,000	500,000
Deferred Revenue from Asset Sales (See Note 13)	9,500,000	9,500,000
Total Deferred Revenue, net	$ 10,019,653	$ 9,499,653

7. Notes Payable

Convertible Notes

The Company entered into a Convertible Note and Warrant Purchase Agreement (the "Convertible Notes"), pursuant to which it issued $9,662,755 of Convertible Notes to existing preferred stockholders. The loan funding was completed in two tranches on August 2, 2012 and September 26, 2012, respectively. Holders of the Convertible Notes were entitled to cumulative interest at an annual rate of 6%. Such interest accrued daily and was cumulative from the respective date. In addition, the holders received warrants (the "Warrants") to purchase preferred stock, which accrued at a monthly rate of 2% of the principal amount until the completion of a Qualified Financing, as defined, or August 1, 2013, whichever was sooner.

The Convertible Notes and associated accrued interest were due and payable on August 1, 2013, unless the Notes converted earlier. Conversion could occur, upon certain triggering events or the holder

EAGLE PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

7. Notes Payable (Continued)

elects to convert. Principal and interest accrued shall convert into shares of preferred stock: a) upon the attainment of a Qualified Financing, or b) on August 1, 2013, whichever is sooner. Upon conversion pursuant to (a), the aggregate amount converted will be divided by the offering price of the Qualified Financing to arrive at the amount of Preferred Stock that will be issued. Upon conversion pursuant to (b), the aggregate amount converted will be divided by $1.82 to arrive at the amount of Preferred Stock that will be issued.

The Series C Preferred Share financing (See Note 9) represented a Qualified Financing whereby the Convertible Notes for those participating investors converted to Series C Preferred Shares.

The Convertible Notes agreement was structured such that a portion of the shares of the Company's Series A Preferred Stock, Series B Preferred Stock and Series B-1 Preferred Stock, collectively the "Special Conversion Preferred", held by a holder, that did not participate in the financing to the full extent of its pro rata share of Preferred Stock ownership (a "Non-Fully Participating Holder"), was converted into shares of the Company's Common Stock, and any dividends accumulated to date were forfeited.

The option for existing preferred stockholders to participate in the Convertible Notes expired on October 1, 2012. On October 2, 2012, the total number of Preferred Stock shares converted to Common Stock of Non-Fully Participating Holders was 8,943,447 shares. Upon conversion from preferred to common, those investors forfeited all accrued dividends from their investment date, which amounted to $3.3 million.

Warrants

The Company accounts for the Warrants as liability instruments. The Company estimated the initial fair value of the warrants associated with the Notes to be $654,527 using a Probability-Weighted Expected Returns valuation model. At each reporting period, any changes to the fair value of the warrants will be recorded in the statements of operations. As of September 30, 2013 and September 30, 2012, 944,210 and 198,534 warrants, respectively, were issued and outstanding in connection with the Convertible Notes.

The valuation model considered three scenarios. Two of the scenarios assume a stockholder exit, either through sale, or dissolution. The third scenario assumes operations continue as a private company and no exit transaction occurs. The following assumptions were used in the valuation: exercise price of $1.82; implied stock price of $1.82; expected volatility of 64%; expected dividend rate of 6%; risk free interest rate of 0.83% and expiration date of six years.

The following is a description of the key terms of the warrants:

- *Exercise period* — Exercisable, in whole or in part, during the six year term commencing on the earliest to occur of: (a) the consummation of a Qualified Financing, (b) immediately prior to the consummation of a Change of Control (but subject to and contingent upon such consummation of a Change of Control) and (c) the date one year after the Initial Closing or August 1, 2013.

EAGLE PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

7. Notes Payable (Continued)

- *Exercise Price* — The purchase price for the Warrant Shares issuable shall be: (a) $1.82, or (b) the offering price of a Qualified Financing should this occur prior to August 1, 2013.

- *No Rights as Stockholders* — Prior to the exercise of the warrants, no holder of warrants (solely in its capacity as a holder of warrants) is entitled to any rights as a stockholder of the Company, including, without limitation, the right to vote, receive notice of any meeting of stockholders or receive dividends, allotments or other distributions.

Warrant Liability

As of September 30, 2013, the estimated fair value of the Convertible Note warrant liability was $1,706,829 which resulted in a charge to other income and expense of $1,052,302 for the year ended September 30, 2013. Upon completion of the qualified offering, the warrants became exercisable into Series C Preferred Shares. The increase in the fair value of the warrant liability is primarily attributable to the liquidation preference of the Series C Preferred Shares to receive 2 times the original investment upon a liquidation event under certain circumstances. As of September 30, 2012, the value of the warrant liability was unchanged from its inception; therefore, there were no charges recorded to other expense to reflect any decrease or increase in fair value of the preferred stock warrants issued. This liability will continue to be marked-to-market with adjustments reflected in results of operations. The future charges could be material.

Debt Discount

In connection with the Convertible Notes described above and as a result of the warrants issued with the Convertible Notes, the Company determined that a discount to the debt should be recorded in the amount of $654,527, representing its fair value and recorded as a discount to the debt instrument and amortized over the life of the instrument. The amount recorded as interest expense during the year ended September 30, 2012 was approximately $109,000 in the statements of operations and approximately $545,000 remained unamortized at September 30, 2012. Due to the conversion of the Convertible Notes to Preferred Stock, the balance of the unamortized debt discount was written off during the year ended September 30, 2013, resulting in interest expense of $545,000.

Beneficial Conversion Feature

A convertible financial instrument includes a beneficial conversion feature if the effective conversion price is less than the Company's market price of Preferred Stock on the commitment date. The effective price paid for a share is the amount allocated to the convertible instrument, divided by the number of shares the holder is entitled to upon conversion. If the convertible financial instrument is issued with warrants and/or other detachable instruments, the amount allocated to the convertible instrument is the face amount less the allocation to the detachable instruments.

In connection with the Convertible Notes described above and as a result of the warrants issued with the Convertible Notes, the Company determined that the conversion rate represented a beneficial conversion feature. Accordingly, a discount on the notes was recorded in the amount of $654,527. The discount was amortized ratably with a corresponding non-cash charge to interest expense. The amount recorded as interest expense during the year ended September 30, 2012 was approximately $109,000 in the statements of operations and approximately $545,000 remained unamortized at September 30,

EAGLE PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

7. Notes Payable (Continued)

2012. For the year ended September 30, 2013, the amount recorded as interest expense was approximately $545,000 in the statements of operations and $0 remains unamortized at September 30, 2013.

8. Related Party Transactions

In 2011, the Company entered into agreements with Scott Tarriff, President and Chief Executive Officer to purchase 549,451 shares of Series B-1 Preferred Stock for $1,000,001. The Company received promissory notes in the aggregate amount of $1,000,001, which were netted against the Series B-1 convertible preferred stock in the balance sheets. Due to the consummation of the Convertible Notes (see Note 7) in August 2012, the promissory notes were settled, Mr. Tarriff relinquished 549,451 shares, and all interest accrued was forgiven. The Company recorded a loss on the settlement of debt in the amount of $51,379.

9. Shares Subject to Redemption — Convertible Preferred Stock

Series A Convertible Preferred Stock

On March 8, 2007, the Company issued 20,237,911 shares of Series A Convertible Preferred Stock, par value $0.001 (the "Series A Preferred Stock"). The outstanding shares of the Series A Preferred Stock (as amended in connection with the issuance of the Series B Preferred Stock) is redeemable after August 11, 2013 at a redemption price per share equal to the Original Issue Price of $0.971 per share plus accrued but unpaid dividends (see "Redemption" below). The outstanding shares of the Series A Preferred Stock were recorded at their estimated fair value of $19,651,000 which equaled the sale price on the date of issuance. The amount was adjusted for net offering costs of $179,806. The fair value of the Series A Preferred Stock has been increased through periodic accretions using the interest method for dividends (see "Preferred Stock Dividends" below) so that the carrying value equals the redemption amount on the redemption date. Accumulated dividends on the Series A Preferred Stock were $5,721,608 and $6,563,976 as of September 30, 2013 and 2012, respectively. The liquidation value of the Series A Preferred Stock was $20,236,596 and $26,214,976 as of September 30, 2013 and 2012, respectively.

Series B Convertible Preferred Stock

On August 11, 2008, the Company issued 16,052,343 shares of Series B Convertible Preferred Stock, par value $0.001 (the "Series B Preferred Stock"). The Series B Preferred Stock is redeemable as described above for the Series A Preferred Stock at a redemption price per share equal to the Original Issue Price of $1.82 per share plus accrued but unpaid dividends (see "Redemption" below). The outstanding shares of the Series B Preferred Stock were recorded at their estimated fair value of $29,215,266, which equaled the sale price on the date of issuance. The amount was adjusted for net offering costs of $125,714. The fair value of the Series B Preferred Stock has been increased through periodic accretions using the interest method so that the carrying value equals the redemption amount on the redemption date. Accumulated dividends on the Series B Preferred Stock were $7,111,465 and $7,251,787 as of September 30, 2013 and 2012, respectively. The liquidation value of the Series B Preferred Stock is $30,215,567 and $36,467,053 as of September 30, 2013 and 2012, respectively.

EAGLE PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

9. Shares Subject to Redemption — Convertible Preferred Stock (Continued)

Series B-1 Convertible Preferred Stock

The Company consummated an offering of Series B-1 Convertible Preferred Stock, par value $0.001 (the "Series B-1 Preferred Stock") to its existing investors in two stages in February 2011 and July 2011. The Company issued an aggregate of 10,177,085 shares of Series B-1 Preferred Stock. The Series B-1 Preferred Stock is redeemable at a redemption price per share equal to the Original Issue Price of $1.82 per share plus accrued but unpaid dividends (see "Redemption" below). The outstanding shares of the Series B-1 Preferred Stock were recorded at their estimated fair value of $17,522,294 which equaled the sale price on the date of issuance. The amount was adjusted for net offering costs of $144,250. On August 2, 2012 the Company entered into a Payoff and Exchange Agreement with an Officer/Director (see Note 8). The Company accepted a total of 549,451 shares of Series B-1 Preferred Stock in exchange for satisfaction of the principal amount of debt. The total number of outstanding shares of Series B-1 Preferred Stock was 9,627,634 as of September 30, 2012. The fair value of the Series B Preferred Stock has been increased through periodic accretions using the interest method so that the carrying value equals the redemption amount on the redemption date. Accumulated dividends on redeemable shares were $2,535,434 and $1,569,415 as of September 30, 2013 and 2012, respectively. The liquidation value of the Series B-1 Preferred Stock is $19,518,535 and $19,092,099 as of September 30, 2013 and 2012, respectively.

Series C Convertible Preferred Stock

The Company consummated an offering of Series C Convertible Preferred Stock, par value $0.001 (the "Series C Preferred Stock") on April 11, 2013. The Company issued an aggregate of 11,023,232 shares of Series C Preferred Stock. The Series C Preferred Stock is redeemable at a redemption price per share equal to the Original Issue Price of $1.82 per share plus accrued but unpaid dividends (see "Redemption" below). The outstanding shares of the Series C Preferred Stock were recorded at their estimated fair value of $20,062,296 which equaled the sale price on the date of issuance. The amount was adjusted for net offering costs of $167,465. The fair value of the Series C Preferred Stock has been increased through periodic accretions using the interest method so that the carrying value equals the redemption amount on the redemption date. Accumulated dividends on redeemable shares were $567,241 as of September 30, 2013. The liquidation value of the Series C Preferred Stock is $20,629,537 as of September 30, 2013.

On October 2, 2012, holders of Preferred Stock who elected not to participate in the Convertible Notes (see "Notes Payable") had their Preferred Stock shares convert to Common Stock. Upon conversion from preferred to common, the investors forfeited all accumulated dividends from their investment date. The Series A Preferred Stock converted 5,289,405 shares to Common Stock and forfeited $1,718,102 in accumulated dividends, the Series B Preferred Stock converted 3,357,782 shares to Common Stock and forfeited $1,519,922 in accumulated dividends, and Series B-1 converted 296,260 shares to Common Stock and forfeited $48,572 in accumulated dividends. Concurrent with the conversion, the Company reduced the amounts authorized for the Series A, Series B, and Series B-1 Preferred Stock to 14,948,506 shares, 12,694,561 shares and 9,331,374 shares, respectively.

Preferred Stock Voting

The holders of Preferred Stock have voting rights equal to the common stockholders.

EAGLE PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

9. Shares Subject to Redemption — Convertible Preferred Stock (Continued)

Redemption

Redemption is subject to written election of at least two-thirds of Series A Preferred Stockholders, Series B Preferred Stockholders, Series B-1 Preferred Stockholders and Series C Preferred Stockholders voting as a single class. The redemption is to be paid in three installments: 33 1/3% ninety (90) days after a redemption request on or after April 11, 2018, 50% on the one-year anniversary of the redemption request and the remaining amount on the two-year anniversary of the redemption request.

Conversion

Each share of Preferred Stock is convertible at the option of the holder, at any time after the date of issuance, into Common Stock on a one-for-one basis, subject to certain adjustments for dilution, if any, resulting from certain future stock issuances. Additionally, the Preferred Stock automatically converts into Common Stock concurrent with the closing of a firm commitment underwritten initial public offering ("Qualified IPO") of Common Stock under the Securities Act of 1933, as amended, in which the Company receives at least $40,000,000 in gross proceeds and the offering price is not less than five times the Original Issue Price of Series A Preferred, Series B Preferred, Series B-1 Preferred Stock and Series C Preferred Stockholders, respectively. The Company has reserved sufficient shares of Common Stock at September 30, 2013 and September 30, 2012 for issuance upon the conversion of the Preferred Stock.

Preferred Stock Dividends

Holders of Series A, Series B, Series B-1 and Series C Preferred Stockholders are entitled to cumulative dividends at an annual rate of 6% when and if declared. Such dividends shall accrue daily and shall be cumulative from the respective date of issuance of each such share of Preferred Stock, whether declared or not.

Dividends will be paid only when declared by the Board of Directors out of legally available funds or upon the first to occur of (i) payment of the Original Issue Price of each share of Preferred Stock in connection with a redemption or liquidation event or (ii) upon conversion of the Preferred Stock into Common Stock, unless the conversion is done in connection with a Qualified IPO or the sale of the Company under certain conditions ("Qualified Sale"), which will cause the holder to forfeit such dividends.

No dividends have been declared as of or for any period prior to September 30, 2013. Accumulated dividends accrued for Series A, Series B, Series B-1 and Series C Preferred Stock was as follows:

	September 30,	
	2013	2012
Series A	$ 5,721,608	$ 6,563,976
Series B	7,111,465	7,251,787
Series B-1	2,535,434	1,569,415
Series C	567,241	—
Total	**$ 15,935,748**	**$ 15,385,178**

EAGLE PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

9. Shares Subject to Redemption — Convertible Preferred Stock (Continued)

Liquidation Preference

Upon any liquidation, dissolution or winding up (a "Liquidation Event") of the Company (including consolidation or merger), holders of Preferred Stock are entitled to be paid first out of the assets of the Company, prior to any payment to the holders of Common Stock in the following order of priority: first, the holders of Series C Preferred Stock will receive an amount two times (2x) the sum of (i) the Original Issue Price of such shares (such amount to be subject to proportionate adjustment in the event of any stock dividend, stock split, combination of shares, reorganization, recapitalization, reclassification or other similar event affecting the Series C Preferred Stock, and occurring after the date of filing of this Restated Certificate), plus (ii) an amount equal to the aggregate of all dividends accrued but unpaid, or declared but unpaid, in respect of such shares of Series C Preferred Stock; second, the holders of Series B and Series B-1 Preferred Stock will receive an amount equal to the Original Issue Price of each share of such Preferred Stock plus all accrued but unpaid dividends; and third, the holders of Series A Preferred Stock will receive an amount equal to the Original Issue Price for each share of such Preferred Stock plus all accrued but unpaid dividends. Thereafter, the holders of Series A, Series B, Series B-1 and Series C Preferred Stock (each a "Class") will fully participate with holders of Common Stock on an "as converted" basis for all remaining assets distributable to stockholders. However, if the amount that each Class of preferred stock would receive is greater than three times the original issue price per share (the "Maximum Participation Amount"), then the holders would be entitled to receive, with respect to each share, the greater of (a) the Maximum Participation Amount or (b) the amount each holder would have received if the holder had converted the Preferred Stock into Common Stock immediately prior to the Liquidation Event.

10. Common Stock and Stock-Based Compensation

In December of 2007, the Company's Board of Directors approved an incentive compensation plan enabling the Company to grant multiple stock based awards to employees, directors and consultants, the most common being stock options and restricted stock awards. Awards vest equally over a period of four years from grant date. Vesting is accelerated under a change in control of the Company or in the event of death or disability to the recipient. In the event of termination, any unvested shares or options are forfeited. The Company has reserved and made available 8,800,000 shares for issuance under the plan.

The Company recognized share-based compensation in its statements of operations for the years ended September 30, 2013and 2012 as follows:

	Year ended September 30,	
	2013	2012
Selling, general and administrative	$ 152,740	$ 280,964
Research & development	164,452	121,325
Total	$ 317,192	$ 402,289

EAGLE PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

10. Common Stock and Stock-Based Compensation (Continued)

The following table is a summary of the Company's stock options issued to employees, directors and consultants:

	Number of Stock Option Shares	Weighted Average Exercise Price	Non-Exercisable	Exercisable
Outstanding at September 30, 2010	**3,764,300**	**$ 0.71**	**2,432,515**	**1,331,785**
Granted	825,000	1.37		
Exercised	—			
Forfeited or expired	(372,367)	0.86		
Outstanding at September 30, 2011	**4,216,933**	**0.83**	**1,850,007**	**2,366,926**
Granted	1,253,000	1.37		
Exercised	—			
Forfeited or expired	(727,633)			
Outstanding at September 30, 2012	**4,742,300**	**$ 0.97**	**1,950,143**	**2,792,157**
Granted	1,243,991	0.69		
Exercised	—			
Forfeited or expired	(773,158)			
Outstanding at September 30, 2013	**5,213,133**	**$ 0.87**	**1,939,739**	**3,273,394**

The weighted-average grant-date fair value of options granted during the fiscal years ended September 30, 2013 and 2012 was $0.27 and $0.53, respectively. As of September 30, 2013, there was $431,550 of unrecognized compensation cost, which will be expensed over the next 4 fiscal years.

The weighted average contractual terms of options outstanding as of September 30, 2013 and 2012 was 7.0 and 7.5 years, respectively.

The aggregate pre-tax intrinsic value of options outstanding as of September 30, 2013 and 2012 was $178,857 and $1,844,885, respectively.

11. Income Taxes

The benefit for income taxes shown in the statement of operations is net of $1,840 and $2,000 for minimum state taxes for the years ended September 30, 2013 and 2012, respectively.

EAGLE PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

11. Income Taxes (Continued)

A reconciliation of income taxes at the U.S. federal statutory rate to the benefit for income taxes is as follows:

	Year ended September 30,	
	2013	2012
Federal tax benefit at statutory rate	(34.00)%	(34.00)%
Non-cash interest and change in fair value of warrants liability	13.82%	0.00%
State tax benefit, net of Federal benefits	(14.87)%	(4.00)%
R&D Credit	(5.14)%	(0.72)%
Other	0.22%	0.07%
Net changes in valuation allowance	25.11%	34.65%
Tax benefit	(14.86)%	(4.00)%

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets were as follows:

	September 30,	
	2013	2012
Deferred tax assets		
Net operating loss carryforwards	$ 26,984,000	$ 26,343,000
Prepaid R&D expenses	2,573,000	2,821,000
Research & development credit	2,033,000	1,598,000
Advance billings	208,000	—
Stock based compensation	688,000	553,000
Patent costs	77,000	84,000
Intangible assets	39,000	43,000
Fixed assets	161,000	133,000
Deferred rent expenses	—	4,000
Returns and allowances	24,000	10,000
Charitable contribution carryforward	28,000	27,000
Other	2,000	—
Total deferred tax assets	32,817,000	31,616,000
Deferred tax liabilities		
Prepaid expenses	47,000	49,000
Total deferred tax liabilities	47,000	49,000
Net deferred tax assets	32,770,000	31,567,000
Valuation allowance	**$ (32,770,000)**	**$ (31,567,000)**

Realization of the net deferred tax asset is dependent upon future taxable income, if any, the amount and timing of which are uncertain. Accordingly, the net deferred tax asset has been offset by a full valuation allowance.

EAGLE PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

11. Income Taxes (Continued)

As of September 30, 2013, the Company had federal and state net operating loss carry forwards of $72,794,131 and $37,615,304 respectively. As of September 30, 2013, the Company also had federal and state research and development tax credit carry forwards of $1,750,190 and $282,678 respectively.

In July 2006, the Financial Accounting Standards Board ("FASB") issued ASC 740-10, *Uncertainty in Income Taxes*, which defines the threshold for recognizing the benefits of tax-return positions in the financial statements as "more-likely-than-not" to be sustained by the taxing authorities. This statement also requires explicit disclosure requirements about a Company's uncertainties related to their income tax position, including a detailed roll forward of tax benefits taken that do not qualify for financial statement recognition. There are no such amounts recorded due to the adoption of the tax standard.

The Company files income tax returns in the U.S. federal jurisdiction and New Jersey. The Company's tax years open to examination for federal are from 2010 and for state are from 2009. The Company has no amount recorded for any unrecognized tax benefits as of September 30, 2013 and 2012 nor did the Company record any amount for the implementation of ASC 740-10-25. The Company's policy is to record estimated interest and penalty related to the underpayment of income taxes or unrecognized tax benefits as a component of its income tax provision. During the years ended September 30, 2013 and 2012 the Company did not recognize any interest or penalties accrued for unrecognized tax benefits.

The Company received approval to sell a portion of the Company's New Jersey net operating losses ("NOL's") as part of the Technology Business Tax Certificate Program sponsored by The New Jersey Economic Development Authority. Under the program, emerging biotechnology firms with unused net operating loss carryovers and unused research and development credits are allowed to sell these benefits to other firms. In the year ended September 30, 2013, the Company sold net operating losses totaling $11,028,914 for net proceeds of $900,543 which is reflected as a tax benefit in fiscal 2013. In fiscal year 2012, the Company sold net operating losses totaling $10,739,513 for net proceeds of $783,181 which is reflected as a tax benefit in fiscal 2012. This program is subject to annual renewal and limitations.

12. License Agreements of Development and Commercialization Rights

Development

The Company has entered into several product development agreements with development partners whereby the Company acquired the exclusive rights in the United States and in most cases worldwide rights to a total of thirty three products for ten years following first commercial sale of each product. The Company will share varying percentages of the profits, after, in most cases, recapturing development, legal and certain operating costs, from the sales of the products with the development partners if the products are commercialized. The Company expenses these costs as incurred.

Commercialization Rights

In May 2008, the Company entered into a collaborative product development agreement with a Branded product company, whereby the Company has agreed to develop a product for the Brand Company. Under the terms of the agreement, the Brand Company acquired the exclusive worldwide rights to market the product for ten years following approval. The Company will receive a royalty on

12. License Agreements of Development and Commercialization Rights (Continued)

net sales of the product, dependent upon the achievement of certain goals. In addition, the Company received $750,000 upon signing which was non-refundable and recorded as revenue in the year it was received and it will receive milestones of up to $13,000,000 upon the achievement of certain goals. The Brand Company is also required to pay all out of pocket costs related to the project and also made payments to the Company totaling $2,000,000 for the development of the product, payable at $200,000 per month commencing in April 2008. In July 2013, an arbitration settlement between the two companies was reached. The Company then terminated the contract; therefore no additional revenues will be recognized.

In September 2009, the Company entered into a licensing agreement with a Brand Company whereby the Brand Company has agreed to license a product developed by the Company. Under the terms of the agreement, the Brand Company acquired the exclusive U.S. and Canadian rights to market the product following regulatory approval. The Company received $5,000,000 upon signing and will receive a royalty on net sales of the product for a period of ten years, with the royalty percentage varying depending upon certain events (see Note 3 — Revenue Recognition.) The Company could not allocate the proceeds received at signing between completed research and development (R&D) and in-process R&D that the Company is continuing to work on. Therefore the payment amount of $5,000,000 was bundled with all elements of the agreement and was amortized over the period when R&D expenditures were to occur. The Company recognized $2,000,000 and $3,000,000 in revenue under this arrangement for the years ended September 30, 2011 and 2010, respectively. Additional milestone payments will not be forthcoming as the achievements were not met with the timelines as they were defined.

13. Asset Sales

On March 28, 2012, the Company entered into an Asset Purchase Agreement with Hikma Pharmaceutical Co. LTD, or Hikma. Under the terms of the agreement Hikma acquired exclusive U.S. rights to market Diclofenac/Misoprostal following regulatory approval. The Company received $3,500,000 upon signing the Asset Purchase Agreement. This amount is included in deferred revenue until approval, since it is refundable otherwise. In addition, the Company is entitled to receive another $1,000,000 upon regulatory approval, validation batch manufacturing with inventory released for launch, and sufficient launch inventory. Before approval, this milestone will be reduced for each generic competitor that receives regulatory approval (excluding an "authorized generic" version of the Brand Product); however, shall not be reduced to an amount less than $500,000. The Company will receive a royalty on Net Profits of the product for a period of ten years from the date of the first commercial sale of the product, with the royalty percentage varying depending upon certain events and competition.

On June 24, 2013, Hikma filed a lawsuit against the Company in the United States District Court for the Southern District of New York alleging that we (a) breached the Hikma, Asset Purchase Agreement (APA) by failing to refund the purchase price following Hikma's purported termination of the Hikma APA as a result of us failing to receive timely ANDA approval, and (b) intentionally failed to disclose alleged manufacturing product defects to Hikma. We believe we did not deny Hikma to receive timely ANDA approval entitled to Hikma to terminate the Hikma APA and thus receive a refund of the purchase price, and that the Company did not intentionally fail to disclose alleged manufacturing product defects to Hikma. Should Hikma prevail on its claims, the Company could be required to pay the return of the $3,500,000 purchase price plus interest, as well as other damages. The Company

13. Asset Sales (Continued)

cannot estimate the possible loss or range of loss related to the Hikma litigation beyond the $3,500,000 purchase price. As of September 30, 2013, the $3,500,000 is accrued as part of deferred revenue.

During fiscal year 2010 and 2011, the Company divested another non-core product and received proceeds of $6,500,000, comprised of $5,500,000 as a signing milestone which is recorded in deferred revenues and $500,000 for the initiation of Tech Transfer of which $250,000 remains in deferred revenues and a second payment of $500,000 for the completion of the Tech Transfer of which $250,000 remains in deferred revenues. Under the terms of this agreement, the licensor must obtain all of the following milestones in order for the Company to earn the revenues. These milestones are a) the receipt of an approvable letter from the FDA, b) acknowledgment from the FDA that no further clinical studies will be needed and c) an approval letter from the FDA. If these milestones are not met, then the $6,000,000 in total included in deferred revenue on the balance sheet at September 30, 2013 and 2012 must be refunded and the product rights are returned to the Company. In addition, the Company may receive additional milestones of up to $3,000,000 in the future, dependent on the licensor's actively selling the product in an exclusive market position.

See Note 6 for a summary of Deferred Revenue related to the Asset Sales.

14. Commitments

The Company has no material purchase obligations as of September 30, 2013. At September 30, 2013, purchase obligations in the amount of $1,338,640 represent the contractual commitments under a Contract Manufacturing and Supply Agreement with a supplier. The obligation under the supply agreement is primarily for raw materials and research and development.

The Company moved its office space to a new location in May 2013. The Company leases its office space under a lease agreement that expires on May 31, 2015. Rental expense was $314,105 and $329,373 in the fiscal years ended September 30, 2013and 2012, respectively. The remaining future lease payments under the operating lease are $454,025 as of September 30, 2013, payable monthly through May 31, 2015.

15. Arbitration

On October 26, 2011, the Company filed a Demand for Arbitration with the American Arbitration Association against a commercial partner that licensed one of its products. Eagle's claims include breach of contract relating to the development of a new formulation of the product and lack of effort to seek and obtain regulatory approval, ultimately impacting the marketing and sale of that new formulation. As a result, Eagle alleged that it had been significantly damaged. A three person arbitration panel was appointed. The trial was completed on January 25, 2013.

On July 19, 2013, the American Arbitration Association panel awarded the Company $5,000,000 for damages plus $23,900 for apportioned costs related to the arbitration for breach of contract. The Company received the funds in September 2013 and the amount was recorded in the results of operations, net of expenses of $973,649 in the fourth quarter of fiscal year 2013.

EAGLE PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

16. Subsequent Events

The Company has evaluated subsequent events through the filing date for the September 30, 2013 financial statements. In September 2013, the Company filed a New Drug Application under Section 505(b)(2) for EP-3101 (bendamustine RTD) and notified Teva Pharmaceuticals, the holder of Treanda, the referenced approved drug in our application, of the Company's 505(b)(2) filing and paragraph IV certification. Teva filed a patent infringement lawsuit against the Company in the United States District Court for the District of Delaware on October 21, 2013 to defer the approval of the bendamustine indication. Teva's filing of the lawsuit invoked a 30-month stay of FDA approval of the Company's bendamustine product, which will delay FDA approval until the earlier of the March 2016 expiration of the 30-month stay imposed by the Hatch-Waxman Act, or such time as the district court enters judgment in the Company's favor or otherwise acts to shorten the stay. Moreover, regardless of when the 30-month stay is resolved or expires, the FDA may still be prohibited from approving the Company's 505(b)(2) NDA due to Teva's unexpired orphan drug and pediatric exclusivities for Treanda. Specifically, Teva has received orphan drug and related pediatric exclusivity expiring in September 2015 and May 2016 for the CLL and NHL indications, respectively. When a drug, such as Treanda, has orphan drug exclusivity, the FDA may not approve any other application to market the same drug for the same indication for a period of up to seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. In the United States, pediatric exclusivity adds six months to any existing exclusivity period. If the Company cannot demonstrate that EP-3101 is clinically superior to Treanda, or qualify under certain other limited exceptions, the Company will not be able to enter the market for the CLL indication until September 2015 (assuming the 30-month stay is resolved by that time) or the NHL indication until May 2016.

Table of Contents

Shares

Eagle Pharmaceuticals, Inc.

Common Stock

PRELIMINARY PROSPECTUS

Through and including , 2014 (25 days after the commencement of this offering), all dealers that buy, sell or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

Piper Jaffray **William Blair**

Cantor Fitzgerald

, 2013

PART II
Information not required in prospectus

Item 13. ***Other Expenses of Issuance and Distribution.***

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, payable by Eagle Pharmaceuticals, Inc. (the "Registrant") in connection with the sale of the common stock being registered. All amounts shown are estimates except for the Securities and Exchange Commission ("SEC") registration fee, the FINRA filing fee and the Nasdaq Global Market filing fee.

	Amount to be paid
SEC registration fee	$ *
FINRA filing fee	*
Nasdaq Global Market listing fee	*
Blue sky qualification fees and expenses	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees and expenses	*
Miscellaneous expenses	*
Total	$ *

*To be provided by amendment.

Item 14. ***Indemnification of Directors and Officers.***

The Registrant incorporated under the laws of the State of Delaware. Section 145 of the Delaware General Corporation Law provides that a Delaware corporation may indemnify any persons who were, are, or are threatened to be made, parties to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person is or was an officer, director, employee or agent of such corporation, or is or was serving at the request of such corporation as an officer, director, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was illegal. A Delaware corporation may indemnify any persons who were, are, or are threatened to be made, a party to any threatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person is or was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit provided such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him or her against the expenses (including attorneys' fees) actually and reasonably incurred.

The Registrant's amended and restated certificate of incorporation and amended and restated bylaws, each of which will become effective upon the closing of this offering, provide for the indemnification of its directors and officers to the fullest extent permitted under the Delaware General Corporation Law.

Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duties as a director, except for liability for any:

- transaction from which the director derives an improper personal benefit;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares; or
- breach of a director's duty of loyalty to the corporation or its stockholders.

The Registrant's amended and restated certificate of incorporation includes such a provision. Expenses incurred by any officer or director in defending any such action, suit or proceeding in advance of its final disposition shall be paid by the Registrant upon delivery to it of an undertaking, by or on behalf of such director or officer, to repay all amounts so advanced if it shall ultimately be determined that such director or officer is not entitled to be indemnified by the Registrant.

Section 174 of the Delaware General Corporation Law provides, among other things, that a director who willfully or negligently approves of an unlawful payment of dividends or an unlawful stock purchase or redemption, may be held liable for such actions. A director who was either absent when the unlawful actions were approved or dissented at the time may avoid liability by causing his or her dissent to such actions to be entered in the books containing minutes of the meetings of the board of directors at the time such action occurred or immediately after such absent director receives notice of the unlawful acts.

As permitted by the Delaware General Corporation Law, the Registrant has entered into indemnity agreements with each of its directors and executive officers that require the Registrant to indemnify such persons against any and all costs and expenses (including attorneys', witness or other professional fees) actually and reasonably incurred by such persons in connection with any action, suit or proceeding (including derivative actions), whether actual or threatened, to which any such person may be made a party by reason of the fact that such person is or was a director or officer or is or was acting or serving as an officer, director, employee or agent of the Registrant or any of its affiliated enterprises. Under these agreements, the Registrant is not required to provide indemnification for certain matters, including:

- indemnification beyond that permitted by the Delaware General Corporation Law;
- indemnification for any proceeding with respect to the unlawful payment of remuneration to the director or officer;
- indemnification for certain proceedings involving a final judgment that the director or officer is required to disgorge profits from the purchase or sale of the Registrant's stock;
- indemnification for proceedings involving a final judgment that the director's or officer's conduct was in bad faith, knowingly fraudulent or deliberately dishonest or constituted willful misconduct or a breach of his or her duty of loyalty, but only to the extent of such specific determination;

- indemnification for proceedings or claims brought by an officer or director against us or any of the Registrant's directors, officers, employees or agents, except for claims to establish a right of indemnification or proceedings or claims approved by the Registrant's board of directors or required by law;

- indemnification for settlements the director or officer enters into without the Registrant's consent; or

- indemnification in violation of any undertaking required by the Securities Act or in any registration statement filed by the Registrant.

The indemnification agreements also set forth certain procedures that will apply in the event of a claim for indemnification thereunder.

Except as otherwise disclosed under the heading "Legal Proceedings" in the "Business" section of this registration statement, there is at present no pending litigation or proceeding involving any of the Registrant's directors or executive officers as to which indemnification is required or permitted, and the Registrant is not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

The Registrant has an insurance policy in place that covers its officers and directors with respect to certain liabilities, including liabilities arising under the Securities Act or otherwise.

The Registrant plans to enter into an underwriting agreement which provides that the underwriters are obligated, under some circumstances, to indemnify the Registrant's directors, officers and controlling persons against specified liabilities, including liabilities under the Securities Act.

Item 15. ***Recent sales of unregistered securities.***

The following sets forth information regarding all unregistered securities sold by the Registrant since October 1, 2010:

Issuance of Preferred Stock

In February 2011, we issued an aggregate of 6,784,722 shares of our Series B-1 preferred stock to 17 accredited investors at a price per share of $1.82, for aggregate consideration of $12.3 million, in reliance on Rule 506 of Regulation D. In July 2011, we issued an aggregate of 3,392,363 shares of our Series B-1 preferred stock to 17 accredited investors at a price per share of $1.82, for aggregate consideration of approximately $6.2 million, in reliance on Rule 506 of Regulation D.

In April 2013, we issued 5,494,506 shares of our series C preferred stock to one accredited investor at a price per share of $1.82, for aggregate consideration of approximately $10.0 million, in reliance on Section 4(2) of the Securities Act. Concurrently, the convertible promissory notes issued in August and September of 2012 were converted into an aggregate of 5,528,726 shares of our series C preferred stock.

Issuance of Convertible Promissory Notes and Warrants

In August and September 2012, we issued convertible promissory notes, with an interest rate of 6%, for an aggregate consideration of $9.7 million to 15 accredited investors. In connection with the issuance of such convertible promissory notes, we issued preferred stock warrants to purchase an aggregate of 944,210 shares of our series C preferred stock at a price per share of $1.82 to 15 investors.

Issuances of Common Stock and Options to Purchase Common Stock

In October 2012, we issued an aggregate of 8,943,447 shares of Common Stock upon conversion of 5,289,405 shares of our series A preferred stock, 3,357,782 shares of series B preferred stock and 296,260 shares of series B-1 preferred stock.

From October 1, 2010 through the date of this prospectus, we have granted under our 2007 Plan stock options to purchase an aggregate of 3,826,991 shares of our common stock to employees and directors, having exercise prices ranging from $1.37 to $0.69 per share. Of these, options to purchase an aggregate of 837,554 shares have been cancelled without being exercised. During the period from October 1, 2010 through the date of this prospectus, no shares of our common stock were issued upon the exercise of stock options issued under the 2007 Plan.

The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about the Registrant.

Unless otherwise stated, the sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(2) of the Securities Act (or Regulation D promulgated thereunder), or Rule 701 promulgated under Section 3(b) of the Securities Act in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701.

Item 16. ***Exhibits and financial statement schedules.***

(a) Exhibits.

Exhibit Number	Description of Exhibit	Previously Filed	Filed Herewith	To be Filed by Amendment
1.1	Form of Underwriting Agreement			X
3.1	Fifth Amended and Restated Certificate of Incorporation, as currently in effect	X		
3.2	Form of Amended and Restated Certificate of Incorporation to become effective upon the closing of this offering			X
3.3	Amended and Restated By-Laws, as currently in effect	X		
3.4	Form of Amended and Restated Bylaws to become effective upon the closing of this offering			X
4.1	Form of Common Stock Certificate of the Registrant			X
4.2	Third Amended and Restated Investor Rights Agreement, dated April 11, 2013, by and among the Registrant and certain of its stockholders	X		
5.1	Opinion of Cooley LLP			X
10.1	Form of Indemnity Agreement by and between the Registrant and its directors and officers	X		

Exhibit Number	Description of Exhibit	Previously Filed	Filed Herewith	To be Filed by Amendment
10.2†	Eagle Pharmaceuticals, Inc. 2007 Incentive Compensation Plan and Form of Stock Option Agreement thereunder	X		
10.3†	Eagle Pharmaceuticals, Inc. 2014 Equity Incentive Plan and Form of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice thereunder			X
10.4†	Eagle Pharmaceuticals, Inc. 2014 Employee Stock Purchase Plan			X
10.5†	Eagle Pharmaceuticals, Inc. Non-Employee Director Compensation Policy			X
10.6†	Employment Agreement by and between the Registrant and Scott Tarriff dated March 8, 2007			X
10.7†	Offer Letter by and between the Registrant and Paul Bruinenberg dated September 7, 2011	X		
10.8†	Offer Letter by and between the Registrant and Steven Krill dated September 7, 2011	X		
10.9†	Offer Letter by and between the Registrant and David Riggs dated November 7, 2013	X		
10.10	Lease Agreement between the Registrant and Mack-Cali Chestnut Ridge L.L.C. dated May 28, 2013, as amended on July 1, 2013			X
10.11(a)*	Development and License Agreement, by and between the Registrant and SciDose, LLC, dated September 24, 2007	X		
10.11(b)*	Development and License Agreement, by and between the Registrant and SciDose, LLC, dated June 12, 2007, as amended March 18, 2008, March 25, 2008, December 3, 2008 and July 16, 2013		X	
10.12*	License and Sublicense Agreement, by and between the Registrant and Lyotropic Therapeutics, Inc., dated October 16, 2008		X	
10.13*	License and Development Agreement, by and between the Registrant and The Medicines Company, effective as of September 24, 2009, as amended January 2010 and September 1, 2012		X	
10.14*	Supply Agreement, by and between the Registrant and The Medicines Company, dated September 24, 2009	X		
10.15*	Agreement for the Supply of Argatroban and Topotecan, by and between the Registrant and Cipla Limited, dated December 14, 2012, as amended August 30, 2013		X	
10.16*	Supply and Distribution Agreement, by and between the Registrant and Sandoz AG, dated January 28, 2013		X	

Exhibit Number	Description of Exhibit	Previously Filed	Filed Herewith	To be Filed by Amendment
10.17*	Development and License Agreement, by and between the Registrant and Robert One, LLC (bendamustine), dated March 18, 2008, as amended November 11, 2009 and July 16, 2013	X		
10.18*	Development and License Agreement, by and between the Registrant and Robert One, LLC (pemetrexed), dated February 13, 2009, as amended December 23, 2010 and July 16, 2013	X		
23.1	Consent of BDO USA, LLP, an Independent Registered Public Accounting Firm			X
23.2	Consent of Cooley LLP (included in Exhibit 5.1)			X
24.1	Power of Attorney (included in the signature page hereto)			

†Management contract or compensatory plan or arrangement

*Confidential treatment requested as to certain portions, which portions are omitted and filed separately with the Securities and Exchange Commission

(b) Financial statement schedules.

No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or the notes thereto.

Item 17. *Undertakings*.

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the Underwriting Agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The Registrant hereby undertakes that:

(a) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(b) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Act, the Registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Woodcliff Lake, State of New Jersey, on the day of , 2013.

EAGLE PHARMACEUTICALS, INC.

By: _____

Scott Tarriff
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Scott Tarriff and David E. Riggs, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this registration statement (including post-effective amendments), and to sign any registration statement for the same offering covered by this registration statement that is to be effective upon filing pursuant to Rule 462(b) promulgated under the Securities Act, and all post-effective amendments thereto, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
_____ Scott Tarriff	President, Chief Executive Officer and Member of the Board of Directors (Principal Executive Officer)	, 2013
_____ David E. Riggs	Chief Financial Officer (Principal Financial and Accounting Officer)	, 2013
_____ Jay Moorin	Chairman of the Board of Directors	, 2013
_____ Steven Ratoff	Member of the Board of Directors	, 2013

Table of Contents

Signature	Title	Date
Sander Flaum	Member of the Board of Directors	, 2013
Michael Graves	Member of the Board of Directors	, 2013
Alain Schreiber, M.D.	Member of the Board of Directors	, 2013

EXHIBIT INDEX

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23.1	Consent of BDO USA, LLP, an Independent Registered Public Accounting Firm			X
23.2	Consent of Cooley LLP (included in Exhibit 5.1)			X
24.1	Power of Attorney (included in the signature page hereto)			

†Management contract or compensatory plan or arrangement

*Confidential treatment requested as to certain portions, which portions are omitted and filed separately with the Securities and Exchange Commission

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

DEVELOPMENT AND LICENSE AGREEMENT

This Development and License Agreement ("AGREEMENT") is made and entered into June 12, 2007 (the "EFFECTIVE DATE") by and between SciDose, LLC, having its principal place of business at 123 Blackberry Lane, Amherst, MA 01002 ("SCIDOSE"); and Eagle Pharmaceutical, Inc. having its principal place of business at 470 Chestnut Ridge Road, Woodcliff Lake, NJ 07677 ("EAGLE"). SCIDOSE and EAGLE may be referred to herein individually as a "PARTY" and collectively as the "PARTIES."

RECITALS

WHEREAS, EAGLE is in the business of developing, making, marketing and selling, and possesses confidential proprietary information related to, pharmaceutical products for the treatment of diseases; and

WHEREAS, SCIDOSE is engaged in the research and development of, and possesses confidential proprietary information related to, pharmaceutical and therapeutic products, processes and technologies, including SCIDOSE'S proprietary formulation of argatroban and [*]; and

WHEREAS, EAGLE desires to obtain ownership of, or license to, certain of SCIDOSE'S intellectual property rights related to the PRODUCTS (as defined herein), in the TERRITORY (as hereafter defined), under the terms and conditions specified herein; and

WHEREAS, SCIDOSE desires to assign or license such intellectual property rights to EAGLE, under the terms and conditions specified herein.

NOW, THEREFORE, in consideration of the foregoing and the covenants and promises contained in this AGREEMENT, the PARTIES agree as follows:

AGREEMENT

1. **Definitions**

1.1 "505(b)(2)" means a 505(b)(2) Application filed with the FDA, or any foreign equivalent filed with the FDA to obtain MARKETING AUTHORIZATION for the PRODUCT in such country.

1.2 "AFFILIATE" means, with respect to any other person or entity, any other person or entity that directly or indirectly controls, is controlled by, or is under common control with, such person or entity. For purposes of this definition only, "control," "controlled by" and "under common control with" shall mean the possession of the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of voting stock or partnership interest, by

contract or otherwise. In the case of a corporation, the direct or indirect ownership of fifty percent (50%) or more of its outstanding voting shares or the ability otherwise to elect a majority of the board of directors or other managing authority of the entity shall in any event be deemed to confer control, it being understood that the direct or indirect ownership of a lesser percentage of such shares shall not necessarily preclude the existence of control.

1.3 "ASSIGNED PATENTS" means (i) the PATENT APPLICATIONS set forth in Schedule I, all PATENT APPLICATIONS claiming priority to such PATENT APPLICATIONS, any of their progeny and any PATENTS issuing from, directly or indirectly, or based upon any of the foregoing, and (ii) the inventions described or claimed in any of the foregoing.

1.4 "CLAIMS" has the meaning set forth in Section 9.1.1.

1.5 "CONFIDENTIAL INFORMATION" has the meaning set forth in Section 6.1.

1.6 "CONTROL(LED)" means the ability to grant a license or sublicense as provided for herein without violating the terms of any agreement or other arrangement with any THIRD PARTY.

1.7 "COST OF GOODS" means, in respect of any Product, the amount paid by EAGLE to its contract manufacturer for the manufacturing and release of such finished PRODUCT including the cost of the active pharmaceutical ingredient, raw materials and packaging materials used in such finished PRODUCT.

1.8 "DEFAULT" has the meaning set forth in Section 8.2.2.

1.9 "DISCLOSING PARTY" means the PARTY disclosing CONFIDENTIAL INFORMATION to the other PARTY hereunder.

1.10 "DOLLAR(S)" means United States dollars.

1.11 "FDA" means the United States Food and Drug Administration, or any successor entity that may be established hereafter which has substantially the same authority or responsibility currently vested in the United States Food and Drug Administration.

1.12 "FIRST COMMERCIAL SALE" means, with respect to a PRODUCT, the first sale by EAGLE or its LICENSEES to a THIRD PARTY following receipt of a MARKETING AUTHORIZATION for such PRODUCT; provided, however, that the PRODUCT shipped by EAGLE

or its LICENSEES to a THIRD PARTY prior to receipt of MARKETING AUTHORIZATION therefor shall be deemed for the purposes hereof a FIRST COMMERCIAL SALE to the extent such PRODUCT is

sold to a THIRD PARTY for sale after such MARKETING AUTHORIZATION is obtained.

1.13 "GROSS PROFIT" means NET SALES minus COST OF GOODS minus SALES FORCE COSTS.

1.14 "GROSS PROFIT MARGIN" means the fraction, expressed as a percentage, the numerator of which is the GROSS PROFIT and the denominator of which is the NET SALES.

1.15 "EAGLE INDEMNITEE" has the meaning set forth in Section 9.1.1.

1.16 "EAGLE KNOW-HOW" means all KNOW-HOW CONTROLLED by EAGLE that is necessary or useful for SCIDOSE in connection with SCIDOSE'S performance of its obligations under this AGREEMENT. EAGLE PATENT RIGHTS are excluded from the definition of EAGLE KNOW-HOW.

1.17 "EAGLE PATENT RIGHTS" means all PATENTS and PATENT APPLICATIONS CONTROLLED by EAGLE that are necessary for SCIDOSE in connection with SCIDOSE'S performance of its obligations under this AGREEMENT.

1.18 "INVENTIONS" means any and all ideas, concepts, methods, procedures, processes, improvements, inventions and discoveries, whether or not patentable, that are conceived or made in the course of the performance of activities conducted in connection with this AGREEMENT including the development or manufacture of the PRODUCTS.

1.19 "JOINT INVENTION" has the meaning set forth in Section 10.3.

1.20 "JOINT PATENT APPLICATIONS" has the meaning set forth in Section 10.5.

1.21 "KNOW-HOW' means all technical, scientific and other know-how, data, materials, information, trade secrets, ideas, formulae, inventions, discoveries, processes, machines, manufactures, compositions of matter, improvements, protocols, techniques, works of authorship, and results of experimentation and testing (whether or not patentable) in written, electronic, oral or any other form.

1.22 "LAW(S)" means any applicable local, state or federal rule, regulation, statute or law in any jurisdiction relevant to the activities undertaken pursuant to this AGREEMENT.

1.23 "LICENSEE" means any person or entity, including EAGLE AFFILIATES, to which EAGLE grants a license under the ASSIGNED PATENTS or LICENSED SCIDOSE TECHNOLOGY to sell, have sold and/or import the PRODUCT.

1.24 "MARKETING AUTHORIZATION" means, with respect to any Product, the requisite governmental approval (e.g., ANDA or 505(b)(2) or equivalent) for the marketing and sale of such PRODUCT in the TERRITORY.

1.25 "NET SALES" means, with respect to any Product, the amount invoiced by (or in the absence of an invoice, the amounts payable to) EAGLE or its AFFILIATES for the sale to THIRD PARTIES of such PRODUCT less the following: (i) customary administration fees, drug wholesaler fees, charge-backs, rebates (including Medicaid, Medicare and similar rebates) and trade and customary quantity discounts actually allowed and taken, including shelf stock adjustments, cash and volume discounts, chargebacks, promotional allowances, inventory obsolescence; (ii) allowances actually given for returned PRODUCT; (iii) documented freight, postage, shipping costs and insurance paid by EAGLE (if separately stated); (iv) government-mandated and other rebates customary in the industry; (v) value added tax, sales, use or turnover taxes, excise taxes and customs duties and (vi) if applicable, expenses related to (A) PRODUCT recalls in accordance with Section 7.4, (B) infringement litigation in accordance with Sections 11.1.3, 11.2.2(b) and/or 11.2.3(a), and (C) marketing costs (other than SALES FORCE COSTS) directly related to Argatroban and/or [*] (or, as applicable, the REPLACEMENT PRODUCTS related thereto). NET SALES shall be deemed to accrue upon the date of the invoice for a PRODUCT. In addition, NET SALES by EAGLE hereunder are subject to the following, as accrued on EAGLE's book in good faith:

(a) In the case of pharmacy incentive programs, hospital performance incentive program, charge backs, disease management programs, similar programs or discounts on "bundles" of products, all discounts and the like shall be allocated proportionately based on sales of comparable products to THIRD PARTIES on a standalone basis; and

(b) In the case of any sale or other disposal of the PRODUCT by EAGLE to an AFFILIATE for resale, the NET SALES shall be calculated as above on the value charged or invoiced on the first arm's length sale to a THIRD PARTY;

1.26 “NON-DISCLOSURE AGREEMENT” means that agreement entered into between the PARTIES on April 13, 2006 providing for confidential treatment of the PARTIES’ information.

1.27 “PATENT” means: (i) any letters patent and utility models including any extension, substitution, registration, confirmation, reissue, supplemental protection certificate, re-examination or renewal thereof; and (ii) to the extent valid and enforceable rights are granted by a governmental authority thereunder, a PATENT APPLICATION.

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1.28 “PATENT APPLICATION” means an application for letters patent, including a provisional application, converted provisional application, continuation application, a continued prosecution application, a continuation-in-part application, a divisional application, a re-examination application, and a reissue application, including the applications listed on Schedule 1 hereto.

1.29 “PERSON” means any natural person, corporation, company, partnership, limited partnership, limited liability company, firm, association, trust, government, governmental agency, or any other entity, whether acting in an individual, fiduciary or other capacity.

1.30 “PRODUCT(S)” means (i) all parenteral formulations of Argatroban and [*] and (ii) two molecules to be determined by at later date in accordance with Section 2.7.

1.31 “PRODUCT FAILURE” means, in respect of any PRODUCT, (i) rejection by the FDA of the filing of the 505(b)(2) or ANDA application, as applicable, (ii) failure to receive MARKETING AUTHORIZATION by the FDA following such application filing or (iii) the failure to complete the milestone in respect of such Product set forth in Schedule Ill within thirty (30) days of the date set forth on Schedule Ill (as the same may be extended by Agreement of the PARTIES).

1.32 “RECIPIENT” means the PARTY receiving CONFIDENTIAL INFORMATION hereunder.

1.33 “REPLACEMENT PRODUCT” means, (i) with respect to Argatroban and [*], a 505(b)(2) PRODUCT and (ii) with respect to the THIRD AND FOURTH PRODUCTS, a PRODUCT with an anticipated ANDA filing, in each case selected by the Development Committee to replace such PRODUCT which is subject to a PRODUCT FAILURE.

1.34 “RESPONSIBLE PARTY” has the meaning set forth in Section 10.5.

1.35 “ROYALTY RATE” means, (i) with respect to Argatroban and [*], [*] and (ii) with respect to the THIRD AND FOURTH PRODUCTS, [*].

1.36 “ROYALTY TERM” means, with respect to a PRODUCT, the period of time commencing on the date of the FIRST COMMERCIAL SALE of a PRODUCT and expiring upon the later of: (a) ten (10) years thereafter; and (b) the expiration date of the last VALID PATENT CLAIM covering the manufacture, use, importation or sale of the PRODUCT in the TERRITORY.

1.37 “SALES FORCE COSTS” means the costs of any hospital sales force hired to market and sell the PRODUCTS (provided, however, that Eagle shall have no

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obligation to hire a hospital sales force for the marketing and selling of Argatroban or [*]).

1.38 “SCIDOSE INDEMNITEE” has the meaning set forth in Section 9.1.2.

1.39 “SCIDOSE KNOW-HOW’ means all existing and future KNOW-HOW owned or CONTROLLED by SCIDOSE, that is necessary or useful for EAGLE to develop, make, have made, use, offer for sale, sell, have sold and import the PRODUCTS. SCIDOSE PATENT RIGHTS are excluded from the definition of SCIDOSE KNOW-HOW.

1.40 “SCIDOSE LICENSED TECHNOLOGY” means, collectively, the SCIDOSE PATENT RIGHTS and the SCIDOSE KNOW-HOW, excluding the ASSIGNED PATENTS.

1.41 “SCIDOSE PATENT RIGHTS” means all of the existing and future PATENTS and PATENT APPLICATIONS owned or CONTROLLED by SCIDOSE which claim the composition, development, manufacture, offer for sale, sale, import or use of the PRODUCTS, and that are necessary or useful to develop, make, have made, use, sell, have sold or import the PRODUCTS.

1.42 “SOLE INVENTION” has the meaning set forth in Section 10.3.

1.43 “SUBLICENSEE” means any person or entity, including its AFFILIATES, to which EAGLE grants a sublicense to sell, have sold and/or import the PRODUCT pursuant to the license set forth in Section 2.2.

1.44 "TERM" has the meaning set forth in Section 13.1.

1.45 "TERRITORY" means all of North America, including the United States, its territories and possessions (including, Puerto Rico, Virgin Islands and Guam) and Canada.

1.46 "THIRD AND FOURTH PRODUCTS" has the meaning set forth in Section 2.7.

1.47 "THIRD PARTY" means any entity other than SCIDOSE, EAGLE and their respective AFFILIATES.

1.48 "VALID PATENT CLAIM" means either: (a) a claim of an issued and unexpired PATENT that is included in the ASSIGNED PATENTS or the SCIDOSE LICENSED TECHNOLOGY and covering the manufacture, use, import or sale of a PRODUCT, which PATENT has not (i) expired or been canceled with prejudice, (ii) been declared invalid by an irreversible and unappealable decision of a court or other appropriate body of competent jurisdiction, (iii) been admitted to be invalid or unenforceable through reissue, disclaimer, or otherwise, or (iv) been abandoned; or (b) a claim filed and kept pending in good faith that is

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included in a PATENT APPLICATION that is included in the ASSIGNED PATENTS or the SCIDOSE LICENSED TECHNOLOGY and covering the manufacture, use, import or sale of a PRODUCT, which PATENT APPLICATION has not been (i) cancelled with prejudice, (ii) withdrawn from consideration without the ability to resubmit or re-file, (iii) finally determined to be unallowable by the applicable governmental authority, or (iv) abandoned.

2. **Assignment and Licenses**

2.1 Assignment to EAGLE. SCIDOSE hereby transfers, sells and assigns, and agrees to transfer, sell and assign, to EAGLE all right, title and interest in the ASSIGNED PATENTS and all intellectual property rights therein, including all income, royalties, damages, claims, and payments now or hereafter due or payable with respect thereto, and in and to all causes of action, either in law or in equity for present or future infringement based on the ASSIGNED PATENTS. SCIDOSE shall, at EAGLE sole cost and expense, take such further actions and provide such cooperation and assistance (including, without limitation, the execution and delivery of any all affidavits, declarations, oaths, exhibits, assignments, powers of attorney or other documentation), requested by EAGLE to more fully and effectively effectuate the purposes of the above assignment.

2.2 License to EAGLE. SCIDOSE hereby grants to EAGLE (i) an exclusive, perpetual, royalty-bearing (as provided in Section 3.2) license, with the right to grant sublicenses, under SCIDOSE'S interest in the SCIDOSE LICENSED TECHNOLOGY solely to develop, make, have made, use, sell, have sold, offer for sale or import the PRODUCTS in the TERRITORY. Upon expiration of the ROYALTY TERM, the foregoing license shall be royalty-free. In the event that any technology is licensed to SCIDOSE that is useful for the PRODUCTS, or an improvement to the PRODUCTS, to the extent permitted by SCIDOSE's agreement with the licensor, SCIDOSE shall promptly notify EAGLE of such technology and offer EAGLE the use of such technology to the greatest extent permitted by such agreement. In the event that EAGLE elects, in its sole discretion, to use such technology, then the PARTIES shall negotiate in good faith a commercially reasonable amount that EAGLE will reimburse SCIDOSE, which amount shall represent a portion of any fees that SCIDOSE must pay under such agreement, based on EAGLE's proportional use under the license in connection with the PRODUCTS as compared to SCIDOSE's aggregate use under the license for any purpose.

2.3 SCIDOSE Research Rights and Limitations. Notwithstanding anything to the contrary in this AGREEMENT and without limiting any other retained rights, the license granted under Section 2.2 shall be subject to the retained right of SCIDOSE and its AFFILIATES: (i) to practice the SCIDOSE LICENSED TECHNOLOGY for the conduct of research and development of products (other than the Product) that it is developing either itself or with others; and (ii) to

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develop, make, have made, use, sell, offer for sale, import and license products other than the PRODUCTS; provided, however, that with respect to the foregoing clauses (i) and (ii), such products do not violate the restrictions in Section 2.6 or 8.4.

2.4 No Implied Rights or Licenses. Neither PARTY grants to the other any rights or licenses, including without limitation to any SCIDOSE LICENSED TECHNOLOGY or other intellectual property rights, whether by implication, estoppel or otherwise, except to the extent expressly provided for under this AGREEMENT.

2.5 License to SCIDOSE. EAGLE hereby grants to SCIDOSE a non-exclusive, worldwide (to the extent of EAGLE's rights), royalty-free license under (a) EAGLE KNOW-HOW and EAGLE PATENT RIGHTS, if any, and (b) the SCIDOSE LICENSED TECHNOLOGY that is licensed exclusively to EAGLE hereunder, in each case only to the extent useful or necessary for SCIDOSE to fulfill its obligations under this AGREEMENT or for the manufacture or sale of the PRODUCTS outside the Territory.

2.6 Mutual Covenant. Each PARTY covenants and agrees that (i) it and its AFFILIATES shall not use or practice the intellectual property rights licensed under this AGREEMENT except as expressly permitted by this AGREEMENT and (ii) any use or practice of the intellectual property rights licensed under this AGREEMENT except as expressly permitted by this AGREEMENT that results in material harm to the other PARTY shall constitute a material breach of this AGREEMENT. Notwithstanding the foregoing, each PARTY covenants and agrees to cease any non-permitted use and to take all actions necessary to assign to the other PARTY any inventions made through use or practice of such PARTY'S intellectual property rights outside the scope of the license rights granted hereunder.

2.7 Selection of Additional Products. Within ninety (90) days after the EFFECTIVE DATE, each PARTY shall nominate up to four candidates as proposed additional PRODUCTS. Thereafter the PARTIES shall mutually agree in good faith upon the selection of the two additional PRODUCTS (the "THIRD AND FOURTH PRODUCTS") to be included in this Agreement. Criteria for the selection of the additional PRODUCTS shall include (i) market potential; (ii) the potential for the entry of future competing products; (iii) the ability of the PARTIES to develop non-fringing formulations; (iv) the costs of development; and (v) the projected time to market. The failure of the PARTIES to select either of the THIRD AND FOURTH PRODUCTS on or before [*] days after the EFFECTIVE DATE will be deemed a PRODUCT FAILURE for purposes of this Agreement.

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3. **Milestones: Royalty Payments: Royalty Reports**

3.1 Milestone Payments.

3.1.1 EAGLE shall pay to SCIDOSE the respective milestone payments in accordance with and on the respective dates provided in Schedule II hereto. Such milestone payments shall be in addition to any royalty or other payments due under this AGREEMENT and are allocated among the PRODUCTS as follows:

Argatroban	[*]
[*]	[*]
THIRD PRODUCT	[*]
FOURTH PRODUCT	[*]

3.1.2 In the event of any PRODUCT FAILURE, then, subject to Sections 3.1.3 and 3.1.4, (a) if such PRODUCT FAILURE relates to Argatroban or [*], then SCIDOSE shall be obligated to refund to EAGLE an amount equal to the portion of all milestone payments paid by EAGLE and allocated to such PRODUCT, and (b) if such PRODUCT FAILURE relates to either of the THIRD AND FOURTH PRODUCTS, SCIDOSE shall refund to EAGLE an amount equal to the portion of all milestone payments paid by EAGLE and allocated to such PRODUCT. In the event of a PRODUCT FAILURE with respect to any PRODUCT prior to payment of all milestone payments, future milestone payments in respect of such PRODUCT, if any, shall be allocated towards a REPLACEMENT PRODUCT.

Example: EAGLE pays [*] to SCIDOSE upon execution of this Agreement and an additional [*] on [*] in accordance with Schedule II. On [*], a PRODUCT FAILURE occurs with respect to Argatroban. An amount equal to [*] of the milestone payments previously made by EAGLE to SCIDOSE (i.e., [*]), will be required to be refunded by SCIDOSE to EAGLE, subject to Section 3.1.3

3.1.3 In the event SCIDOSE does not repay any amounts to be refunded by it by the later of [*] or the date of the milestone failure, SCIDOSE shall issue to EAGLE a promissory note in the principal amount of the unpaid amounts which shall be due and payable on [*]. Interest on the unpaid principal portion of such note shall accrue at the rate of [*] per year and shall be due and payable with all unpaid interest on the maturity date. Principal and interest under the note may be pre-paid at anytime without premium or penalty. Upon repayment in full of such amount, (i) the license granted pursuant to this Agreement with respect to the LICENSED TECHNOLOGY for the failed PRODUCT shall terminate and EAGLE shall assign the ASSIGNED PATENTS related solely to the failed PRODUCT to SCIDOSE and (ii) the license granted by EAGLE pursuant to Section 2.5 of this Agreement for the failed PRODUCT shall terminate.

3.1.4 Notwithstanding any other provisions the provisions of this Section 3.1, all milestone shall be deemed met and no refund of any milestone payment shall be payable to EAGLE in the event that, as of [*], payments are received from any

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THIRD PARTY with respect to any PRODUCT which results in payment to EAGLE of at least [*]. In the event that, as of [*], payments are received from THIRD PARTIES from PRODUCTS which total in the aggregate less than [*], the amount to be refunded to EAGLE pursuant to Section 3.1.2 shall be reduced by an amount equal to the positive difference, if any, between (a) the amount to be refunded to EAGLE pursuant to Section 3.1.2 and (b) the difference between (i) [*], less (b) the total payments received by EAGLE from any such THIRD PARTY.

Example: Assume that the total payments received by EAGLE with respect to all PRODUCTS is [*] and that SCIDOSE has not refunded to EAGLE any milestone payments paid and allocated to the failed Argatroban PRODUCT (i.e., [*]). The amount to be refunded [*] shall be reduced by an amount equal to the positive difference, if any, between (a) the amount to be refunded to EAGLE pursuant to Section 3.1.2

[*] and (b) the difference between (i) [*], less (ii) the total payments received by EAGLE from any such THIRD PARTY [*], or [*]. Therefore, the amount to be refunded would equal [*].

3.2 Royalties. For the applicable ROYALTY TERM for each PRODUCT, EAGLE shall pay SCIDOSE royalties on sales of PRODUCTS by EAGLE and its AFFILIATES in the TERRITORY in an amount equal to the ROYALTY RATE times the GROSS PROFIT from the number of units of PRODUCTS sold; provided, however, that, if, at any time during the first ten (10) years after the FIRST COMMERCIAL SALE of such PRODUCT, there is no VALID PATENT CLAIM covering the manufacture, use, import or sale of a PRODUCT in a country in the Territory, then (i) with respect to Argatroban and [*] (or any 505(b)(2) REPLACEMENT PRODUCT, as applicable), the ROYALTY RATE shall be reduced to [*] in such country and (ii) with respect to the THIRD AND FOURTH PRODUCTS (or any ANDA REPLACEMENT PRODUCT, as applicable), the ROYALTY RATE shall be reduced to [*] in such country.

3.3 Reports. EAGLE shall notify SCIDOSE in writing within forty-five (45) days after the FIRST COMMERCIAL SALE of any PRODUCT in the TERRITORY. Commencing with the FIRST COMMERCIAL SALE of any PRODUCT in the TERRITORY, EAGLE shall furnish to SCIDOSE within thirty (30) days of the end of each calendar quarter, or as of the end of each calendar year, a written report (due in conjunction with the corresponding royalty payment equal to the ROYALTY RATE times the GROSS PROFIT from the number of units of PRODUCTS sold during that past quarter) showing, according to the volume of units of the PRODUCTS sold (by PRODUCT and SKU) during the reporting period: (a) the gross invoiced sales of the PRODUCTS sold during the reporting period, and the amounts deducted therefrom to determine GROSS PROFITS, COST OF GOODS and NET SALES from such gross invoiced sales (including with specificity, the applicable deductions therefrom; and (b) the accrued royalties

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paid or payable for such period. Any royalty payments for such prior fiscal year payable to SCIDOSE which were not previously paid shall be paid to SCIDOSE on the date such annual report is due.

4. **Product Development; Commercialization**

4.1 Development Committee. The PARTIES agree to work together in good faith in the collaboration under this Agreement and to keep each other reasonably informed of its activities hereunder. Additionally, and in support of the foregoing, promptly after the Effective Date, the PARTIES will form a four-member committee (the "Development Committee"), equally represented by EAGLE and SCIDOSE, for the management of the development of the PRODUCTS, which will consist of the Chief Executive Officer and Chief Scientific Officer of each of EAGLE and SCIDOSE. Each Party shall have the right, from time to time, to substitute new members, on a permanent or temporary basis, for any of its previously designated members of the Development Committee. Each Party shall bear its own costs associated with participation in the Development Committee.

4.1.1 The Development Committee shall generally oversee and facilitate the development of the Products. Each party shall promptly provide the other and the Development Committee with a copy of any FDA correspondence within 48 hours of receipt thereof and it will be the responsibility of EAGLE, with the oversight and approval of the Development Committee, to create an appropriate response thereto.

4.1.2 During the Term, the Development Committee shall meet at least once each calendar quarter or at such other frequency as the Development Committee determines. The PARTIES shall meet on a date and time and at a location determined by the Development Committee; the PARTIES anticipate alternating meetings between the Party's respective sites. Upon written notice by either Party to the other that a meeting is required or requested, a meeting will be held within thirty (30) calendar days of such notice on a date and time and at a location to be agreed upon by the PARTIES, or sooner if warranted by the circumstances. Notices requesting such a meeting shall include adequate information describing the activity to be reviewed. Any meetings of the Development Committee may be held in person at a location to be agreed to by the PARTIES, or by videoconference to teleconference.

4.1.3 In the event of a PRODUCT FAILURE, the Development Committee shall select a REPLACEMENT PRODUCT within one hundred twenty (120) days of such failure. In the event the Development Committee fails to select the REPLACEMENT PRODUCT within such period, EAGLE shall be entitled to a refund in accordance with Section 3.1.2.

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4.2 Approval of the Product. Following, and subject to, the successful completion of the development to the reasonable satisfaction of EAGLE and SCIDOSE according to the criteria to be developed by the Development Committee, including obtaining favorable patent opinions and successful completion of any required pivotal biostudy, as applicable EAGLE shall prepare and submit the ANDA for the THIRD AND FOURTH PRODUCTS to the FDA as soon as reasonably practical. SCIDOSE shall use commercially reasonable efforts to assist EAGLE in the preparation and filing of the 505(b)(2) or ANDA applications and any follow-up communications with the FDA and shall promptly comply with all of EAGLE's reasonable requests for information relating thereto. Each of the PARTIES shall promptly provide the other and the Development Committee with copies of all documents and correspondence received from regulatory authorities that relate to obtaining MARKETING AUTHORIZATION and each of the PARTIES shall use commercially reasonable efforts to obtain permission for the other party to attend all meetings with regulatory authorities in respect thereof.

4.3 Commercialization. The PARTIES hereby acknowledge that, during the Term, Eagle shall be the sole and exclusive distributor for the PRODUCTS in the Territory, either directly or through its AFFILIATES and/or SUBLICENSEES. All activities related to the sales and

marketing of the Products in the Territory, including the launch date of such PRODUCT, will be the sole responsibility of Eagle. Eagle shall arrange for the manufacture, testing, packaging, labeling, transportation and storage of Eagle's requirements of commercial supplies of the PRODUCTS hereunder from a third-party contract manufacturer (such third-party contract manufacturer being referred to hereafter as the "Third-Party Supplier"). Eagle may grant a right to a Third-Party Supplier to make, test, package, label, store and transport the PRODUCTS for sale by Eagle in the Territory hereunder.

4.4 Patent Marking and PRODUCT Marking.

(a) EAGLE shall place appropriate patent and/or patent pending markings on the PRODUCT or the packaging therefor. The content, form, size, location and language of such markings shall be in accordance with the LAWS and practices of the country in which the applicable units of the PRODUCT are distributed.

(b) EAGLE shall be responsible for all packaging (non-commercial and commercial) and labeling of the PRODUCT.

5. **Records; Audits; Payment Terms**

5.1 Records. EAGLE shall keep complete and accurate records in sufficient detail to make the reports required hereunder to properly reflect all gross sales, GROSS PROFITS and NET SALES of the PRODUCTS on which EAGLE is required

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hereunder to pay royalties and to verify the determination of all amounts payable hereunder.

5.2 Audits. Not more than once per calendar year, upon the written request of SCIDOSE and not less than thirty (30) business days prior notice, EAGLE shall permit an independent certified public accounting firm of recognized national standing in the United States, selected by SCIDOSE and reasonably acceptable to EAGLE, at SCIDOSE'S expense, to have access during EAGLE's normal business hours to such of the records of EAGLE as may be reasonably necessary to verify the accuracy of any amounts reported, actually paid or payable under this AGREEMENT for any year ending not more than twenty-four (24) months prior to the date of such request. If such accounting firm concludes that additional royalty amounts were owed to SCIDOSE during such period, EAGLE shall pay such additional royalties (including interest on such additional royalties at the rate of eight percent [*] per annum, compounded annually, or the maximum rate allowed under LAW, whichever is less from the date such royalty amounts were payable) within [*] days after the date SCIDOSE delivers to EAGLE such accounting firm's written report so concluding. The fees charged by such accounting firm shall be paid by SCIDOSE; provided however, that if the audit discloses that the royalties payable by EAGLE for the audited period are more than [*] of the royalties actually paid for such period (excluding interest pursuant to this Section 4.2), then EAGLE shall pay the reasonable fees and expenses charged by such accounting firm.

5.3 Payment Method. EAGLE shall pay all royalties that accrue under Section 3.2 during a calendar quarter within [*] days after the end of [*]. All payments by EAGLE under this AGREEMENT shall be paid in DOLLARS, and all such payments shall be made by bank wire transfer in immediately available funds to such account as SCIDOSE shall designate in writing not less than thirty (30) days before such payment is due.

6. **Confidentiality**

6.1 In General. For the TERM and for a period of five (5) years thereafter, each PARTY shall maintain in confidence all information and materials of the other PARTY (including, but not limited to, KNOW-HOW and samples of the PRODUCT) disclosed or provided to it by the other PARTY (either pursuant to this AGREEMENT or the NON-DISCLOSURE AGREEMENT) and identified as confidential in writing or, if disclosed verbally or by observation, summarized in writing and submitted to RECIPIENT within thirty (30) days of the oral or visual disclosure thereof (together with all embodiments thereof, the "CONFIDENTIAL INFORMATION"). CONFIDENTIAL INFORMATION may also include information regarding intellectual property and confidential or proprietary information of THIRD PARTIES. In addition, and notwithstanding the foregoing, INVENTIONS that, under Article 9 are to be owned by one PARTY shall be

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deemed CONFIDENTIAL INFORMATION of such PARTY and not the other PARTY, even if such INVENTIONS initially are generated and disclosed by the other PARTY. The terms and conditions of this AGREEMENT and the NON-DISCLOSURE AGREEMENT also shall be deemed CONFIDENTIAL INFORMATION of both PARTIES. Notwithstanding the foregoing, CONFIDENTIAL INFORMATION shall not include that portion of information or materials that the RECIPIENT can demonstrate by contemporaneous written records was (i) known to the general public at the time of its disclosure to the RECIPIENT, or thereafter became generally known to the general public, other than as a result of actions or omissions of the RECIPIENT; (ii) known by the RECIPIENT prior to the date of disclosure by the DISCLOSING PARTY; (iii) disclosed to the RECIPIENT on an unrestricted basis from a THIRD PARTY not under a duty of confidentiality to the DISCLOSING PARTY; or (iv) independently developed by the RECIPIENT by personnel that did not have access to or use of CONFIDENTIAL INFORMATION of the DISCLOSING PARTY.

Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or known to the general public or in the rightful possession of the RECIPIENT unless the combination itself and principle of operation thereof are published or known to the general public or are in the rightful possession of the RECIPIENT.

6.2 Additional Protections. Each PARTY shall take reasonable steps to maintain the confidentiality of the CONFIDENTIAL INFORMATION of the other PARTY, which steps shall be no less protective than those that such PARTY takes to protect its own information and materials of a similar nature, but in no event less than a reasonable degree of care. Neither PARTY shall use or permit the use of any CONFIDENTIAL INFORMATION of the other PARTY except for the purposes of carrying out its obligations or exercising its rights under this AGREEMENT, and neither PARTY shall copy any CONFIDENTIAL INFORMATION of the other PARTY except as may be reasonably useful or necessary for such purposes. All CONFIDENTIAL INFORMATION of a PARTY, including all copies and derivations thereof, is and shall remain the sole and exclusive property of the DISCLOSING PARTY and subject to the restrictions provided for herein. Neither PARTY shall disclose any CONFIDENTIAL INFORMATION of the other PARTY other than to those of its directors, officers, AFFILIATES, employees, licensors, independent contractors, LICENSEES, SUBLICENSEES, assignees, agents and external advisors directly concerned with the carrying out of this AGREEMENT, on a strictly applied "need to know" basis, and provided such disclosure is subject to written confidentiality and non-use obligations no less protective than those provided herein. Other than as expressly permitted herein, RECIPIENT may not use CONFIDENTIAL

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INFORMATION of the other PARTY in applying for PATENTS or securing other intellectual property rights.

6.3 Permitted Disclosures. The obligations of. Sections 6.1 and 6.2 shall not apply to the extent that RECIPIENT is required to disclose information by LAW, judicial order by a court of competent jurisdiction, or rules of a securities exchange or requirement of a governmental agency for purposes of obtaining approval to test or market the PRODUCT, or discloses information to a patent office for the purposes of filing a PATENT as permitted in this AGREEMENT; provided that the RECIPIENT shall provide prior written notice thereof to the DISCLOSING PARTY and sufficient opportunity for the DISCLOSING PARTY to review and comment on such required disclosure and request confidential treatment thereof or a protective order therefor. Notwithstanding the foregoing, either PARTY may disclose the terms and conditions of this AGREEMENT and the NONDISCLOSURE AGREEMENT to actual or potential acquirers, investors and lenders and their respective representatives under written confidentiality agreements at least as protective of the DISCLOSING PARTY'S rights as the terms and conditions of this Article 5.

6.4 Irreparable Injury. The PARTIES acknowledge that either PARTY'S breach of this Article 5 would cause the other PARTY irreparable injury for which it would not have an adequate remedy at LAW. In the event of a breach, the nonbreaching PARTY shall be entitled to injunctive relief in addition to any other remedies it may have at LAW or in equity, without necessity of posting a bond.

6.5 Return of CONFIDENTIAL INFORMATION. Each PARTY shall return or destroy all CONFIDENTIAL INFORMATION of the other PARTY in its possession upon termination or expiration of this AGREEMENT, except any CONFIDENTIAL INFORMATION that a PARTY is required by law to retain or that is necessary to allow such PARTY to perform or enjoy any of its rights or obligations that expressly survive the termination or expiration of this AGREEMENT.

7. Regulatory Matters

7.1 In General. Each PARTY has conducted and shall conduct its activities in connection with the PRODUCTS in accordance with the practices of a reasonable industry expert and in material compliance with all LAWS and, except as specifically provided in this AGREEMENT, shall bear all its own costs of doing so. Each PARTY shall promptly notify the other in writing of any information that comes to its attention concerning the safety or efficacy of the PRODUCTS, including, without limitation, any threatened or pending action by any regulatory authority with respect thereto.

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7.2 Complaints and Communications. EAGLE shall be responsible for handling all complaints and communications (including with regulatory authorities) relating to the PRODUCTS in the TERRITORY.

7.3 Adverse Reaction Reporting. EAGLE shall be responsible for handling all adverse event reporting (including with regulatory authorities) relating to the PRODUCT in the TERRITORY.

7.4 PRODUCT Recalls. In the event that a PRODUCT is recalled from the market for any reason whatsoever, EAGLE shall be responsible for: (a) conducting all recall activities; and (b) all costs associated with any such recall, subject to any indemnification by SCIDOSE; provided, however, that notwithstanding anything to the contrary contained in this Agreement, any such costs shall be deducted from Net Sales and retained by EAGLE, prior to the computation of GROSS PROFIT of any PRODUCT. The PARTIES shall keep the other fully informed in writing of any notification or other information, whether received directly or indirectly, that might (i) affect the marketability, safety or effectiveness of any Product, (ii) result in liability issues or otherwise necessitate action on the part of either party or (iii) result in recall or seizure of any Product.

7.5 Ownership of 505(b)(2) Filing. The 505(b)(2) or ANDA filing (or other MARKETING AUTHORIZATION) contemplated herein shall be owned by and in the name of EAGLE, including all information and data contained therein or used to support such filing.

8. **Representations, Warranties; Covenants; Limitation of Liability**

8.1 By Both PARTIES. Each PARTY represents and warrants to the other that as of the EFFECTIVE DATE: (a) it has the full corporate power to enter into and perform this AGREEMENT; (b) this AGREEMENT constitutes its legal, valid and binding obligation; (c) neither it nor any of its contractors is debarred, or is in the process of being debarred, under the Generic Drug Enforcement Act of 1992, 21 U.S.C. §335; (d) each of such PARTY'S employees, officers, contractors and consultants has executed an agreement that requires such employee, officer, contractor or consultant, to the extent permitted by LAW, to assign all INVENTIONS, PATENTS, and KNOW-HOW made by or on behalf of such PARTY during the course of and as a result of the performance of such PARTY'S obligations under this AGREEMENT, to such PARTY; and (e) each of such PARTY'S employees, officers, contractors and consultants is subject to an executed agreement that requires such employee, officer, contractor or consultant to maintain as confidential any information CONTROLLED by such PARTY, or provided by the other PARTY, that is CONFIDENTIAL INFORMATION under this AGREEMENT.

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8.2 By EAGLE; Diligence.

8.2.1 EAGLE covenants to SCIDOSE that, conditioned upon SCIDOSE's fulfillment of its obligations under this Agreement, upon and after the EFFECTIVE DATE, EAGLE shall use reasonable commercial efforts to (i) develop the PRODUCTS and file for MARKETING AUTHORIZATION for the PRODUCTS in the TERRITORY as quickly as practicable after the successful completion of all stability testing and data required for such MARKETING AUTHORIZATION, including completion of all stability procedures, (ii) obtain approval of the MARKETING AUTHORIZATION for the PRODUCTS in the TERRITORY, and (iii) upon receipt of MARKETING AUTHORIZATION of a PRODUCT, use reasonable commercial efforts to commercialize and market such PRODUCT; provided, however, that Eagle shall have no obligation to hire a hospital sales force for the marketing and selling of Argatroban or [*].

8.2.2 The PARTIES acknowledge and agree that the DEVELOPMENT COMMITTEE shall, prior to MARKETING AUTHORIZATION for Argatroban or [*] (or any 505(b)(2) REPLACEMENT PRODUCT), formulate an expected business plan (which shall include a detailed budget). If at any time EAGLE's GROSS PROFIT MARGIN for such PRODUCTS for two consecutive fiscal quarters is less than, or reasonably expected to be less than the gross margin set forth in such business plan by an amount equal to or greater than [*], then EAGLE shall have no obligation to continue to commercialize or market such PRODUCT.

8.2.3 If at any time EAGLE's GROSS PROFIT MARGIN for the THIRD AND FOURTH PRODUCT (or applicable strength thereof or any REPLACEMENT PRODUCT related thereto) for two consecutive fiscal quarters is less than, or reasonably expected to be less than, [*], then EAGLE shall have no obligation to continue to commercialize or market such PRODUCT.

8.2.4 If the marketing of a PRODUCT is discontinued pursuant to Section 8.2.2 or 8.2.3, the PARTIES shall use their commercially reasonable efforts to sell such PRODUCT to a THIRD PARTY. If the PARTIES are unable to sell such PRODUCT to a THIRD PARTY within one hundred twenty (120) days, then SCIDOSE shall also have the right to require EAGLE, at SCIDOSE'S sole election and cost, to use reasonable efforts to provide SCIDOSE, to the extent permitted by applicable LAW, with access to and use of the 505(b)(2) filing (or other MARKETING AUTHORIZATION) and shall grant to SCIDOSE, WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, a perpetual, irrevocable, royalty-free, non-exclusive license, with the right to sublicense, to such PRODUCT, the SCIDOSE LICENSED TECHNOLOGY, the ASSIGNED

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PATENTS, EAGLE PATENT RIGHTS and EAGLE KNOW-HOW solely to the extent necessary to manufacture, or have manufactured solely for sale in the TERRITORY and to develop, register, and sell such PRODUCT solely in the TERRITORY. In the event that any such license is granted, SCIDOSE shall pay royalties to EAGLE on the sale of such PRODUCT in the TERRITORY, according to the provisions of Articles 3 and 4, applied mutatis mutandi. As between the PARTIES, EAGLE shall be responsible for all development activities, and for the preparation, filing and maintenance of applications for MARKETING AUTHORIZATION for the finished PRODUCT in the TERRITORY.

8.2.5 In the event that EAGLE materially fails to perform its obligations under Section 8.2.1 in respect of any PRODUCT and fails to cure such default within sixty (60) days after SCIDOSE's written notice thereof detailing such default (a "DEFAULT"), SCIDOSE shall have the right to require EAGLE, at SCIDOSE'S sole election and cost, on a PRODUCT-by-PRODUCT basis, to use reasonable efforts to provide SCIDOSE, to the extent permitted by applicable LAW, with access to and use of the 505(b)(2) filing (or other MARKETING AUTHORIZATIONS) in which such DEFAULT occurred, and shall grant to SCIDOSE, WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, a perpetual, irrevocable, royalty-free, non-exclusive license, with the right to sublicense, to the PRODUCT, the ASSIGNED PATENTS, the SCIDOSE LICENSED TECHNOLOGY, the

EAGLE PATENT RIGHTS and the EAGLE KNOW-HOW solely to the extent necessary to manufacture, or have manufactured solely for sale in such country and to develop, register, and sell the PRODUCTS the TERRITORY. In the event that any such license is granted, SCIDOSE shall pay royalties to EAGLE on the sale of such PRODUCT in the TERRITORY, according to the provisions of Articles 3 and 4, applied mutatis mutandi.

8.3 By SCIDOSE. SCIDOSE represents and warrants to EAGLE that (a) SCIDOSE owns all right, title and interest in the ASSIGNED PATENTS and CONTROL over the LICENSED TECHNOLOGY, (b) the formulation for, manufacture, use, import, offer for sale and sale of the PRODUCT, as described in the PATENT APPLICATIONS set forth in Schedule I, does not and will not infringe or misappropriate the intellectual property rights of any THIRD PARTY, (c) EAGLE's exercise of the license to the SCIDOSE LICENSED TECHNOLOGY granted herein will not infringe or misappropriate the intellectual property rights of any THIRD PARTY, (d) SCIDOSE and its employees and contractors complied with, and shall comply with, all LAWS in developing the formulation and manufacturing methods and processes for the PRODUCTS, and (e) neither SCIDOSE nor any of its employees or contractors violated, or will violate, any

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terms of confidentiality or non-compete agreements in developing any of the PRODUCT technology methods, processes or formulations.

8.4 Non-Compete. During the Term, SCIDOSE shall not, directly or indirectly, and shall cause its Affiliates to not, directly or indirectly, (i) develop or perform any formulation or any developmental or other work or studies on or with respect to any PRODUCT for its own use or benefit in the Territory or for the use or benefit of any PERSON in the TERRITORY, or provide any PERSON with access to any intellectual property for the development of parenteral formulations of Argatroban or [*] (or, following the determination of the THIRD AND FOURTH PRODUCTS, any formulation work in respect thereof or, as applicable any REPLACEMENT PRODUCT) in any strength; (ii) manufacture for, or supply to, any PERSON any parenteral formulations of Argatroban or [*] (or, following the determination of the THIRD AND FOURTH PRODUCTS, any formulation work in respect thereof or, as applicable any REPLACEMENT PRODUCT), in any strength, for sale anywhere in the TERRITORY; or (iii) sell or distribute any parenteral formulations of Argatroban or [*] (or, following the determination of the THIRD AND FOURTH PRODUCTS, any formulation work in respect thereof or, as applicable any REPLACEMENT PRODUCT), in any strength, anywhere in the TERRITORY.

8.5 Limitation of Liability and Exclusion of Damages.

8.5.1 EXCEPT IN THE CASE OF (A) A BREACH OF ARTICLE 5, (B) THIRD PARTY CLAIMS AND (C) CLAIMS REGARDING INFRINGEMENT (THE LIMITATIONS OF WHICH ARE GOVERNED BY SECTIONS 8.5.2 AND 8.5.3 BELOW, WITHOUT LIMITING THE PARTIES' OBLIGATIONS UNDER ARTICLE 8, IN NO EVENT SHALL SCIDOSE'S LIABILITY TO EAGLE ARISING OUT OF THIS AGREEMENT EXCEED [*] OF THE ROYALTIES PAID TO SCIDOSE BY EAGLE IN ANY CALENDAR YEAR.

8.5.2 WITH RESPECT TO INFRINGEMENT CLAIMS OTHER THAN "AT-RISK" (AS DEFINED IN SECTION 8.5.3 BELOW), THE LIMITATION PROVIDED IN SECTION 8.5.1 SHALL NOT APPLY; PROVIDED, HOWEVER, THAT (A) IN NO EVENT IN ANY CALENDAR YEAR SHALL SCIDOSE BE OBLIGATED TO MAKE PAYMENTS IN SATISFACTION OF ITS OBLIGATIONS PROVIDED IN SECTION 11.1.3 THAT EXCEED [*] OF THE ROYALTIES PAID TO SCIDOSE BY EAGLE IN SUCH CALENDAR YEAR AND (B) IN NO EVENT SHALL SCIDOSE'S LIABILITY IN RESPECT OF SUCH CLAIMS EXCEED A MAXIMUM AMOUNT EQUAL TO THE TOTAL AMOUNT RECEIVED BY SCIDOSE UNDER THIS AGREEMENT INCLUDING, FOR THE AVOIDANCE OF DOUBT, ALL MILESTONE PAYMENTS AND ROYALTY PAYMENTS.

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8.5.3 In the event the parties' elect to launch a PRODUCT "at-risk" (i.e., to commence selling a PRODUCT where prior to the first commercial sale of the PRODUCT there is a claim that the PRODUCT infringes upon third party patent rights and the patent litigation regarding such claim has not been concluded), SCIDOSE agrees that [*] of all royalties paid by EAGLE with respect to such PRODUCT shall be placed in escrow pending resolution of the claim of infringement. In the event it is determined that the PRODUCT does infringe upon a THIRD PARTY patent, the amounts held in escrow shall be applied towards payment required as a result of such determination and, as required, SCIDOSE shall be liable for up to [*] of all royalties paid by EAGLE with respect to such PRODUCT. In the event it is determined that the PRODUCT does not infringe upon a THIRD PARTY patent, such escrowed funds shall be released to SCIDOSE.

8.5.4 EXCEPT IN THE CASE OF (A) A BREACH OF ARTICLE 5, (B) THIRD PARTY CLAIMS AND (C) CLAIMS REGARDING INFRINGEMENT, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING WITHOUT LIMITATION, DAMAGES RESULTING FROM LOSS OF USE, LOSS OF PROFITS, INTERRUPTION OR LOSS OF BUSINESS OR OTHER ECONOMIC LOSS) ARISING OUT OF THIS AGREEMENT OR WITH RESPECT TO A PARTY'S PERFORMANCE OR NON-PERFORMANCE HEREUNDER EVEN IF ADVISED OF THE POSSIBILITY THEREOF.

The limitation on liability and exclusion of damages under this Section 8.5: (i) apply even if a PARTY had or should have had knowledge, actual or constructive, of the possibility of such damages; (ii) are a fundamental element of the basis of the bargain between the PARTIES and this AGREEMENT would not be entered into without such limitations and exclusions and (iii) shall apply whether a claim is based on breach of contract, breach of warranty, tort (including negligence), product liability, strict liability or otherwise, and notwithstanding any failure of essential purpose of any limited remedy herein. Moreover, the remedies under this AGREEMENT are intended to be exclusive, and the limitation on liability and exclusion of damages under this Section 8.5 are intended to apply even if there is a total and fundamental breach of this AGREEMENT, and the essential purpose of these provisions is to limit the PARTIES' respective liabilities hereunder.

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9. Indemnification; Insurance

9.1 Indemnity.

9.1.1 By SCIDOSE. Subject to the limitations set forth in Article 9, SCIDOSE shall defend, indemnify and hold EAGLE, EAGLE'S AFFILIATES, EAGLE'S LICENSEES, EAGLE's SUBLICENSEES and the respective shareholders, directors, officers, employees, representatives and agents of each of the foregoing (each, a "EAGLE INDEMNITEE") harmless from and against all losses, liabilities, damages, costs and expenses (including reasonable attorneys' fees and costs of investigation and litigation, regardless of outcome) resulting from all claims, demands, actions and other proceedings by or on behalf of any THIRD PARTY (including any governmental authority) (collectively, "CLAIMS") to the extent arising from: (a) the breach of any representation, warranty, covenant or material obligation of SCIDOSE under this AGREEMENT; or (b) the negligence, recklessness or willful misconduct of SCIDOSE in the performance of its obligations under this AGREEMENT, except in each case to the extent such claim, demand, action or proceeding arises from EAGLE'S material breach of this AGREEMENT or the negligence, recklessness or willful misconduct of a EAGLE INDEMNITEE.

9.1.2 By EAGLE. EAGLE shall defend, indemnify and hold SCIDOSE, SCIDOSE'S AFFILIATES, and the respective shareholders, directors, officers, employees and agents of each of the foregoing (each, a "SCIDOSE INDEMNITEE") harmless from and against all losses, liabilities, damages, costs and expenses (including reasonable attorneys' fees and costs of investigation and litigation, regardless of outcome) resulting from all CLAIMS to the extent arising from: (a) the breach of any representation, warranty, covenant or material obligation of EAGLE under this AGREEMENT; or (b) the negligence, recklessness or willful misconduct of EAGLE or its LICENSEES or any of their respective THIRD PARTY agents or subcontractors in the performance of its or their obligations under this AGREEMENT, except in each case to the extent such claim, demand, action or proceeding arises from SCIDOSE'S material breach of this AGREEMENT or the negligence, recklessness or willful misconduct of a SCIDOSE INDEMNITEE.

9.2 Insurance. EAGLE, at its own expense, shall maintain comprehensive general liability insurance, excluding product liability insurance, in the minimum amount of [*] per occurrence and in the aggregate and shall maintain product liability insurance in the minimum amount of [*] per occurrence and [*] in the aggregate. Such policies shall include a provision that SCIDOSE shall be given thirty (30) days written notice prior to cancellation or material change, including non-payment, in such a policy. The insurance carriers must be rated A-, VII or better by A.M. Best Company. EAGLE shall maintain such insurance for the TERM, and shall from time to time provide copies of certificates of such insurance to SCIDOSE upon its request. If the insurance policy is written on a claims-made

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basis then the coverage must be kept in place for at least three (3) years after the termination of this AGREEMENT.

SCIDOSE, at its own expense, shall maintain comprehensive general liability insurance, in the initial minimum amount of [*] per occurrence and [*] in the aggregate, along with general umbrella insurance in the additional amount of at least [*], and thereafter in such amounts as the shall be reasonably determined by the parties. Such policies shall include a provision that EAGLE shall be given thirty (30) days written notice prior to cancellation or material change, including non-payment, in such a policy. The insurance carriers must be rated A-, VII or better by A.M. Best Company. SCIDOSE shall maintain such insurance for the TERM, and shall from time to time provide copies of certificates of such insurance to EAGLE upon its request. If the insurance policy is written on a claims-made basis then the coverage must be kept in place for at least three (3) years after the termination of this AGREEMENT.

9.3 Procedures. If any CLAIM covered by Section 9.1 is brought: (i) the indemnified PARTY shall promptly notify the indemnifying PARTY in writing of such CLAIM, (ii) the indemnifying PARTY shall assume, at its cost and expense, the sole defense of such CLAIM through counsel selected by the indemnifying PARTY and reasonably acceptable to the other PARTY, except that those indemnified may at their option and expense select and be represented by separate counsel and if they so participate, (iii) the indemnifying PARTY and those indemnified shall cooperate with one another in such defense; (iv) the indemnifying PARTY shall maintain control of such defense, except that the indemnifying PARTY may settle a CLAIM as to one indemnified only with the consent of such person or entity, not to be unreasonably withheld; (v) the indemnifying PARTY will have authority to consent to the entry of any judgment, to enter into any settlement or otherwise to dispose of such CLAIM, provided that the indemnifying PARTY obtains the prior written consent of those indemnified, not to be unreasonably withheld; and (vi) the indemnifying PARTY shall pay the full amount of any judgment, award or settlement with respect to such CLAIM and all other costs, fees and expenses that have been incurred or agreed, as the case may be, by the indemnifying PARTY in its defense or settlement of the CLAIM. In the event that the indemnifying PARTY fails to promptly assume

defense of any such CLAIM, or to continue to vigorously defend such CLAIM, the indemnified PARTY, in its sole discretion, may take control of the action at the indemnifying PARTY'S expense.

10. **INVENTIONS, KNOW-HOW and PATENTS**

10.1 Existing Intellectual Property. Other than as expressly provided in this AGREEMENT, neither PARTY grants nor shall be deemed to grant any right, title or interest to the other PARTY in any PATENT, PATENT APPLICATION,

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KNOW-HOW or other intellectual property right owned or CONTROLLED by such PARTY.

10.2 Disclosure. Each PARTY shall promptly disclose to the other in writing all INVENTIONS arising from separate activities relating to improvements to the PRODUCT and all INVENTIONS arising from joint activities (including any INVENTIONS first made, conceived or first reduced to practice as a result of such activities), or those of its agents or independent contractors, in connection with the performance of its obligations or activities under this AGREEMENT.

10.3 Ownership of INVENTIONS. Except for INVENTIONS that fall within the definition of ASSIGNED PATENTS and are therefore owned by EAGLE pursuant to Section 2.1, (a) all INVENTIONS made solely by employees, agents or independent contractors of a PARTY during the performance of this AGREEMENT (each, a "SOLE INVENTION") shall be the exclusive property of such PARTY, and (b) if employees, agents or independent contractors of each of SCIDOSE and EAGLE jointly develop any INVENTION during the performance of activities conducted in connection with this AGREEMENT (each, a "JOINT INVENTION"), EAGLE and SCIDOSE shall each own an undivided one-half(%) interest in and to such JOINT INVENTION, and shall have the right to freely exploit and grant licenses under any such JOINT INVENTION and any PATENT claiming such JOINT INVENTION without consent of or a duty of accounting to the other PARTY. For the avoidance of doubt, the determination as to whether an INVENTION has been "solely" or "jointly" made shall be based upon whether employees, agents or independent contractors of a PARTY would be or are properly named as an inventor on a corresponding PATENT APPLICATION under United States inventorship LAWS.

10.4 Individual PATENT Filings. Each PARTY shall have sole discretion and right to prepare, file, prosecute, maintain and defend PATENT APPLICATIONS or PATENTS for INVENTIONS it solely owns under this AGREEMENT, and shall be responsible for related interference proceedings. Each PARTY shall confer with the other PARTY and shall give due consideration to the other PARTY'S suggestions regarding the prosecution of such PATENT APPLICATIONS, and shall copy the other PARTY on any official actions and submissions in such PATENT APPLICATIONS. Costs incurred with respect to PATENT APPLICATIONS shall be borne by the PARTY with the right to prosecute each such PATENT APPLICATION. For the avoidance of doubt, EAGLE shall have the sole discretion and right to prosecute, maintain and defend the PATENT APPLICATIONS included in the ASSIGNED TECHNOLOGY.

10.5 Joint PATENT Filings. With respect to all PATENT APPLICATIONS on JOINT INVENTIONS that are jointly owned by the PARTIES (the "JOINT PATENT APPLICATIONS"), the PARTIES shall determine which PARTY shall be responsible for filing, prosecuting and maintaining PATENT APPLICATIONS

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and PATENTS on behalf of both PARTIES (the "RESPONSIBLE PARTY") based on a good faith determination of the relative contributions of the PARTIES to the INVENTION and the relative interests of the PARTIES in the INVENTION. At least twenty (20) days prior to the contemplated filing of such PATENT APPLICATION, the RESPONSIBLE PARTY shall submit a substantially completed draft of the JOINT PATENT APPLICATION to the other PARTY for its approval, which shall not be unreasonably withheld or delayed. Except as set forth below, the PARTIES shall share equally the costs of the preparation, filing, prosecution and maintenance of all JOINT PATENT APPLICATIONS. If either PARTY elects not to pay its portion of any shared costs for a JOINT PATENT APPLICATION or PATENT issuing therefrom, the other PARTY may proceed with such JOINT PATENT APPLICATION in its own name and at its sole expense, in which case the PARTY electing not to pay its share of costs hereby agrees to transfer and assign and shall transfer and assign its entire right, title and interest in and to such JOINT PATENT APPLICATION to the other PARTY and such INVENTION shall be treated as a SOLE INVENTION of the assignee for the purposes of Sections 10.3 and 10.4 and this Section 10.5.

10.6 Assignment. Notwithstanding anything in this Article 10 to the contrary, nothing herein shall modify or interfere with the assignment to EAGLE of the ASSIGNED PATENTS pursuant to Section 2.1.

10.7 Further Actions. Each PARTY shall cooperate with the other PARTY to execute all documents and take all reasonable actions to effect the intent of this Article 9.

11. **Infringement**

11.1 Infringement of THIRD PARTY Rights.

11.1.1 Notice. If the development, manufacture, use, import or sale of the PRODUCT results in a claim for PATENT infringement by a THIRD PARTY, the PARTY to this AGREEMENT first having notice shall promptly notify the other PARTY in writing. The notice shall set forth the facts of the claim in reasonable detail.

11.1.2 Litigation Related to the PRODUCT. EAGLE shall have the option, but not the obligation, to defend any claim that the development, manufacture, use, import or sale of any PRODUCT infringes a THIRD PARTY patent or misappropriates THIRD PARTY KNOW-HOW. SCIDOSE shall cooperate with EAGLE, at EAGLE's request, in such defense, and shall have the right to be represented by counsel of its own choice, at SCIDOSE'S expense.

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11.1.3 Liability. Notwithstanding anything contained herein to the contrary, in the event of any THIRD PARTY claims a PRODUCT infringes a THIRD PARTY patent or misappropriates THIRD PARTY KNOW-HOW or otherwise brings an action, litigation or Claim relating to a breach of Sections 8.3(b) or (c), subject to Section 8.5.2, SCIDOSE and EAGLE shall [*] of the costs and expenses of such litigation (including reasonable attorneys' expenses and fees) and any liability for any damage award or settlement, or any such other Claim. For the avoidance of doubt, in the event EAGLE reasonably expects to incur any costs, expenses and reasonable attorney's fees in connection with any such action or CLAIM or is required to pay any royalties, license fees or such other amounts to a THIRD PARTY in order to develop, make, have made, use, offer for sale, sell, have sold or import the Product in any country, then EAGLE shall have the right to deduct such amounts from royalty payments due to SCIDOSE under this AGREEMENT.

11.2 Infringement By THIRD PARTIES

11.2.1 Notice of Infringement. If any VALID PATENT CLAIM is infringed by a THIRD PARTY, or any KNOW HOW utilized in the manufacture, use, import or sale of the PRODUCT is misappropriated by a THIRD PARTY, the PARTY first having knowledge of such infringement or misappropriation shall promptly notify the other PARTY in writing. The notice shall set forth the facts of such infringement or misappropriation in reasonable detail.

11.2.2 Prosecution of Actions Relating to SCIDOSE LICENSED TECHNOLOGY.

(a) SCIDOSE shall have the primary right, but not the obligation, to institute, prosecute and control any action or proceeding with respect to any infringement by a THIRD PARTY of SCIDOSE LICENSED TECHNOLOGY using counsel of its own choice, at its own expense. EAGLE shall cooperate with SCIDOSE at SCIDOSE'S request and expense in the prosecution of such action or proceeding. If SCIDOSE determines that EAGLE is an indispensable PARTY to the action, EAGLE hereby consents to be joined, and SCIDOSE shall defend, indemnify and hold each EAGLE INDEMNITEE harmless from any counterclaims filed against such EAGLE INDEMNITEE (except for CLAIMS for which EAGLE has an obligation to defend, indemnify and defend SCIDOSE under Section 9.1.2). EAGLE shall have the right to be represented in that action by its own counsel and at its own expense.

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(b) If SCIDOSE fails to bring an action or proceeding within a period of thirty (30) days after receiving written notice from EAGLE of such infringement or misappropriation by a THIRD PARTY, EAGLE shall have the right to bring and control any such action using counsel of its own choice, and at its own expense. If EAGLE determines that SCIDOSE is an indispensable PARTY to the action, SCIDOSE hereby consents to be joined. In such event, SCIDOSE shall have the right to be represented in such action by its own counsel at its own expense. No settlement, consent judgment or other voluntary final disposition of a suit under this Section 11.2.2 may be entered into without the joint consent of EAGLE and SCIDOSE (which consent shall not be unreasonably withheld or delayed). EAGLE shall be entitled to deduct its costs of litigation from royalty payments due under Section 3.2.

(c) Awards. If either PARTY brings an action for infringement or misappropriation by a THIRD PARTY under this Section 11.2.2, any damages or other monetary awards or payments in settlement recovered by such PARTY shall be applied first to defray the costs and expenses incurred by both PARTIES in the action. Any remainder shall be [*] by the PARTIES [*] of any amount thereafter shall be retained by the PARTY bringing the action, and the balance retained by the other PARTY.

11.2.3 Prosecution of Actions Related to the Products.

(a) Except as otherwise provided in Section 11.2.2, EAGLE shall have the primary right, but not the obligation, to institute, prosecute and control any action or proceeding with respect to infringement or misappropriation by a THIRD PARTY in the TERRITORY of any PATENT, PATENT APPLICATION or KNOW-HOW owned or CONTROLLED by EAGLE related to any PRODUCT, using counsel of its own choice, at its own expense. SCIDOSE shall cooperate with EAGLE at EAGLE's request and expense in the prosecution of such action or proceeding. If EAGLE determines that SCIDOSE is an

indispensable PARTY to the action, SCIDOSE hereby consents to be joined, and EAGLE shall defend, indemnify and hold each SCIDOSE INDEMNITEE harmless from any counterclaims filed against such SCIDOSE INDEMNITEE (except for CLAIMS for which SCIDOSE has an obligation to defend, indemnify and defend EAGLE under Section 9.1.1). In such event, SCIDOSE shall have the right to be represented in that action by its own counsel and at its own expense. EAGLE shall be

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entitled to deduct its costs of litigation from royalty payments due under Section 3.2.

(b) If EAGLE fails to bring an action or proceeding within a period of thirty (30) days after receiving written notice from SCIDOSE of such infringement or misappropriation by a THIRD PARTY related to any PRODUCT, SCIDOSE shall have the right to bring and control any such action using counsel of its own choice, and at its own expense. If SCIDOSE determines that EAGLE is an indispensable PARTY to the action, EAGLE hereby consents to be joined, and SCIDOSE shall defend, indemnify and hold each EAGLE INDEMNITEE harmless from any counterclaims filed against such EAGLE INDEMNITEE. In such event, EAGLE shall have the right to be represented in such action by its own counsel at its own expense. No settlement, consent judgment or other voluntary final disposition of a suit under this Section 11.2.3 may be entered into without the joint consent of both EAGLE and SCIDOSE (which consent shall not be unreasonably withheld or delayed).

(c) Awards. If either PARTY brings an action for infringement or misappropriation by a THIRD PARTY under this Section 11.2.3, any damages or other monetary awards or payments in settlement recovered by such PARTY shall be applied first to defray the costs and expenses incurred by both PARTIES in the action. Any remainder shall be [*] by the PARTIES as [*] of any amount thereafter shall be retained by the PARTY bringing the action, and the balance retained by the other PARTY.

12. **Further Responsibilities of SCIDOSE**

12.1 Within ten (10) business days after the EFFECTIVE DATE, SCIDOSE shall provide EAGLE with all data generated before the EFFECTIVE DATE that relates to the formulation, process and manufacturing of the PRODUCTS and shall promptly provide to EAGLE any such additional data that is generated during the Term. All such data shall be for the exclusive use of EAGLE in the TERRITORY.

12.2 SCIDOSE shall promptly provide EAGLE with all validated analytical methods for the testing of the Argatroban and [*] PRODUCTS and Argatroban and [*] active pharmaceutical ingredient required for filing and maintenance of MARKETING AUTHORIZATIONS for the PRODUCTS in the TERRITORY.

12.3 SCIDOSE shall promptly provide EAGLE with all stability data generated on research formulations and pilot batches of the PRODUCTS. Furthermore,

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SCIDOSE shall successfully complete all research stability studies and promptly provide EAGLE with all data therefrom.

12.4 SCIDOSE shall provide EAGLE with technical support as reasonably requested by EAGLE relating to the scale-up of the manufacturing process for the PRODUCTS and the manufacturing of the FDA filing lots of the PRODUCTS at EAGLE's contract manufacturer. In addition, SCIDOSE will assist EAGLE in responding to FDA questions on the 505(b)(2) filing that relate to the manufacturing process of such PRODUCT or related analytical methods.

12.5 SCIDOSE shall promptly provide EAGLE with all information, back-up information, data and correspondence utilized in the filing of the ASSIGNED PATENTS. Furthermore, SCIDOSE shall assist EAGLE with the compilation of information for and filing of further PATENT APPLICATIONS relating to the PRODUCT in the TERRITORY. All such PATENT APPLICATIONS shall be owned by EAGLE.

12.6 SCIDOSE shall assist EAGLE in gathering toxicology information from the literature or any other scientific information required to support the 505(b)(2) filings for the Argatroban and [*] PRODUCTS.

12.7 All reasonable, out-of-pocket costs and expenses pre-approved by EAGLE, including travel expenses, incurred by SCIDOSE in the performance of its activities under this Article 12 shall be borne by EAGLE.

13. **Term and Termination**

13.1 Expiration. The term of this AGREEMENT (the "TERM") shall commence on the EFFECTIVE DATE and shall expire upon the expiration of all royalty obligations, unless earlier terminated as provided herein.

13.2 Termination for Default. Each PARTY shall have the right to terminate this AGREEMENT by written notice to the other PARTY for a material failure to comply with the terms of this AGREEMENT by the other PARTY, provided such failure to comply is not corrected by the failing PARTY within [*] after written notice of any failure to make timely payment of royalties or any other amount, when due hereunder, or within [*] after receipt of written notice of any other failure from the non-failing PARTY.

13.3 Additional Termination Rights. The PARTIES hereto shall have the additional termination rights:

13.3.1 If the costs and expenses of the clinical trials for Argatroban or [*] are reasonably expected to be greater than [*], then EAGLE may terminate this Agreement with respect to such PRODUCT.

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13.3.2 If either or both of the 505(b)(2) applications for Argatroban or [*] has not been accepted by the FDA on or before the date that is [*] from the EFFECTIVE DATE, then Eagle may terminate this Agreement with respect to such PRODUCT.

13.3.3 If the PARTIES reasonably determine that a generic version of [*] will enter the market prior to [*], then the PARTIES may mutually agree to terminate this Agreement in respect of [*].

13.4 Effect of Termination.

13.4.1 Except as other wise provided in Section 13.4.3 below, the provisions of Sections 2.1 (further assurances), 2.2 (license), 2.3, 2.4, 2.6 (further assurances), 3.3, 7.4, 8.5, 12.7, 13.4, 16.2, 16.4, 16.7, 16.9 and 16.10 and Articles 5, 6, 9, 10, 11, 14 and 15 (and in each case together with any defined terms applicable to such provisions) shall survive termination of this AGREEMENT for any reason whatsoever.

13.4.2 If this AGREEMENT is terminated by EAGLE pursuant to Section 13.2, then EAGLE shall have an exclusive, royalty-free, fully-paid up, perpetual license to the LICENSED TECHNOLOGY to make, sell and have sold the PRODUCTS in the TERRITORY.

13.4.3 If this AGREEMENT is terminated by SCIDOSE pursuant to Section 13.2 or 13.3, then EAGLE shall (A) transfer and assign to SCIDOSE all rights to (i) the ASSIGNED PATENTS and (ii) the MARKETING AUTHORIZATIONS to the PRODUCT and (B) automatically be deemed to have granted to SCIDOSE, WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, a perpetual, irrevocable, royalty-free, exclusive license, with the right to sublicense, to the PRODUCT, the SCIDOSE LICENSED TECHNOLOGY, the ASSIGNED PATENTS, the EAGLE PATENT RIGHTS and the EAGLE KNOW-HOW solely to the extent necessary to manufacture, or have manufactured anywhere in the world solely for sale in the TERRITORY and develop, register, and sell and have sold the PRODUCTS in the TERRITORY. If the event EAGLE fails to execute any document or instrument necessary to effectuate the foregoing, EAGLE hereby grants an irrevocable power of attorney to SCIDOSE solely for such purposes. In the event of a termination of this AGREEMENT pursuant to Section 13.2, Sections 3.3, 5.1-5.3 (but only with respect to PRODUCTS sold by EAGLE), 7.4, 8.5, 12.7, 13.4, 16.2, 16.4, 16.7, 16.9 and 16.10 and Articles 6, 9, 10, 14 and 15 (and in each case together with any defined terms applicable to such provisions) shall survive termination of this AGREEMENT.

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13.4.4 If this Agreement is terminated by EAGLE pursuant to Sections 13.3.1, 13.3.2 or 13.3.3, then the license granted by SCIDOSE in respect of such PRODUCT(S) shall terminate immediately and EAGLE shall be entitled to the repayment of the paid milestone in respect of such PRODUCT(S) as if there had been a PRODUCT FAILURE.

13.4.5 If the PARTIES terminate this Agreement pursuant to Section 13.3.3, then [*] shall be deemed a PRODUCT FAILURE and subject to Sections 3.1.2 and 4.1.3, the PARTIES will use their good faith efforts to agree to a REPLACEMENT PRODUCT and the milestones will paid and to be paid will be applied to such new PRODUCT.

13.4.6 This Agreement shall automatically terminate upon the initiation of any proceeding in bankruptcy, reorganization, dissolution, liquidation or arrangement for the appointment of a receiver or trustee to take possession of the assets of a party hereto or similar proceeding under the law for release of creditors by or against a party hereto or if a party hereto shall make a general assignment for the benefit of its creditors. All licenses and rights to licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code (the "Code"), licenses of rights to "intellectual property" as defined under Section 101(35A) of the Code. Either party, as a licensee of such rights under this Agreement (the "non-Bankrupt Party"), shall retain and may fully exercise all of its rights and elections under the Code, and upon commencement of a bankruptcy proceeding by or against the other party (the "Bankrupt Party") under the Code, shall be entitled to a complete duplicate of, or complete access to (as the non-Bankrupt Party deems appropriate), any such intellectual property and all embodiments of such intellectual property. Such intellectual property and all embodiments thereof shall be promptly delivered to the non-Bankrupt Party (a) upon any such commencement of a bankruptcy proceeding upon written request therefor by the non-Bankrupt Party, unless the Bankrupt Party elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under (a) above, upon the rejection of this Agreement by or on behalf

of the Bankrupt Party upon written request therefor by the non-Bankrupt Party, and each party hereby acknowledges and agrees that the foregoing shall serve as its consent to such transfer of the intellectual property and all embodiments thereof. The foregoing provisions of this Section 13.4.6 are without prejudice to any rights the non-Bankrupt Party may have arising under the Code or other applicable law.

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13.4.7 Notwithstanding anything in this AGREEMENT to the contrary, if this AGREEMENT is terminated for any reason whatsoever, EAGLE shall pay SCIDOSE all accrued milestone payments and accrued royalties in accordance with the terms of this AGREEMENT.

13.4.8 Termination of this AGREEMENT by a PARTY shall not be an exclusive remedy and all other remedies will be available to the terminating PARTY, in equity and at LAW.

13.4.9 If this Agreement is terminated in respect of any Product, then this Agreement shall continue in full force and effect in respect of any other the Product.

13.4.10 The termination or expiration of this Agreement shall not affect any payment or other obligations or liabilities that have accrued prior to or on the date of such termination or expiration, and the PARTIES shall retain all rights and remedies (at law or in equity) in respect of any breach hereof.

14. **Assignment**

Unless otherwise expressly permitted hereunder, neither PARTY may assign any of its rights or delegate any of its duties under this AGREEMENT without the prior written consent of the other PARTY, except that either PARTY may assign its rights and responsibilities hereunder without the other PARTY'S consent as part of: (i) either (a) the sale of all or substantially all of the assets or the entire business to which this AGREEMENT relates or (b) a merger, consolidation, reorganization or other combination with or into another person or entity; or (ii) the transfer or assignment to an AFFILIATE, in each case, pursuant to which the surviving entity or assignee assumes the assigning or merging PARTY'S obligations hereunder in writing. Subject to confidentiality obligations, each PARTY shall use reasonable efforts to notify the other PARTY at least thirty (30) days in advance of any such assignment. Any assignment made in violation of this Article 14 shall be null and void. Notwithstanding the foregoing, EAGLE acknowledges that SCIDOSE intends to use TherDose Parma Limited, an Indian Private Limited company, solely to perform analytical testing for the PRODUCTS, and SCIDOSE agrees that it shall remain responsible to EAGLE for all acts and omissions of Thermoses.

15. **Notices**

Any notice or other communication or payment herein required or permitted to be given shall be deemed sufficient if and when personally delivered in writing or if and when given by United States registered or certified mail, postage prepaid, return receipt requested, properly addressed to the respective addresses of the PARTIES as written below. Notices so given shall be effective upon the earlier to occur of (i) receipt by the

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PARTY to which notice is given, or (ii) the fourth (41) business day following the date such notice was posted, whichever occurs first.

If to EAGLE, addressed to:

Eagle Pharmaceutical, Inc.
470 Chestnut Ridge
Woodcliff Lake, NJ 07677
Attn: Scott Tariff, Chief Executive Officer

Fax: With copies (which shall not constitute notice), to:

Orrick, Herrington & Sutcliffe LLP
666 Fifth Avenue
New York, NY 10103
Attn: R. King Milling, Jr., Esq.
Fax: (212) 506-5151

If to SCIDOSE, addressed to:

SciDose, LLC
123 Blackberry Lane
Amherst, MA 01002

Attention: Joseph F. Bohan
President & CEO

With copies (which shall not constitute notice), to:

Cohen Tauber Spievack & Wagner LLP
420 Lexington Avenue, Suite 2400
New York, New York 10170
Attention: Laurence Tauber

16. **Miscellaneous**

16.1 Force Majeure. Neither PARTY shall be held liable or responsible to the other PARTY nor be deemed to have defaulted under or breached this AGREEMENT for failure or delay in fulfilling or performing any term of this AGREEMENT to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of the affected PARTY; provided, however, that the foregoing shall not be applied to excuse or delay any payment obligation of EAGLE under this AGREEMENT; provided, further, that upon cessation of such force majeure event, such PARTY shall promptly resume performance hereunder. Notwithstanding the foregoing, in the event that any force majeure event shall continue for more than ninety (90) days, the PARTY not subject to

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such force majeure event may, in its sole discretion, terminate this AGREEMENT upon written notice to the other PARTY.

16.2 Severability. All the terms and provisions of this AGREEMENT are distinct and severable, and if any term or provision is held unenforceable, illegal or void in whole or in part by any court, regulatory authority or other competent authority it shall to that extent be deemed not to form part of this AGREEMENT, and the enforceability, legality and validity of the remainder of this AGREEMENT shall not be affected thereby.

16.3 Variation. This AGREEMENT may not be amended, varied or modified in any manner except by an instrument in writing signed by a duly authorized officer or representative of each PARTY hereto.

16.4 Forbearance and Waiver. No waiver by a PARTY in respect of any breach shall operate as a waiver in respect of any subsequent breach. No forbearance, failure or delay by a PARTY in exercising any right or remedy shall operate as a waiver thereof, nor shall any single or partial forbearance, exercise or waiver of any right or remedy prejudice its further exercise of any right or remedy under this AGREEMENT or at LAW.

16.5 Counterparts. This AGREEMENT may be executed in more than one counterpart, each of which constitutes an original and all of which together shall constitute one enforceable agreement.

16.6 No Partnership. The relationship of the PARTIES is that of independent contractors and this AGREEMENT shall not operate so as to create a partnership or joint venture of any kind between the PARTIES.

16.7 Construction. The PARTIES have participated jointly in the negotiation and drafting of this AGREEMENT. In the event that an ambiguity or question of intent or interpretation arises, this AGREEMENT shall be construed as if drafted jointly by the PARTIES and no presumption or burden of proof shall arise favoring or disfavoring any PARTY by virtue of the authorship of any of the provisions of this AGREEMENT. Except where the context otherwise requires, where used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word “or” is used in the inclusive sense (and/or). The captions of this AGREEMENT are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this AGREEMENT or the intent of any provision contained in this AGREEMENT. The term “including” as used herein means “including without limitation.”

16.8 Entire Agreement. This AGREEMENT and Schedules attached hereto constitute the entire understanding between the PARTIES and supersedes any prior or

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contemporaneous written or oral understanding, negotiations or agreements between and among them respecting the subject matter hereof. This AGREEMENT shall be binding upon, and inure to the benefit of, the PARTIES and their respective successors and assigns.

16.9 Governing LAW. This AGREEMENT shall be governed by and construed in accordance with the LAWS of the State of Delaware without regard to its or any other jurisdiction’s choice of LAW rules. Any disputes under this AGREEMENT shall be brought in the state or federal courts located in New York. The PARTIES submit to the personal jurisdiction of such courts for any such action, agree that such courts provide a convenient forum for any such action, and waive any objections or challenges to venue with respect to such courts.

16.10 Publicity. Except as otherwise provided in Article 5 and subject to either PARTY'S reporting obligations under applicable state and federal (including securities) LAWS, SCIDOSE and EAGLE shall not use the other PARTY'S name in publicity materials or other public disclosures without the prior written consent of the other PARTY, such consent not to be unreasonably withheld or delayed. Notwithstanding the foregoing, SCIDOSE and EAGLE shall prepare and issue a joint press release reasonably acceptable to both PARTIES announcing the relationship created under this AGREEMENT. During the TERM, EAGLE shall inform SCIDOSE prior to issuing a press release or other public disclosure regarding the achievement of clinical or other developmental milestones for a PRODUCT. If EAGLE intends to mention in such public disclosure the use of proprietary technology in a PRODUCT as having been developed by SCIDOSE, such mention must be approved in writing by SCIDOSE (such approval not to be unreasonably withheld or delayed).

16.11 Termination of NON-DISCLOSURE AGREEMENT. All provisions of, rights granted and covenants made in the NON-DISCLOSURE AGREEMENT are hereby terminated and of no further force and effect and are superseded in their entirety by the provisions of, rights granted and covenants made in this AGREEMENT. The PARTIES acknowledge and agree that any disclosure made pursuant to the NON-DISCLOSURE AGREEMENT shall be governed by the terms and conditions of Article 5 of this AGREEMENT.

16.12 Compliance with LAWS. Each PARTY will comply with all LAWS in performing its obligations and exercising its. rights hereunder. Nothing in this AGREEMENT shall be deemed to permit EAGLE or its LICENSEES to export, re-export or otherwise transfer any information or materials transferred hereunder or PRODUCT manufactured therefrom without complying with LAWS.

[Signature Page Follows]

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IN WITNESS WHEREOF, the PARTIES hereto have caused their authorized representatives to execute this AGREEMENT by signing below:

Signed:

For and on behalf of:		For and on behalf of:	
SCIDOSE, LLC		EAGLE PHARMACEUTICAL, INC.	
Signature	/s/ Joseph F. Bohan	Signature	/s/ Scott Tarriff
Name:	Joseph F. Bohan	Name:	Scott Tarriff
Title:	President & CEO	Title:	Chief Executive Officer

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SCHEDULE I

PATENT APPLICATIONS

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SCHEDULE II

Milestones

Pursuant to Section 3.1, the following payments shall be payable by EAGLE to SCIDOSE upon occurrence of the following milestone events with respect to each of the PRODUCTS:

Milestone Event	Milestone Payment (US DOLLARS)
Upon the execution of this AGREEMENT	[*]
On or before [*]	[*]

On or before [*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]

SCHEDULE III

MILESTONES TO BE COMPLETED BY SCIDOSE

Item	Description of Activity	Timing
1	FDA acceptance of the 505(b)(2) for the Argatroban and [*] PRODUCTS	[*] months from execution of this Agreement
2	FDA acceptance of the 505(b)(2) or ANDA filings for the additional two PRODUCTS	[*] months from the transfer of technical information by SCIDOSE to EAGLE

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SCHEDULE IV

Allocation of Milestones

Product	Signing Date	FDA filing Acceptance of 505(b)(2) or ANDA (as applicable)	Commercial Launch
Argatroban	[*]	[*]	[*]
[*]	[*]	[*]	[*]
Product#3	[*]	[*]	[*]
Product #4	[*]	[*]	[*]

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AMENDMENT NO. 1 TO
DEVELOPMENT AND LICENSING AGREEMENT

THIS AMENDMENT NO. 1 TO THE DEVELOPMENT AND LICENSING AGREEMENT (this "**Amendment**") is made as of March 18, 2008 (the "**Amendment Date**"), by and between Eagle Pharmaceuticals, Inc. ("**EAGLE**"), and SciDose LLC, ("**SCIDOSE**"), and amends that certain Development and Licensing Agreement dated as of June 12, 2007, (the "**Original Agreement**"), by and between the EAGLE and SCIDOSE. Capitalized terms used herein and not otherwise defined shall have the meanings ascribed to such terms in the Original Agreement.

WHEREAS, EAGLE and SCIDOSE desire to amend the Original Agreement, as more particularly set forth herein.

NOW, THEREFORE, in consideration of the foregoing, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Amendment to Section 1.28 of the Original Agreement is hereby amended by deleting the entire clause thereof and replacing it with:

1.28 "NET SALES" means, with respect to any PRODUCT, the amount invoiced by (or in the absence of an invoice, the amounts payable to) EAGLE or its AFFILIATES for the sale to THIRD PARTIES of such PRODUCT less the following: (i) customary administration fees, drug wholesaler fees, charge-backs, rebates (including Medicaid, Medicare and similar rebates) and trade and customary quantity discounts actually allowed and taken, including shelf stock adjustments, cash and volume discounts, chargebacks, promotional allowances, inventory obsolescence; (ii) allowances whether paid or accrued for returned PRODUCT; (iii) documented freight, postage, shipping costs and insurance paid by EAGLE (if separately stated); (iv) government-mandated and other rebates customary in the industry; (v) value added tax, sales, use or turnover taxes, excise taxes and customs duties and (vi) if applicable, expenses related to (A) PRODUCT recalls in accordance with Section 7.4, (B) infringement litigation in accordance with Sections 11.1.3, 11.2.2(b) and/or 11.2.3(a), and (C) marketing costs (other than SALES FORCE COSTS) directly related to the PRODUCTS (or, as applicable, the REPLACEMENT PRODUCTS related thereto). NET SALES shall be deemed to accrue upon the date of the invoice for the PRODUCT. In addition, NET SALES by EAGLE hereunder are subject to the following, as accrued on EAGLE's book in good faith:

(a) In the case of pharmacy incentive programs, hospital performance incentive program, charge backs, disease management programs, similar programs or discounts on "bundles" of products, all discounts and the like shall be allocated proportionately based on sales of comparable products to THIRD PARTIES on a standalone basis; and

(b) In the case of any sale or other disposal of the PRODUCT by EAGLE to an AFFILIATE for resale, the NET SALES shall be calculated as above on the value charged or invoiced on the first arm's length sale to a THIRD PARTY;

(c) All accruals in accordance with United States Generally Accepted Accounting Principles "US GAAP".

2. Amendment to Section 1.30 of the Original Agreement is hereby amended by deleting the entire clause thereof and replacing it with:

1.30 "PRODUCT(S)" means (i) all parenteral formulations of Argatroban and [*]; (ii) [*] and (iii) BIVALIRUDIN.

3. Amendment to Section 1.35 of the Original Agreement is hereby amended by deleting the entire clause thereof and replacing it with:

1.35 "ROYALTY RATE" means, (i) with respect to Argatroban, [*] and Bivalirudin, [*]; and (ii) with respect to [*], [*].

4. Amendment to Section 1.45 of the Original Agreement is hereby amended by deleting the entire clause thereof and replacing it with:

1.45 "TERRITORY" means worldwide (excluding China) for 505(b)(2) PRODUCT applications, however, TERRITORY means only North America (including the United States, its territories and possessions and Canada) for ANDA PRODUCT applications.

5. Amendment to Section 3.1 of the Original Agreement is hereby amended by the addition of the following clauses thereof:

3.1.5 In the event EAGLE licenses PRODUCT to a THIRD PARTY, any milestone payments received by EAGLE with respect to commercialization of the PRODUCT in the US market [*] between SCIDOSE and EAGLE; however, subject to Section 3.1.4, any milestone payment received with respect to commercialization of the PRODUCT ex-US will be wholly paid to SCIDOSE.

6. Amendment to Section 11.2.3(a) of the Original Agreement is hereby amended by deleting the entire Section 11.2.3(a) thereof and replacing it with:

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11.2.3(a) Except as otherwise provided in Section 11.2.2, EAGLE shall have the primary right, but not the obligation, to institute, prosecute and control any action or proceeding with respect to infringement or misappropriation by a THIRD PARTY in the TERRITORY of any PATENT, PATENT APPLICATION or KNOW-HOW owned or CONTROLLED by EAGLE related to the PRODUCT, using counsel of its own choice, at its own expense. SCIDOSE shall cooperate with EAGLE at EAGLE's request and expense in the prosecution of such action or proceeding. If EAGLE determines that SCIDOSE is an indispensable PARTY to the action, SCIDOSE hereby consents to be joined, and EAGLE shall defend, indemnify and hold each SCIDOSE INDEMNITEE harmless from any counterclaims filed against such SCIDOSE INDEMNITEE (except for CLAIMS for which SCIDOSE has an obligation to defend, indemnify and defend EAGLE under Section 9.1.1). In such event, SCIDOSE shall have the right to be represented in that action by its own counsel and at its own expense. EAGLE shall be entitled to deduct its costs of litigation from royalty payments of any PRODUCT due under Section 3.2.

7. Amendment to Section 13.4 of the Original Agreement is hereby amended by the addition of two following clauses thereof:

13.4.10 In the event of termination by either PARTY pursuant to Section 13.1, 13.2, EAGLE shall have the right, but not the obligation, to sell off any inventory on hand or in transit to EAGLE. For any PRODUCT sales, EAGLE will appropriately pay SCIDOSE its ROYALTY RATE.

13.4.11 In the event SCIDOSE terminates the Agreement pursuant to Section 13.1, 13.2, EAGLE shall have the right to cancel any purchase orders placed, which have not yet shipped.

8. Effect on the Original Agreement. Except as specifically amended herein, the Original Agreement, all other documents, instruments and agreements executed and/or delivered in connection therewith, shall remain in full force and effect, and are hereby ratified and confirmed. As of the Amendment Date, each reference in the Original Agreement to "this Agreement," "hereunder," "hereof," "herein" or words of like import shall mean and be a reference to the Original Agreement as amended hereby.

9. Entire Agreement. The Original Agreement, as modified by this Amendment, and the other writings specifically identified therein and herein or contemplated thereby and hereby, is complete, reflects the entire agreement of the Parties with respect to the subject matter hereof, and supersedes all previous written or oral negotiations, commitments and writings.

[The remainder of this page has been intentionally left blank]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed and delivered by their respective proper and duly authorized representatives as of the date first set forth above.

EAGLE PHARMACEUTICALS, INC.

By: /s/ Scott Tarriff
Name: Scott Tarriff
Title: President and CEO

SCIDOSE, LLC

By: /s/ Joseph Bohan
Name: Joseph Bohan
Title: President and CEO

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

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[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

AMENDMENT NO. 2 TO
DEVELOPMENT AND LICENSING AGREEMENT

THIS AMENDMENT NO. 2 TO THE DEVELOPMENT AND LICENSING AGREEMENT (this "**Amendment**") is made as of March 25, 2008 (the "**Amendment Date**"), by and between Eagle Pharmaceuticals, Inc. ("**EAGLE**"), and SciDose LLC, ("**SCIDOSE**"), and amends that certain Development and Licensing Agreement dated as of June 12, 2007, which was subsequently amended on March 18, 2008, (the "**Original Agreement**"), by and between the EAGLE and SCIDOSE. Capitalized terms used herein and not otherwise defined shall have the meanings ascribed to such terms in the Original Agreement.

WHEREAS, EAGLE and SCIDOSE desire to amend the Original Agreement, as more particularly set forth herein.

NOW, THEREFORE, in consideration of the foregoing, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Amendment to Section 1.45 of the Original Agreement is hereby amended to read in its entirety as it appears in this Amendment:

   1.45 "TERRITORY" means the following:

   (i) Worldwide (excluding China) for [*] and Argatroban.
   (ii) Worldwide for Bivalirudin.
   (iii) North America (including the United States, its territories and possessions and Canada) for [*].

2. Amendment to Section 3.2 of the Original Agreement is hereby amended by the addition of the following sentence at the end of the clause:

   "In the event EAGLE licenses the Bivalirudin PRODUCT to a THIRD PARTY for marketing in China, any Royalties received by EAGLE from such THIRD PARTY license will be [*] to SCIDOSE."

3. Effect on the Original Agreement. Except as specifically amended herein, the Original Agreement, all other documents, instruments and agreements executed and/or delivered in connection therewith, shall remain in full force and effect, and are hereby ratified and confirmed. As of the Amendment Date, each reference in the Original Agreement to "this Agreement," "hereunder," "hereof," "herein" or words of like import shall mean and be a reference to the Original Agreement as amended hereby.

4. Entire Agreement. The Original Agreement, as modified by this Amendment, and the other writings specifically identified therein and herein or contemplated thereby and hereby,

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is complete, reflects the entire agreement of the Parties with respect to the subject matter hereof, and supersedes all previous written or oral negotiations, commitments and writings.

IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed and delivered by their respective proper and duly authorized representatives as of the date first set forth above.

EAGLE PHARMACEUTICALS, INC.

By: /s/ Scott Tarriff
Name: Scott Tarriff

Title: President and CEO

SCIDOSE, LLC

By: /s/ Joseph Bohan
Name: Joseph Bohan
Title: President and CEO

---

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

AMENDMENT NO. 3 TO
DEVELOPMENT AND LICENSING AGREEMENT

THIS AMENDMENT NO. 3 TO THE DEVELOPMENT AND LICENSING AGREEMENT (this "**3rd Amendment**") is made as of December 3rd, 2008 (the "**Amendment Date**"), by and between Eagle Pharmaceuticals, Inc. ("**EAGLE**"), and SciDose LLC, ("**SCIDOSE**"), and amends that certain Development and Licensing Agreement dated as of June 12, 2007, as amended (the "**Original Agreement**"), by and between the EAGLE and SCIDOSE. Capitalized terms used herein and not otherwise defined shall have the meanings ascribed to such terms in the Original Agreement.

WHEREAS, EAGLE and SCIDOSE desire to amend the Original Agreement, as more particularly set forth herein.

NOW, THEREFORE, in consideration of the foregoing, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Amendment to Section 1.30 of the Original Agreement is hereby amended by deleting the entire clause thereof and replacing it with:

1.30 "PRODUCT(S)" means (i) all parenteral formulations of Argatroban, (ii) all parenteral formulations of Bivalirudin, which, from and after the Amendment Date, shall replace any reference to [*] when used in the Original Agreement, (iii) all parenteral formulations of [*], which, from and after the Amendment Date, shall be deemed the THIRD PRODUCT and (iv) [*] which, from and after the Amendment Date, shall be deemed the FOURTH PRODUCT, and together with the THIRD PRODUCT, the THIRD AND FOURTH PRODUCTS.

2. Amendment to Section 1.35 of the Original Agreement is hereby amended by deleting the entire clause thereof and replacing it with:

1.35 "ROYALTY RATE" means (i) with respect to any PRODUCT that is subject to a 505(b)(2) application, [*], and (ii) with respect to any PRODUCT that is subject to an ANDA application, [*].

3. Amendment to Section 1.45 of the Original Agreement is hereby amended by deleting the entire clause thereof and replacing it with:

1.45 "TERRITORY" means the following:

(i) Worldwide (excluding China) for Argatroban, [*] and [*]

(ii) Worldwide for Bivalirudin.

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4. Amendment to Section 1.46 of the Original Agreement is hereby amended by deleting the entire clause thereof and replacing it with:

1.45 "THIRD AND FOURTH PRODUCTS" has the meaning, subject to Section 2.7 of the Original Agreement, set forth in the Amendment to Section 1.30 in the first paragraph of this 3rd Amendment.

5. Amendment to Section 3.1.1 of the Original Agreement is hereby amended by deleting the entire Section 3.1.1 thereof and replacing it with:

EAGLE shall pay to SCIDOSE the respective milestone payments in accordance with and on the respective dates provided in Schedule II hereto. Such milestone payments shall be in addition to any royalty or other payments due under this AGREEMENT and are allocated among the PRODUCTS as follows:

Argatroban	[*]
Bivalirudin	[*]
THIRD PRODUCT	[*]
FOURTH PRODUCT	[*]

6. Amendment to Schedule III of the Original Agreement is hereby amended by deleting the entire schedule thereof and replacing it with:

SCHEDULE III

MILESTONES TO BE COMPLETED BY SCIDOSE

Item	Description of Activity	Timing
1	FDA acceptance of the 505(b)(2) for the Argatroban PRODUCT	[*] months from execution of the Original Agreement

2	FDA acceptance of the 505(b)(2) for the Bivalirudin PRODUCT	[	]
3	FDA acceptance of the 505(b)(2) or ANDA filings for the THIRD AND FOURTH PRODUCTS	[	]

7. Effect on the Original Agreement. Except as specifically amended herein, the Original Agreement, all other documents, instruments and agreements executed and/or delivered in connection therewith, shall remain in full force and effect, and are hereby ratified and confirmed. As of the Amendment Date, each reference in the Original Agreement to "this Agreement," "hereunder," "hereof," "herein" or words of like import shall mean and be a reference to the Original Agreement as amended hereby.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

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8. Entire Agreement. The Original Agreement, as modified by this 3rd Amendment, and the other writings specifically identified therein and herein or contemplated thereby and hereby, is complete, reflects the entire agreement of the Parties with respect to the subject matter hereof, and supersedes all previous written or oral negotiations, commitments and writings.

[The remainder of this page has been intentionally left blank]

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IN WITNESS WHEREOF, the Parties have caused this 3rd Amendment to be executed and delivered by their respective proper and duly authorized representatives as of the date first set forth above.

EAGLE PHARMACEUTICALS, INC.

By: /s/ Scott Tariff
Name: Scott Tarriff
Title: President and CEO

SCIDOSE, LLC

By: /s/ Joseph Bohan
Name: Joseph Bohan
Title: President and CEO

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EXECUTION VERSION

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AGREEMENT

THIS AGREEMENT (this "Agreement") is made as of July 16, 2013 by and between Eagle Pharmaceuticals, Inc. ("EAGLE"), SciDose LLC("SCIDOSE"), Robert One ("ROBERT") and Therdose, LLC ("THERDOSE"; and, collectively with SCIDOSE AND ROBERT, the "SCIDOSE PARTIES").

WHEREAS, EAGLE and the SCIDOSE"PARTIES have entered into various agreements listed on Exhibit A, including amendments thereto and side letters in respect thereof (collectively, the "DEVELOPMENT AGREEMENTS");

WHEREAS, EAGLE and ROBERT desire to amend the DEVELOPMENT AGREEMENTS and have reached other agreements in respect thereof, as more particularly set forth herein.

NOW, THEREFORE, in consideration of the foregoing, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Amendments to the 2008 Eagle/Robert Agreement.

(a) Amendment to Section 1. Section 1 of that certain Development and License Agreement dated as of March 18, 2008, as amended (the "2008 Eagle/Robert Agreement"), by and between the EAGLE and ROBERT is hereby amended by adding the following new definition as a new Section 1.41:

"1.41 "BENDAMUSTINE PRODUCTS" means, together, the Bendamustine parenteral formulation product (i.e., the RTU Bendamustine product licensed hereunder) and EAGLE [*] Bendamustine product.".

(b) Amendment to Section 1.32. The first sentence of Section1.32 of the 2008 Eagle/Robert Agreement is hereby amended by deleting such sentence only and replacing it with:

"1.32 "PRODUCT(S)" means five (5) ANDA or 505(b)(2) products as set forth in Exhibit A, and will expressly include the BENDAMUSTINE PRODUCTS."

(c) Amendment to Section 1.37. Section 1.37 of the 2008 Eagle/Robert Agreement is hereby amended by deleting such Section in its entirety and replacing it with the following:

"1.37 "ROYALTY RATE" means (i) with respect to any PRODUCT that is subject to a 505(b)(2) application, [*] and (ii) with respect to any PRODUCT that is subject to an ANDA application, [*]; provided, however, that, with respect to the BENDAMUSTINE PRODUCTS, the ROYALTY RATE means [*]."

(d) Amendment to Section 3.2. Section 3.2 of the 2008 Eagle/Robert Agreement is hereby amended by deleting such Section its entirety and replacing it with the following:

"For the applicable ROYALTY TERM for each PRODUCT, EAGLE shall pay ROBERT royalties on sales of PRODUCTS by EAGLE and its AFFlLIATES in the TERRITORY in an amount equal to the ROYALTY RATE multiplied by the GROSS PROFIT from the number of units of PRODUCTS sold; provided, however, that, (i) at any time during [*] after the FIRST COMMERCIAL SALE of a PRODUCT, there is no VALID PATENT CLAIM covering the manufacture, use, import or sale of such PRODUCT in a country in the Territory, then (i) with respect to a PRODUCT (or any REPLACEMENT PRODUCT, as applicable) other than the BENDAMUSTINE PRODUCTS, the ROYALTY RATE shall be reduced to [*] in such country. Notwithstanding the foregoing, EAGLE shall no longer have an obligation to pay royalties to ROBERT or any of' its AFFILIATES in respect of the sales of BENDAMUSTINE PRODUCTS after EAGLE has paid royalties to ROBERT in an amount equal to [*] from the sales of BENDAMUSTINE PRODUCTS (the "ROYALTY CAP") and, after EAGLE shall have paid the ROYALTY CAP, the license in respect of the BENDAMUSTINE PRODUCTS shall be [*]."

(e) Amendment to Section 8.4. Section 8.4 of the 2008 Eagle/Robert Agreement is hereby amended by adding the following sentence:

''Notwithstanding the foregoing, ROBERT and any of its AFFILIATES shall be entitled to develop, manufacture and Commercialize ANDA formulations for its own account in respect of [*]."

(f) Effect on the 2008 Eagle/Robert Agreement. Except as specifically amended herein, the 2008 Eagle/Robert Agreement, al1 other documents, instruments and agreements executed and/or delivered in connection then with, shall remain in full force and effect, and are hereby ratified and confirmed.

2. Amendments to the 2009 Eagle/Robert Agreement. On December 23, 2010, the ROBERT and EAGLE amended the February 13, 2009 License and Development Agreement (the "2009 Eagle/Robert Agreement") to include [*] and [*] as PRODUCTS. The parties hereto

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

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agree that such amendment, in respect of such products only, is hereby terminated and of no force and effect and that EAGLE shall have no rights, and ROBERT shall have no obligations, in respect of such products under the 2009 Eagle/Robert Agreement or otherwise. For the avoidance of doubt, except as set forth in this Section 2, the 2009 Eagle/Robert Agreement, all other documents, instruments and agreements executed and/or delivered in connection therewith, shall remain in full force and effect.

3. Sharing of Expenses, Costs and Awards.

(a) The parties hereto agree that any damages award paid to or recovered by EAGLE in the arbitration styled "Eagle Pharmaceutical, Inc. v. The Medicines Company, American Arbitration Association Case# 13 122 Y 02642" (the "Arbitration") shall be [*] by EAGLE and SCIDOSE; provided, however, that, prior to the distribution of any portion of such award to SCIDOSE, EAGLE shall deduct from such award the following:

(i) [*] paid by EAGLE to Greenberg Traurig LLP in respect of the Arbitration through June 30. 2013 (subject to later true up) including [*] as set forth on the exhibit attached hereto;

(ii) excluding fees set forth in Section 3(a)(i) above, any [*] payable by EAGLE to Greenberg Traurig LLP in respect of the Arbitration;

(iii) subject to Section 4 below, [*]; and

(iv) [*] incurred in respect or the development and licensing of the bivalirudin and Arbitration support as set forth on Exhibit C attached hereto.

Payment of SCIDOSl's portion of such award, if not paid directly by The Medicines Company to SCI DOSE, shall be remitted to SCIDOSE within [*] of payment by The Medicines Company.

(b) By way of example, if the award in the Arbitration equals [*], such award would be distributed as follows:

(i) To EAGLE, an amount equal to approximately [*] in reimbursement of amounts previously paid to Greenberg Traurig as described in Section 3(a)(l) above, then

(ii) To Greenberg Traurig, an amount equal to [*] in satisfaction of the amounts described in Section 3(a)(ii) above, then

(iii) To EAGLE, [*] to reimburse EAGLE fix costs incurred in respect of the Arbitration as described in Section 3(a)(iii) above, then

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

(iv) To EAGLE [*] to EAGLE to reimburse EAGLE for out- of-pocket expenses actually incurred as described in Section 3(a)(iv) above, then

(v) To the SCIDOSE PARTIES, [*], and to EAGLE, [*].

4. Side Letter Clarification. Pursuant to a side letter dated May 22, 2009 (the "2009 Side Letter''), the parties hereto acknowledged that, subject to the terms of the 2009 Side Letter, EAGLE shall [*] in creating the 505(b)(2) Data (as defined in the 2009 Side Letter) related to the applicable 505(b)(2) Product (as defined in the 2009 Side Letter). The parties hereto hereby agree that, for purposes of the 2009 Side Letter, "[*] shall mean (i) for Angiomax®) (bivalirudin), [*] of any award in the Arbitration and (ii) for all other products developed and sold under the DEVELOPMENT AGREEMENTS,[*] of GROSS PROFIT (as defined in the DEVELOPMENT AGREEMENTS).

5. Aggregate Limitation on all Payments from EAGLE to SClDOSE PARTIES and AFFILIATES. The parties hereto agree that, during the 90-day period beginning on the date hereof they will negotiate in good faith the parameters, consideration and conditions around a [*] aggregate cap of amounts owed by EAGLE to the SCIDOSE PARTIES under the DEVELOPMENT AGREEMENTS.

6. Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original and any of which shall constitute a single document. A facsimile (or pdf) signature of an authorized signatory of any party hereto shall be valid and binding and constitute due execution and delivery of this Agreement by such party hereto.

7. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of State of Delaware without regard to its conflict of law rules or principles.

[The remainder of this page has been intentionally left blank.]

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IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed and delivered by their respective proper and duly authorized representatives as of the date first set forth above.

EAGLE PHARMACEUTICALS, INC.

By: _____
Name: Scott Tarriff
Title: President and CEO

ROBERT ONE, LLC

By: /s/ Joseph Bohan
Name: Joseph Bohan
Title: President and CEO

SCIDOSE, LLC

By: /s/ Joseph Bohan
Name:
Title:

THERDOSE, LLC

By: /s/Joseph Bohan
Name:
Title:

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IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed and delivered by their respective proper and duly authorized representatives as of the date first set forth above.

EAGLE PHARMACEUTICALS, INC.

By: /s/ Scott Tariff
Name: Scott Tarriff
Title: President and CEO

ROBERT ONE, LLC

By: /s/ Joseph Bohan
Name: Joseph Bohan
Title: President and CEO

SCIDOSE, LLC

By: /s/ Joseph Bhan
Name:
Title:

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THERDOSE, LLC

By: /s/ Joseph Bohan
Name:
Title:

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Exhibit A

List of Agreements between EAGLE and SCIDOSE PARTIES

Agreement Date	Development Partner
June 12, 2007	Development and License Agreement by and between Eagle Pharmaceuticals, Inc. and SciDose, LLC
September 24, 2007	Development and License Agreement by and between Eagle Pharmaceuticals, Inc. and SciDose, LLC
March 18, 2008	Development and License Agreement between Eagle Pharmaceuticals, Inc. and Robert One, LLC
February 13, 2009	Development and License Agreement between Eagle Pharmaceuticals, Inc. and Robert One, LLC

May 22, 2009	Letter Amendment — Eagle & SciDose / Robert One
March 18, 2008	Amendment No. 1 to Development and Licensing Agreement
March 25, 2008	Amendment No. 2 to Development and Licensing Agreement
November 20, 2009	Amendment
December 23, 2010	Letter Amendment — Eagle & SciDose / Robert one
December 3, 2008	Amendment No. 3 to Development and Licensing Agreement

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Exhibit B

	$000's	Commentary
BIVALIRUDIN ARBITRATION		
Greenberg Legal Expenses		
Greenberg Fees	[*]	Greenberg Legal — [*]
*Greenberg Out of Pocket	[*]	Greenberg out of pocket — needs to be reconciled
*Estimated Total Payments made by Eagle through 6/30/13	**[*]**	

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Exhibit C

	$000's	Commentary
Bivalirudin		
Milestone Payment	[*]	6/12/07 Agreement
OOP	[*]	Unreimbursed Eagle expenses ('07-'08)
Orrick — Contracting	[*]	Legal
FLH	[*]	Legal
Clotting	[*]	Clotting Study
***Estimated Total Payments made by Eagle through 6/30/13**	**[*]**	

**All costs are subject to true up*

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Exhibit 10.12

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

EXECUTION VERSION

LICENSE AND SUBLICENSE AGREEMENT

BETWEEN

LYOTROPIC THERAPEUTICS, INC.

AND

EAGLE PHARMACEUTICALS, INC.

Confidential

TABLE OF CONTENTS

		Page
ARTICLE 1	DEFINITIONS	1
1.1	Definitions	1
1.2	Headings; Interpretation	7
ARTICLE 2	SCOPE OF THE COLLABORATION	8
2.1	Objectives	8
ARTICLE 3	GRANT OF RIGHTS	8
3.1	License Grant	8
3.2	Non-Use of Trademarks	9
3.3	United States Law	9
3.4	Additional Covenants and Agreements	9
3.5	Manufacturing	9
ARTICLE 4	DEVELOPMENT PROGRAM	9
4.1	Development Program	9
4.2	Eagle Responsibilities	10
4.3	Lyotropic Responsibilities	11
4.4	Costs and Expenses	11
ARTICLE 5	COMMERCIALIZATION OBLIGATIONS	12
5.1	Regulatory Compliance	12
5.2	Labeling and Patent Marking	12
5.3	Exploitation Efforts	12
5.4	Exploitation Efforts in the United States	12
5.5	Exploitation efforts in Ex-US Regions	12
5.6	Trademarks	13
ARTICLE 6	ROYALTIES AND OTHER CONSIDERATIONS	13
6.1	Royalty Payments	13
6.2	Sublicense by Eagle	13
6.3	Payment Terns	13
6.4	Royalty Term	14

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Confidential

TABLE OF CONTENTS
(continued)

		Page
ARTICLE 7	REPORTS AND RECORDS	14
7.1	Record Retention	14
7.2	Audit	14
7.3	Interest	15
ARTICLE 8	REPRESENTATIONS AND WARRANTIES	15
8.1	Legal Authority	15
8.2	No Conflicts	15
8.3	Litigation	15
8.4	Additional Representations, Warranties and Covenants of Lyotropic	15
8.5	Additional Representations, Warranties and Covenants of Eagle	17
8.6	DISCLAIMER OF WARRANTY	17
ARTICLE 9	CONFIDENTIALITY	17
9.1	Definition	17
9.2	Exclusions	18
9.3	Disclosure and Use Restriction	18
9.4	Authorized Disclosure	18
9.5	Injunctive Relief	19
ARTICLE 10	PATENT PROSECUTION, INFRINGEMENT AND RIGHTS IN DEVELOPED TECHNOLOGY	19
10.1	Prosecution of Lyotropic Patent Rights	19
10.2	Infringement of Lyotropic Patent Rights	20
10.3	Third Party Litigation	21
10.4	EPIL Intellectual Property	21
10.5	Retained Rights	21
10.6	Rights in Developed Technology	21
ARTICLE 11	TERMINATION	22
11.1	Term	22
11.2	Termination Events	22
11.3	Return of Information; Assignment and License	23
11.4	Cumulative Remedies	23
11.5	Effect of Termination	23
11.6	Disposition of Product	24
11.7	Survival	24

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Confidential

TABLE OF CONTENTS
(continued)

		Page
ARTICLE 12	INDEMNIFICATION	24
12.1	Indemnification By Eagle	24
12.2	Indemnification By Lyotropic	24
12.3	Indemnification Procedure	24
12.4	Insurance	26
ARTICLE 13	LIMITATION OF LIABILITY	27
13.1	LIMITATION OF LIABILITY	27
ARTICLE 14	DISPUTE RESOLUTION	27
14.1	Good Faith Negotiations	27
14.2	Arbitration	27

ARTICLE 15 MISCELLANEOUS 28

15.1 Publicity 28
15.2 Assignment 28
15.3 Governing Law 28
15.4 Force Majeure 28
15.5 Waiver 28
15.6 Notices 28
15.7 No Agency 29
15.8 Entire Agreement 30
15.9 Severability 30
15.10 Successors and Assigns 30
15.11 Counterparts 30
15.12 Further Assurances 30

EXHIBIT A LYOTROPIC PATENTS AND PRODUCT PATENTS

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LICENSE AND SUBLICENSE AGREEMENT

This LICENSE AND SUBLICENSE AGREEMENT (this "Agreement") is made and entered into this 16th day of October, 2008 (the "Effective Date"), between Lyotropic Therapeutics, Inc., a Virginia corporation ("Lyotropic"), and Eagle Pharmaceuticals, Inc., a Delaware corporation ("Eagle").

RECITALS

WHEREAS, Lyotropic has exclusive, sublicensable rights under a license from Elan Pharma International Limited, a company incorporated under the laws of Ireland ("EPIL"), to the EPIL Intellectual Property (as defined hereinafter) pursuant to that certain license agreement between EPIL and Lyotropic dated as of August 17th, 2004 (the "EPIL License Agreement");

WHEREAS, Lyotropic has exclusive, licensable rights under the Lyotropic IP (as defined in Article 1);

WHEREAS, Eagle wishes to develop and market, directly or through sublicenses, throughout the world, a low volume high concentration injectable pharmaceutical formulation of dantrolene sodium for humans for the treatment of malignant hyperthermia and additional potential indications, and to secure the assistance of Lyotropic in the laboratory and preclinical development thereof, using Lyotropic's laboratory scale, non-GLP facilities and expertise; and WHEREAS, Lyotropic desires to sublicense to Eagle the EPIL Intellectual Property (and has obtained from EPIL the consent and authorization necessary to do so) and to license the Lyotropic IP, and Eagle desires to accept such sublicense and license, as applicable, on the terms and conditions set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the mutual covenants and promises contained in this Agreement and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Lyotropic and Eagle agree as follows:

ARTICLE 1
DEFINITIONS

1.1 Definitions. Unless otherwise specifically set forth herein, the following terms shall have their indicated meanings when used in this Agreement:

"505(b)(2) Application" shall mean a new drug application filed with the FDA pursuant to Section 505(b)(2) of the Act.

"Act" means, as applicable, the United States Federal Food, Drug and Cosmetic Act of 1938, as amended (21 U.S.C. §§ 301 et seq.), and in those circumstances under this Agreement when this Agreement applies to activities in any jurisdiction outside the United States, any counterpart statutes in effect in such jurisdiction.

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"Affiliate" means, with respect to a Person, any other Person that controls, is controlled by or is under common control with, such first Person. For purposes of this definition only, "control" means (a) to possess, directly or indirectly, the power to direct the management or policies of a Person, whether through ownership of voting securities, by contract relating to voting rights or corporate governance or otherwise, or (b) to own, directly or indirectly, more than fifty percent (50%) of the outstanding voting securities or other voting ownership interest of such Person or such lesser maximum ownership percentage permitted in those jurisdictions restricting foreign ownership.

"API" means dantrolene, and any salt forms thereof, each of which dissociates to the free acid dantrolene in the body.

"Applicable Laws" means all applicable laws, statutes, rules, regulations, guidelines, guidances, ordinances, orders, decrees, writs, judicial or administrative decisions and the like of any nation or government, any state or other political subdivision thereof, any entity exercising executive, judicial, regulatory or administrative functions of or pertaining to government (including any governmental authority, agency, department, board, commission or instrumentality of any governmental unit or any political subdivision thereof), any tribunal or arbitrator of competent jurisdiction, and any trade organization whose regulations have the force of law.

"cGLP" means the practices set forth in the United States Current Good Laboratory Practices (21 CFR 58) and counterparts thereof in jurisdictions outside the United States where Product is sold or that otherwise may be applicable to the exploitation of the Product.

"cGMP" means the practices set forth in the United States Current Good Manufacturing Practices (21 CFR 200, 211 and 600) and the applicable counterparts thereof in jurisdictions outside the United States where Product is sold or that otherwise may be applicable to the Manufacture of Product.

"Commercially Reasonable Efforts" means, with respect to a Party, or the research, development, Manufacture or Exploitation of the Product, as applicable, efforts and resources commonly used in the research-based pharmaceutical industry by companies of similar size to such Party for formulations or products, as applicable, with similar commercial and scientific potential at a similar stage in their lifecycle, taking into consideration their safety and efficacy, their cost to develop, the competitiveness of alternative formulations or products, as applicable, the anticipated or actual nature and extent of their market exclusivity (including Patent coverage and regulatory exclusivity), the likelihood of regulatory approval, and their estimated profitability, including the amounts of marketing and promotional expenditures and all other relevant factors.

"Competitive Product" means, with respect to any jurisdiction within the Territory, (i) any injectable drug product for humans containing the API or (ii) any drug product with a labeled indication for the treatment or management of malignant hyperthermia crisis.

"Confidential Information" has the meaning set forth in Section 9.1.

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"Control" (including variations thereof, such as "Controlled" or "Controlling") means, with respect to any item of know-how, intellectual property, or rights therein, possession of (a) the right, whether directly or indirectly, and whether by ownership, license or otherwise, to assign, or grant a license, sublicense or other right to or under, such item and (b) the right to disclose such item as provided for herein without violating the terms of any agreement with a Third Party, except to the extent that any of the foregoing rights arise by virtue of the grant of rights under this Agreement.

"Developed Technology" means any Improvements to the Lyotropic IP that are or were conceived, created, developed or otherwise Invented by a Party or an Affiliate of a Party, or by a Third Party (under contract with a Party or an Affiliate of a Party) individually or jointly, as a direct result of fulfilling obligations or exercising rights, including the sharing of Confidential Information, under this Agreement, and relating to the Product or to the IP Protection Rights licensed under this Agreement.

"Development Program" has the meaning set forth in Article 4.1.

"Eagle Developed Technology" means Developed Technology conceived, created, developed or otherwise Invented or acquired solely by an employee or agent of Eagle or one of its Affiliates or by a Third Party under contract with Eagle or one of its Affiliates.

"EPIL Intellectual Property" means all IP Protection Rights licensed to Lyotropic under the EPIL License Agreement.

"Ex-US Region" means either of the following three regions (each a "Region") outside of the United States, which collectively with the United States comprise all of the countries of the world: (i) Europe; (ii) Rest of World; and (iii) Japan.

"Ex-US Trigger Date" means the earlier of: (i) [*] after the receipt of Regulatory Approval Of the Product in such Ex-US Region; and (ii) [*] after the Effective Date of this Agreement, or in the case of [*] after the Effective Date of this Agreement.

"Exploit," "Exploiting" or "Exploitation" means to make, use, offer for sale, sell and import, including to research, develop, formulate, modify, enhance, improve, optimize, Manufacture, store, handle, hold/keep for inventory, formulate, lease, rent, distribute, promote, market, export, or otherwise make available or deal in respect of, a product or process, or have an Affiliate or Third Party do any of the foregoing on behalf of a Party.

"FDA" means the United States Food and Drug Administration, or any successor agency to its responsibilities with respect to drugs.

"First Commercial Sale" means the first sale for monetary value for use or consumption by a member of the general public of the Product in a country in the Territory after receipt of all Regulatory Approvals for the sale of such Product has been obtained in such country. For the avoidance of doubt, sales prior to receipt of all Regulatory Approvals, such as so-called "treatment IND sales," "named patient sales" and "compassionate use sales," shall not be construed as a First Commercial Sale.

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"Fully-Loaded Cost of Goods" means, with respect to Eagle's Manufacture and/or acquisition of Supplied Items and supply thereof as referred to in Section 6.2, Eagle's fully-loaded internal and external costs applicable to the Supplied Items, determined in accordance with GAAP by Eagle and consistent with Eagle's financial reports in the ordinary course of its business, which costs shall include, without limitation:

(a) the cost of goods produced, which shall include direct labor, material, overhead and Third Party expenses, but shall not include any intellectual property acquisition or licensing costs or royalties directly allocable to the Manufacture, use or sale of the Supplied Items;

(b) costs incurred by Eagle for the packaging, transport, customs clearance, and storage of such Supplied Items directly allocable to the Manufacture of the Supplied Items (including the costs for containers, freight, duties, insurance, and warehousing);

(c) costs incurred by Eagle associated with (i) stability and other product testing and activities relating to quality assurance and quality control, (ii) regulatory affairs activities and/or (iii) product liability and loss insurance; provided that, in each case such costs are directly applicable to the Supplied Items; and

(d) logistics costs (including labor costs) incurred by Eagle that are directly allocable to the Manufacture of the Supplied Items (including, for example, a percentage of Eagle Manufacturing department salary and salary-related costs allocated directly to the Supplied Items).

"GAAP" means United States generally accepted accounting principles as in effect from time to time, consistently applied.

"Generically-labeled Product" means a drug product which has received Regulatory Approval from the Regulatory Authority of a country to be marketed in such country as a Therapeutic Equivalent of the Product being sold in such country by Eagle or its Affiliates under this Agreement.

"Generic Sale Date" means, in respect of any country in the Territory, the date of the first commercial sale of a Generically-labeled Product by a Third Party in such country.

"Improvements" means, with respect to any Information, Inventions, or the intellectual property that is the subject matter of any IP Protection Rights, patentable or material non-patentable improvements, variations, updates, adaptations, modifications or upgrades or enhancements.

"Information" means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, principles, practices, formulae, instructions, documentation, skills, techniques, procedures, experiences, ideas, Inventions, discoveries, technical assistance, designs, drawings, reports, procedures, computer programs, apparatuses, specifications, data, results and other information and material, including without limitation: the process and results of high-throughput screening and any other drug discovery and development

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technology; biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, Manufacturing and quality control data and information, including study designs and protocols; assays and biological methodology; Manufacturing and quality control procedures and data, including test procedures; and synthesis, purification and isolation techniques; in each case, whether or not confidential, proprietary, patented or patentable, and whether or not in written, electronic or any other form now known or hereafter developed.

"Intellectual Property Claim" means the claim of any Third Party (including the assertion of any counterclaims and/or cross-claims with respect thereto) that the Exploitation of the Product in any country in the Territory infringes or misappropriates IP Protection Rights in such country.

"Invent" means, with respect to any Invention, Improvement or Information related to such Invention or Improvement, the act of conceiving, creating, discovering, developing, and/or reducing to practice such Invention, Improvement or Information.

"Invention" means any process, method, composition of matter, article of Manufacture, discovery or finding (including without limitation any Improvement thereto).

"IP Protection Rights" means any and all legal means of establishing rights in and to ideas, Inventions, discoveries, know-how, data, databases, documentation, reports, materials, writings, designs, computer software, processes, principles, methods, techniques and other information, including Patents, registered designs, design rights, copyrights (including rights in computer software and database rights) and any rights or property similar to any of the foregoing in any part of the world, whether registered or not, together with the right to apply for the registration of any such rights.

"Joint Developed Technology" means Developed Technology conceived, created, developed or otherwise invented or acquired jointly by (i) employees or agents of Lyotropic and Eagle or their respective Affiliates, (ii) an employee or agent of Eagle and a Third Party under contract with Lyotropic or one of its Affiliates, (iii) an employee or agent of Lyotropic and a Third Party under contract with Eagle or one of its Affiliates or (iv) a Third Party under contract with Lyotropic or one of its Affiliates and a Third Party under contract with Eagle or one of its Affiliates.

"Lyotropic Developed Technology" means Developed Technology conceived, created, developed or otherwise invented or acquired by an employee or agent of Lyotropic or one of its Affiliates or a Third Party under contract with Lyotropic or one of its Affiliates.

"Lyotropic IP" means all IP Protection Rights which are necessary or helpful to Exploit the Product or to enforce rights against Third Parties pursuant to Section 10.2, and which are Controlled by Lyotropic or any of its Affiliates as of the Effective Date and during the term of this Agreement, including the Lyotropic Patents and Lyotropic Developed Technology, but expressly excluding the EPIL Intellectual Property.

"Lyotropic Patents" means all Patents which are Controlled by Lyotropic or any of its Affiliates as of the Effective Date, as set forth on Exhibit A hereto, and during the term of this Agreement, including Lyotropic Developed Technology, but expressly excluding EPIL Intellectual Property;

Exhibit A shall be updated by Lyotropic as appropriate from time to time during the term of this Agreement.

"Manufacture" and "Manufacturing" means, with respect to a product or compound, the synthesis, manufacturing, processing, formulating, compounding, filling, finishing, packaging, labeling, holding and quality control testing of such product or compound.

"Net Sales" means, with respect to the Product, for any period of determination, the gross amount invoiced by Eagle or any of its Affiliates or licensed distributors for the sale of such Product by Eagle or any of its Affiliates or licensed distributors to Third Parties in the Territory ("Gross Sales"), less (a) trade, quantity and cash discounts and rebates allowed and given by Eagle; (b) any adjustments for price adjustments, billing errors, rejected goods, returns, product recalls and damaged goods (excluding goods damaged while under the control of Eagle or its Affiliates or Third Party suppliers or distributors); (c) credits, charge-backs, direct or indirect rebates, fees, reimbursements, and similar payments provided to wholesalers and other distributors, buying groups, health care insurance carriers, pharmacy benefit management companies, health maintenance organizations, other institutions or health care organizations or other customers; (d) rebates, adjustments and allowances or other price reductions provided to any governmental or Regulatory Authority with respect to any state or federal Medicare, Medicaid or similar programs; (e) any invoiced charge for freight, insurance, handling, or other transportation costs, to the extent specifically invoiced to the customer; (f) any accrued floor stock adjustments; (g) any reasonable and customary provision for uncollectible accounts with respect to sales of the Products per se, to the extent such reserve is determined in accordance with GAAP, until such amounts with respect to the Products are actually collected; (h) any duties, taxes or excises incurred by Eagle in connection with the shipment of the Product from Eagle to its customers and expenses paid or incurred by Eagle (and its Affiliates) for activities related to the warehousing, destruction, shipping, and distribution of the Product; (i) credits or discounts related to sales promotions such as trade show discounts and stocking allowances; (j) payments made to Third Parties pursuant to Section 10.5; and (k) any other specifically identifiable amounts included in the Product's gross sales that will have been or ultimately will be credited and that are substantially similar to those listed above.

The foregoing deductions from Gross Sales shall only be deducted once and only to the extent not otherwise deducted from Gross Sales. Eagle will not use the Product as a "loss leader" or bundle the Product with sales of its other products in any discounting program that would result in financially disadvantaging the Product relative to other products.

For purposes of determining Net Sales, (i) Net Sales shall be calculated and reported consistent with GAAP and Eagle's financial statements except that Eagle is permitted to make payments to Third Parties pursuant to Section 10.5 and (ii) the Product shall be deemed to be sold when invoiced (or at such earlier time in accordance with GAAP) and a "sale" shall not include transfers, uses or dispositions for preclinical, clinical or regulatory purposes so long as such excluded items are not deducted from Gross Sales in the calculation of Net Sales. For purposes of calculating Net Sales, sales between or among Eagle and its Affiliates shall be excluded from Gross Sales.

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"Net Profit" means Net Sales less Fully Loaded Cost of Goods less SG&A Allocation. "Non-Product Patents" has the meaning set forth in Section 10.1.1.

"Party" means any signatory to this Agreement.

"Patents" means (a) all national, regional and international patents and patent applications, including provisional patent applications, (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and continued prosecution applications, (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents and design patents and certificates of Invention, (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b) and (c)), and (e) any similar rights, including so-called pipeline protection, or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any such foregoing patent applications and patents.

"Person" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

"Pilot Batch" means a batch of Product Manufactured during the Development Program at a volume sufficient for process development, stability testing and related quality testing reasonably required by the Development Program, using excipients reasonably anticipated to be clinically safe and made available in containers suitable for the purpose under the Development Program, but which batch does not need to comply with cGMP or cGLP.

"Product" means an injectable human drug product containing dantrolene as the sole API therein.

"Product Patent(s)" means one or more Lyotropic Patents the claims of which solely or predominantly cover the Product, including the Product Patents listed as such on Exhibit A hereto, which Exhibit shall be updated by agreement of the Parties from time to time during the term of this Agreement as appropriate.

"Regulatory Approval" means all approvals (including, where applicable, pricing and reimbursement approval and schedule classifications), product and/or establishment licenses, registrations or authorizations of any Regulatory Authority necessary for the Exploitation, commercialization, use, storage, importation, exportation, transportation, offering for sale, or sale of the Product in a regulatory jurisdiction within the Territory, including any applicable IND.

"Regulatory Authority" means any national, regional state, provincial or local regulatory authority, department, bureau, commission, council or other governmental authority in the Territory involved in the granting of approvals (including pricing and reimbursement approvals),

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licenses, registrations or authorizations for the marketing, sale, manufacturing, testing, labeling, packaging, shipping or supply of drug products, including the FDA.

"Sales Forecast" means the estimate of number of units of the Product anticipated to be sold in any period.

"SG&A Allocation" means, with respect to the Product, the sum of direct overhead and direct labor costs (including those related to Product sales) for such Product, which, in respect of such Product, shall not exceed the lower of (i) ten percent (10%) of Net Sales and (ii) $1,000,000 annually.

"Supplied Items" means the Product or precursors or components thereof. "Territory" means worldwide, subject to the provisions of Section 5.5.3.

"Therapeutic Equivalent" has the meaning in the United States given to it by the FDA in the current edition of the "Approved Drug Product with Therapeutic Equivalence Evaluations" (i.e., the "Orange Book"), as the same may be amended from time to time during the term of this Agreement, and in countries outside the United States a substantially similar meaning, namely, two drug products are therapeutic equivalents which are: (1) pharmaceutical equivalents in that they contain identical amounts of the same active drug ingredient in the same dosage form and route of administration, and (2) are substitutable in that (a) they can be substituted at the pharmacy level without prior physician approval, or (b) they are mandated or required to be substituted by any applicable Regulatory Authority or under Applicable Law. The Parties agree that Dantrium®, approved in NDA #018264 and currently marketed by Procter & Gamble in the United States, shall not be considered a Therapeutic Equivalent of the Product.

"Third Party" means any Person other than Eagle, Lyotropic and the Affiliates of Eagle or Lyotropic.

"Transfer Price" means the purchase price paid to Eagle by a Third Party for finished Supplied Items, supplied by Eagle.

"Valid Claim" means a claim in a pending patent application or an issued and unexpired patent that: (a) has not been finally cancelled, withdrawn, abandoned or rejected by any administrative agency or other body of competent jurisdiction not subject to further appeal; (b) has not been revoked, held invalid, or declared unpatentable or unenforceable in a decision of a court or other body of competent jurisdiction that is unappealable or unappealed within the time allowed for appeal; (c) has not been rendered unenforceable through disclaimer, abandonment, withdrawal or otherwise and (d) with respect to a claim in a pending patent application, such claim is actively prosecuted in good faith and is believed in good faith to meet the requirements of patentability in the relevant jurisdictions.

1.2 Headings; Interpretation. The Section headings contained in this Agreement are for convenience of reference only, do not form a part of this Agreement and shall not affect in any way the meaning or interpretation of this Agreement. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words "include," "includes" and "including" shall be deemed to be followed by the phrase "but not

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limited to." All references herein to Articles, Sections and Exhibits shall be deemed references to Articles and Sections of, and Exhibits to, this Agreement unless the context shall otherwise require. All Exhibits and Schedules attached to this Agreement shall be deemed incorporated herein by reference as if fully set forth herein. Words such as "herein," "hereof," "hereto," "hereby" and "hereunder" refer to this Agreement and to the Exhibits, taken as a whole. Except as otherwise expressly provided herein: (a) any reference in this Agreement to any agreement shall mean such agreement as amended, restated, supplemented or otherwise modified from time to time; and (b) any reference in this Agreement to any law shall include corresponding provisions of any successor law and any regulations and rules promulgated pursuant to such law or such successor law.

ARTICLE 2
SCOPE OF THE COLLABORATION

2.1 Objectives. The Parties agree, pursuant and subject to the terms of this Agreement, that:

(i) Lyotropic sublicenses to Eagle all of Lyotropic's rights under the EPIL License Agreement and Eagle undertakes all of the obligations of a sublicensee thereunder; (ii) Lyotropic exclusively licenses to Eagle all rights under Lyotropic IP to Exploit the Product in the Territory; and, (iii) Eagle assures and permits Lyotropic to participate in the development as set forth herein.

ARTICLE 3
GRANT OF RIGHTS

3.1 License Grant. Subject to Section 3.3 and the other terms and conditions of this Agreement, Lyotropic hereby grants to Eagle and its Affiliates and Eagle accepts:

3.1.1 An exclusive (even as to Lyotropic and EPIL, except as to Lyotropic's performance of its obligations in respect of the Development Program), transferable (solely in conjunction with an assignment of this Agreement pursuant to Section 15.2) sublicense under the EPIL

Intellectual Property, with rights to sub-license, to develop, have developed, make, have made, use, have used, offer for sale, have offered for sale, market, have marketed, promote, have promoted, sell, have sold, import, have imported, and otherwise Exploit or have Exploited the EPIL Intellectual Property for the Product in the Territory, subject to the terms and conditions of the EPIL License Agreement.

3.1.2 An exclusive (even as to Lyotropic, except as to the Lyotropic's performance of its obligations in respect of the Development Program), transferable (solely in conjunction with an assignment of this Agreement pursuant to Section 15.2) license under the Lyotropic IP, with rights to sub¬license, to develop, have developed, make, have made, use, have used, offer for sale, have offered for sale, market, have marketed, promote, have promoted, sell, have sold, import, have imported, and otherwise Exploit or have Exploited the Lyotropic IP for the Product in the Territory.

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3.1.3 Eagle agrees that during the term of this Agreement it will use the EPIL Intellectual Property only as explicitly provided and in accordance with the term and conditions of this Agreement and the EPIL License Agreement.

3.1.4 Eagle shall have the right to sublicense its rights provided in this Agreement, subject to the prior approval of EPIL as set forth in the EPIL License Agreement. Any sublicense granted hereunder shall be on the same terms mutatis mutandis as the terms of this Agreement insofar as they are applicable. Notwithstanding the foregoing, Eagle shall ensure that in a sublicense: (i) Lyotropic shall have the same rights of audit and inspection vis-à-vis a sublicensee as Lyotropic has vis-à-vis Eagle pursuant to this Agreement; (ii) the sublicensee is bound by a confidentiality obligation that is comparable to the confidentiality provisions of this Agreement; and (iii) the sublicensee has an obligation to make timely reports of all amounts paid to Eagle under the sublicense and the basis therefore. Eagle shall be liable to Lyotropic for all acts and omissions of any sublicensee as though such acts and omissions were by Eagle. Where a sublicense has been granted under this Article 3.1.4, upon termination of this Agreement for any reason the rights of sublicensees who are permitted or consented to under this Agreement and who are not then in default shall survive, and such sublicensees shall have the right to obtain an equivalent written license from Lyotropic, provided that the terms of such license shall be no less favorable to Lyotropic than the terms of this Agreement. Eagle shall inform Lyotropic promptly of the entry into force or termination of any sublicense and the identity of the sublicensee, and provide a copy of such sublicense agreement sufficient for Lyotropic to determine that Eagle's obligations with respect to sublicensing are satisfied by the sublicense agreement.

3.2 Non-Use of Trademarks. Except as set forth explicitly in this Agreement, neither Party shall have the right to use the trademarks, trade names or logos of the other Party, nor any adaptation thereof, nor the names of any employees or consultants of such other Party, without the prior written consent of such other Party in each instance, except that either Party may use the other Party's name in its general list of collaborators and either Party may use the other Party's name to the extent required by Applicable Law, including pursuant to the Securities Act of 1933, as amended, and the rules and regulations thereunder.

3.3 United States Law. The determination of whether Information and Inventions are conceived, discovered, developed or otherwise made by a Party for the purpose of allocating proprietary rights (including IP Protection Rights) therein, shall, for purposes of this Agreement, be made in accordance with applicable United States Law.

3.4 Additional Covenants and Agreements.

3.4.1 Lyotropic covenants and agrees that, from and after the Effective Date until the termination of this Agreement, neither it nor any of its Affiliates shall seek to develop or Exploit (directly or indirectly) the Product (except as otherwise provided herein) or any Competitive Product in the Territory. Eagle covenants and agrees that, from and after the Effective Date until the termination of this Agreement, neither it nor any of its Affiliates shall seek to develop or Exploit (directly or indirectly) any Competitive Product in the Territory.

3.4.2 Promptly after the Effective Date, Lyotropic shall, at its cost and expense, use good faith reasonable efforts to disclose to Eagle in writing, or via mutually acceptable

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electronic media, copies or reproductions of all EPIL Intellectual Property and Lyotropic IP reasonably necessary in order to enable Eagle to Exploit its rights granted under this Article 3. In addition, during the term of this Agreement, Lyotropic shall promptly disclose to Eagle in writing, or via mutually acceptable electronic media, on an ongoing basis, copies or reproductions of all new EPIL Intellectual Property (of which Lyotropic has been informed by EPIL, and to which Lyotropic has reasonable access) and new Lyotropic IP reasonably necessary or useful to develop, have developed, make, have made, use, have used, offer for sale, have offered for sale, market, have marketed, promote, have promoted, sell, have sold, import, have imported, and otherwise Exploit or have Exploited the EPIL Intellectual Property, Lyotropic IP and Product in the Territory. Such EPIL Intellectual Property and Lyotropic IP and other information shall be automatically deemed to be within the scope of the licenses granted herein without payment of any additional compensation.

3.4.3 Lyotropic covenants and agrees that, from and after the Effective Date until the termination of this Agreement, it shall promptly provide Eagle with any copies of material correspondence to or from EPIL in respect of the EPIL License Agreement, including any written notice of termination for breach or otherwise pursuant to Clause 7 of the EPIL License Agreement, subject to Confidentiality Agreements in place between and among Lyotropic, EPIL and Eagle.

3.4.4 Lyotropic acknowledges that any termination or material breach of the EPIL License Agreement will constitute irreparable harm and that Eagle shall be entitled to seek specific performance or injunctive relief to enforce Eagle's rights as sublicensee under the EPIL License Agreement in

addition to whatever remedies Eagle may otherwise be entitled to at law or in equity.

3.5 Manufacturing. Eagle shall be solely responsible to Manufacture or have manufactured the Product or intermediates, both for clinical development and following receipt of Regulatory Approval of the Product for commercial supply.

ARTICLE 4
DEVELOPMENT PROGRAM

4.1 Development Program. Promptly following the Effective Date, Eagle and Lyotropic shall each designate a development program manager to coordinate its activities under this Agreement (each a "Development Program Manager"). The Development Program Managers shall be the primary contacts between Eagle and Lyotropic with respect to their respective activities under this Agreement and shall meet to determine the goals, strategy and principal activities for the development of the Product. The written record of such meetings shall be deemed to be the "Development Program". Each Development Program Manager shall respond to all reasonable requests and other communications from the other Development Program Manager. Each of Eagle and Lyotropic will use its Commercially Reasonable Efforts to fulfill its obligations set forth in the Development Program, recognizing that the Development Program will call in part for experimental and scientific work with its attendant uncertainties, and there is no guarantee that the goals identified in the Development Program can be achieved. Subject to the Development Program and the other terms and conditions contained in this

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Agreement, Eagle shall have control over and responsibility for executing all aspects of the Development Program, including planning, strategy, administrative management and fiscal control. The Development Program Managers will discuss the possibility of pursuing additional indications beyond malignant hyperthermia for the use of the Product. Subject to Section 3.4.1, each Party may at its own expense investigate additional indications for the Product outside of the Development Program.

4.2 Eagle Responsibilities. Eagle will be responsible for (and such activities shall be subject to the approval of the Development Program Managers):

4.2.1 Subject to the development of the Product as a result of the Development Program, Eagle, at its expense, using its Commercially Reasonable Efforts to file with the FDA and seek to obtain Regulatory Approval from the FDA of a 505(b)(2) Application for the Product as soon as commercially reasonable; provided, however, that, Eagle shall have the right to control the timing, content and administration of the submission of the 505(b)(2) Application, which shall be filed in Eagle's name;

4.2.2 With the assistance of Lyotropic, designing and managing contracted preclinical activities necessary to advance the Development Program and support a 505(b)(2) Application filing; Eagle will use Commercially Reasonable Efforts to provide assistance to Lyotropic for conducting or managing the performance of a Third Party under contract with respect to any stability, preclinical, biological and toxicology studies reasonably required by the Development Program to develop the Product;

4.2.3 Submitting all marketing materials for approval by the applicable Regulatory Authority;

4.2.4 Identifying and contracting with the appropriate contract Manufacturer, if applicable;

4.2.5 Procuring and supplying the API for use in meeting the requirements for development and feasibility studies;

4.2.6 Funding and conducting pivotal bioequivalence, animal study and clinical trials of the Product for malignant hyperthermia for submission to the FDA, if required;

4.2.7 Adverse event reporting in compliance with U.S. and foreign regulations pertaining to drugs in development and marketed drugs;

4.2.8 Directing, funding and controlling legal and litigation relating to the Product, which shall include freedom-to-operate opinions, Hatch-Waxman litigation and settlement negotiations, subject to the terms and conditions of the EPIL License Agreement and Article 10 hereof; and

4.2.9 Exploiting the Product in the Territory in accordance with Section 5.3.

4.3 Lyotropic Responsibilities. Lyotropic will be responsible for (and such activities shall be subject to the approval of the Development Program Managers):

4.3.1 Development of a dosage form of the Product reasonably anticipated to satisfy relevant dissolution, stability and safety/toxicity requirements for purposes of filing the 505(b)(2) Application for the Product;

4.3.2 Undertaking, directly or by contracting with Third Parties, preclinical studies as may be necessary to establish a reasonable proof of concept for the formulation for the Product;

4.3.3 Designing a Manufacturing process for finished Product in the form of a proposed Manufacturing batch record at the laboratory scale;

4.3.4 Developing with Eagle the specifications of the API and finished Product;

4.3.5 Developing a Product formulation reasonably anticipated to be capable of being Manufactured in a commercially practicable manner in accordance with standard pharmaceutical industry practices and cGMP requirements applicable in the United States;

4.3.6 Providing sufficient non-cGLP materials to Eagle and its contractors for studies they may reasonably conduct pursuant to the Development Program;

4.3.7 Assisting Eagle in designing and managing contracted preclinical activities necessary to advance the Development Program and support an 505(b)(2) Application filing with the FDA;

4.3.8 Conducting and managing the performance of a Third Party under contract with respect to any stability, preclinical, biological and toxicology studies reasonably required by the Development Program to develop the Product;

4.3.9 Conducting initial stability work (60-day stability) on lab scale non-cGLP formulation of Product, and delivering to Eagle such number of Pilot Batches to be determined in accordance with the Development Program;

4.3.10 Using its best efforts to address any modifications required to the formulation as a result of the development process; and

4.3.11 Transferring the technology in respect of the Product to Eagle and to the designated cGLP/cGMP facility selected by Eagle.

4.4 Costs and Expenses. Each Party shall be responsible for all costs and expenses incurred by it in performing their responsibilities under this Article 4; provided, however, Eagle shall be responsible for all Third Party costs pre-approved in writing by Eagle and incurred by Lyotropic in the development of the Product according to the Development Program, including (i) the costs of preclinical studies, in vivo studies or analytical methods development and studies, pilot or pivotal biostudies, and (ii) reasonable travel and lodging expenditures by Lyotropic

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required to perform its responsibilities in conducting or managing such studies or transferring technology in respect of the Product.

ARTICLE 5
COMMERCIALIZATION OBLIGATIONS

5.1 Regulatory Compliance. All activities in respect of the Exploitation of the Product in the Territory shall be conducted by Eagle in compliance with Applicable Laws and the Regulatory Approval in the country in which the Product is Exploited.

5.2 Labeling and Patent Marking. The Product shall be packaged by Eagle and labeled in a manner consistent with the requirements of the Regulatory Authorities and all Applicable Laws in the country in which it will be Exploited and, where legally permissible, shall identify any applicable Patent Rights consistent with any patent marking requirements and with the requirements of the EPIL License Agreement.

5.3 Exploitation Efforts. Following receipt of Regulatory Approval of the Product by the applicable Regulatory Authority in any country in the Territory, Eagle shall use Commercially Reasonable Efforts to Exploit the Product in such country in the Territory.

5.4 Exploitation Efforts in the United States. Eagle shall use Commercially Reasonable Efforts to (i) fulfill its obligations set forth in the Development Program and (ii) file with the FDA a 505(b)(2) Application for the Product in the United States on or before March 31, 2010; provided, however, that the Parties recognize that the Development Program will call in part for experimental and scientific work with its attendant uncertainties, and there is no guarantee that the goals identified in the Development Program can be achieved; provided further, however, that if clinical trials in respect of the Product are required by the FDA to be undertaken before filing, then Eagle shall no longer be obligated to use Commercially Reasonable Efforts to file with the FDA a 505(b)(2) Application for the Product in the United States on or before March 31, 2010 and shall thereafter, without any predetermined filing date, be obligated to use Commercially Reasonable Efforts to file with the FDA a 505(b)(2) Application for the Product in the United States.

5.5 Exploitation Efforts in Ex-US Regions.

5.5.1 Eagle shall use Commercially Reasonable Efforts to obtain Regulatory Approval of the Products in the Ex-US Regions in accordance with this Section 5.5.1. Before the Ex-US Trigger Date, Eagle shall directly or through Affiliates, (i) for the Europe Region, in any [*] of the following countries: France, Germany, United Kingdom, Spain, Italy, Turkey, Russia and Poland (at least one of which shall at the time be a member of the European Union); (ii) for the Rest of World, in any one or more of the following countries: Korea, Australia, Canada or Brazil (or Japan, if within [*] of the Effective Date of this Agreement), and (iii) in Japan, either (x) make commercial sales of the Product or (y) enter into a bona fide sublicense agreement for value whereby the sublicensee is obligated to use Commercially Reasonable Efforts to make commercial sales of the Product in the applicable country.

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5.5.2 Notwithstanding the provisions of Section 5.5.1, if (i) a Third Party has asserted or threatened to assert an Intellectual Property Claim or product liability claim in respect of the Product against Eagle, an Affiliate, sublicensee or Lyotropic; (ii) the FDA has delivered to Eagle or Lyotropic written notice of safety or efficacy concerns in respect of the Product; (iii) there are manufacturing or supply issues which arise from Regulatory Authorities (for example, an FDA Section 483 Notice) or which are otherwise in addition to those normally encountered in the course of development of a pharmaceutical product with respect to the Product in a Region; (iv) the commercial sale of the Product in a Region would violate any Applicable Law (other than commercially selling the Product without Regulatory Approval); (v) the Regulatory Authority in a country has required a clinical trial to be performed before granting Regulatory Approval of the Product; or (vi) Eagle reasonably determines that Exploitation in any country listed in Section 5.5.1 is no longer viable, and further, if Eagle, in its sole discretion, believes the condition causes an adverse impact on Eagle's ability to meet the requirements of Section 5.5.1, then Eagle shall provide notice to Lyotropic in respect thereof (including a description of the existence of the applicable condition and whether it is applicable to the Territory, or only a specific Region or country). During the period beginning from the date such notice is received by Lyotropic and for so long as (x) the condition continues to cause an adverse impact in the judgment of Eagle, and (y) Eagle uses Commercially Reasonable Efforts to remove the condition (or in the case of a requirement for a clinical trial, complete the clinical trial) or otherwise to diminish its adverse impact, then the Ex-US Trigger Date shall be extended by such period in such Region where applicable. If Eagle fails or ceases to use Commercially Reasonable Efforts (1) to remove the condition or (2) otherwise diminish its adverse impact, then the Ex-US Trigger Date will not be extended.

5.5.3 If Eagle fails to Exploit the Product in an Ex-US Region in accordance with Section 5.5.1 and 5.5.2, then (i) such Ex-US Region and all of the countries within such Region (other than any country in which Eagle shall have, prior thereto, either (x) made commercial sales of the Product or (y) entered into a bona fide sublicense agreement for value whereby the sublicensee is obligated to use Commercially Reasonable Efforts to make commercial sales of the Product in the applicable country) shall be removed from the definition of Territory of this Agreement; (ii) Eagle shall immediately discontinue Exploitation of the Product in such Region and all of the countries of such Region (other than any country in which Eagle shall have, prior thereto, either (x) made commercial sales of the Product or (y) entered into a bona fide sublicense agreement for value whereby the sublicensee is obligated to use Commercially Reasonable Efforts to make commercial sales of the Product in the applicable country); and (iii) Eagle shall, if and to the extent requested by Lyotropic, transfer to Lyotropic any and all rights, privileges, licenses and Information developed by Eagle or by Third Parties on behalf of Eagle and relating to the Exploitation of the Product in such Region and the countries of that Region (other than any country in which Eagle shall have, prior thereto, either (x) made commercial sales of the Product or (y) entered into a bona fide sublicense agreement for value whereby the sublicensee is obligated to use Commercially Reasonable Efforts to make commercial sales of the Product in the applicable country), including registration dossiers worldwide, in the same manner and to the same extent as set forth under Sections 11.3 and 11.5.2 as if this Agreement were terminated with respect to such Region. These constitute the exclusive remedy of Lyotropic for failure by Eagle to Exploit the Product in any Ex-US Region in satisfaction of Section 5.5.1

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or 5.5.2 and for the avoidance of any doubt, such failure shall not constitute nor be grounds for a material breach of the Agreement by Eagle.

5.5.4 Notwithstanding the foregoing, if Lyotropic uses any rights, privileges, licenses, Information or know-how developed by Eagle, including under the Development Program, relating to the Exploitation of the Product provided under Section 5.5.3 (iii) and Exploits the Product in any country in which Eagle shall have been obligated to discontinue the Exploitation of the Product pursuant to Section 5.5.3, then Lyotropic shall pay to Eagle royalty payments equal to [*] of Net Sales of Product made by Lyotropic or its Affiliates in the country, and in the event Lyotropic sublicenses to any Third Party the rights to sell the Product in such country, payments in an amount equal to [*] of any consideration received by Lyotropic in respect of such sublicense for such country, for the royalty term and under the terms and conditions equivalent to those set forth in Section 6.4.

5.6 Trademarks. Eagle shall have the right to determine the trademark and any other related logos, trade names, and similar source identifiers that are created or selected for use to be used on and with the Product.

ARTICLE 6
ROYALTIES AND OTHER CONSIDERATIONS

6.1 Royalty Payments. Eagle shall pay to Lyotropic royalty payments equal to [*] of the Product made by Eagle or its Affiliates in the Territory.

6.2 Sublicense by Eagle. In the event that Eagle sublicenses to any Third Party any of its rights under this Agreement, Eagle shall pay Lyotropic [*] of any consideration received by Eagle in respect of such sublicense. For the purposes of this Section 6.2 "any consideration" includes sublicense fees, milestone payments, one time payments, equity investments (to the extent that any consideration received by Eagle for such equity issuance shall have been greater than the then fair market value of such equity) and royalties, but excluding consideration received for reimbursement of future direct expenditures in developing the Product. Payments received by Lyotropic and Eagle, as applicable, under a supply agreement for the Supplied Items shall be considered "consideration" for purposes of Section 5.4 and this Section 6.2; provided, however that such consideration shall be computed by deducting the Fully-Loaded Cost of Goods of the Supplied Items from the Transfer Price of the Supplied Items.

6.3 Payment Terms. All royalties owed by Eagle under Section 6.1 shall be payable to Lyotropic [*], within [*] after [*]. All amounts owed by Eagle under Section 6.2 shall be payable to Lyotropic within [*] of receipt by Eagle. All payments to Lyotropic under this Agreement shall be paid in United States Dollars by wire transfer of immediately available funds to a bank account in the United States as Lyotropic may reasonably designate. For sales made or amounts paid to Eagle in foreign currency, the United States Dollar equivalent value shall be calculated using the exchange rate prevailing at the close of the date three (3) days prior to the date any payment becomes due, as published the next business day in the Wall Street Journal, Eastern Edition.

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6.4 Royalty Term. Eagle's royalty obligations under Sections 6.1 and 6.2 shall terminate, on a country-by-country basis, upon the earlier of: (i) the later of (a) ten (10) years from the date of the First Commercial Sale of the Product in such country and (b) the expiration or invalidation in such country of the last Patent that includes at least one Valid Claim covering the Product in such country or other governmental authorized market exclusivity (including but not limited to Orphan Drug market exclusivity) in such country; and (ii) in respect of any country in the Territory in which Eagle or its Affiliates are selling the Product, as of the beginning of the first fiscal quarter following the [*] in which [*] by Eagle or its Affiliate in such country during such quarter are [*] (measured by country currency) of the [*] in such country for the [*] immediately prior to the [*]. The Parties agree further to incorporate into the analysis an adjustment of quarterly Net Profit to account for any cyclical nature of sales peculiar to the Product if the Parties in good faith mutually determine that it is reasonable and appropriate to do so. Following the termination of royalty obligations pursuant to this Section 6.4, the license granted to Eagle under this Agreement with respect to such country shall be fully paid.

ARTICLE 7
REPORTS AND RECORDS

7.1 Record Retention. Eagle shall prepare and maintain in accordance with GAAP (and shall ensure that its Affiliates shall maintain) complete and accurate books, records and accounts that fairly reflect their respective Net Sales, any other income or consideration received, costs or expenditures or other matters with respect to the Product in sufficient detail to confirm the accuracy of any payments required hereunder, which books, records and accounts shall be retained by Eagle until the later of (a) twelve (12) months after the end of the period to which such books, records and accounts pertain, and (b) the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by Applicable Law. Within forty-five (45) days after the end of each quarter of each calendar year following the First Commercial Sale, Eagle shall deliver to Lyotropic complete and accurate written reports setting forth such particulars of the business conducted by Eagle during the preceding quarter under this Agreement as shall be necessary and pertinent to an itemized accounting for royalty payments due hereunder, and a projection of Sales Forecast for the coming quarter. Each report received by Lyotropic may be shared with EPIL and shall be treated as "Confidential Information" subject to the terms of Article 9.

7.2 Audit. Upon reasonable prior written notice by Lyotropic or EPIL, Eagle shall grant access, during normal business hours at an Eagle facility in the United States, to an independent certified public accounting firm, or other firm specializing in pharmaceutical license audits, of nationally recognized standing reasonably acceptable to Eagle, to such of the records of Eagle (and its Affiliates) as may be reasonably necessary to verify the accuracy of all reports, sales and payments due to Lyotropic for any calendar quarter ending not more than twelve (12) months prior to the date of such request; provided, however, that Eagle shall not be subject to more than one such audit in any twelve (12)-month period. The accounting firm shall disclose to each Party only whether such sales or payments are correct or incorrect and the specific details concerning any discrepancies. Lyotropic or EPIL, as applicable, shall bear the cost of such audit unless the audit reveals an under-reporting or underpayment in excess of the greater of [*] or [*] of royalty payments payable for such period, in which case Eagle shall bear the cost of the audit,

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rectify such underpayment and pay Lyotropic applicable interest as required by Section 7.3. Any overpayment shall be promptly repaid by Lyotropic. All payments required under this Section 7.2 shall be made not later than [*] after notice of the required payment is received by the Party to whom the notice is directed. The results of such accounting firm shall be final, absent manifest error, and shall be treated as "Confidential Information" subject to the terms of Article 9.

7.3 Interest. Any payments due under this Agreement by either Party that are not paid by the date such payments are due and are not subject to a bona fide dispute shall bear interest at [*] per month from the date such payments are due until paid in full. The foregoing interest shall be due from the Party owing the payment amount without any special notice and shall be in addition to any other remedies that the Party entitled to such payment may have pursuant to this Agreement.

ARTICLE 8
REPRESENTATIONS AND WARRANTIES

8.1 Legal Authority. Each of Lyotropic and Eagle represents and warrants as follows: (a) such Party is a corporation duly organized, validly existing and in good standing under the laws of the state in which it is incorporated and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as is contemplated to be conducted by this Agreement; (b) such Party has the legal power, authority and right to enter into this Agreement and to perform its respective obligations set forth herein; and (c) this Agreement has been duly executed and delivered by such Party and constitutes the valid and binding obligation of such Party, enforceable against such Party in accordance with its terms, except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors' rights generally and by general equitable principles.

8.2 No Conflicts. Each of Lyotropic and Eagle represents and warrants that, as of the date of this Agreement, it is not a party to any agreement or arrangement with any Third Party or under any obligation or restriction, including pursuant to its corporate charter, bylaws or comparable governing documents, that in any way limits or conflicts with its entering into this Agreement or its ability to fulfill any of its obligations under this Agreement.

8.3 Litigation. Each of Lyotropic and Eagle represents and warrants that it is not aware of any pending or threatened litigation (and has not received any communication) that alleges that such Party's activities related to this Agreement have violated, or that by conducting the activities as contemplated herein such Party would violate, any of the intellectual property rights of any other Person.

8.4 Additional Representations, Warranties and Covenants of Lyotropic. Lyotropic hereby represents, warrants and covenants to Eagle as follows:

(i) The EPIL License Agreement attached hereto as Exhibit B is the current version of the agreement between EPIL and Lyotropic in respect of dantrolene.

(ii) Lyotropic has completed initial formulation work in respect of the Product and believes that such formulation work can be replicated as a Pilot Batch.

(iii) Neither Lyotropic nor any of its employees or consultants who shall be undertaking any activities related to this Agreement or the Product has been debarred or is the subject of debarment or other disciplinary proceedings by any Regulatory Authority in the Territory;

(iv) Neither Lyotropic nor any of its Affiliates has received any written notice from any Person, or has knowledge, of any actual or threatened claim or assertion that the development of the Product infringes (or would infringe) or misappropriates any intellectual property rights of any Third Party;

(v) There is no action or proceeding pending or, to Lyotropic's knowledge, threatened that questions the validity of this Agreement or any action taken by Lyotropic in connection with the effectiveness of this Agreement;

(vi) Lyotropic has no knowledge of any patent or pending patent application that, if issued, would be infringed by the use of the Product, Lyotropic IP or EPIL Intellectual Property for the treatment of malignant hyperthermia as contemplated by this Agreement;

(vii) Lyotropic has not violated the trade secrets or misappropriated the confidential information or intellectual property of any Third Party in connection with the development of the Product or Lyotropic IP;

(viii) Lyotropic has the right, to grant the sublicense granted to Eagle herein, subject to the terms and conditions of the EPIL License Agreement;

(ix) To Lyotropic's knowledge, as of the Effective Date, there is no unauthorized use, infringement or misappropriation of any of the Lyotropic IP or EPIL Intellectual Property by any Third Party, including any current or former employee or consultant of Lyotropic and its Affiliates;

(x) Lyotropic has the right to grant the licenses granted to Eagle herein and owns all right, title and interest in and to, or has a license, sublicense or otherwise permission to use and license, all of the Lyotropic IP. Lyotropic has not granted or assigned and will not during the term of this Agreement grant or assign to any Third Party any license, title, ownership interest or similar right with respect to the Product or EPIL Intellectual Property or the Lyotropic IP related to the API. Lyotropic further represents and warrants that no Third Party Controls, including jointly with Lyotropic, any Lyotropic IP related to the Product;

(xi) During the term of this Agreement, Lyotropic shall comply with and maintain in force all licenses, consents, permits and authorization and maintain all facilities which may be required with respect to its performance of its obligations hereunder, including any and all licenses under the License Agreement;

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(xii) Lyotropic and its Affiliates have not as of the Effective Date granted or placed, and will not during the term of this Agreement grant or place, any liens, security interests and/or other encumbrances in or on the Lyotropic IP that would conflict or interfere (including as due to a default or breach of a Third Party obligation of Lyotropic) with the sublicense and licenses granted to Eagle herein;

(xiii) Lyotropic and its Affiliates shall comply, in all material respects, with all Applicable Law in performing their respective obligations provided herein; and

(xiv) Lyotropic has made available to or provided Eagle with copies of all Information in Lyotropic's Control regarding the Product, Lyotropic IP and EPIL Intellectual Property that Lyotropic believes could reasonably be expected to be material to assessing the commercial potential for the Product or the ability to gain Regulatory Approval of the Product in a timely manner.

8.5 Additional Representations, Warranties and Covenants of Eagle. Eagle hereby represents, warrants and covenants to Lyotropic as follows:

(i) There is no action or proceeding pending or, to Eagle's knowledge, threatened that questions the validity of this Agreement or any action taken by Eagle in connection with the effectiveness of this Agreement;

(ii) During the term of this Agreement, Eagle shall comply with and maintain in force all licenses, consents, permits and authorizations and maintain all facilities that may be required to be maintained with respect to the performance of its obligations hereunder;

(iii) Eagle shall not, and shall not permit or cause its Affiliates to, during the term of this Agreement, grant or place any liens, security interests and/or other encumbrances in or on the rights licensed and sublicensed to it under this Agreement that would conflict or interfere (including as due to a default or breach of a Third Party obligation of Eagle) with the full performance of this Agreement and operation of its terms, including those terms upon termination of the Agreement, by Eagle;

(iv) Eagle shall, and shall cause its Affiliates, Sublicensees, and Third Party contractors to, comply in all material respects with all Applicable Law in performing their respective obligations provided herein; and

(v) Neither Eagle nor any of its employees or consultants who shall be undertaking any activities related to this Agreement or the Product has been debarred or is the subject of debarment or other disciplinary proceedings by any Regulatory Authority in the Territory.

8.6 DISCLAIMER OF WARRANTY. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN THIS ARTICLE 8, (I) NEITHER LYOTROPIC NOR EAGLE MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, UNDER THIS AGREEMENT, AND LYOTROPIC AND EAGLE EACH

SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE, VALIDITY OR SCOPE OF PATENTS AND NON-INFRINGEMENT OF THIRD PARTY RIGHTS, AND (II) THE LICENSES GRANTED HEREUNDER ARE MADE ON AN 'AS IS' BASIS.

ARTICLE 9
CONFIDENTIALITY

9.1 Definition. "Confidential Information" of a Party shall mean all Information provided by or on behalf of such Party to another Party either in connection with the discussions and negotiations pertaining to, or in the course of performing, this Agreement, including the terms of this Agreement; data; knowledge; practices; processes; ideas; research plans; engineering designs and drawings; research data; manufacturing processes and techniques; scientific, manufacturing, marketing and business plans; and financial and personnel matters relating to the disclosing Party or to its present or future products, sales, suppliers, customers, employees, investors or business.

9.2 Exclusions. Notwithstanding the foregoing, Information of a Party shall not be deemed Confidential Information with respect to a receiving Party for purposes of this Agreement if such receiving Party can affirmatively demonstrate through the production of written documentation that such Information:

9.2.1 was generally available or known to parties reasonably skilled in the field to which such Information pertains, or was otherwise part of the public domain, at the time of its disclosure to such receiving Party;

9.2.2 became generally available or known to parties reasonably skilled in the field to which such Information pertains, or otherwise became part of the public domain, after its disclosure to such receiving Party through no fault of the receiving Party;

9.2.3 was disclosed to such receiving Party or its Affiliates, other than under an obligation of confidentiality or non-use, by a Third Party who had no obligation to the Party that Controls such Information not to disclose such Information or know-how to others; or

9.2.4 was independently discovered or developed by such receiving Party or its Affiliates, as evidenced by their written records, without the use of Confidential Information belonging to the Party that Controls such Information.

9.3 Disclosure and Use Restriction. Except as expressly provided herein, the Parties agree that, during the term of this Agreement and for five (5) years thereafter, each Party and its Affiliates shall keep completely confidential and shall not publish or otherwise disclose and shall not use for any purpose except for the purposes contemplated by this Agreement any Confidential Information of the other Party or such other Party's Affiliates.

9.4 Authorized Disclosure. Each Party may disclose Confidential Information of another Party to the extent that such disclosure is:

9.4.1 Required by Governmental Order. Made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction; provided, however, that such Party shall first have given notice to the other Party (the "Controlling Party") and given the Controlling Party a reasonable opportunity to quash such order and to obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and provided further that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order;

9.4.2 Required by Law. Otherwise required by law; provided, however, that the disclosing Party shall (a) provide the Controlling Party with reasonable advance notice of and an opportunity to comment on any such required disclosure, (b) if requested by the Controlling Party, seek confidential treatment with respect to any such disclosure to the extent available, and (c) use good faith efforts to incorporate the comments of the Controlling Party in any such disclosure or request for confidential treatment;

9.4.3 Required by Regulatory Authority. Made by such Party to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; provided, however, that reasonable measures shall be taken to assure confidential treatment of such

information; or

9.4.4 Required by Agreement. Made by such Party, in connection with the performance of this Agreement, to Affiliates, research parties, employees, consultants, representatives, sublicensees, development partners, investors or agents; provided, that each such party, prior to disclosure thereto, shall have executed confidentially agreements containing terms of confidentiality and non-use at least equivalent in scope to those set forth in this Article 9.

9.5 Injunctive Relief. The Parties acknowledge that any breach of this Article 9 will constitute irreparable harm and that the non-breaching Party shall be entitled to specific performance or injunctive relief to enforce this Article 9 in addition to whatever remedies such Party may otherwise be entitled to at law or in equity.

ARTICLE 10
PATENT PROSECUTION, INFRINGEMENT AND RIGHTS IN DEVELOPED TECHNOLOGY

10.1 Prosecution of Lyotropic Patent Rights.

10.1.1 Eagle (and sublicensees of Eagle granted the right to sell or distribute the Product) shall have the sole right, at their cost and expense, to obtain, prosecute and maintain throughout the world the Product Patents. Lyotropic shall have the sole right, at its cost and expense, to obtain, prosecute and maintain throughout the world the Lyotropic Patents which are not Product Patents (the "Non-Product Patents"). Each Party shall, and shall cause its Affiliates and sublicensees to, cooperate fully with the other Party in the preparation, filing, prosecution,

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enforcement and maintenance of all Lyotropic Patents. Such cooperation includes (a) promptly executing all papers and instruments and requiring employees to execute such papers and instruments as reasonable and appropriate so as to enable the Controlling Party to file, prosecute, enforce and maintain the Lyotropic Patents in any country; (b) promptly informing the other Party in reasonable detail of any Improvements by such Party or any of its Affiliates or agents; and (c) promptly informing the other Party of any matters of which such Party is aware that may affect the preparation, filing, prosecution or maintenance of any such Lyotropic Patent. In addition, Lyotropic and Eagle shall use Commercially Reasonable Efforts to file and prosecute Lyotropic Patents which are Product Patents, including cooperating with Eagle in filing and prosecuting Product Patents which are divisionals, continuations, continuations-in-part, provisionals, converted provisionals, continued prosecution applications or otherwise claim priority to any Non-Product Patents.

10.1.2 Each Party shall provide the other Party with drafts of all patent applications and other material submissions to and correspondence with any patent authorities in the Territory to the extent such applications or submissions relate to the Lyotropic Patents, in sufficient time, preferably not less than thirty (30) days but in any event not less than fifteen (15) days prior to the date a reply is required by the relevant patent authorities in the Territory, to allow for review and comment by such Party. In addition, each Party shall provide the other Party with an opportunity to consult with and provide comments regarding the filing and contents of any such application, submission or correspondence in the Territory. Each Party agrees to reasonably consider such consultations and comments, it being understood that the Party controlling the application Patent, as set forth in Section 10.1.1, retains the right to determine whether to comply with or incorporate such comments, if at all. If (x) Lyotropic elects not to pursue the filing, prosecution or maintenance of a Non-Product Patent in a particular country in the Territory or to take any other action with respect to a Non-Product Patent in a particular country in the Territory that is necessary or useful to establish or preserve rights with respect to the Product, or (y) Eagle elects not to pursue the filing, prosecution or maintenance of a Product Patent in a particular country in the Territory or to take any other action with respect to a Product Patent in a particular country in the Territory that is (i) necessary or useful to establish or preserve rights with respect to the Product, or (ii) relates to subject matter and claims which would not cover the Product, then such Party ("Notifying Party") shall so notify the other Party ("Other Party") promptly in writing and in good time to enable the Other Party to meet any deadlines by which an action must be taken to establish or preserve any such rights in such Lyotropic Patent in such country in the Territory. Upon receipt of any such notice or if, at any time, a Party fails to initiate any such action within thirty (30) days after a request by the Other Party that it do so (and thereafter diligently pursue such action), such Other Party shall have the right, but not the obligation, to pursue the filing or registration, or support the continued prosecution or maintenance, of such Lyotropic Patent at its expense in such country in the Territory. If the Other Party elects to pursue such filing or registration, as the case may be, or continue such support, then it shall inform the Notifying Party of such election and the Notifying Party shall, and shall cause its Affiliates to (x) reasonably cooperate with the Other Party in this regard, and (y) without additional consideration, such Lyotropic Patent shall continue to be a Lyotropic Patent, owned by Lyotropic and subject to the terms of this Agreement.

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10.2 Infringement of Lyotropic Patent Rights.

10.2.1 Eagle and Lyotropic shall inform each other promptly in writing of any alleged or suspected infringement of any Lyotropic Patents by a Third Party Exploiting a Product or Competitive Product in the Territory and shall provide to each other all available evidence thereof. Each Party shall provide reasonable assistance to the other Party, including providing access to relevant records, papers, information, samples, specimens and other evidence, making its employees available at reasonable business hours, and joining any action to the extent necessary to maintain the action.

10.2.2 In respect of any alleged or suspected actual or constructive infringement of any Lyotropic Patents by a Third Party Exploiting a Product or Competitive Product in the Territory, in each case which is likely to have an effect or impact on the sales or commercial potential of the Product in the Territory, most particularly where a Third Party files an ANDA or a 505(b)(2) Application containing a Paragraph IV certification with the FDA targeting or referencing the Product, Eagle (or sublicensees of Eagle granted the right to sell or distribute the Product) shall have the sole right to institute a suit and

control the prosecution, settlement negotiation, settlement or compromise thereof or defend against any suit alleging the invalidity or noninfringement or unenforceability of the Lyotropic Patents with respect thereto (a "Product Litigation").

10.2.3 In the event Eagle (or sublicensees of Eagle granted the right to sell or distribute the Product) brings or desires to bring a Product Litigation, Lyotropic shall use its best efforts to cooperate fully, including, if required to bring such Product Litigation, the furnishing of a special power of attorney for the purpose of bringing suit in Lyotropic's name and/or being named as a party in such suit and, as necessary, becoming a client of Eagle's or Eagle's sublicensee's, as the case may be, legal counsel and agreeing that such legal counsel will act solely under the instruction of Eagle or Eagle's sublicensee, as the case may be, and will sign a waiver permitting such legal counsel to take instructions solely from Eagle or Eagle's sublicensee, as the case may be. Notwithstanding anything to the contrary contained in the foregoing, nothing in this Section 10.2.3 shall obligate either Party to take any action in violation of any Applicable Laws, or to waive its rights to bring any action, claim or counterclaim against the other Party. Additionally, Lyotropic may engage its own legal counsel, at its own cost and expense, to represent it in any Product Litigation, subject to Eagle's or Eagle's sublicensee's control of such Product Litigation. Eagle or its sublicensee shall keep Lyotropic or its designated legal counsel reasonably informed as to the progress of such action and shall provide Lyotropic reasonable and timely opportunity to advise. With respect to any recovery related to the Product which is realized by either Party as a result of such Product Litigation, after reimbursement first of any litigation expenses of Eagle, and second of any litigation expenses of Lyotropic to the extent related to claims of invalidity or unenforceability of one of more patent claims in a Non-Product Patent, such recovery shall be shared in accordance with the Net Sales split set forth in Section 6.1; provided, however, that if Eagle has sublicensed its commercialization rights for the Product in the country in which such Product Litigation has been brought and Eagle does not participate in such Product Litigation, any proceeds from such Product Litigation received by Eagle, less all expenses and costs incurred by Eagle in such Product Litigation, shall be shared with Lyotropic in accordance with the percentages set forth in Section 6.2. Notwithstanding anything to the contrary above, with respect Product Litigation involving claims of invalidity or unenforceability of one or more patent claims in a Non-Product Patent, which claims could cover

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drug products other than the Product, legal counsel engaged by Lyotropic shall have the right to participate with co-equal control with respect to such claims of invalidity or enforceability.

10.2.4 Notwithstanding the above, in respect of any alleged or suspected actual or constructive infringement by a Third Party of a Non Product Patent, if Eagle does not bring Product Litigation, then Lyotropic shall have the right in its sole discretion to institute product Litigation and control the prosecution, settlement negotiation, settlement or compromise thereof, including the defending the invalidity or non-infringement or unenforceability of the Non Product Patent. In the event Lyotropic brings or desires to bring such Product Litigation, Eagle shall use its best efforts to cooperate fully, including, if required to bring such action, the furnishing of a special power of attorney for the purpose of bringing suit in Eagle's name and/or being named as a party in such suit and, as necessary, becoming a client of Lyotropic's legal counsel and agreeing that such legal counsel will act solely under the instruction of Lyotropic and will sign a waiver permitting such legal counsel to take instructions solely from Lyotropic. Notwithstanding anything to the contrary contained in the foregoing, nothing in this section shall obligate either Party to take any action in violation of any applicable Laws, or to waive its rights to bring any action, claim or counterclaim against the other Party. Additionally, Eagle may engage its own legal counsel, at its own cost and expense, to represent it in any such Product Litigation, subject to Lyotropic's control of such Product Litigation. Lyotropic shall keep Eagle or its designated legal counsel reasonably informed as to the progress of such action and shall provide Eagle reasonable and timely opportunity to advise. Any recovery related to the Product which is realized by either Party as a result of such litigation, after reimbursement first of any litigation expenses of Lyotropic, and second of any litigation expenses of Eagle, then shall be shared in accordance with the following split percentages: Lyotropic [*]; [*].

10.3 Third Party Litigation. In the event that a Third Party institutes a patent or other infringement suit against either Eagle or Lyotropic or any of their respective Affiliates or any Eagle sublicensees during the term of this Agreement, in any case alleging that the Manufacture, use or sale of a Product in the Territory infringes one or more patent or other intellectual property rights held by such Third Party (an "Infringement Suit"), the Parties shall cooperate with one another in defending such suit. Eagle shall have the first right to direct and control, at its expense, any Infringement Suit (including settlement negotiations, settlement or compromise thereof) to the extent that it relates to the manufacture, use or sale of a Product. To the extent that any amounts become payable to any Third Party as a result of such action, whether through judgment or settlement, then Eagle shall be responsible for such damages; provided, however, that Eagle shall deduct from Net Sales, prior to any payments made to Lyotropic pursuant to Section 6.1, all such damages payable to any Third Party and any costs and expenses associated with any Infringement Suit.

10.4 EPIL Intellectual Property. With respect to the prosecution, enforcement or defense of any rights under the EPIL Intellectual Property, Lyotropic hereby licenses to Eagle all such rights under the EPIL License Agreement and agrees to cooperate with Eagle in exercising such rights under Lyotropic's name and Eagle hereby agrees to be bound to such EPIL License Agreement as a sublicensee, accept the obligations of a sublicensee thereunder, and cooperate with Lyotropic in fulfilling its obligations under such provisions.

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10.5 Retained Rights. Nothing in this Article 10 shall prevent Eagle from obtaining, at its own expense, any license or other rights from Third Parties it deems appropriate in order to permit the full and unhindered exercise of its rights under this Agreement. Any royalty or other payments made to Third Parties in connection with such license or other rights shall be subtracted from Gross Sales in calculating Net Sales, as provided in Article 1 "Net Sales", for purposes of any payments made pursuant to Section 6.1.

10.6 Rights in Developed Technology.

10.6.1 Eagle shall own Eagle Developed Technology. Lyotropic shall own Lyotropic Developed Technology. Lyotropic and Eagle shall jointly own Joint Developed Technology.

10.6.2 Lyotropic shall promptly disclose to Eagle any Lyotropic Developed Technology and Joint Developed Technology, and Eagle shall promptly disclose to Lyotropic any Eagle Developed Technology and Joint Developed Technology.

10.6.3 Developed Technology dependant upon Lyotropic Patents. With respect to Developed Technology which cannot be practiced without infringing Lyotropic Patents (the "Licensed Developed Technology"), the following shall apply. Eagle hereby grants to Lyotropic and Lyotropic hereby accepts an exclusive worldwide, paid-up, irrevocable license, including the right to grant sublicenses, under the Licensed Developed Technology, for the purpose of developing, manufacturing, marketing, distributing and selling pharmaceutical formulations; provided, however, that the rights granted by Eagle to Lyotropic under this Section 10.6.3 exclude the rights to Exploit the Product in the Territory during the term of this Agreement, except as permitted or required to satisfy its obligations under this Agreement.

10.6.4 Each Party shall, and shall cause its Affiliates and sublicensees to, cooperate fully with the other Party in the preparation, filing, prosecution, enforcement and maintenance of IP Protection Rights in Developed Technology.

10.6.5 Nothing in this Section 10.6 shall modify or interfere with the rights and obligations of EPIL and the Parties to Developed Technology as established in and pursuant to the EPIL License Agreement.

10.7 Patent Term Extension. Lyotropic shall cooperate with Eagle in obtaining patent term extension or supplemental protection certificates or their equivalents in any country in the Territory with respect to the patent rights covering the Product. In the event that elections with respect to obtaining such patent term extension, supplemental protection certificates or their equivalents are to be made with respect to Product Patents, Eagle shall have the right to make the election and Lyotropic agrees to abide by such election; with respect to Non-Product Patents, Eagle shall have the right to make the election, provided, however, if Eagle does not elect to do so with respect to any country in the Territory, Lyotropic shall have the right to do so, and Eagle shall duly cooperate with Lyotropic.

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ARTICLE 11
TERMINATION

11.1 Term. This Agreement shall enter into effect on the Effective Date and shall remain in full force and effect on a country-by-country basis until terminated in accordance with this Article 11.

11.2 Termination Events. This Agreement may be terminated prior to expiration of the term of this Agreement as follows:

11.2.1 Termination Upon Insolvency. Each Party shall promptly notify the other Party in writing upon the initiation of any proceeding in bankruptcy, reorganization, dissolution, liquidation or arrangement for the appointment of a receiver or trustee to take possession of the assets of such Party (hereinafter referred to as the "Insolvent Party") or similar proceeding under the law for release of creditors by or against the Insolvent Party or if the Insolvent Party shall make a general assignment for the benefit of its creditors. If the applicable circumstance described above shall have continued for sixty (60) days undismissed, unstayed, unbonded and undischarged, the other Party (hereinafter referred to as the "Solvent Party") may terminate this Agreement upon written notice to the Insolvent Party on or after ninety (90) days of the Insolvent Party providing the notice referenced above; provided, however, that if the Insolvent Party prior thereto provides for the cure of all of its defaults under this Agreement (if any) and provides reasonable adequate assurance of its future performance of its obligations hereunder, then the Solvent Party shall not have the right to terminate this Agreement pursuant to this Section 11.2.1. All licenses and rights to licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code (the "Code"), licenses of rights to "intellectual property" as defined under Section 101(35A) of the Code. Eagle, as the licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Code. The foregoing provisions of this Section 11.2.1 are without prejudice to any rights Eagle may have arising under the Code or other Applicable Law.

11.2.2 Termination for Material Breach.

11.2.2.1 Upon any material breach or default of this Agreement by Lyotropic, Eagle shall have the right to terminate this Agreement and the rights, privileges and licenses granted hereunder upon giving [*] notice to Lyotropic. Such termination shall become effective upon the expiration of such [*] period unless Lyotropic shall have cured all such breaches and defaults prior to the expiration of such [*].

11.2.2.2 Upon any material breach or default of this Agreement by Eagle, Lyotropic shall have the right to terminate this Agreement and the rights, privileges and licenses granted hereunder upon giving [*] notice to the Eagle. Such termination shall become effective upon the expiration of such [*] period unless Eagle shall have cured all such breaches and defaults prior to the expiration of such [*] period.

11.2.3. Eagle shall have the right at any time to terminate this Agreement in whole by giving ninety (90) days notice thereof in writing to Lyotropic if in its sole discretion commercial development of the Product is no longer commercially reasonable, provided Eagle has paid all sums due under this Agreement.

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11.3 Return of Information; Assignment and License. Upon termination of this Agreement as a result of Eagle's material breach hereof pursuant to Section 11.2.2.2, or as a result of Eagle's insolvency pursuant to Section 11.2.1 or by Eagle pursuant to Section 11.2.3, Eagle shall, and shall cause its Affiliates to, return to Lyotropic any and all data, files, records and other materials in its possession or control that relate to the EPIL Intellectual Property, the Lyotropic IP or the Product or that contain or comprise Information and Inventions or other Confidential Information (except one copy of each that may be retained for archival purposes), and such may be used by Lyotropic in its sole discretion, including commercialization of the Product directly or through another licensee.

11.4 Cumulative Remedies. The rights and remedies set forth in this Article 11 are cumulative and in addition to any other rights that may be available to the Parties.

11.5 Effect of Termination.

11.5.1 The termination or expiration of this Agreement for any reason shall be without prejudice to any rights which shall have accrued to the benefit of any Party prior to such termination or expiration. Such termination or expiration shall not relieve any Party from obligations which are expressly indicated to survive termination or expiration of this Agreement.

11.5.2 Upon the termination of this Agreement pursuant to Section 11.2.2.2 or as a result of Eagle becoming an Insolvent Party pursuant to Section 11.2.1 or by Eagle pursuant to Section 11.2.3, all rights and licenses granted to Eagle pursuant to this Agreement shall automatically and immediately terminate and Eagle immediately shall discontinue Exploitation of the Product. In addition, upon the request of Lyotropic, Eagle shall cooperate with Lyotropic to transfer to Lyotropic or its designee(s) such rights, privileges and properties as Eagle or its Affiliates or sublicensees may have established during the term of this Agreement throughout the Territory relating to the Product, its development and commercialization, including but not limited to contractual rights with Third Parties such as suppliers, scientific or clinical service organizations, rights in any and all regulatory filings and approvals, specifically including but not limited to, a 505(b)(2) Application filing and approval, and Eagle Developed Technology and Joint Developed Technology. Lyotropic shall reimburse Eagle all of Eagle's out-of-pocket costs and expenses incurred in complying with the foregoing requests.

11.5.3 Upon the termination of the Agreement pursuant to Section 11.2.2.1 or as a result of Lyotropic becoming an Insolvent Party pursuant to Section 11.2.1, then, in such event, Lyotropic shall, contemporaneously with the termination of this Agreement and in exchange for the good and valuable consideration set forth herein (the sufficiency of which is hereby acknowledged by Lyotropic), fully assign all of its rights and interests in, under and to the EPIL License Agreement (without regard to any termination thereunder) and EPIL Intellectual Property and Eagle shall assume the obligations, and remain entitled to all the rights and benefits, of Lyotropic thereunder, all subject to the terms and conditions of the EPIL License Agreement, and Lyotropic shall thereafter have no further rights with respect to the EPIL License Agreement or EPIL Intellectual Property. Eagle shall reimburse Lyotropic all of Lyotropic's out-of-pocket costs and expenses incurred in complying with the foregoing requests.

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11.6 Disposition of Product. Upon any termination of this Agreement other than for which Section 11.5.3 would be applicable, Eagle shall within thirty (30) days after the effective date of such termination notify Lyotropic in writing of the amount of each Product which Eagle and its Affiliates then have completed on hand, the sale of which would, but for the termination, be subject to royalty. At Lyotropic's sole election, evidenced by written consent, Lyotropic may grant Eagle and/or its Affiliates written permission during [*] such termination to sell that amount of Product, provided that Eagle shall pay royalties owing thereon in accordance with the provisions of this Agreement.

11.7 Survival. In addition to all rights that have accrued as of the date of termination, the following provisions shall survive the termination of this Agreement for whatever reason: Articles 1, 7, 9, 12, 13, 14 and 15 and Sections 8.6, 10.3, 10.6, 11.3, 11.5, 11.6 and 11.7 In addition, any other provision required to interpret and enforce the Parties' rights and obligations under this Agreement shall also survive, but only to the extent required for the observation and performance of the aforementioned surviving rights or portions of this Agreement.

11.8 Sublicense Rights. Nothing in this Article 11 shall limit or restrict in any way the rights of Eagle as a sublicensee pursuant to Section 2.2.4 of the EPIL License Agreement.

ARTICLE 12
INDEMNIFICATION

12.1 Indemnification By Eagle. Eagle shall at all times during the term of this Agreement and thereafter, indemnify, defend and hold Lyotropic and its Affiliates and their respective officers, directors, employees and agents, and the successors and assigns of the foregoing ("Lyotropic Indemnified Parties"), harmless from and against all liability, demands, damages, including expenses or loses including death, personal injury, illness or property damage of any kind whatsoever, including legal expenses and reasonable attorneys' fees (collectively, "Losses") arising directly or indirectly out of (a) any breach of this Agreement by Eagle or its Affiliates or (b) the gross negligence or willful misconduct or willful omissions by Eagle or its Affiliates or permitted Third Party Manufacturers, except to the extent of those Losses for which, as applicable, Lyotropic has an obligation to indemnify the Eagle Indemnified Parties pursuant to Section 12.2.

12.2 Indemnification By Lyotropic.

12.2.1 Subject to Section 12.2.2, Lyotropic shall defend, indemnify and hold Eagle and its Affiliates and their respective officers, directors, employees and agents ("Eagle Indemnified Parties") harmless from and against all Losses arising directly or indirectly out of (a) any breach of this Agreement or the EPIL License Agreement by Lyotropic, EPIL or its Affiliates or (b) the gross negligence or willful misconduct or willful omissions by Lyotropic, EPIL or its Affiliates, except to the extent of those Losses for which Eagle has an obligation to indemnify the Lyotropic Indemnified Parties pursuant to Section 12.1.

12.2.2 Lyotropic's indemnification obligations in respect of (a) any breach of the EPIL License Agreement by EPIL or its Affiliates or (b) the gross negligence or willful misconduct or willful omissions by EPIL or its Affiliates (an "EPIL Claim") shall be limited to

the amount of corresponding indemnification received by Lyotropic from EPIL under the EPIL License Agreement on account of Losses of the Eagle Indemnified Parties; provided, however, that (i) Lyotropic shall pursue in good faith any EPIL Claim against EPIL and shall seek indemnification for an amount not less than indemnification sought by Eagle in respect thereof, (ii) Eagle shall be entitled to participate in (including receiving copies of all relevant written correspondence and pleadings), but not control any litigation related to such EPIL Claims and to employ counsel of its choice for such purpose; (iii) Eagle's consent shall be required prior to the entry of any judgment, enter into any settlement or otherwise dispose of any EPIL Claim on account of Losses of the Eagle Indemnified Parties, on such terms as the Eagle, in its sole discretion, shall deem appropriate.

12.3 Indemnification Procedure.

12.3.1 Notice of Claim. The indemnified Party (the "Indemnified Party") shall give the indemnifying Party (the "Indemnifying Party") prompt written notice (an "Indemnification Claim Notice") of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification, but in no event shall the Indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party shall furnish promptly to the Indemnifying Party copies of all papers and official documents received in respect of any Losses.

12.3.2 Third Party Claims. The obligations of an Indemnifying Party under this Article 12 with respect to Losses arising from claims of any Third Party that are subject to indemnification as provided for in Section 12.1 or 12.2 (a "Third Party Claim") shall be governed by and be contingent upon the following additional terms and conditions, subject to Section 10.3:

12.3.2.1 Control of Defense. At its option, the Indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within thirty (30) days after the Indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the Indemnifying Party shall not be construed as an acknowledgment that the Indemnifying Party is liable to indemnify any Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the Indemnifying Party of any defenses it may assert against any Indemnified Party's claim for indemnification. Upon assuming the defense of a Third Party Claim, the Indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the Indemnifying Party. In the event the Indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the Indemnifying Party all original notices and documents (including court papers) received by any Indemnified Party in connection with the Third Party Claim. Should the Indemnifying Party assume the defense of a Third Party Claim, the Indemnifying Party shall not be liable to the Indemnified Party or any other Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim. In the event that it is ultimately determined that the Indemnifying Party is not obligated to indemnify, defend or

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hold harmless an Indemnified Party from and against the Third Party Claim, the Indemnified Party shall reimburse the Indemnifying Party for any and all costs and expenses (including attorneys' fees and costs of suit) and any Losses incurred by the Indemnifying Party in its defense of the Third Party Claim with respect to such Indemnified Party.

12.3.2.2 Right to Participate in Defense. Without limiting Section 12.3.2.1, any Indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; provided, however, that such employment shall be at the Indemnified Party's own expense unless (i) the employment thereof has been specifically authorized by the Indemnifying Party in writing or (ii) the Indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 12.3.2.1 (in which case the Indemnified Party shall also control the defense).

12.3.2.3 Settlement. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that will not result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnified Party in any manner, and as to which the Indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the Indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the Indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the Indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 12.3.2.1, the Indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss provided it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld or delayed). The Indemnifying Party shall not be liable for any settlement or other disposition of a Loss by an Indemnified Party that is reached without the written consent of the Indemnifying Party. Regardless of whether the Indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnified Party shall admit any liability with respect to, or settle, compromise or discharge, any Third Party Claim without the prior written consent of the Indemnifying Party.

12.3.2.4 Cooperation. Regardless of whether the Indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall, and shall cause each other Indemnified Party to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making indemnified Parties and

other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the Indemnifying Party shall reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.

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12.3.2.5 Expenses. Except as provided above, the costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any claim shall be reimbursed on a calendar quarter basis by the Indemnifying Party, without prejudice to the Indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the Indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

12.4 Insurance.

12.4.1 At all times from and after the Effective Date for the duration of this Agreement and for such period thereafter as necessary to cover the insured risks, Eagle shall have and maintain such type and amounts of liability insurance covering the development, manufacture, supply, use and sale of the Product as is normal and customary in the pharmaceutical industry generally for parties similarly situated, and shall upon request provide Lyotropic with a copy of its policies of insurance in that regard, along with any amendments and revisions thereto.

12.4.2 Upon commencement of any clinical trial programs involving the EPIL Intellectual Property, Lyotropic IP or Product, Eagle shall maintain product liability insurance in an amount of not less than [*], or such lesser amount as the Parties may agree is commercially reasonable for the scope and scale of such clinical trial program(s) or as may be required to comply with applicable governmental regulation. Eagle may satisfy the foregoing obligation by establishing that the contract research organization conducting the clinical trial program(s) has in force such insurance, that such insurance covers such clinical trial program(s) and that Lyotropic and EPIL are additional named insureds on such insurance. Eagle shall provide Lyotropic with evidence of coverage contemplated hereby, in the form of certificates of insurance as a condition precedent to commencing any clinical trial and as reasonably requested, indicating that Lyotropic and EPIL are additional named insureds on such insurance.

12.4.3. Eagle shall, starting thirty (30) days prior to anticipated receipt of 505(b)(2) Application approval of the Product and extending through the remaining term of this Agreement, carry product liability insurance in an amount of not less than [*] combined single limit. Eagle may satisfy the foregoing obligation by establishing that the marketer of the Product has in force such insurance, that such insurance covers the marketing of the Product, and that Lyotropic and EPIL are additional named insured on such insurance. Eagle shall provide Lyotropic with evidence of coverage contemplated hereby, in the form of certificates of insurance, indicating that Lyotropic and EPIL are additional named insured on such insurance.

ARTICLE 13
LIMITATION OF LIABILITY

13.1 LIMITATION OF LIABILITY. EXCEPT FOR EACH PARTY'S INDEMNIFICATION OBLIGATIONS IN RESPECT OF THIRD PARTY CLAIMS UNDER THIS AGREEMENT, NONE OF LYOTROPIC, EAGLE OR ANY OF THEIR RESPECTIVE AFFILIATES SHALL BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING FOR LOST PROFITS), WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE,

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ARISING OUT OF ANY BREACH OF OR FAILURE TO PERFORM ANY OF THE PROVISIONS OF THIS AGREEMENT.

ARTICLE 14
DISPUTE RESOLUTION

14.1 Good Faith Negotiations. In the event of any dispute or disagreement among the Parties as to the interpretation of any provision of this Agreement or the performance of obligations hereunder, the matter, upon written request of any Party, shall first be referred to the chief executive officers of the Parties for decision. Such chief executive officers shall promptly meet in a good faith effort to resolve the dispute.

14.2 Arbitration.

14.2.1 Procedures. Any dispute arising from or relating to this Agreement that is not resolved by the Parties' chief executive officers pursuant to Section 14.1 shall be determined before a tribunal of three arbitrators in New York, New York in accordance with the Commercial Arbitration Rules of the American Arbitration Association (the "AAA"). One arbitrator shall be selected by Lyotropic, one arbitrator shall be selected by Eagle and the third arbitrator shall be selected by mutual agreement of the first two arbitrators or by the AAA, if the arbitrators appointed by the Parties are unable to select a third arbitrator within thirty (30) days.

14.2.2 Patent Disputes. Any claim, dispute, or controversy concerning the validity, enforceability, or infringement of any patent contained in the Lyotropic Patents licensed hereunder shall be resolved in any court having jurisdiction thereof. In the event that, in any arbitration proceeding, any issue shall arise concerning the validity, enforceability, or infringement of any patent contained in the Lyotropic Patents licensed hereunder, the arbitrators shall, to the extent possible, resolve all issues other than validity, enforceability, and infringement; in any event, the arbitrators shall not delay the arbitration proceeding for the purpose of obtaining or permitting either Party to obtain judicial resolution of such issues, unless an order staying the arbitration proceeding shall be entered by a court of competent jurisdiction. No Party hereto shall raise any issue concerning the validity, enforceability, or infringement

of any patent contained in the Lyotropic Patents licensed hereunder in any proceeding to enforce any arbitration award hereunder, or in any proceeding otherwise arising out of any such arbitration award.

14.2.3 Costs. The costs of such arbitration shall be borne proportionate to the finding of fault as determined by the arbitration panel. Judgment on the arbitration award may be entered by any court of competent jurisdiction.

ARTICLE 15
MISCELLANEOUS

15.1 Publicity. No Party hereto shall originate any publicity, news release or other public announcement, written or oral, relating to this Agreement or the existence of a collaboration among the Parties, without the prior written approval of the other Parties except as otherwise permitted by this Agreement or required, in the reasonable judgment of the disclosing

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Party's attorneys, by Applicable Law, including the Securities Act of 1933, as amended, and the rules and regulations thereunder or as promulgated by an applicable securities exchange governing body.

15.2 Assignment. Either Party may assign this Agreement in its entirety only with the other party's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed; provided, however, that either party may assign this Agreement to an Affiliate or in connection with a merger, sale of such party or all (or substantially all) of its assets or similar reorganization; and provided further, that any such assignment with respect to subject matter of the EPIL License Agreement is subject to the terms and conditions thereof.

15.3 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

15.4 Force Majeure. In the event that any Party fails to perform any of its obligations under this Agreement (other than an obligation to pay money) due to any act of God, fire, casualty, flood, war, strike, lockout, failure of public utilities, injunction, act of a governmental authority (including enactment of any governmental law, order or regulation permanently or temporarily prohibiting or reducing the level of research, development or production work hereunder or the manufacture, use or sale of the Product), epidemic, destruction of production facilities, riot, insurrection, inability to procure or use materials, labor, equipment, transportation or energy in quantities sufficient to meet experimentation or manufacturing needs, or any other cause beyond the reasonable control of the Party invoking this Section 15.4; provided, in each case, that such Party shall have used Commercially Reasonable Efforts to avoid such failure, then such Party shall promptly give written notice of such occurrence to the other Party, and thereupon the affected Party's performance shall be excused and the time for performance shall be extended for the period of delay or inability to perform due to such occurrence.

15.5 Waiver. The waiver by any Party of a breach or a default of any provision of this Agreement by another Party shall not be construed as a waiver of any succeeding breach of the same or any other provision, nor shall any delay or omission on the part of any Party to exercise or avail itself of any right, power or privilege that it has or may have hereunder operate as a waiver of any right, power or privilege by such Party.

15.6 Notices. Any and all notices or other communications made or given pursuant to this Agreement shall be in writing and shall be delivered (i) by express overnight or two-day international courier service, (ii) by certified or registered mail, return receipt requested, or (iii) by confirmed facsimile or other electronic transmission (with confirming copy to follow by express overnight courier service):

In the case of Eagle:

Eagle Pharmaceuticals, Inc.
470 Chestnut Ridge Road
Woodcliff Lake, New Jersey 07677
Attention: Scott Tarriff, President and Chief Executive Officer

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Fax: (201) 391-2430
e-mail: starriff@eagleus.com

With a copy (not constituting notice) to:

Orrick, Herrington & Sutcliffe LLP
666 Fifth Avenue
New York, NY 10103-0001
Attn: R. King Milling, Jr., Esq.
Fax: (212) 506-5151
e-mail: kmilling@orrick.com

In the case of Lyotropic:

Lyotropic Therapeutics, Inc.
10487 Lake Ridge Parkway, Suite 400
Ashland, VA 23005

Attn: Vincent M. Conklin, President
Fax: (804) 550-1309
Email: vconklin@lyotropics.com

With a copy (not constituting notice) to:

Genevieve K. Dybing McCandlish Holton PC
1111 East Main Street, Suite 1500
PO Box 718
Richmond, VA 23218
Fax: (804) 775-3800
Email: gdybing@lawmh.com

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such communication shall be deemed to have been given (a) when delivered, if personally delivered or sent by facsimile on a business day, (b) on the business day after dispatch, if sent by nationally-recognized overnight courier, and (c) on the third business day following the date of mailing, if sent by mail. It is understood and agreed that this Section 15.6 is not intended to govern the day-to-day business communications necessary between the Parties in performing their duties, in due course, under the terms of this Agreement. Notices provided in accordance with this Section 15.6 shall be deemed delivered upon receipt of the notice by the Party being sent the notice.

15.7 No Agency. Nothing herein shall be deemed to constitute any Party as the agent or representative of any other Party, or the Parties hereto as joint venturers or partners for any purpose. Lyotropic shall be an independent contractor, not an employee or partner of Eagle or EPIL, and the manner in which Lyotropic performs its obligations under this Agreement shall be within Lyotropic's sole discretion. Eagle shall be an independent contractor, not an employee or partner of Lyotropic or EPIL, and the manner in which Eagle performs its obligations under this Agreement shall be within Eagle's sole discretion (subject to Eagle's compliance with its obligations under this Agreement). No Party hereto shall be responsible for the acts or omissions of any other Party, and no Party shall have authority to speak for, represent or bind any other Party in any way without prior written authority from such other Party.

15.8 Entire Agreement. This Agreement and the Exhibits and Schedules attached hereto (which Exhibits and Schedules are deemed to be a part of this Agreement for all purposes)

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contain the full understanding of the Parties with respect to the subject matter hereof and supersede all prior understandings and writings relating thereto. No waiver, alteration or modification of any of the provisions hereof shall be binding unless made in writing and signed on behalf of the Parties by their respective officers thereunto duly authorized.

15.9 Severability. In the event that any provision of this Agreement is held by a court of competent jurisdiction to be unenforceable because it is invalid or in conflict with any law of any relevant jurisdiction, the validity of the remaining provisions shall not be affected, and the rights and obligations of the Parties shall be construed and enforced as if the Agreement did not contain the particular provisions held to be unenforceable.

15.10 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their permitted successors and assigns.

15.11 Counterparts. This Agreement may be executed in any number of counterparts (including signature by facsimile), each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

15.12 Further Assurances. Each Party hereby agrees, without further consideration, to execute and deliver such documents and take such other actions as the other Party may reasonably request to carry out the provisions hereof and further the intent of this Agreement.

[Signature Page Follows]

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Confidential

IN WITNESS WHEREOF, the Parties hereto have caused this License and Sublicense Agreement to be executed as a sealed instrument in their names by their properly and duly authorized officers or representatives as of the date first above written.

LYOTROPIC THERAPEUTICS, INC.		EAGLE PHARMACEUTICALS, II \)C.	
By:	/s/ Vincent M. Conklin	By:	/s/ Scott Tarriff
Name:	Vincent M. Conklin	Name:	Seott Tarriff
Title:	President	Title:	President and CEO

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Confidential

Exhibit A

Lyotropic Patents

Treatment Using Dantrolene

US Ser No 10/788A13 [2004-0242646]

PCT/USO4/006135 WO 2005/013919

Aus — 2004 — 262507

Can - 2,516,667

EPO - 04,775,816.4

Jap — 2006-508935

Product Patents

Treatment Using Dantrolene

US Ser No 10/788,413 [2004-0242646]

PCT/USO4/006135 WO 2005/013919

Aus — 2004 — 262507

Can - 2,516,667

EPO - 04,775,816.4

Jap — 2006-508935

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Exhibit 10.13

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LICENSE AND DEVELOPMENT AGREEMENT

This LICENSE AND DEVELOPMENT AGREEMENT (this "Agreement"), is entered into as of the Effective Date by and between THE MEDICINES COMPANY, a Delaware corporation located at 8 Sylvan Way, Parsippany, N.J. 07054 ("MDCO"), and EAGLE PHARMACEUTICALS, INC., a Delaware corporation located at 470 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677 ("Eagle").

BACKGROUND

WHEREAS, MDCO and Eagle mutually desire to enter into the arrangements contemplated herein for the purpose of undertaking a Development Program (as defined in Section 1.1 below), the objective of which is to develop the Existing Product and the Next Products (each as defined in Section 1.1 below); and

WHEREAS, Eagle desires to have MDCO Exploit (as defined in Section 1.1 below) the Products, subject to the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, and other good and valuable consideration received by the Parties, the sufficiency of which is hereby acknowledged, the Parties hereto agree as follows:

ARTICLE 1. DEFINITIONS

1.1. Unless otherwise specifically set forth herein, the following terms shall have their indicated meanings when used in this Agreement.

"AAA" has the meaning set forth in Section 12.2.

"Act" means, as applicable, the United States Federal Food, Drug and Cosmetic Act of 1938, as amended (21 U.S.C. §§ 301 et seq.), and in those circumstances under this Agreement when this Agreement applies to activities in any jurisdiction outside the United States, any counterpart statutes in effect in such jurisdiction.

"Active Ingredient" means Argatroban.

"Affiliate" means, with respect to a Person, any other Person that controls, is controlled by or is under common control with, such first Person. For purposes of this definition only, "control" means (a) to possess, directly or indirectly, the power to direct the management or policies of a Person, whether through ownership of voting securities, by contract relating to voting rights or corporate governance or otherwise, or (b) to own, directly or indirectly, more than fifty percent (50%) of the outstanding voting securities or other voting ownership interest of such Person or such lesser maximum ownership percentage permitted in those jurisdictions restricting foreign ownership.

"Applicable Laws" means all applicable laws, statutes, rules, regulations, guidelines, guidances, ordinances, orders, decrees, writs, judicial or administrative decisions and the like of any nation or government, any state or other political subdivision thereof, any entity exercising executive, judicial, regulatory or administrative functions of or pertaining to government (including any Governmental Authority), any tribunal or arbitrator of competent jurisdiction, and any trade organization whose regulations have the force of law, including applicable laws in respect of sales and marketing of pharmaceutical products.

"Authorized Generic" means a product containing the Active Ingredient that is (a) marketed by or on behalf of Eagle, its Affiliates, licensees or Sublicensees (other than by MDCO, its Affiliates or Sublicensees as provided in this Agreement) as a generic product, and (b) is chemically identical to a branded Product.

"Baxter" means Baxter International, Inc.

"Breaching Party" has the meaning set forth in Section 10.2. "CEO" and "CEOs" has the meaning set forth in Section 12.1.

"cGCP" means the practices set forth in the United States Current Good Clinical Practices (21 C.F.R. Parts 50, 54 and 56) and counterparts thereof in jurisdictions where the Products are developed or sold.

"cGLP" means the practices set forth in the United States Current Good Laboratory Practices (21 CFR 58) and counterparts thereof in jurisdictions where the Products are developed or sold.

"cGMP" means the practices set forth in the United States Current Good Manufacturing Practices (21 CFR 210 and 211) and the applicable counterparts thereof in jurisdictions where the Products are developed or sold or that otherwise may be applicable to the Manufacture of Products.

"Change of Control" means: (1) the sale of all or substantially all of Eagle's assets or business (including all the assets and business relating to this Agreement and the assignment of this Agreement, the Supply Agreement, the Quality Agreement and the Pharmacovigilance Agreement) to an M&A Party; (2) a merger, reorganization or consolidation involving Eagle and an M&A Party, in which the voting securities of Eagle outstanding immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (3) a transaction or series of related transactions in which an M&A Party, or an M&A Party and its Affiliates acting in concert, acquire more than fifty percent (50%) of the voting equity securities or management control of Eagle; *provided, however*, that, with respect to any sale described in clause (1), and with respect to a transaction described in clause (2) or (3) if this Agreement is assigned by Eagle to such M&A Party or its Affiliate in accordance with Section 13.2, all references to Eagle in this Agreement following such Change of Control shall mean, as applicable, such M&A Party or such Affiliate of such M&A Party as assignee of Eagle.

"Claim" means, outside the context of any patent application or patent, any notice of investigation, action, demand, cause of action, claim, suit or proceeding.

"Clinical Supplies" means supplies of the Products, manufactured, packaged and labeled in compliance with cGMP and Applicable Law, in such form and dosage as is necessary for Eagle to comply with its obligations pursuant to the Development Program, and suitable for use in the conduct of pre-clinical or human clinical trials of the Products in or for the United States, including its territories, possession and Puerto Rico pursuant to the Development Program.

"Code" has the meaning set forth in Section 2.7.

"Commercially Reasonable Efforts" means, with respect to a Party's obligations to conduct the research, development, Manufacture or Exploitation of the Products, as applicable, efforts and resources commonly used in the pharmaceutical industry for formulations or products, as applicable, with similar commercial and scientific potential at a similar stage in their lifecycle, taking into consideration their safety and efficacy, their cost to develop, the competitiveness of alternative formulations or products, as applicable, the anticipated or actual nature and extent of their market exclusivity (including Patent coverage and regulatory exclusivity), the likelihood of Regulatory Approval, and their estimated profitability, including the amounts of marketing and promotional expenditures and all other relevant factors.

"Complaint" means any information concerning any side effect, injury, toxicity or sensitivity reaction, or any unexpected incident or adverse drug experience (as that term is defined in Section 505-1 of the Act), in or involving a subject or, in the case of pre-clinical studies, an animal in a toxicology study, and the seriousness thereof, whether or not determined to be attributable to the Active Ingredient or Product, including any such information received by either Party from its Affiliates, Distributors, licensees, Sublicensees or other Third Parties.

"Confidential Information" has the meaning set forth in Section 9.2. "Confidentiality Agreement" has the meaning set forth in Section 9.2.

"Control" (including variations thereof, such as "Controlled" or "Controlling") means, with respect to a Party and any item of Know-How, intellectual property, or rights therein, possession by such Party or its Affiliates of (a) the right, whether directly or indirectly, and whether by ownership, license or otherwise, to assign, or grant a license, sublicense or other right to or under, such item as provided for herein without violating the terms of any agreement with a Third Party or (b) the right to disclose such item as provided for herein without violating the terms of any agreement with a Third Party, except to the extent that any of the foregoing rights arise by virtue of the grant of rights under this Agreement.

"Cover" (including variations thereof such as "Covered," "Coverage," or "Covering") means that the Manufacture, use, importation, offer for sale, or sale of the Product to which such term is being applied would infringe a Valid Claim of the Patent to which such term is being applied in

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the absence of a grant of rights under such Patent. The determination of whether an item or process is Covered by a Valid Claim shall be made on a country by country basis.

"Development Cap" has the meaning set forth in Section 3.6.

"Development Plan" means the Product specifications and an overall budget for the activities set forth therein, together with specific timelines and deliverables, in each case with respect to Eagle's activities to develop the Existing Product and the Next Products.

"Development Program" means the development activities undertaken by Eagle pursuant to this Agreement and the Initial Development Plan and any subsequent Development Plans for the purpose of developing the Existing Product and the Next Products.

"Dispute" has the meaning set forth in Section 12.1.

"Distributor" means, with respect to a Party and a Product, a Third Party appointed by such Party or its Affiliates to distribute and sell such Product, which Third Party purchases such Product from such Party or its Affiliates but does not otherwise make any royalty or other payment to such Party or its Affiliates with respect to the Eagle Intellectual Property licensed to MDCO hereunder.

"Dollars" or ("$") means United States Dollars or the lawful currency of the United States of America.

"Eagle" has the meaning set forth in the introductory paragraph.

"Eagle Intellectual Property" means (a) the Eagle Know-How, the Eagle Patents and any other IP Protection Rights in the Eagle Know-How, and (b) Eagle's interest in the Joint Intellectual Property.

"Eagle Know-How" means Know-How that (a) is Controlled by Eagle on the Effective Date or is solely developed by or on behalf of Eagle (other than by MDCO) or otherwise comes within Eagle's Control during the Term, and (b)(i) is necessary or useful for the development, use, Manufacture or Exploitation of the Active Ingredient or any Product, or (ii) was or is used, or is generated, by or on behalf of Eagle (other than by MDCO) in the development, use, Manufacture or Exploitation of the Active Ingredient or any Product. Eagle Know-How excludes Eagle's interest in the Joint Know-How, but expressly includes the SciDose Know-How (as defined in the SciDose License Agreement). ·

"Eagle Patents" means Patents that describe or claim Eagle Know-How and expressly includes the SciDose Patent Rights (as defined in the SciDose License Agreement).

"Effective Date" means the later of: (i) the effective date of the Supply Agreement, and (ii) the date the side letter among Eagle, MDCO and SciDose has been executed by authorized representatives of Eagle, MDCO and SciDose.

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"Existing Product" means liquid Argatroban injectable pharmaceutical product having a concentration of lmg/mL presented in a 50mL vial.

"Exploit," "Exploiting" or "Exploitation" means to offer for sale, sell and import, including to store, handle, hold/keep for inventory, distribute, promote, market, export or otherwise make available or deal in respect of, a product or process, or have an Affiliate, Distributor or

Sublicensee do any of the foregoing on behalf of a Party. "Exploiting" excludes any activities related to Manufacturing.

"FDA" means the United States Food and Drug Administration, or any successor agency to its responsibilities with respect to drugs.

"Field" means any and all human uses.

"First Commercial Sale" means, with respect to a Product, the first sale for monetary value for use or consumption by a member of the general public of such Product in a country in the Territory after receipt of all Regulatory Approvals for the sale of such Product has been obtained in such country. For the avoidance of doubt, sales prior to receipt of all Regulatory Approvals, such as so-called "treatment IND sales," "named patient sales" and "compassionate use sales," shall not be construed as a First Commercial Sale.

"GAAP" means United States generally accepted accounting principles as in effect from time to time, consistently applied.

"Generic Competing Product" means, with respect to any given jurisdiction, any product containing the Active Ingredient, including, for purposes of clarity, any AP-rated version of the GSK Product, that has received Regulatory Approval from the FDA and is being sold by a Third Party for not less than thirty (30) consecutive days, where in such jurisdiction (a) no Regulatory Approval is required for the introduction of such product into commerce in such jurisdiction for use in humans or the delivery of such product for such introduction into commerce in such jurisdiction for use in humans or (b) such product has received Regulatory Approval through an abbreviated process (including, with respect to the United States, Abbreviated New Drug Applications under Section 505(j) of the Act (21 USC 355(j)) or New Drug Applications under Section 505(b)(2) of the Act (21 USC 355(b)(2)) or outside the United States, any counterparts thereof); *provided*, *however*, that any pharmaceutical product containing the Active Ingredient (other than a Product that is an AP-rated version of the GSK Product) and marketed or otherwise Exploited by Baxter or its Affiliates shall not be a Generic Competing Product; provided, further, for purposes of clarity, any pharmaceutical product marketed or otherwise Exploited by Baxter or its Affiliates that is an AP-rated version of the GSK Product shall be a Generic Competing Product hereunder.

"Governmental Authority" means any court, tribunal, arbitrator, agency (including the FDA), legislative body, department, board, commission, official or other instrumentality of (a) any

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government of any country, (b) a federal, state, province, county, city or other political subdivision thereof or (c) any supranational body.

"Gross Profit" means, with respect to a Product, with respect to a Party or its Affiliates and with respect to a calendar quarter, (a) Net Sales of such Product during such calendar quarter, plus (b) Sublicensing Revenue received with respect to such Product during such calendar quarter, minus (c) the Supply Cost for the units of such Product sold during such calendar quarter.

"GSK Product" means GlaxoSmithKline's Argatroban product that has received Regulatory Approval from the FDA on or before the Effective Date.

"Indemnitee" has the meaning set forth in Section 11.3.

"Indemnitor" has the meaning set forth in Section 11.3.

"Initial Development Plan" has the meaning set forth in Section 3.5. "Insolvency Event" has the meaning set forth in Section 10.5. "Insolvent Party" has the meaning set forth in Section 10.5.

"Invention" means any Know-How conceived, reduced to practice, or developed in the course of performing activities under this Agreement.

"IP Protection Rights" means any and all legal means of establishing rights in and to ideas, information, discoveries, Know-How, data, databases, documentation, reports, materials, writings, designs, computer software, processes, principles, methods, techniques and other information, including Patents, registered designs, design rights, copyrights (including rights in computer software and database rights), trade secret rights, and any rights or property similar to any of the foregoing in any part of the world, whether registered or not, together with the right to apply for the registration of any such rights, as appropriate.

"Joint Intellectual Property" means (a) the Joint Know-How, and (b) the Joint Patents and any other IP Protection Rights in the Joint Know-How.

"Joint Know-How" means Know-How that is made jointly by one or more employees, agents, consultants, and contractors of MDCO and its Affiliates, on the one hand, and by one or more employees, agents, consultants and contractors of Eagle and its Affiliates, on the other hand; *provided*, *however*, that, patentable Know-How is Joint Know-How if one or more employees, agents, consultants or contractors from each of MDCO and Eagle would be considered inventors of such Know-How in accordance with United States patent laws.

"Joint Patents" means Patents that describe or claim Joint Know-How.

"Joint Steering Committee" or "JSC" has the meaning set forth in Section 3.4.1.

"Know-How" means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, principles, practices, formulae, instructions,

documentation, skills, techniques, procedures, experiences, ideas, compositions of matter, article of manufacture, discoveries, findings, technical assistance, designs, drawings, reports, procedures, computer programs, apparatuses, specifications, data, results and other information and material, including the process and results of drug discovery and development technology, biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, Manufacturing and quality control data and information, including study designs and protocols; assays and biological methodology; Manufacturing and quality control procedures and data, including test procedures; and synthesis, purification and isolation techniques, or improvements to any of the preceding; in each case, whether or not confidential, proprietary, patented or patentable, and whether or not in written, electronic or any other form now known or hereafter developed.

"Logistics Coordinator" has the meaning set forth in Section 7.4.1.

"Losses" has the meaning given to that term in Section 11.1. In calculating Losses, the duty to mitigate on the part of the Party suffering the Loss shall be taken into account.

"Manufacture" and "Manufacturing" means, with respect to a product or compound, the synthesis, manufacturing, processing, formulating, compounding, filling, finishing, validating, testing, releasing, packaging, labeling, holding and quality control testing of such product or compound.

"Marketing Plan(s)" means the sales and marketing plans for the Existing Product and the Next Products in the Field in the Territory, the initial form of which is attached hereto as Exhibit A, and which may be amended from time to time by MDCO in its reasonable discretion and in consultation with Eagle.

"M&A Party" means any of the following or their respective Affiliates: (a) Fresenius SE, (b) Hospira, Inc., (c) Teva Pharmaceutical Industries, Ltd. or (d) Baxter.

"MDCO" has the meaning set forth in the introductory paragraph.

"MDCO Intellectual Property" means the (a) MDCO Know-How, (b) the MDCO Patents and any other IP Protection Rights in the MDCO Know-How, and (c) MDCO's interest in the Joint Intellectual Property.

"MDCO Know-How" means Know-How that (a) is Controlled by MDCO on the Effective Date or is solely developed by or on behalf of MDCO (other than by Eagle) or otherwise comes within MDCO's Control during the Term, and (b) is used, or generated by, MDCO in the development, use, Manufacture or Exploitation of the Active Ingredient or Product in the Field in the Territory. MDCO Know-How excludes MDCO's interest in the Joint Know-How.

"MDCO Patents" means Patents that describe or claim MDCO Know-How.

"NDA" means a New Drug Application and all amendments and supplements thereto for a Product submitted by Eagle to the FDA or any other applicable Regulatory Authority, including all documents, data and other information included in an accepted NDA submission for Regulatory Approval to market and sell such Product in the Field in the Territory.

"Net Sales" means, with respect to a Product, the total gross amount invoiced on sales of the Products by MDCO and its Affiliates to non-Sublicensee Third Parties (including to Distributors) in the Field in the Territory, less such items, as determined from the books and records of MDCO or its Affiliates, as applicable, that such entity deducts from such gross amount for purposes of determining the net sales account used in the preparation of its independently audited financial statements and otherwise in accordance with GAAP, including cash discounts, returns, charge-backs, rebates, fees for services and Third Party administrative fees allocable to such product and amounts previously included in Net Sales that are written-off as uncollectible; provided that if any such written-off amounts are subsequently collected, such collected amounts shall be included in Net Sales in the period in which they are subsequently collected. For purposes of this Agreement, "sale" shall include any transfer or other distribution or disposition of such Product other than transfers or other distributions or dispositions of such Product, at no charge or at a nominal charge, for pre-clinical, clinical or regulatory purposes or to physicians or hospitals for promotional purposes, provided such transfer, distribution or disposition is not made in exchange for lower prices on other MDCO products, as applicable, or for other noncash consideration. In the event that consideration in addition to or in lieu of money is received for the sale of such Product in an arms-length transaction, the fair market value of such consideration shall be included in the determination of Net Sales for such sale. To the extent that such Product is sold in other than an arms-length transaction, Net Sales for such sale shall be the average sales price of such Product sold in arms-length transactions during

the applicable royalty reporting period in the country in which the non-arms-length transaction occurred. If MDCO or any of its Affiliates sell such Product as part of a discounting program that financially disadvantages the Product(s) relative to other MDCO products, then all such discounts shall be reasonably allocated proportionately between sales of the Products, as applicable, and sales of any other MDCO products. MDCO will not use a Product as a "loss leader" or bundle a Product with sales of its other products in any discounting program that would result in financially disadvantaging such Product relative to other MDCO products.

For purposes of calculating Gross Profits, Net Sales may apply to sales of Product(s) by Eagle or its Affiliates, in which case Net Sales shall have the meaning set forth above with all references to "MDCO" replaced by "Eagle".

"Next Products" means (a) liquid Argatroban injectable pharmaceutical product having a concentration of 1 mg/mL in 100mL minibag presentation, and (b) liquid Argatroban injectable pharmaceutical product having a concentration of Img/mL in 150mL minibag presentation.

"Paid Party" has the meaning set forth in Section 4.9.

"Paying Party" has the meaning set forth in Section 4.9.

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"Party" means either Eagle or MDCO. "Parties" means Eagle and MDCO.

"Patents" means (a) all national, regional and international patents and patent applications, including nonprovisional and provisional patent applications, (b) all patent applications filed either from such patents, nonprovisional patent applications or provisional patent applications or from an application claiming priority from any of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and continued prosecution applications, (c) any and all patents that have issued or in the future issue from the foregoing patent applications described in clauses (a) or (b) of this definition, including utility models, petty patents and design patents and certificates of invention, (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidation, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications described in clauses (a), (b) or (c) of this definition, and (e) any similar rights, including so-called pipeline protection, or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any such foregoing patent applications and patents.

"Person" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a Governmental Authority.

"Pharmacovigilance Agreement" has the meaning set forth in Section 8.3.4.

"Product(s)" means any drug product containing the Active Ingredient, including the Existing Product and the Next Products.

"Proposed ROW Transaction" has the meaning set forth in Section 2.6.2. "Quality Agreement" has the meaning set forth in Section 8.6.

"Regulatory Approval" means, with respect to a country in the Territory and a Product, any and all approvals, licenses, registrations or authorizations of any Regulatory Authority necessary to commercially Exploit such Product in such country.

"Regulatory Authority" means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agency, department, bureau, commission, council or other Governmental Authority regulating or otherwise exercising authority with respect to the development, Manufacture, use, handling, storage, distribution, sale, promotion, marketing, labeling, reimbursement, pricing or other Exploitation of drugs in the Territory.

"Representative" means, with respect to any Person, any of its Affiliates and any of its or its 1 Affiliates' directors, officers, employees, agents and advisors (including financial, legal and accounting advisors).

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"ROW" means one or more countries in the world except for (a) the Territory and (b) China, unless and until Eagle regains rights to the relevant Product in respect of such country.

"ROW Notice" has the meaning set forth in Section 2.6.2. "Royalty" has the meaning set forth in Section 4.5.1. "SAE" has the meaning set forth in Section 8.3.1.

"Safety Data" means adverse event or adverse experience information, as defined under 21 C.F.R. §600.80, or the equivalent under any other applicable law, and other information regarding health risks posed by a Product or the Active Ingredient, including Complaints and information from clinical studies.

"Safety Database" has the meaning set forth in Section 8.4.

"Sale Transaction" means: (a) the sale of all or substantially all of Eagle's assets or business (including all the assets and business relating to this Agreement and the assignment of this Agreement, the Supply Agreement, the Quality Agreement and the Pharmacovigilance Agreement); (b) a merger, reorganization or consolidation involving Eagle, in which the voting securities of Eagle outstanding immediately prior thereto cease to represent at least fifty percent (50%) of

the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (c) a transaction or series of related transactions in which Eagle sells more than fifty percent (50%) of the voting equity securities or management control of Eagle; *provided, however*, that, with respect to any sale described in clause (a), and with respect to a transaction described in clause (b) or (c), if this Agreement is assigned by Eagle to the relevant Third Party or its Affiliate in accordance with Section 13.2, all references to Eagle in this Agreement following such Sale Transaction shall mean, as applicable, such Third Party or such Affiliate of such Third Party as assignee of Eagle.

"SciDose" means SciDose, LLC, a limited liability company having its principal place of business at 196 N. Pleasant Street, Suite 16, Amherst, MA 01002.

"SciDose License Agreement" means the Development and Licensed Agreement entered into by and between SciDose and Eagle effective as of June 12, 2007, as amended March 18, 2008, and, subject to Section 6.2.5, as further amended from time to time during the Term.

"sNDA" means an application submitted to the FDA to allow a sponsor to make changes in a drug product that already has an approved NDA, which for major changes requires FDA approval of the supplemental NDA prior to distribution of the drug product made using the change (i.e., any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product) and for minor changes requires submission of the supplemental NDA at least thirty (30) days prior to distribution of the drug product made using the change (i.e., any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a moderate potential to have an adverse effect on the

identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product), or as determined by the FDA.

"Solvent Party" has the meaning set forth in Section 10.5.

"Sublicensee" means, with respect to any Product, a Third Party to whom MDCO or Eagle, as applicable, has granted a sublicense or license, as applicable, under any Eagle Intellectual Property, which shall, for the avoidance of doubt, exclude any Third Party acting solely as a Distributor with respect to such Product.

"Sublicensing Revenue" means all consideration received by MDCO or its Affiliates with respect to rights granted to a Sublicensee(s) to Exploit a Product(s) for sale in the Territory, but excluding the sum of (a) consideration received by MDCO or its Affiliates as payments for actual direct costs for performing development or Exploitation activities or activities undertaken by MDCO or its Affiliates for, or in collaboration with, such Sublicensee(s) or their Affiliates, in each case in Canada, and (b) consideration paid by such Sublicensee(s) to MDCO or its Affiliates to purchase such Product(s); *provided, however*, that any consideration greater than the applicable Supply Cost shall not be so excluded.

Sublicensing Revenue shall also include consideration other than cash received for granting the Sublicense. Where the consideration received for granting such rights is not cash, then the "Sublicensing Revenue" shall be deemed to be the fair market value for such non-cash consideration received by Licensee or its Affiliates in exchange for the granting of such rights.

For purposes of calculating Gross Profits, Sublicensing Revenue may apply to Sublicenses granted by Eagle or its Affiliates, in which case Sublicensing Revenue shall have the meaning set forth above with all references to "MDCO" replaced by "Eagle".

"Supply Agreement" has the meaning set forth in Section 8.6.

"Supply Cost" means, with respect to Eagle's Manufacture or acquisition of a unit of a Product and supply thereof to MDCO, Eagle's external costs, determined in accordance with GAAP by Eagle and consistent with Eagle's financial reports in the ordinary course of its business, which costs shall include:

(a) the cost of goods produced, which shall include direct material, excipients, active pharmaceutical ingredients, overhead and Third Party expenses, but, notwithstanding anything to the contrary herein, shall not include any intellectual property acquisition or licensing costs or royalties directly allocable to the Manufacture, use, offer for sale, sale or importation of such Product;

(b) costs incurred by Eagle for the packaging, transport and storage of such unit of such Product directly allocable to the Manufacture of such Product (including the costs for containers, freight, duties, insurance, and warehousing); and

(c) costs incurred by Eagle associated with (i) stability and other product testing and activities relating to quality assurance and quality control, (ii) external regulatory affairs activities or (iii) product liability and loss insurance; provided that, in each case such costs are directly applicable to such unit of such Product;

provided, however, that any costs of managing the Manufacturing and supply logistics shall be excluded.

For purposes of calculating Gross Profits, Supply Cost may apply to sales of Product(s) by Eagle or its Affiliates, in which case Supply Cost shall mean Eagle's costs to Manufacture or acquire a unit of the relevant Product for sale by Eagle or its Affiliates, determined as set forth above.

"Term" has the meaning set forth in Section 10.1. "Terminating Party" has the meaning set forth in Section 10.2.

"Territory" means the United States of America, including its territories and possessions, and Puerto Rico and Canada.

"Third Party" means any Person other than the Parties and the Parties' respective Affiliates. "Third Party Payment" has the meaning set forth in Section 4.5.2.

"Trigger Date" has the meaning set forth in Section 2.5.

"Valid Claim" means a claim in a pending patent application or an issued and unexpired patent that: (a) has not been finally cancelled, withdrawn, abandoned or rejected by any administrative agency or other body of competent jurisdiction not subject to further appeal; (b) has not been revoked, held invalid, or declared unpatentable or unenforceable in a decision of a court or other body of competent jurisdiction that is unappealable or unappealed within the time allowed for appeal; (c) has not been rendered unenforceable through disclaimer, abandonment, withdrawal or otherwise; and (d) with respect to a claim in a pending patent application, such claim is being actively prosecuted in. good faith and is believed in good faith to meet the requirements of patentability in the relevant jurisdiction; provided, however, that this clause (d) shall not apply to any such claims that have been pending for more than four (4) years from the priority date of the applicable patent application.

1.2. Words such as "herein", "hereinafter", "hereof' and "hereunder" refer to this Agreement as a whole and not merely to a section, paragraph or clause in which such words appear, unless the context otherwise requires. Enumerative references to sections, paragraphs or clauses, or exhibits, without reference to an explicit agreement, document or exhibit, refer to this Agreement or exhibits attached to this Agreement, as applicable. The singular shall include the plural, and each masculine, feminine and neuter reference shall include and refer also to the others, unless the context otherwise requires. The words "include", "includes" and "including" are deemed to be followed by "without limitation" or words of similar import. Except where the context otherwise requires, the word "or" is used in the inclusive sense (and/or).

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ARTICLE 2. GRANT OF LICENSES

2.1. **License Grant to MDCO**. Subject to the terms and conditions hereof, Eagle hereby grants to MDCO an exclusive (even as to Eagle, except to the extent necessary for Eagle to perform its obligations hereunder), royalty-bearing license, including, subject to Section 2.3, the right to grant sublicenses, under the Eagle Intellectual Property to use, develop, Manufacture and have Manufactured, offer for sale, market, promote, sell, import and otherwise Exploit the Products in the Field in the Territory. For purposes of clarity, except pursuant to Section 2.5, in no event shall Eagle, itself or through its Affiliates or any Third Party, launch any Authorized Generic version of a Product in the Territory.

2.2. **Reservation of Rights**. Eagle hereby retains any and all rights in the Eagle Intellectual Property that are not expressly granted to MDCO hereunder. Nothing in Section 2.1 limits Eagle's ability to perform its obligations under this Agreement, the Supply Agreement or the Quality Agreement. For purposes of clarity and without limitation, Eagle has exclusively retained (even as to MDCO), but subject to Section 2.6, the right to perform (alone or with Third Parties) any and all activities related to the use, research, manufacture and development of Products outside the Field and the Territory, to Exploit the Products outside the Field in the Territory and in all fields outside the Territory, and to fully use and exploit Eagle Intellectual Property to research, develop, use, Manufacture and Exploit products other than Products.

2.3. **Sublicenses**. MDCO shall have the right to grant to its Affiliates or to one or more Third Parties, through one or more tiers of Sublicensees, sublicenses under the licenses granted to MDCO in Section 2.1 to use, develop, Manufacture and have Manufactured, offer for sale, market, promote, sell, import and otherwise Exploit the Products in the Field in the Territory, subject to Eagle's prior written consent (not to be unreasonably withheld); *provided, however*, that Eagle's consent is not required for MDCO to sublicense its rights to Manufacture or have Manufactured the Products to the extent MDCO is permitted to Manufacture or have Manufactured the Products in accordance with the Supply Agreement. Any such sublicense shall be subject and subordinate to the terms of this Agreement, including Section 2.2. MDCO shall provide Eagle with a copy of each sublicense agreement with any Sublicensee promptly after executing the same.

2.4. **Distributorships**. MDCO has the right to appoint its Affiliates as distributors of the Products in any country of the Territory, and MDCO and its Affiliates shall have the right to appoint any Third Party(ies) as Distributor(s).

2.5. **Certain Marketing Rights**. With respect to Products in the United States only, beginning on the date (the "Trigger Date") that is later of (i) June 30, 2012 and (ii) the date on which a Generic Competing Product has been sold by a Third Party for thirty (30) consecutive days (in accordance with the definition of Generic Competing Product), whether with Eagle's and MDCO's prior written consent or if applicable, upon (or as part of) settlement of a litigation under Section 5.4 that allows a Third Party to sell or offer for sale in the United States any Generic Competing Product, or otherwise, then (A) solely in the United States, in lieu of future

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milestone, Royalty and Sublicensing Revenue obligations set forth in Sections 4.1, 4.2, 4.3, 4.4 and 4.5, each of MDCO, on the one hand, and Eagle and its Affiliates, on the other hand, shall equally share the Gross Profits with respect to the Existing Product and the Next Products, in accordance with Sections 4.12 (Allocation of Gross Profits) and 4.13 (Gross Profit Reporting and Reconciliation) and (B) if Eagle has, on or before the Trigger Date, closed a Change of Control transaction, then both MDCO and its Affiliates and Eagle and its Affiliates shall have the right to sell and market and otherwise Exploit the Existing Product and Next Products in the United States, subject to the foregoing clause (A) of this Section 2.5.

2.6. **Right of First Negotiation for Products in the ROW**.

2.6.1. Notwithstanding anything to the contrary in this Agreement, after the Effective Date, neither Eagle nor its Affiliates shall enter into any agreement granting to any Third Party the right to develop, use, offer for sale, market, promote, sell, import or otherwise Exploit Products in the ROW nor shall Eagle or its Affiliates directly or indirectly sell Products to any Third Party in the ROW, except as permitted by this Section 2.6; *provided, however*, that Eagle and its Affiliates shall have the right to enter into agreements with contract research organizations, academic or other non-commercial research and development organizations, clinical collaborators, specialty contract sales organizations and other similar service providers working on Eagle's or its Affiliates' behalf in connection with the development by Eagle or its Affiliates of Products in the Field in the ROW.

2.6.2. Except as otherwise provided in Section 2.6.1, if Eagle or its Affiliates desire to enter into an agreement granting any rights to any Third Party to develop, use, offer for sale, market, promote, sell, import or otherwise Exploit any Product in the Field in the ROW, Eagle shall notify MDCO in writing of Eagle's desire to grant such rights prior to conducting substantive negotiations with any such Third Party (the "ROW Notice"). MDCO may, within thirty (30) days after receipt of the ROW Notice, deliver to Eagle a written notice as to whether MDCO wishes to negotiate with Eagle to enter into a transaction (the "Proposed ROW Transaction") related to the rights set forth in the ROW Notice. If MDCO notifies Eagle in writing within such thirty (30) day period that it does not wish to negotiate with Eagle to enter into the Proposed ROW Transaction, or fails to notify Eagle in writing within such thirty (30) day period that MDCO wishes to negotiate with Eagle to enter into the Proposed ROW Transaction, then Eagle shall be free to negotiate and enter into a definitive agreement with a Third Party with respect to the Proposed ROW Transaction.

2.6.3. If, within the thirty (30) day period described in Section 2.6.2, MDCO notifies Eagle that it wishes to negotiate with Eagle to enter into the Proposed ROW Transaction, then the Parties shall exclusively negotiate in good faith the terms of the Proposed ROW Transaction for a period of sixty (60) days after Eagle's receipt of MDCO's written notice of interest in the Proposed ROW Transaction; *provided, however*, that if the Parties fail to execute a definitive agreement with respect to the Proposed ROW

Transaction within such sixty (60) day period, then Eagle shall be free to enter into a definitive written agreement with a Third Party with respect to the Proposed ROW Transaction; *provided, however* that such Third Party agreement shall provide such Third Party with no better terms, in the aggregate, than those last offered to MDCO.

2.6.4. The right of first negotiation set forth in this Section 2.6 shall apply separately with respect to each Proposed ROW Transaction.

2.7. Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement are and will otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code (Title 11, U.S. Code), as amended (the "Code"), licenses of rights to "intellectual property" as defined in Section 101(35A) of the Code. The Parties will retain and may fully exercise all of their respective rights and elections under the Code. Eagle agrees that MDCO, as licensee of rights under this Agreement, will retain and may fully exercise all of its rights and elections under the Code or any other provisions of Applicable Law outside the United States that provide similar protection for "intellectual property." The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against Eagle or its Affiliates under the Code or analogous provisions of Applicable Law outside the United States, MDCO will be entitled to a complete duplicate of (or complete access to, as appropriate) such intellectual property and all embodiments of such intellectual property, which, if not already in MDCO's possession, will be promptly delivered to it upon such MDCO's request therefor. Any agreements supplemental hereto will be deemed to be "agreements supplementary to" this Agreement pursuant to Section 365(n) of the Code.

2.8. No Implied Licenses. Only licenses and rights expressly granted herein shall be of legal force and effect. No license or other right shall be created hereunder by implication, estoppel or otherwise.

2.9. Challenge. Neither MDCO nor any of its Affiliates shall directly challenge, or directly assist any Third Party in challenging, in any forum the validity, enforceability, scope or any other elements of the Eagle Patents. Without limiting the generality of the foregoing, MDCO specifically agrees that filing a request for reexamination, attempting to institute an interference, or filing an opposition with respect to any Eagle Patent or foreign counterparts thereof will be deemed a "challenge" under this Section 2.9.

ARTICLE 3. DEVELOPMENT PROGRAM AND PRODUCT EXPLOITATION

3.1. Objectives. The objective of the Parties in undertaking the Development Program is for Eagle to develop the Existing Product and the Next Products, for which Eagle shall use Commercially Reasonable Efforts to seek and obtain Regulatory Approvals in the United States of America, including its territories, possessions and Puerto Rico and that can thereupon be Exploited by MDCO.

3.2. Eagle's Development Responsibilities.

3.2.1. Eagle shall use Commercially Reasonable Efforts to (a) perform the obligations at and by such times set forth in the Development Plan and for which Eagle is designated as being responsible, in each case under the direction and supervision of the Joint Steering Committee and in compliance with good scientific practices, all Applicable Law, including cGLP and cGCP, where applicable, and (b) develop, and obtain Regulatory Approval from the FDA in its name for, the Existing Product and the Next Products.

3.2.2. Eagle shall procure, at its expense, the Active Ingredient to meet its requirements for development and feasibility studies and any other activities under the Development Program.

3.2.3. Eagle, at its expense, shall use Commercially Reasonable Efforts to file with the FDA and obtain Regulatory Approval from the FDA an sNDA for the Next Products; *provided*, *however*, that, subject to Eagle's obligations set forth in this ARTICLE 3, Eagle shall have the right to control the content and administration of the submission of the sNDA.

3.2.4. Eagle shall use Commercially Reasonable Efforts to ensure that the Existing Product and the Next Products will be capable of being Manufactured in a commercially practicable manner in accordance with customary pharmaceutical industry practices, cGMP requirements applicable in the United States, and in accordance with all other Applicable Laws.

3.3. **MDCO's Development Responsibilities**. Upon the reasonable request of Eagle, and subject to Section 3.6, MDCO shall use Commercially Reasonable Efforts to assist Eagle in performing its responsibilities under the Development Plan.

3.4. **Joint Steering Committee**.

3.4.1. **Formation and Appointments**. Promptly following the Effective Date, a Joint Steering Committee for the Development Program shall be formed (the "Joint Steering Committee" or "JSC"). Each of MDCO and Eagle shall appoint two (2) individuals to the Joint Steering Committee. MDCO and Eagle shall have the right to change these appointments and designate substitutes for one or all of its appointments. Each Party shall notify the other Party in writing as soon as practicable upon making or changing any of these appointments. The Joint Steering Committee shall be disbanded upon expiration or termination of this Agreement in its entirety.

3.4.2. **Meetings.** The Joint Steering Committee shall meet on such dates and at such times as agreed to by the members appointed by MDCO and Eagle until such time as the Joint Steering Committee determines or the Parties mutually agree to alternative meeting dates or times. Such meetings may be conducted by telephone or videoconference. At each meeting of the Joint Steering Committee, the Eagle representatives shall provide an update of the Development Program activities conducted since the last meeting, the

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results thereof and the budget consumed thereby, as well as plans for the Development Program activities to be conducted thereafter and the budget therefor. MDCO and Eagle shall each be responsible for its own costs in connection with participating in the meetings of the Joint Steering Committee.

3.4.3. **Decision-Making; Dispute Resolution**. The principal purpose of the Joint Steering Committee shall be to provide a forum for open communication between the Parties with respect to (a) the development of the Existing Product and the Next Products, including the process for Manufacturing such Products, (b) Manufacturing and supply logistics, and (c) progress in the Territory pursuant to the Marketing Plan, including providing the members of the JSC with forecasts for Products in accordance with the Supply Agreement. The members of Joint Steering Committee shall collaborate in good faith on the conversion of the Product from the vial to the minibag presentation. The Joint Steering Committee may make recommendations regarding the overall strategy for the Development Program, and shall provide advice, guidance, direction and other recommendations with respect to the conduct of the Development Program; *provided*, *however*, that in no event shall Eagle amend the Product specifications, deliverables, budget or timelines set forth in the Development Plan without the approval of the Joint Steering Committee. If the JSC is unable to resolve any dispute or unanimously agree on any changes to the Product specifications, deliverables, overall budget or timelines set forth in the Development Plan, such dispute or disagreement shall be referred to the CEO of Eagle and the CEO of MDCO for resolution, and the CEOs shall use their reasonable and good faith efforts to resolve the matter in good faith within thirty (30) days after such referral, subject to Section 12.1.

3.5. **Development Plan**. As of the Effective Date the Parties have mutually agreed on an initial Development Plan attached hereto as Exhibit B (the "Initial Development Plan"), with respect to the continuing development of the Existing Product and the development of the Next Products. From time to time during the Term, the Joint Steering Committee, subject to Section 3.4, may revise the Initial Development Plan or any subsequent Development Plan for the purpose of making such changes thereto as it, in its judgment, may deem necessary or appropriate.

3.6. **Funding of Development Program**. MDCO shall reimburse Eagle up to [*] (the "Development Cap") for Eagle's internal and out-of-pocket costs for conducting the Development Program for the Next Products after the Effective Date; *provided*, *however*, that if such post-Effective Date costs incurred on or before the receipt of Regulatory Approval by the FDA for the Next Products are less than the Development Cap, then MDCO shall reimburse Eagle for internal and out-of-pocket costs incurred by Eagle in developing the Next Products prior to the Effective Date, up to the Development Cap for such pre-Effective Date and post-Effective Date costs, in the aggregate. Eagle shall provide MDCO with a budget and other documentation reasonably requested by MDCO in connection with such payments, which budget shall be made a part of the Development Plan and shall be included within Exhibit B. MDCO shall make the payments described in this Section 3.6 within thirty (30) days after MDCO's

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receipt of an invoice therefor, which invoice shall not be issued by Eagle more frequently than monthly.

3.7. **Records; Reports**.

3.7.1. Each Party shall maintain, or cause to be maintained, records of its respective activities under the Development Program in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall be complete and accurate and shall fully and properly reflect all work done and results achieved in the performance of its respective activities under the Development Program, and which shall be retained by such Party for at least five (5) years after the termination of the Development Program, or for such longer period as may be required by Applicable Law (the "Retention Period"); provided always that before Eagle or MDCO destroys any such record upon expiration of the applicable

Retention Period, such Party shall offer the other Party in writing to transfer such record to the other Party and shall, should the other Party declare in writing that it wishes to have such record transferred, transfer it to the other Party, at the other Party's cost, without unreasonable delay and before destroying any records related to Eagle Intellectual Property or Joint Intellectual Property upon expiration of the applicable Retention Period, such Party shall offer to the other Party in writing to transfer such record to the other Party and shall, should the other Party declare in writing that it wishes to have such record transferred, transfer it to the other Party, at the other Party's cost, without unreasonable delay. Such records shall include books, records, reports, research notes, charts, graphs, comments, computations, analyses, recordings, photographs, computer programs and documentation thereof, samples of materials and other graphic or written data generated by any Party in connection with the Development Program, including any data required to be maintained pursuant to Applicable Laws.

3.7.2. During the Term, Eagle shall respond to reasonable requests from MDCO for access to or copies of Know-How generated by Eagle pursuant to the Development Program.

3.7.3. If requested by MDCO, Eagle shall cause appropriate individuals working on the Development Program to be available for meetings in person, teleconference or video conference at the facilities where such individuals are employed at times reasonably convenient to Eagle and such individuals.

3.8. **Post-Regulatory Approval**. Eagle shall (a) maintain Regulatory Approval(s) of the Products in the Field in the Territory at all times during the Term following receipt of the same, subject to MDCO's cooperation with such efforts as may be required to maintain such Regulatory Approval(s) and (b) conduct any post-Regulatory Approval development programs for the Product(s) that are required by or negotiated with the FDA as a condition to obtaining or maintaining Regulatory Approval of the Product(s).

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3.9. **Product Exploitation by MDCO**.

3.9.1. MDCO shall use Commercially Reasonable Efforts to have adequate sales and marketing personnel to meet its obligations under this Agreement.

3.9.2. If Regulatory Approval for an Existing Product or Next Product in the Field is obtained by Eagle in any country in the Territory, then MDCO shall use Commercially Reasonable Efforts to detail and promote, market and sell such Product to maximize the sales of such Product in the Field in such country.

3.9.3. If Regulatory Approval for an Existing Product or Next Product in the Field is obtained by Eagle in any country in the Territory, then, except as otherwise expressly provided herein, MDCO shall have responsibility for all advertising, marketing, promotion, distribution, selling and other Exploitation activities, including developing strategies and tactics related to such activities for such Product in the Field in such country.

3.9.4. MDCO shall, subject to its obligations set forth herein, (a) use Commercially Reasonable Efforts to prepare appropriate promotional campaigns and materials, and designate qualified commercial personnel, to seek to Exploit the Products in the Field in such country as set forth in the Marketing Plan, and (b) include Eagle in such efforts in an advisory and consultative capacity.

3.9.5. Subject to any conditions or limitations set forth in this Agreement, including Section 2.5 and this Section 3.9, in respect of any Product in the Field and in any country in the Territory, it shall be MDCO's sole right and responsibility to (a) use Commercially Reasonable Efforts to launch such Product in the Field in such country as soon as reasonably practicable after receipt of the applicable Regulatory Approval, (b) develop advertising and promotional materials related to such Product in such country, (c) record sales for such Product in such country, (d) handle all returns of the Product in such country, (e) handle all aspects of order processing, invoicing and collection of receivables, (1) collect data (in its discretion) regarding sales to hospitals and other end users of such Product in such country, (g) monitor inventory levels of such Product in such country, (h) provide first line customer support and pharmacovigilance for such Product in such country (and after such initial support, pharmacovigilance support shall be handled in accordance with ARTICLE 8 and the Pharmacovigilance Agreement), (i) warehouse the Products for sale in such country, (j) determine the prices for such Product and any discounts and rebates that may be offered thereto, including decisions relating to customer allowances and credits, (k) manage commercial accounting/record keeping related to sale of the such Product and, with respect thereto, manage accounts payable, accounts receivable, and keep accurate records by customer and by SKU of pricing, rebates, chargebacks, deductions, returns, in accordance with GAAP and in a manner consistent with MDCO's practices for its products other than the Products, (1) assume all responsibility for negotiating and managing contracts with MDCO customers with

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respect to such Product in such country; and (m) use Commercially Reasonable Efforts to obtain reimbursement authorization in all jurisdictions in the Territory where Regulatory Approval for the Product has been obtained.

ARTICLE 4. MILESTONE PAYMENTS; ROYALTIES

4.1. **Milestone Payments**. In partial consideration of the grant to MDCO of the licenses set forth in Section 2.1, MDCO will pay to Eagle the following initial payment provided in Section 4.1.1 and, subject to satisfaction of the applicable conditions set forth in Sections 4.1.2 through 4.1.3, the applicable milestone payments set forth therein:

4.1.1. Five Million Dollars ($5,000,000) upon the Effective Date;

4.1.2. [*] within five (5) days after Regulatory Approval by the FDA of the NDA filed by Eagle for the Existing Product; *provided, however*, that, if such Regulatory Approval is received (a) after [*] and on or before [*], then MDCO shall pay to Eagle only [*] after such Regulatory Approval is received, (b) after [*] and on or before [*], then MDCO shall pay to Eagle only [*] after such Regulatory Approval is received, (c) after [*] and on or before [*], then MDCO shall pay to Eagle only [*] after such Regulatory Approval is received, and (d) after [*], then MDCO shall [*] upon receipt of such Regulatory Approval.

4.1.3. [*] upon Eagle's filing with the FDA the sNDA in respect of both of the Next Products; and

4.1.4. [*] upon Eagle's receipt of the Regulatory Approval by the FDA of the sNDA in respect of both of the Next Products.

For purposes of clarity, each milestone payment set forth in this Section 4.1 shall be paid only once, upon the first achievement of the applicable milestone event.

4.2. **Sales Milestone Payments**. In addition to the milestone payments set forth in Section 4.1, following the First Commercial Sale, on the terms and subject to the conditions contained herein, MDCO shall additionally be obligated to pay to Eagle up to an additional [*] (pursuant to Sections 4.2.1, 4.2.2 and 4.2.3) as follows:

4.2.1. If the aggregate Net Sales of all Products in the Territory at any time after the Effective Date equals at least [*], then MDCO shall pay to Eagle [*];

4.2.2. If the aggregate Net Sales of all Products in the Territory at any time after the Effective Date equals at least [*], then MDCO shall pay to Eagle [*]; and

4.2.3. If the aggregate Net Sales of all Products in the Territory at any time after the Effective Date equals at least [*], then MDCO shall pay to Eagle [*].

For purposes of clarity, each milestone payment set forth in this Section 4.2 shall be paid only once, upon the first achievement of the applicable milestone event. Such milestone payments shall be paid no later than [*] following the end of the calendar quarter in which the milestone was first achieved.

4.3. **Catch-Up Milestone Payments With Respect to the Existing Product Regulatory Approval Milestone Payment**.

4.3.1. If the FDA approves the NDA for the Existing Product within the time period set forth in Section 4.1.2(a) and no Generic Competing Product has been sold in the Territory on or before [*], then MDCO shall pay Eagle a milestone payment equal to [*].

4.3.2. If the FDA approves the NDA for the Existing Product within the time period set forth in Section 4.1.2(b), then MDCO shall pay Eagle the following milestone payments:

(a) [*] if no Generic Competing Product has been sold in the Territory on or before [*], and

(b) an additional [*] if no Generic Competing Product has been sold in the Territory on or before [*].

4.3.3. If the FDA approves the NDA for the Existing Product within the time period set forth in Section 4.1.2(c), then MDCO shall pay Eagle the following milestone payments:

(a) [*] if no Generic Competing Product has been sold in the Territory on or before [*],

(b) an additional [*] if no Generic Competing Product has been sold in the Territory on or before [*], and

(c) an additional [*] if no Generic Competing Product has been sold in the Territory on or before [*].

4.3.4. If the FDA approves the NDA for the Existing Product after [*], MDCO shall pay Eagle the following milestone payments:

(a) [*] if no Generic Competing Product has been sold in the Territory on or before [*],

(b) an additional [*] if no Generic Competing Product has been sold in the Territory on or before [*],

(c) an additional [*] if no Generic Competing Product has been sold in the Territory on or before [*], and

(d) an additional [*] if no Generic Competing Product has been sold in the Territory on or before [*].

Payments pursuant to this Section 4.3 shall be made by MDCO to Eagle within [*] after MDCO's receipt of an invoice therefor. For purposes of clarity, the payments set forth in Sections 4.3.1, 4.3.2, 4.3.3 and 4.3.4 shall be mutually exclusive, and in no event will MDCO be required to make payments

pursuant to more than one of such Sections.

4.4. **Sublicense Revenue Sharing**. Subject to Section 4.12, MDCO shall pay to Eagle [*] of all Sublicensing Revenue received by MDCO or its Affiliates; *provided*, *however*, that, subject to Section 2.5, if any Third Party (or Eagle or its Affiliates if Section 8.1.3 applies) launches or otherwise Exploits any Generic Competing Product on or before [*] (even if the launch of such Generic Competing Product occurs on or before [*], but the thirty (30) consecutive day sale period described in the definition of Generic Competing Product has not yet been achieved as of [*] but is achieved thereafter within thirty (30) days after such launch date), then from and after the launch date of such Generic Competing Product, the portion of Sublicensing Revenue payable to Eagle with respect to Products pursuant to this Section 4.4 shall be reduced to [*] of such Sublicensing Revenue. Such portion of Sublicensing Revenue shall be payable quarterly, within forty-five (45) days after the end of the calendar quarter in which the applicable Sublicensee pays to MDCO or its Affiliate the underlying Sublicensing Revenue.

4.5. **Royalties**.

4.5.1. **Royalty Payments**. In addition to the milestone and Sublicensing Revenue payments set forth in Sections 4.1, 4.2, 4.3 and 4.4, and subject to Sections 4.5.2 and 4.5.3, MDCO shall pay Eagle [*] of Net Sales (such amounts owed to Eagle pursuant to this Section 4.5, the "Royalty"); *provided*, *however*, that, subject to Section 2.5, if any (a) Third Party (or Eagle or its Affiliates if Section 8.1.3 applies) launches or otherwise Exploits any Generic Competing Product on or before [*] (even if the launch of such Generic Competing Product occurs on or before [*], but the thirty (30) consecutive day sale period described in the definition of Generic Competing Product has not yet been achieved as of June 30, 2012 but is achieved thereafter within thirty (30) days after such launch date), then from and after the launch date of such Generic Competing Product, the Royalty shall be reduced to [*] of any such Third Party Payments made by MDCO, its Affiliates or any such Distributor or Sublicensee; *provided*, *however*, in no event shall such credit cause any milestone payment or royalties payable to Eagle pursuant to Sections 4.1, 4.2, 4.3 or 4.4 or this Section 4.5 for any particular calendar quarter, to be reduced to less than [*] of the amount that would otherwise be payable for such period; provided, further, that MDCO may carry forward any unused amounts and may credit such unused amounts against future milestone or royalty payments in future calendar quarters.

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4.5.3. **Royalty Adjustments for Excessive Supply Costs**. If the per unit Supply Cost of a Product exceeds [*] of the Net Sales of such Product for [*] and such excess Supply Cost is reasonably expected to continue following [*] period, the Parties shall negotiate in good faith an equitable reduction in the Royalty payable by MDCO to Eagle with respect to the Net Sales and the portion of Sublicensing Revenue payable to Eagle. If the Parties are unable to negotiate such a reduction within such [*] period, then the CEOs shall meet at a mutually agreed upon time and location for the purpose of resolving such dispute and shall engage in good faith discussions or negotiations to resolve such dispute.

4.6. **Expiration of Royalty Obligations**. Unless this Agreement is earlier terminated in accordance with ARTICLE 10, the obligation of MDCO to pay Royalties to Eagle in respect of a Product shall expire on a Product-by-Product and country-by-country basis on the later of (a) [*] after the First Commercial Sale of such Product in such country, and (b) the date of expiration of the last Valid Claim within the Eagle Patents Covering the sale of such Product in such country. Upon such expiration, the license under the Eagle Intellectual Property granted to MDCO in each such country shall be fully-paid, royalty-free and irrevocable.

4.7. **Timing of Royalty Payments**. Royalty payments to Eagle shall be made [*], no later than [*] following [*] in which the Products are sold. Notwithstanding the foregoing, for each of the [*] following the First Commercial Sale of the Existing Product, MDCO shall, within [*] following the [*], pay to Eagle the estimated Royalty for [*] and at [*] following such First Commercial Sale of the Existing Product, MDCO and Eagle shall "true-up" such estimated amounts paid to Eagle to the extent of any overpayment (in which case Eagle shall reimburse MDCO for the amount of any such overpayment) or underpayment (in which case MDCO shall pay Eagle the amount of the underpayment) as part of the calculation and payment of the Royalty for each of [*].

4.8. **Audit**. For a period of three (3) years after the calendar year to which the records relate, MDCO shall keep complete and accurate records pertaining to the sale or other disposition of the Products in sufficient detail to permit Eagle to confirm the accuracy of all payments due hereunder and Eagle shall keep complete and accurate records pertaining to the Development Program costs, the Supply Cost and all components of Gross Profit (if applicable) in sufficient detail to permit MDCO to confirm the accuracy of all payments made or due hereunder. Each Party shall have the right to cause an independent, nationally-recognized, certified public accountant to which the other Party has no reasonably, well-founded objection to audit such records to confirm, if MDCO is audited, the gross invoiced sales amounts, the Net Sales and royalty or Gross Profit payments in respect thereof, or if Eagle is audited, the Development Program costs, Supply Cost and Gross Profit payments; *provided*, *however*, that such auditor shall not disclose the audited Party's Confidential Information to the auditing Party, except to the extent such disclosure is necessary to verify the amount of royalties and other payments due under this Agreement, and such auditor shall enter into a non-disclosure agreement reasonably acceptable to the audited Party. Such audits may be exercised once a year on reasonable notice to the audited Party and during normal business hours, within three (3) years after the royalty or other period to which such records relate. Any amounts shown to be owing by such audits shall

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be paid promptly. The auditing Party shall bear the cost of such audit unless such audit discloses that the audited Party has overcharged or underpaid the auditing Party by more than [*] from the amounts actually owed for the period audited, in which case, the audited Party shall bear the reasonable cost of such audit.

4.9. **Tax Matters**. If Applicable Laws require withholding of income taxes or other taxes imposed upon payments set forth in this ARTICLE 4, the Party making such payment (the "Paying Party") shall make such withholding payments as required and subtract such withholding payments from the payments set forth in this ARTICLE 4. The Paying Party shall submit appropriate proof of payment of the withholding taxes to the other Party (the "Paid Party") within a

reasonable period of time. At the request of the Paid Party, the Paying Party shall, at its cost, give the Paid Party such reasonable assistance, which shall include the provision of appropriate certificates of such deductions made together with other supporting documentation as may be required by the relevant tax authority, to enable the Paid Party to claim exemption from such withholding or other tax imposed or to obtain a repayment thereof or reduction thereof and shall upon request provide such additional documentation from time to time as is reasonably required to confirm the payment of tax.

4.10. **Currency Exchange**. With respect to Net Sales invoiced or expenses incurred in U.S. Dollars, the Net Sales or expense amounts and the amounts due to the receiving Party hereunder shall be expressed in U.S. Dollars. With respect to Net Sales invoiced or expenses incurred in a currency other than U.S. Dollars, the Net Sales or expense shall be expressed in the currency in which such Net Sales were invoiced or such expense was incurred together with the U.S. Dollar equivalent, calculated using the average of the spot rate on the first and last business days of the calendar quarter in which the Net Sales were made or the expense was incurred. The "closing mid-point rates" found in the "dollar spot forward against the dollar" table published by The Financial Times or any other publication as agreed to by the Parties shall be used as the source of spot rates. All payments shall be made in U.S. Dollars.

4.11. **Late Payment and Interest**. Any payments due under this Agreement by either Party that are paid but were overcharged, or not paid by the date such payments are due, shall bear interest at the lesser of [*] per month and the highest rate permitted under Applicable Law from the date such overpaid amounts were made until repaid in full or from the date such unpaid payments are due until paid in full. The foregoing interest shall be in addition to any other remedies that the overcharged or underpaid Party may have pursuant to this Agreement.

4.12. **Allocation of Gross Profits**. If the provisions of Section 2.5 apply with respect to a Product, then solely in the United States, in lieu of future milestone, Royalty and Sublicensing Revenue obligations set forth in Sections 4.1, 4.2, 4.3, 4.4 and 4.5 with respect to such Product, MDCO and Eagle shall share Gross Profits with respect to such Product as follows: [*] to Eagle and [*] to MDCO. The calculation of Gross Profits shall be made in accordance with Section 4.13.

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4.13. **Gross Profit Reporting and Reconciliation**. If the provisions of Section 2.5 apply with respect to a Product, then, solely with respect to the United States:

4.13.1 Within thirty (30) days after the end of each calendar quarter, each Party shall submit a written report to the other Party setting forth in reasonable detail, separately with respect to each such Product during such calendar quarter, as applicable, Net Sales of each Product, Sublicensing Revenue and Supply Cost incurred by or on behalf of the reporting Party in the United States during such calendar quarter. Such report shall provide supporting detail for such Net Sales, Sublicensing Revenue and Supply Cost.

4.13.2 Within fifteen (15) days after receipt of each Party's reports under Section 4.13.1, Eagle shall submit to MDCO a written report setting forth in reasonable detail the calculation of Gross Profit and the calculation of any net amount owed by Eagle to MDCO or by MDCO to Eagle, in order to ensure equal sharing of Gross Profits as specified in Section 4.12.

4.13.3 The net amounts payable under Section 4.13.2 shall be paid by Eagle or MDCO, as the case may be, within [*] after receipt of each such written report; provided that in the event of a dispute as to the amounts under Section 4.13.2, the disputing Party shall pay the amount not in dispute and shall provide written notice within such [*] period after receipt of the written report in question, specifying in detail such dispute. The Parties shall promptly thereafter meet and negotiate in good faith a resolution to such dispute. If the Parties are unable to resolve such dispute within [*] after notice by the disputing Party, the matter shall be resolved in accordance with ARTICLE 12.

ARTICLE 5. INTELLECTUAL PROPERTY

5.1. **Ownership and Retention of Rights**. Subject to the licenses granted by Eagle herein, Eagle shall retain all rights in the Eagle Intellectual Property (other than the Joint Intellectual Property) and MDCO shall retain all rights in the MDCO Intellectual Property (other than the Joint Intellectual Property), and the Parties shall jointly own, and each Party shall have an undivided interest in, the Joint Intellectual Property. Determining whether an Invention is solely or jointly owned by MDCO or Eagle shall be resolved in accordance with United States patent laws concerning inventorship.

5.2. **Prosecution and Maintenance of the Eagle Patents and Joint Patents**. Eagle shall be responsible for the filing, prosecution and maintenance of the Eagle Patents and Joint Patents, and shall cooperate with MDCO with respect thereto. Eagle will provide MDCO with access to all documentation, filings and communications to or from the respective patent offices in the Territory with respect to the Eagle Patents and Joint Patents, at reasonable times and on reasonable notice. Eagle shall allow MDCO to participate in all aspects of the preparation, filing, prosecution and maintenance of the Eagle Patents, including by proposing claims and amendments thereto, and providing recommendations on the substance of responses to official communications from any patent granting authority. Eagle shall have the right to make any final

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decisions regarding the filing, prosecution and maintenance of the Eagle Patents; provided that Eagle, its agents and attorneys shall take into consideration MDCO's proposals and recommendations in respect thereof; provided further that Eagle shall not fail to implement or incorporate any material MDCO proposals or recommendations without first discussing such matter with MDCO. MDCO and Eagle shall each be responsible for [*] of all fees and costs associated with the preparation, filing, prosecution and maintenance of the Eagle Patents in the Territory after the Effective Date, including out of-pocket expenses incurred by MDCO in response to requests from Eagle for access to any employees of MDCO or information in furtherance of the preparation, prosecution, or maintenance of the Eagle Patents. Eagle and MDCO shall equally split any such fees and costs for the Joint Patents after the Effective Date. For the avoidance of doubt, Eagle shall not be responsible for legal expenses of MDCO incurred pursuant to MDCO's review or comment rights pursuant to this Section 5.2. Eagle shall not abandon any Eagle Patent or Joint Patent without at least ninety (90) days' prior written notice to MDCO. If Eagle elects to

abandon any Eagle Patent or Joint Patent in any country in the Territory, MDCO shall have the right to continue to prosecute and maintain such Patent in such country, in Eagle's name (with respect to the Eagle Patents) or jointly in both Parties' names (with respect to the Joint Patents) and MDCO and Eagle shall [*] be responsible for [*] of all such expenses; *provided, however*, that, to the extent not already paid by Eagle to MDCO, MDCO shall have the right to deduct Eagle's portion of such patent costs and expenses against payments owed to Eagle pursuant to ARTICLE 4.

5.3. **Regulatory Data Protection**. To the extent required or permitted by Applicable Law, Eagle will promptly, accurately and completely list, with the applicable Regulatory Authorities during the Term, all applicable Patents for all Products throughout the world that have become the subject of an application for Regulatory Approval submitted to the FDA or other Regulatory Authority. Such listings shall include all so called "Orange Book" listings required under the Hatch-Waxman Act and all so called "Patent Register" listings as required in Canada. Prior to making any such filings or listings with any Regulatory Authority in the Territory, the Parties will meet to evaluate and identify all applicable Patents, and Eagle shall list such Patents in the Territory and take into consideration MDCO's suggestions in respect thereof.

5.4. **Enforcement of the Eagle Intellectual Property and the Joint Intellectual Property**. MDCO shall have the first right to assert, in the name of Eagle or MDCO or the Parties' jointly, any IP Protection Rights Covering the Products in the Territory, including the Eagle Patents and Joint Patents, against any Third Party that seeks to or actually makes, uses, imports, sells or offers for sale anywhere in the Territory a product containing the Active Ingredient, and MDCO shall have the right to direct and control litigation concerning such IP Protection Rights in regular consultation with Eagle regarding litigation strategy and tactics using counsel of MDCO's choice and mutually agreeable to Eagle, and Eagle shall join such litigation if necessary or useful for MDCO to pursue such litigation or collect damages. Eagle agrees to take such action as reasonably requested by MDCO to ensure that MDCO shall have standing to bring an enforcement action pursuant to this Section 5.4. Any settlement of such litigation must be pursuant to Eagle's consent; *provided, however*, that if MDCO does not assert such IP Protection Rights in the Territory, then Eagle shall be entitled to assert such IP Protection Rights in the

Territory and direct and control such litigation, at Eagle's expense. Each of MDCO and Eagle shall cooperate fully and keep the other informed with respect to the progress of any such action, and, MDCO and Eagle shall regularly consult regarding litigation strategy and tactics. All costs, fees and expenses incurred by MDCO and Eagle pursuant to any action taken pursuant to this Section 5.4 shall be shared equally by the Parties. Any recovery obtained by MDCO or Eagle as a result of any enforcement pursuant to this paragraph, whether by judgment, award, decree or settlement, shall be applied (a) first to reimburse MDCO and Eagle for their respective direct, out-of-pocket expenses (including legal fees) incurred to obtain such recovery and (b) any remaining amount will be shared equally between Eagle and MDCO.

5.5. **Defense of Claims Brought by Third Parties**. If a Party becomes aware of any claim that the practice by either Party of the Eagle Intellectual Property or Joint Intellectual Property in the development, use, Manufacture or Exploitation of the Active Ingredient or the Product in the Territory infringes the IP Protection Rights of any Third Party, such Party shall promptly notify the other Party. In any such instance, the Parties shall cooperate and shall mutually agree upon an appropriate course of action. Each Party shall provide to the other Party copies of any notices it receives from Third Parties regarding any Patent nullity actions regarding the Eagle Patents or the Joint Patents, any declaratory judgment actions and any alleged infringement or misappropriation of Third Party IP Protection Rights relating to the development, use, Manufacture or Exploitation of the Active Ingredient or the Product(s) in the Territory. Such notices shall be provided promptly, but in no event more than fifteen (15) days following receipt thereof. Each Party shall be responsible for its own costs incurred pursuant to this Section 5.5.

ARTICLE 6. REPRESENTATIONS, WARRANTIES AND COVENANTS

6.1. **Representations, Warranties and Covenants of MDCO and Eagle**. MDCO and Eagle each represents and warrants to the other, as of the Effective Date, and, as applicable, covenants to the other Party, that:

6.1.1. It is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation and has all requisite power and authority, corporate or otherwise, to conduct its business as now being conducted, to own, lease and operate its properties and to execute, deliver and perform this Agreement.

6.1.2. Neither it, nor any of its employees or consultants who shall be undertaking any activities related to this Agreement, the Active Ingredient or the Products, has been debarred or is the subject of debarment or other disciplinary proceedings by any Regulatory Authority anywhere in the world.

6.1.3. No consent, approval, order or authorization of, or registration, declaration or filing with, any Governmental Authority is required to be obtained or made by or with respect to such Party in connection with its execution, delivery and performance of this Agreement.

6.1.4. The execution, delivery and performance by it of this Agreement, and the transactions contemplated hereby, have been duly authorized by all necessary corporate action and equity holder action and will not (a) violate any Applicable Laws or (b) result in a breach of or constitute a default under any material agreement, mortgage, lease, license, permit or other instrument or obligation to which it is a party or by which it or its properties may be bound or affected.

6.1.5. This Agreement is a legal, valid and binding obligation of it, enforceable against it in accordance with its terms and conditions, except as such enforceability may be limited by applicable bankruptcy, insolvency, moratorium, reorganization or similar laws, from time to time in effect, affecting creditors' rights generally.

6.1.6. It is not under any obligation to any Third Party, contractual or otherwise, that is conflicting with the terms of this Agreement or that would limit the ability of such Party to fulfill its obligations hereunder in any material respect.

6.1.7. It has or will acquire all necessary properties, rights and assets needed by it to perform its obligations hereunder with respect to the Development Plan.

6.1.8. It shall comply, and shall use Commercially Reasonable Efforts to ensure that all of its Affiliates and Third Party agents and contractors, if any, shall comply, with all Applicable Laws in the performance of its obligations pursuant to this Agreement.

6.2. **Representations, Warranties and Covenants of Eagle**. Eagle represents and warrants to MDCO, as of the Effective Date, and, as applicable, covenants to MDCO, that:

6.2.1. Eagle has (and will for the term of any such grant hereunder maintain) the right to grant the licenses set forth in Section 2.1.

6.2.2. To the best of Eagle's knowledge, (a) Eagle is the sole and exclusive owner of (or, in the case of licensed rights, the exclusive licensee of) the entire right, title and interest in and to the Eagle Intellectual Property that exists on the Effective Date, free and clear of all encumbrances, security interests, options and licenses; (b) the Eagle Patents are valid and enforceable, (c) other than the Eagle Know-How and the Eagle Patents existing as of the Effective Date and licensed to MDCO hereunder, there is no Know-How or Patents owned by or licensed to Eagle or its Affiliates that (i) was used or generated by Eagle or its Affiliates in the development, use, Manufacture or Exploitation of the Active Ingredient or Product prior to the Effective Date, or (ii) is used in or is otherwise necessary or useful for the development, use, Manufacture or Exploitation of the Active Ingredient or Product as contemplated by this Agreement.

6.2.3. Eagle's employees who have had or will have access to the Confidential Information of MDCO are (or in the case of employees hired after the Effective Date, will be) bound by written agreements that contain (a) confidentiality provisions that will

protect the confidentiality of the Confidential Information of MDCO in the manner contemplated by this Agreement, including ARTICLE 9 and (b) invention assignment provisions that assign to Eagle all of such employees' right, title and interest in and to any Eagle Intellectual Property.

6.2.4. (a) No claim of infringement of the Patents of any Third Party has been made, nor to Eagle's knowledge threatened, against Eagle or any of its Affiliates with respect to the development, use, Manufacture or Exploitation of the Active Ingredient or any Product; (b) there are no other claims, judgments or settlements against or owed by Eagle or to which Eagle is a party or, to the best of Eagle's knowledge, pending or threatened claims or litigation, in either case relating to the Active Ingredient or any Product; (c) to the best of Eagle's knowledge, there is no valid basis for any claim that the Patents or other intellectual property rights of any Third Party have been or would be infringed or misappropriated with respect to the development, use, Manufacture or Exploitation of the Active Ingredient or any Product; and (d) (i) prior to the Effective Date, the so-called Paragraph IV notice letter was properly sent by Eagle (or on behalf of Eagle) in accordance with all Applicable Laws (including 21 CFR 314.95) to the holder of the NDA for Argatroban, and to the owner of the Patent listed in the Orange Book for Argatroban, and (ii) no lawsuit in response to the Paragraph IV notice letter was served upon, or filed by any Third Party against, Eagle or any of its Affiliates within forty-five (45) days after receipt by such NDA holder and such Patent owner of such Paragraph IV notice letter.

6.2.5. Prior to the Effective Date, Eagle has provided MDCO with a correct copy of all provisions of the SciDose License Agreement and of all amendments thereto, in each case relevant to the transactions contemplated hereby and by the Supply Agreement. All payments required to be made by Eagle under the SciDose License Agreement prior to the Effective Date have been made, and Eagle is in compliance in all material respects with its obligations thereunder. The SciDose License Agreement remains in full force and effect as of the Effective Date and such agreement is the only agreement as of the Effective Date between Eagle and any Affiliate or Third Party that (a) imposes an obligation to pay royalties or other payments to a Third Party based on the development, use or Exploitation of Product in the Field in the Territory, or the Manufacture of the Active Ingredient or the Product, or (b) imposes any other obligation on Eagle or its Sublicensees, or grants any rights to any Third Party, with respect to the development, use or Exploitation of the Product in the Field in the Territory or the Manufacture of the Active Ingredient or the Product.

6.2.6. Eagle shall (a) develop and maintain the Safety Database in accordance with customary pharmaceutical industry practices and in compliance with all Applicable Laws, and (b) ensure that the Safety Database includes comprehensive Safety Data and Complaint information resulting from the activities of Eagle, its Affiliates, licensees, Distributors, Sublicensees and agents throughout the world with respect to the Active Ingredient and Products.

6.3. **Representations, Warranties and Covenants of MDCO**. MDCO represents and warrants to Eagle, as of the Effective Date, and, as applicable, covenants to Eagle, that MDCO's employees who have had or will have access to the Confidential Information of Eagle are (or in the case of employees hired after the Effective Date, will be) bound by written agreements that contain (i) confidentiality provisions that will protect the confidentiality of the Confidential Information of Eagle in the manner contemplated by this Agreement, including ARTICLE 9, and (ii) invention assignment provisions that assign to MDCO all of such employees', agents', and consultants' right, title and interest in and to any Joint Intellectual Property.

6.4. **LIMITATIONS ON WARRANTIES.** OTHER THAN THE REPRESENTATIONS AND WARRANTIES MADE BY THE PARTIES PURSUANT TO SECTIONS 6.1, 6.2, 6.3 AND 9.1, THE PARTIES DISCLAIM ANY AND ALL OTHER WARRANTIES WHETHER EXPRESS OR

IMPLIED, INCLUDING ANY WARRANTIES OF NON-INFRINGEMENT, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY WARRANTY ARISING FROM COURSE OF DEALING OR USAGE OF TRADE.

ARTICLE 7. MANUFACTURING AND SUPPLY

7.1. **Clinical Supply**. Eagle shall use Commercial Reasonable Efforts to Manufacture or cause to be Manufactured all Clinical Supplies of the Existing Product and the Next Products for the Development Program, including the completion of pre-clinical work and human clinical trials. Eagle shall not supply the Products to any Person, other than MDCO or its designee, for use or Exploitation in the Territory.

7.2. **Commercial Supply**. Eagle will use Commercially Reasonable Efforts to establish a commercial Manufacturing process for Manufacturing or causing to be Manufactured commercial supplies of the Existing Product and the Next Products on the scale and in the amounts required to meet MDCO's commercial requirements for the Territory. Eagle will supply MDCO with MDCO's commercial supply requirements of the Existing Product and the Next Products pursuant and subject to the Supply Agreement and the Quality Agreement.

7.3. **Supply Price**. Subject to the terms and conditions of the Supply Agreement, MDCO shall acquire Product from Eagle at the Supply Cost.

7.4. **Manufacturing Logistics Support.**

7.4.1. Eagle shall dedicate the efforts of one of its full-time employees to managing the Manufacturing and supply logistics in order for Eagle to supply commercial quantities of the Existing Product and the Next Products to MDCO in accordance with this Agreement and the Supply Agreement, in accordance with the Parties' agreement on the scope of activities to be conducted by such employee (such employee, the "Logistics Coordinator"). The Logistics Coordinator shall be an employee of Eagle and not MDCO, and Eagle shall be solely responsible for all obligations owed to such individual as an employee, including all salary, bonus and benefits.

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7.4.2. Provided that Eagle has provided an invoice therefor to MDCO at least [*] before the start of each calendar quarter described in this Section 7.4.2, MDCO shall pay Eagle [*] on or before the [*] starting January 1, 2010 and [*] on or before the [*] starting January 1, 2011, to offset the costs of Eagle providing the Logistics Coordinator; *provided, however*, that if Regulatory Approval for the Existing Product is not obtained on or before June 30, 2010, the payments owed pursuant to this Section 7.4.2 shall cease until such Regulatory Approval is obtained and thereafter MDCO shall continue to make such [*] payments. For the avoidance of doubt, in no event shall MDCO owe Eagle greater than [*] pursuant to this Section 7.4.2.

ARTICLE 8. ADDITIONAL COVENANTS

8.1. **Compliance And Cooperation; Further Assurances**.

8.1.1. During the Term, MDCO and Eagle shall (a) comply in all material respects with all Applicable Laws relating to the development, Manufacture, use, sale, importation and other Exploitation of any of the Products; and (b) promptly notify the other if it becomes aware of any material information that would reasonably be expected to adversely impact the achievement of the objectives of the Development Program or the development, Manufacture, use, sale, importation or other Exploitation of the Products in any jurisdiction, including any information adverse to the assertion of the IP Protection Rights that are the subject of the licenses granted in Section 2.1, the continued effectiveness of any Regulatory Approvals of any Products, or otherwise relevant to the Exploitation of the Products.

8.1.2. Subject to the terms and conditions herein, the Parties agree that neither Party nor its Affiliates will develop, Manufacture, import, market, sell, offer to sell or distribute in the Territory any product containing the Active Ingredient, except for the Existing Product and Next Products pursuant to this Agreement; *provided, however*, that this Section 8.1.2 shall not restrict the Exploitation of any Product by Eagle in the event that MDCO exercises its right to terminate this Agreement in respect of such Product pursuant to Section 10.3.

8.1.3. The foregoing provisions of this Section 8.1 notwithstanding, if Eagle consummates a Sale Transaction with a Third Party where such Third Party has, prior to the consummation of such Sale Transaction, rights (through ownership or license or other contractual right) to use, develop, make and have made, offer for sale, market, promote, sell, import and otherwise Exploit any product containing the Active Ingredient in the Field in the Territory (a "Third Party Competing Product") and is actually and actively engaged in the clinical development or Exploitation of such Third Party Competing Product prior to the consummation of such Sale Transaction, then:

(A) the Third Party Competing Product shall not be a "Product" for purposes of this Agreement (e.g., the sales of the Third Party Competing Product shall not be

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included in the computation of Gross Profits, and the sale of the rights to Exploit the Third Party Competing Product in the ROW shall not trigger any rights of MDCO pursuant to Section 2.6);

(B) the restrictions set forth in Section 8.1.2 shall not apply to Eagle or such Affiliate with respect to such Third Party Competing Product; *provided, however*, that no Eagle Intellectual Property Rights are granted by Eagle or its Affiliates to such Third Party, or used by Eagle, its Affiliates or such Third Party, in connection with, the use, development, making or having made, offering for sale or selling, marketing, promoting, importing or otherwise Exploiting such Third Party Competing Product;

(C) such Third Party Competing Product shall be treated as a Generic Competing Product for purposes of Sections 4.4 and 4.5.1, and unless and until the provisions of Section 2.5 apply, MDCO shall have the right to reduce its obligations to share Sublicensing Revenue and royalties in the Territory accordingly; provided, that such Sublicensing Revenue and royalty reductions shall continue to apply outside the United States even if Section 2.5 applies with respect to the United States; and

(D) the restrictions set forth in Section 8.1.2 shall no longer apply to MDCO.

8.2. **Equity Financing**. On or before the sixtieth (60th) day following the Effective Date, MDCO shall purchase from Eagle, and Eagle shall sell to MDCO, [*] worth of a new series of Eagle's convertible preferred stock, which [*] providing the purchaser [*] (a) [*], or (b) [*]. Such investment in Eagle shall be at a pre-money valuation of [*], and except as otherwise provided in this Section 8.2, on substantially the same terms as MDCO's prior equity investment in Eagle.

8.3. **Adverse Event Reporting**.

8.3.1. Each Party shall maintain a record of any and all Complaints and other Safety Data it receives, or which its Affiliates, Distributors, licensees, Sublicensees or contractors receive, with respect to the Active Ingredient or Products. Each Party shall notify the other Party in reasonable detail of any Complaint or other Safety Data received by such Party or its Affiliates with respect to the Active Ingredient or Products within sufficient time to allow the other Party and its Affiliates, Distributors, licensees, Sublicensees or contractors (as applicable) to comply with any and all regulatory and other requirements under Applicable Law imposed upon them in any jurisdiction in which or for which such Product is being developed or Exploited by or on behalf of a Party. Each Party shall provide such information to the other Party within five (5) calendar days after its first receipt; *provided*, *however*, that any information relating to a serious adverse experience ("SAE"), as that term is defined at 21 C.F.R. §600.80, shall be provided to the other Party within forty-eight (48) hours after its first receipt. The Party providing the Complaint information or Safety Data shall use Commercially Reasonable Efforts to assist the receiving Party with any follow-up investigation necessary to comply with Applicable Laws with respect to the Active Ingredient or Product. In addition to the

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foregoing, each Party shall promptly notify the other Party if such Party becomes aware of any information or circumstance that are likely to have a material adverse effect on the development, Manufacture or Exploitation of the Product or the Active Ingredient by or on behalf of a Party in any country or jurisdiction of the world.

8.3.2. Eagle shall be responsible for reporting Product adverse events and Complaints to the FDA and all other Regulatory Authorities throughout the world. Eagle shall field, triage and document incoming adverse events and Product defect complaints and promptly supply MDCO with any information with respect thereto, and shall file all such information with the FDA or other Regulatory Authorities throughout the world in accordance with all Applicable Laws. Eagle will be responsible for any follow—up activities with the reporting party and all tracking, trending and signal detection for the Product.

8.3.3. Eagle shall search for evidence of adverse events published in literature by conducting a search of widely used systematic literature review and reference database, such as Medline, Excepta, Medica or Embase, at least once a month, and Eagle shall provide MDCO with the results of such searches and activities. Eagle shall ensure that relevant publications in each country of the Territory are reviewed. If Third Party services are required to be contracted by Eagle with respect to its obligations set forth in this Section 8.3, then such costs shall be borne by Eagle. If any adverse event is found in the literature, Eagle shall report such information to MDCO, and Eagle shall report such information to the FDA and all other Regulatory Authorities throughout the world in accordance with, and to the extent required by, Applicable Laws. For purposes of this Agreement, a literature adverse event is considered to be found on the day that any personnel of Eagle or its designee become aware of the publication of such event.

8.3.4. Within ninety (90) days after the Effective Date the Parties will develop and agree in writing upon safety data exchange procedures governing the coordination of collection, investigation, reporting and exchange of information concerning any adverse experiences, and any Product quality issues and Complaints involving adverse experiences, and any other Safety Data, related to the Active Ingredient or the Product, sufficient to enable each Party to comply with its legal and regulatory obligations and not inconsistent with the terms of the Supply Agreement or this Agreement (the "Pharmacovigilance Agreement").

8.4. **Global Safety Database**. Within six (6) months after the Effective Date, Eagle shall enter into an Agreement with a Third Party reasonably acceptable to MDCO to develop and maintain a global adverse event database for the Active Ingredient and Products (the "Safety Database"). The Safety Database shall be maintained by Eagle at its sole expense and in compliance with all Applicable Laws, and in accordance with industry-standard best practices, and shall include all Safety Data and Complaint information in connection with the activities of Eagle, its Affiliates, licensees, Distributors, Sublicense,es, contractors and agents throughout the world with respect to the Active Ingredient and Products. Eagle shall generate regular written

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reports comprising all adverse events, Complaints and Safety Data for use by MDCO, its Affiliates, Distributors and Sublicensees with respect to the development, use, Manufacture and Exploitation of Products in the Field in the Territory, such reports to be generated at least every thirty (30) days during the Term. Eagle shall provide MDCO, its Affiliates, Distributors and Sublicensees with regular (at least once every thirty (30) days) updates to the information contained in the Safety Database.

8.5. **Recalls, Market Withdrawals or Corrective Actions**. In the event that any Regulatory Authority issues or requests a recall or market withdrawal or takes a similar action in connection with a Product in the Territory, or in the event either Party or any of its Affiliates, licensees, Distributors or

Sublicensees determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal of the Product, the Party notified of such recall or similar action, or the Party that desires, or whose Affiliate, licensee, Distributor or Sublicensee desires, such recall or similar action, shall, within twenty-four (24) hours, advise the other Party thereof by telephone or facsimile. Eagle (itself or via its Affiliates, Distributors, licensees or Sublicensees) shall, in consultation with MDCO, determine whether to conduct a recall of the Product in the Field in the Territory and the manner in which any such recall shall be conducted (except in the case of a government mandated recall, when Eagle (or its Affiliates, licensees or Sublicensees) may act without such advance notice but shall notify MDCO as soon as possible); *provided, however*, that MDCO may conduct a recall of the Product in the Field in the Territory if reasonably determined by MDCO to be necessary or appropriate to comply with Applicable Laws, or to protect the safety of individuals or MDCO's reputation. Each Party (or its Affiliates, licensees or Sublicensees (other than the other Party or its Affiliates or Sublicensees)) shall bear the expense of all recalls conducted by it or on its behalf; provided that this will not limit any remedy that each Party may have against the other Party in connection with such recall. Each Party will make available all of its pertinent records that may be reasonably requested in order to effect a recall conducted by or on behalf of the other Party.

8.6. **Ancillary Agreements**. The Parties, as of the Effective Date, have entered into the Supply Agreement in the form attached hereto as Exhibit C. Within ninety (90) days after the Effective Date, the Parties shall enter into (a) a quality agreement on mutually agreeable and customary terms not inconsistent with the terms of the Supply Agreement or this Agreement (the "Quality Agreement"), and (b) the Pharmacovigilance Agreement.

ARTICLE 9. CONFIDENTIAL INFORMATION; PRESS RELEASE

9.1. **Treatment of Confidential Information**. Each Party agrees to retain in strict confidence and not disclose, divulge or otherwise communicate to any Third Party any Confidential Information of the other Party, whether received prior to, on or after the Effective Date, and further agrees not to use any such Confidential Information for any purpose, except pursuant to, and in order to carry out, the terms and objectives of this Agreement, except that each receiving Party may disclose Confidential Information of the other Party to the Representatives of the receiving Party, who, in each case, (a) need to know such Confidential Information for purposes of the implementation and performance by the receiving Party of this Agreement and (b) will use

such Confidential Information only for such limited purposes. Each Party hereby agrees to use at least the same standard of care in complying with its confidentiality obligations hereunder as it uses to protect its own Confidential Information of comparable sensitivity (but no less than reasonable care) and to exercise reasonable precautions to prevent and restrain the unauthorized disclosure of such Confidential Information by any of its Representatives. Each Party warrants that each of its Representatives to whom any Confidential Information of the other Party is revealed shall previously have been informed of the confidential nature of such Confidential Information and shall have agreed to maintain its confidentiality under terms no less restrictive than those set forth in this ARTICLE 9. Without limiting the generality of any of the foregoing, the Parties agree not to make any disclosure of the other Party's Confidential Information that would be reasonably likely to impair the Parties' ability to obtain U.S. or foreign patents on any patentable invention or discovery described or otherwise embodied in such Confidential Information, without first obtaining the express permission of the disclosing Party to do so. The Confidential Information of each Party may include information from Third Parties disclosed by one Party to this Agreement to the other Party to this Agreement.

9.2. **Confidential Information.** "Confidential Information" means all trade secrets or other proprietary information, including any proprietary data and materials (whether or not patentable or protectable as a trade secret), regarding a Party's technology, products, business, financial status or prospects or objectives regarding the Products, which is disclosed by a Party to the other Party. All information disclosed prior to the Effective Date by one Party to the other Party pursuant to the Mutual Confidentiality Agreement between the Parties dated November 26, 2007 and the Mutual Confidentiality Agreement among the Parties and SciDose dated February 15, 2008 (the "Confidentiality Agreement"), shall be deemed "Confidential Information" of the disclosing Party under this Agreement. Notwithstanding the foregoing, there shall be excluded from the foregoing definition of Confidential Information any of the foregoing that:

9.2.1. either before or after the date of the disclosure to the receiving Party is lawfully disclosed to the receiving Party by a Third Party(ies) without any violation of any obligation to the other Party; or

9.2.2. either before or after the date of the disclosure to the receiving Party becomes published or generally known to the public through no fault or omission on the part of the receiving Party or its Representatives; or

9.2.3. is independently developed by or for the receiving Party without reference to or reliance upon the other Party's Confidential Information as demonstrated by contemporaneous written records of the receiving Party.

9.3. **Release from Restrictions.**

9.3.1. The provisions of Section 9.1 shall not apply to any Confidential Information disclosed hereunder to the extent that such Confidential Information is required to be disclosed by the receiving Party to defend or prosecute litigation with respect to Products

or to comply with Applicable Laws, including filing an Information Disclosure Statement with the U.S. Patent and Trademark Office or any other patent office as permitted hereunder with respect to the Eagle Patents, the Joint Patents or the MDCO Patents, or pursuant to an order of a court or regulatory agency; *provided, however*, that the receiving Party shall provide prior written notice of such disclosure to the other Party and shall take actions as are reasonable and lawful to avoid or minimize the degree of such disclosure, including assisting the other Party in seeking a protective order or other means for preventing disclosure or use. To the extent, if any, that a Party concludes in good faith that it is required by Applicable Laws (or required by stock exchange or quotation system rule) to file or register this Agreement or a notification thereof with any Governmental Authority,

including the U.S. Securities and Exchange Commission, such Party may do so, and the other Party shall cooperate in such filing or notification and shall execute all documents reasonably required in connection therewith. In such situation, the filing Party shall request confidential treatment of sensitive provisions of the Agreement to the extent permitted by law. The Parties shall promptly inform each other as to the activities or inquiries of any such Governmental Authority relating to this Agreement and shall cooperate to respond to any request for further information therefrom.

9.3.2. A Party may disclose this Agreement to a Third Party in connection with or in conjunction with a proposed merger, consolidation, sale of assets that include those related to this Agreement, a permitted assignment of this Agreement, a loan financing, raising of capital, or sale of securities; *provided*, *however*, that the disclosing Party obtains an agreement for the confidential treatment thereof under reasonable and customary terms and conditions.

9.4. **No Implied Rights**. Except as otherwise set forth in this Agreement, nothing herein shall be construed as giving either Party any right, title, interest in or ownership of the Confidential Information of the other Party. For the purposes of this Agreement, specific information disclosed as part of Confidential Information shall not be deemed to be in the public domain, generally known to the public or in the prior possession of the receiving Party merely because it is embraced by more general information in the public domain or generally known to the public or by more general information in the prior possession of the receiving Party.

9.5. **Survival of Confidentiality Obligations**. The confidentiality obligations of the Parties contained in this ARTICLE 9 shall remain binding on both Parties during the Term and for a period of seven (7) years after the expiration or termination of this Agreement, regardless of the cause of such termination. The Parties acknowledge that breach of this ARTICLE 9 may constitute irreparable harm, and that the non-breaching Party shall be entitled to seek specific performance or injunctive relief to enforce this ARTICLE 9 in addition to whatever remedies such Party may otherwise be entitled to at law or in equity.

9.6. **Press Releases; Publicity; Filings**. No public announcement concerning this Agreement or submission of this Agreement, its subject matter or the transactions described herein shall be made, either directly or indirectly, by MDCO or Eagle or their respective Affiliates, except as

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may be legally required by Applicable Laws or required by stock exchange or quotation system rule, without (x) first obtaining the approval of Eagle or MDCO, respectively, and (y) agreement upon the nature, text, and timing of such announcement, which approval and agreement shall not be unreasonably withheld or delayed. The Party desiring to make any such voluntary public announcement shall provide the other Party with a written copy of the proposed announcement in reasonably sufficient time prior to public release to allow such other Party to comment upon such announcement, prior to public release. In the case of press releases or other public communications or submissions required to be made by Applicable Law or by stock exchange or quotation system rule, the Party making such press release, public announcement or submission shall provide to the other Party a copy of the proposed press release, public announcement or submission in written or electronic form upon such advance notice as is practicable under the circumstances for the purpose of allowing the notified Party to review and comment upon such press release, public announcement or submission. Under such circumstances, the releasing Party shall not be obligated to delay making any such press release, public communication or submission beyond the time when the same is required to be made. Either Party may republish any information about this Agreement which had been properly publicized pursuant to this Agreement or which the other Party had improperly publicized.

ARTICLE 10. TERM AND TERMINATION

10.1. **Term**. Except as otherwise specifically provided herein, the term of this Agreement (the "Term") shall commence upon the Effective Date and shall remain in full force and effect, unless earlier terminated in accordance with this ARTICLE 10 or Section 13.1, for so long as the Development Program is continuing and thereafter for as long as MDCO is Exploiting Products for which Royalties are owed to Eagle pursuant to ARTICLE 4.

10.2. **Termination for Cause**. Eagle or MDCO (as applicable, the "Terminating Party") shall have the right to terminate this Agreement, effective [*] after written notice of termination is given to the other Party (the "Breaching Party"), in the event that the Breaching Party fails to remedy any material failure to fulfill its obligations under this Agreement or remains in material breach of the terms or conditions hereof, which failure or breach is specified in such notice; *provided*, *however*, that if the Breaching Party by written notice to the Terminating Party given within said [*] period states that it is in good faith attempting to cure such material failure or breach and such failure or breach is capable of being cured, such [*] period shall be extended by an additional period of [*]. The foregoing provisions of this Section 10.2 notwithstanding, if Eagle seeks to terminate this Agreement pursuant to this Section 10.2, and the material breach by MDCO relates primarily to a particular Product, then Eagle shall have the right to terminate this Agreement solely with respect to such Product, and this Agreement shall remain in full force and effect with respect to all other Products. The Parties shall retain all rights and remedies (at law or in equity) in respect of any breach hereof.

10.3. **Termination by MDCO for Convenience.** At any time following the first anniversary of the Effective Date, MDCO may terminate this Agreement, in its entirety or, subject to the

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proviso set forth in Section 8.1.2, on a Product-by-Product basis, upon not less than sixty (60) days' written notice to Eagle.

10.4. **Effect of Termination.**

10.4.1. In the event of termination of this Agreement by MDCO pursuant to Section 10.2, 10.3, 10.5 or 13.1 or by Eagle pursuant to Section 10.2, 10.5 or 13.1, the rights and licenses granted to MDCO pursuant to Section 2.1 shall terminate; *provided*, *however*, that if this Agreement is terminated by Eagle pursuant to Section 10.2 or by MDCO pursuant to Section 10.3 solely with respect to a particular Product, then the rights and

obligations of each Party under this Agreement shall terminate solely with respect to such Product, and shall remain in full force and effect with respect to all other Products.

10.4.2. If this Agreement is terminated by Eagle pursuant to Section 10.2, 10.5 or 13.1 or by MDCO pursuant to Section 10.2, 10.5 or 13.1, at MDCO's election any sublicense granted by MDCO in compliance with this Agreement the Sublicensee for which is then in good standing and has not contributed to the breach or other circumstance that led to the termination shall remain in full force and effect pursuant to the terms thereof, notwithstanding such termination, but all monies and other obligations due thereunder shall become immediately due to Eagle instead of MDCO, and MDCO shall have no further obligations under such sublicense agreement.

10.4.3. The termination or expiration of this Agreement for any reason shall be without prejudice to any rights which shall have accrued to the benefit of either Party prior to such termination or expiration, including any damages arising from any breach hereunder. Such termination or expiration shall not relieve either Party from obligations which are expressly indicated to survive termination or expiration of this Agreement.

10.4.4. ARTICLES 1, 9, 11, 12 and 13, and Sections 3.7, 4.6 (last sentence thereof with respect to any such licenses in effect on or before the effective date of expiration or termination of this Agreement), 4.8, 4.11, 5.1, 6.4 and 8.5 (last two sentences), this Section 10.4 and, solely with respect to Joint Intellectual Property, Sections 5.2, 5.3 and 5.4, shall survive termination of this Agreement in its entirety or expiration of this Agreement for any reason, in accordance with their respective terms, and for the duration stated, and where no duration is stated, shall survive indefinitely. For the sake of clarity, the Solvent Party may exercise its rights under Section 2.7 if this Agreement is rejected or otherwise terminated by or on behalf of the Insolvent Party in connection with an Insolvency Event.

10.5. **Rights In Bankruptcy**. Each Party (the "Insolvent Party") shall promptly notify the other Party (the "Solvent Party") in writing upon the initiation of any proceeding in bankruptcy, reorganization, dissolution, liquidation or arrangement for the appointment of a receiver or trustee to take possession of the assets of the Insolvent Party or similar proceeding under the law for release of creditors by or against the Insolvent Party or if the Insolvent Party shall make a

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general assignment for the benefit of its creditors (any of the foregoing, an "Insolvency Event"). To the extent permitted by Applicable Law, if the applicable circumstances described above shall have continued for sixty (60) days undismissed, unstayed, unbonded and undischarged, the Solvent Party may terminate this Agreement upon written notice to the Insolvent Party at any time.

ARTICLE 11. INDEMNIFICATION; INSURANCE

11.1. **By MDCO**. MDCO shall indemnify and hold harmless Eagle, its Affiliates, directors, officers, employees and agents, from and against all losses, liabilities, damages and expenses, including reasonable attorneys' fees and costs (collectively, "Losses"), resulting from any Claims by any Third Party to the extent resulting from (a) the breach of any representation, warranty or covenant by MDCO under this Agreement or MDCO's gross negligence or willful misconduct; (b) the use of the Eagle Intellectual Property by MDCO, or its Affiliates beyond the scope of the license granted thereto in Section 2.1; (c) the Manufacture, use, sale, handling, storage or other Exploitation of the Products by or on behalf of MDCO, its Affiliates, Sublicensees, Distributors, customers or end-users; or (d) the use by MDCO of the Confidential Information of Eagle, its Affiliates other than as permitted herein.

11.2. **By Eagle**. Eagle shall indemnify and hold harmless MDCO and its Affiliates, and MDCO's and its Affiliates' directors, officers, employees and agents, from and against all Losses resulting from any Claims by any Third Party to the extent resulting from (a) the breach of any representation, warranty or covenant by Eagle under this Agreement or Eagle's gross negligence or willful misconduct; (b) the development, Manufacture, use, handling, storage or other Exploitation of Products by or on behalf of Eagle, its Affiliates, licensees, Sublicensees, Distributors, customers or end-users (other than MDCO, its Affiliates, Distributors and Sublicensees); and (c) the use by Eagle of the Confidential Information of MDCO other than as permitted herein.

11.3. **Indemnification Procedures**. If a Party (the "Indemnitee") intends to claim indemnification under Sections 11.1 or 11.2, as applicable, it shall promptly notify the other Party (the "Indemnitor") in writing of any Claim for which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have the right to assume the defense thereof with counsel of its choice (provided that such counsel is reasonably acceptable to the Indemnitee); *provided*, *however*, that an Indemnitee shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnitor, if representation of such Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or reasonably-determined - potential differing interests between the Indemnitee and any other Party represented by such counsel in such proceeding. The obligations of this Section 11.3 shall not apply to amounts paid in settlement of any Claim if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld or delayed unreasonably. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any such action, if prejudicial to its ability to defend such action, shall relieve the Indemnitor of any obligation to the Indemnitee under this Section 11.3. The Indemnitee, its employees and agents, shall

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reasonably cooperate with the Indemnitor and its legal representatives in the investigation of any Claim covered by this Section 11.3. The Indemnitor shall not, without the prior written consent of the Indemnitee, agree to any settlement of any such claim that does not include a complete release of the Indemnitee from all liability with respect thereto or that imposes any liability, obligation or restriction on the Indemnitee.

11.4. **Insurance**. Each Party shall maintain insurance, including product liability insurance, with respect to its activities under this Agreement regarding Products in such amount as such Party customarily maintains with respect to similar activities for its other products, but not less than such amount as is reasonable and customary in the industry. Each Party shall maintain such insurance for so long as it continues its activities under this Agreement, and

thereafter for so long as such Party customarily maintains insurance for itself covering similar activities for its other products. MDCO retains the right to insure or self-insure, at its sole discretion, the above coverage.

11.5. No Consequential or Punitive Damages. NEITHER PARTY WILL BE LIABLE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, PUNITIVE OR MULTIPLE DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, OR FOR LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES; *PROVIDED, HOWEVER*, THAT NOTHING IN THIS SECTION 11.5 IS INTENDED TO LIMIT OR RESTRICT (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY WITH RESPECT TO THIRD PARTY CLAIMS OR (B) ANY CLAIMS WITH RESPECT TO A BREACH OF A PARTY'S OBLIGATIONS OF CONFIDENTIALITY OR NON-USE IN ARTICLE 9.

ARTICLE 12. DISPUTE RESOLUTION

12.1. Negotiation Of Parties. In the event of any dispute or controversy arising out of, relating to or in any way connected to the interpretation of any provision of this Agreement, the performance of either Party under this Agreement or any other matter under this Agreement, including any action in tort, contract or otherwise, at equity or law, or (as applicable) any matter which has not been resolved by the JSC pursuant to Section 3.4.3 (each a "Dispute"), MDCO or Eagle may at any time provide the other Party written notice specifying the terms of such Dispute in reasonable detail. As soon as practicable after receipt of such notice, the Chief Executive Officers of both MDCO and Eagle (each a "CEO"; collectively, the "CEOs") shall meet at a mutually agreed upon time and location for the purpose of resolving such Dispute. The CEOs shall engage in good faith discussions or negotiations for a period of up to thirty (30) days to resolve the Dispute or negotiate an interpretation or revision of the applicable portion of this Agreement which is mutually agreeable to both Parties, without the necessity of formal procedures relating thereto. During the course of such discussion or negotiation, the Parties shall reasonably cooperate and provide information that is not materially confidential so that each of the CEOs may be fully informed with respect to the issues in the Dispute.

12.2. Arbitration. In the event any Dispute is not resolved by the CEOs within thirty (30) days after receipt of the written notice of such Dispute provided by a Party to the other Party pursuant to Section 12.1, then MDCO and Eagle shall resolve such Dispute by final and binding arbitration. Whenever MDCO or Eagle decides to institute arbitration proceedings, it shall give written notice to that effect to the other Party. Arbitration shall be held in the metropolitan area of New York, New York, USA, according to the then-current commercial arbitration rules of the American Arbitration Association ("AAA"), except to the extent such rules are inconsistent with this ARTICLE 12. The arbitration will be conducted by a panel of three (3) arbitrators appointed in accordance with AAA rules; provided that each of MDCO and Eagle shall within thirty (30) days after the institution of the arbitration proceedings appoint one arbitrator each, and such arbitrators shall select, if available, a third arbitrator within thirty (30) days thereafter. If the two first arbitrators are unable to select a third arbitrator within such period, the third arbitrator shall be appointed in accordance with AAA rules. Any arbitrator chosen hereunder shall have educational training and industry experience sufficient to demonstrate a reasonable level of relevant scientific, financial, medical and industry knowledge. All arbitrators eligible to conduct the arbitration must agree to render their opinion(s) as soon as reasonably practicable following the final arbitration hearing. The proceedings and decisions of the arbitrators shall be confidential, final and binding on all of the Parties. Judgment on the award so rendered may be entered in a court having jurisdiction thereof. The attorneys' fees of the Parties in any arbitration, fees of the arbitrators and costs and expenses of the arbitration shall be borne by the Parties as determined by the arbitrators. Nothing in this Section 12.2 will preclude either Party from seeking equitable relief in accordance with Section 12.3 or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a Dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding. Notwithstanding the foregoing, the Parties are not required to resolve Disputes related to ownership, filing, prosecution, maintenance, defense or enforcement of Patents pursuant to this Section 12.2.

12.3. Remedies. The Parties acknowledge and agree that, in the event of a breach or a threatened breach by either Party of this Agreement for which it will have no adequate remedy at law, the other Party may suffer irreparable damage and, accordingly, shall be entitled to seek injunctive and other equitable remedies to prevent or restrain such breach or threatened breach, in addition to any other remedy they might have at law or at equity. Each of the Parties acknowledges and agrees that the restrictions set forth in Section 8.1.2 and ARTICLE 9 of this Agreement are reasonable and necessary to protect the legitimate interests of MDCO and that MDCO would not have entered into this Agreement in the absence of such restrictions, and that any breach or threatened breach of any provisions thereof will result in irreparable injury to MDCO for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any such provision, MDCO shall be authorized and entitled to obtain from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance and an equitable accounting of all earnings, profits and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which MDCO

may be entitled in law or equity. Eagle agrees to waive any requirement that MDCO (a) post a bond or other security as a condition for obtaining any such relief, and (b) show irreparable harm, balancing of harms, consideration of the public interest or inadequacy of monetary damages as a remedy.

ARTICLE 13. MISCELLANEOUS

13.1. Force Majeure. Neither MDCO nor Eagle shall be held responsible for any delay or failure in performance (with the exception of the payment of money) hereunder to the extent caused by earthquake, fire, floods, storm, or other acts of God or nature, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, dots, civil commotions, civil or military authorities, acts, omissions or delays in acting by any Governmental Authority or the other Party, laws, regulations and governmental requirements, strikes, embargoes, lockouts or other labor disturbances, or other causes reasonably beyond such Party's control and without such Party's fault or negligence; provided that the affected Party notifies the unaffected Party as soon as reasonably possible, and resumes performance hereunder as soon as reasonably possible following cessation of such force majeure event. Notwithstanding the foregoing, if a force majeure event declared by either MDCO or Eagle persists for a continuous period of six (6) months (and such Party does not resume performance in

accordance with this Agreement prior to such time despite such persistence), the other Party shall have the right to terminate this Agreement without further cost or liability.

13.2. **Assignment**. Neither MDCO nor Eagle may assign its rights under this Agreement, whether by operation of law or otherwise, in whole or in part without the prior written consent of the other Party, which consent shall not be unreasonably withheld, except that (a) either Party shall always have the right, without such consent to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates (provided such assignment to an Affiliate shall not relieve such Party of its obligations herein); and (b) either Party may assign any or all of its rights and delegate any or all of its obligations hereunder, without such consent, to any successor in interest by way of merger, acquisition or sale of all or substantially all of its business or assets to which this Agreement relates; provided that in each case the performing, assigning or delegating Party shall provide the other Party with written notice of such assignment. Any assignment not in accordance with the foregoing shall be void. This Agreement shall inure to the benefit of each Party and its successors and permitted assigns.

13.3. **Severability**. In the event any provision of this Agreement shall for any reason be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other term or provision hereof. The Parties agree that they will negotiate in good faith or will permit a court or arbitrator (in accordance with Article 12) to replace any provision hereof so held invalid, illegal or unenforceable with a valid provision which is as similar as possible in substance to the invalid, illegal or unenforceable provision.

13.4. **Notices**. All communications hereunder shall be in writing and shall be sent (a) by prepaid registered or certified mail, return receipt requested, (b) by overnight express delivery

service by a nationally or globally recognized courier, or (c) via confirmed e-mail, facsimile or telecopy, followed within five (5) days by a copy mailed in the preceding manner, addressed to the other Party at the address shown below or at such other address for which such Party gives notice hereunder. Such notice will be deemed to have been given when delivered or, if delivery is not accomplished by some fault of the addressee, when tendered.

If to MDCO:

The Medicines Company
8 Sylvan Way
Parsippany, NJ 07054
Attention: Paul M. Antinori, Senior Vice President and General Counsel
Fax: 972-656-0746
e-mail: Paul.Antinori@THEMEDCO.com

With a copy to:

WilmerHale
60 State Street
Boston, MA 02109
Attention: David E. Redlick, Esq.
Fax: 617-526-6000
email: david.redlick@wilmerhale.com

If to Eagle:

Eagle Pharmaceuticals, Inc.
470 Chestnut Ridge Road
Woodcliff Lake, New Jersey 07677
Attention: Scott Tarriff, President and Chief Executive Officer
Fax: (201) 391-2430
e-mail: starriff@eagleus.corn

With a copy to:

Orrick, Herrington & Sutcliffe LLP
666 Fifth Avenue
New York, NY 10103
Attention: R. King Milling, Esq.
Fax: 212-506-5151
e-mail: lcmilling@orrick.com

13.5. **Governing Law**. This Agreement shall be governed by and construed in accordance with the laws of New York in force therein without regard to its conflict of law rules or principles.

13.6. **Entire Agreement; Amendments; Waiver**. This Agreement, the Supply Agreement and the side letter among Eagle, MDCO and SciDose effective as of September 24, 2009, together contain the entire understanding of the Parties with respect to the transactions and matters contemplated hereby and thereby, and supersede all prior agreements and understandings relating to the subject matter hereof and thereof, and no representations, inducements, promises

or agreements relating to the subject matter hereof or thereof, whether oral or otherwise, between the Parties not contained herein or therein or incorporated herein or therein by reference shall be of any force or affect. This Agreement may not be modified or amended except in a writing signed by both Parties. No

provision of or right under this Agreement shall be deemed to have been waived by any act or acquiescence on the part of any Party, its agents or employees, but only by an instrument in writing signed by an authorized officer of such Party. No waiver by either Party of any breach of this Agreement by the other Party shall be effective as to any other breach, whether of the same or any other term or condition and whether occurring before or after the date of such waiver. In the event of any inconsistency between or among any provision(s) in this Agreement, the Supply Agreement, the Quality Agreement or the Pharmacovigilance Agreement, the order of interpretation shall be (with the prior-listed agreement superseding any conflicting provision(s) in any subsequently-listed agreement): this Agreement, the Supply Agreement, the Quality Agreement and the Pharmacovigilance Agreement.

13.7. **Captions**. Captions of the Sections and subsections of this Agreement are for reference purposes only and do not constitute terms or conditions of this Agreement and shall not limit or affect the terms and conditions hereof.

13.8. **Exhibits**. All Exhibits annexed hereto or referred to herein are hereby incorporated in and made a part of this Agreement as if set forth in full herein. Any matter or item disclosed on one schedule shall be deemed to have been disclosed on each other schedule to the extent reasonably apparent as constituting disclosure under such other schedule. Any capitalized terms used in any Exhibit but not otherwise defined therein shall be defined as set forth in this Agreement.

13.9. **Independent Contractors**. Each Party represents that it is acting on its own behalf as an independent contractor and is not acting as an agent for or on behalf of the other Party, its Affiliates or any other Third Party (with respect to this Agreement). This Agreement and the relations hereby established by and between MDCO and Eagle do not constitute a partnership, joint venture, agency or contract of employment between them.

13.10. **Cumulative Remedies**. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

13.11. **Waiver of Rule Of Construction.** The Parties agree that they have participated equally in the formation of this Agreement and that the language and terms of this Agreement shall not be presumptively construed against any of them.

13.12. **Counterparts.** This Agreement may be executed in multiple counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Facsimile signatures of the Parties will have the same effect as original signatures. In making proof of this Agreement, it shall not be necessary to produce or account for more than one such counterpart.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

13.13. **Further Assurances.** Each Party shall perform all further acts and things and execute and deliver such further additional instruments or documents as may be necessary which may be reasonably necessary in order to effectuate and give effect to or carry out the purposes of this Agreement

[Next page is signature page.]

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IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

THE MEDICINES COMPANY

By: /s/ Glenn Sblendorio
Name:
Title

EAGLE PHARMACEUTICALS, INC.

By: _____
Name:
Title

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

THE MEDICINES COMPANY

By: _____
Name:
Title

EAGLE PHARMACEUTICALS, INC.

By: /s/ Scott Tarriff
Name:
Title

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EXHIBIT A
Initial Marketing Plan

Exhibit A
Initial Marketing Plan

Product Profile:

- Direct thrombin inhibitor that reversibly binds to the thrombin active site, and is highly selective for thrombin with little or no effect on related serine proteases.
- Considered to be capable of inhibiting the action of both free and clot-associated thrombin.
- Indicated for use as an anticoagulant for prophylaxis or treatment of thrombosis in patients with HITS. Also indicated for use as an anticoagulant in patients with or at risk for HITS undergoing PCI
- Initial dose in HITS: label recommends 2mcg/kg/min as a continuous infusion; however most patients receive doses in range of 0.5-1.5mcg/kg/min
- Initial dose in PCI: start infusion at 25mcg/kg/min and a bolus of 350mcg/kg over 3-5 minutes. Once a therapeutic ACT has been achieved, continue dose for the duration of the procedure
- Branded argatroban sold by GSK in the US, originally developed by Mitsubishi
- Branded argatroban supplied as 2.5 ml vial which must be diluted 100-fold prior to infusion. Eagle's argatroban to be supplied initially in 50 ml vials, [*].
    - Packaged to avoid costly waste of drug
    - RTU: eliminates work required for dilution and potential for dosage error

Messaging:

"MDCO/Eagle argatroban" provides an economic advantage with a reduced cost as compared to branded. It offers convenience, ease of use and the potential for reduced dosing errors in a ready to use formulation. Its use would result in reduced waste with a vial size (50 mg) [*] conducive to the actual dosing regimen. Branded argatroban is sold in 250 mg vials that require dilution before use. [*]

Target audiences:

Primary audience will be [*]. Secondary audiences would be [*].

Target institutions:

[*]

Required resources:

[*]

Market size:

[*]

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Competitive issues (exclusivity):

Branded argatroban (Mitsubishi, Pfizer, GSK)

[*]

Contracting:

[*]

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EXHIBIT B
Initial Development Plan

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EXHIBIT B
Initial Development Plan

Existing Product:

[*]

GOAL

· To obtain FDA approval & launch as soon as possible [*]

Product Specifications:

· [*]

Ingredient	Supplier	Concentration (mg/mL)	Attribute
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]

· [*]

Component	Description	Manufacturer
[*]	[*]	[*]
[*]	[*]	[*]
	[*]	
[*]	[*]	[*]

Existing Product:

CONFIDENTIAL

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[*]

Timelines & Key Deliverables:

· Completion of in progress experimental work to be prepared for potential FDA review questions [*]

· Continuation of [*]

· Additional work as needed to respond to any questions raised by FDA for approval

· Execution of process validation studies and inventory build based on NDA approval timing

Overall Budget:

· Estimated cost going forward [*]

[*]

· To develop, obtain FDA approval & launch as soon as possible [*]

Product Specifications:

· [*]

· [*]

· Product will be filled using [*]

Timelines & Key Deliverables:

· [*]

· Preparation Work for [*]

· FDA Approval/Launch — [*]

Note: Timeline is tentative and dependent on timing of original NDA approval

Overall Budget:

· Estimated cost going forward [*]

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EXHIBIT C
Supply Agreement

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FIRST AMENDMENT TO THE
LICENSE AND DEVELOPMENT AGREEMENT

This FIRST AMENDMENT TO THE LICENSE AND DEVELOPMENT AGREEMENT (this "Amendment") is dated as of January , 2010, by and among The Medicines Company, a Delaware corporation ("MDCO") and Eagle Pharmaceuticals, Inc., a Delaware corporation ("EAGLE", and together with MDCO, the "Parties"). Capitalized terms used herein and not otherwise defined shall have the meanings ascribed to such terms in the Original Agreement (defined below).

WHEREAS, the Parties entered into that certain License and Development Agreement dated September 24, 2009 (the "Original Agreement"); and WHEREAS, the Parties now wish to amend Section 8.2 of the Original Agreement.

NOW, THEREFORE, in consideration of the foregoing, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

1. Amendment to Section 8.2. Section 8.2 of the Original Agreement is hereby deleted in its entirety and replaced with the following:

   8.2 [Intentionally Deleted]

2. Amendment Only as Stated Herein. This Amendment shall only amend the Original Agreement to the extent set forth herein, and all other terms of the Original Agreement and all other documents, instruments and agreements executed and delivered in connection therewith, shall remain in full force and effect.

3. Entire Agreement. The Original Agreement, as amended by this Amendment, constitutes the entire understanding between the Parties with respect to the subject matter hereof and supersedes all prior understandings, negotiations and writings related to the same subject matter between the Parties. The Parties intend the Original Agreement as amended from time to time, to be a complete statement of the terms of their understanding. This Amendment shall be effective as of September 24, 2009.

4. Counterparts. This Amendment may be executed in counterparts, each of which shall be deemed an original and any of which shall constitute a single document. A facsimile signature of an authorized signatory of either Party shall be valid and binding and constitute due execution and delivery of this Agreement by such Party.

5. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of New York in force therein without regard to its conflict of law rules or principles.

IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed as of the date first above written by their duly authorize(' representatives.

THE MEDICINES COMPANY

/s/ Glenn P. Sblendorio
Name: Glenn P. Sblendorio
Title: Executive Vice President and Chief Financial Officer

EAGLE PHARMACEUTICALS, INC.

/s/ Scott Tarriff
Name: Scott Tarriff
Title: President and Chief Financial Officer

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SECOND AMENDMENT TO
LICENSE AND DEVELOPMENT AGREEMENT

THIS SECOND AMENDMENT TO LICENSE AND DEVELOPMENT AGREEMENT (this "Second Amendment"), is made effective as of September 1, 2012 (the "Effective Date"), by and among **THE MEDICINES COMPANY**, a Delaware corporation located at 8 Sylvan Way, Parsippany, N.J. 07054 ("MDCO") and **EAGLE PHARMACEUTICALS, INC.**, a Delaware corporation located at 470 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677 ("Eagle" and together, the "Parties").

WHEREAS, the Parties hereto entered into a License and Development Agreement effective September 24, 2009, as amended by First Amendment to License and Development Agreement dated as of January, 2010 (as so amended, the "License Agreement") for the development, manufacture, distribution, promotion and sale of injectable liquid Argatroban pharmaceutical products; and WHEREAS, certain disputes have arisen between the Parties relating to their obligations under the License Agreement (the "Disputes");

WHEREAS, the Parties have agreed to resolve the Disputes and to amend the License Agreement on the terms and conditions set forth below.

NOW THEREFORE, for and in consideration of the mutual promises and agreements contained herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, and intending to be legally bound hereby, the Parties agree as follows:

1. Definitions. Capitalized terms not expressly defined in this Agreement shall have the meanings ascribed to them in the License Agreement.

2. Supply Cost. The Parties agree that the definition of "Supply Cost" in the License Agreement shall be amended as follows:

   (a) For the nine (9) batches of Product shipped to MDCO prior to the Effective Date of this Second Amendment, the Parties agree that the Supply Cost for each of:

      (i) [*], and

      (ii) [*].

   (b) For all Product supplied to MDCO on or after the Effective Date of this Second Amendment, the Supply Cost shall be the lesser of [*]; provided that [*].

   (c) Based on the provisions of Section 2 (b) of this Second Amendment,

---

Section 4.5.3 of the License Agreement shall no longer apply.

3. Financial Settlement. The Parties agree that, within five (5) business days after the execution of this Second Amendment, MDCO shall pay to Eagle the sum of Four Hundred Seventy-One Thousand Seventy-Seven Dollars ($471,077) in full and final satisfaction of the following claims (See Exhibit I):

(i) all amounts payable to MDCO for recall-related expenses incurred by MDCO prior to the Effective Date of this Second Amendment, including product costs, fees for services, cash discounts, GPO fees, pre-paid inventory, royalties and other recall costs;

(ii) all amounts payable to Eagle for Product sold to MDCO in 2011;

(iii) all amounts payable to Eagle for the Product identified in Section 2 (a) of this Second Amendment;

(iv) all amounts payable to Eagle for royalties on Net Sales of the Product prior to July 1, 2012 (audit rights in the License Agreement still apply);

(v) all amounts payable to Eagle for validation batches of the Product, including validation charges;

(vi) all amounts payable to Eagle under Section 7.4.2 of the License Agreement;

(vii) all amounts payable to Eagle for a shipping and temperature control study conducted in connection with the recall of the Product; and

(viii) all amounts prepaid by MDCO in 2011.

4. MDCO Purchase Order 1284.

(a) MDCO has delivered Purchase Order number 1284, dated October 8, 2012 ("PO 1284"), to Eagle for two thousand units of Finished Product (as defined in the Supply Agreement). Sections 4.3 and 5.2 of the Supply Agreement shall not apply to PO 1284 to the extent inconsistent with this Section 4.

(b) Eagle hereby accepts PO 1284 and agrees to use Commercially Reasonable Efforts to cause its Third Party Manufacturer to make delivery of the Finished Product in the quantities specified in PO 1284 on or before the dates provided therein.

(c) MDCO shall provide for payment for the Finished Product ordered under PO 1284 by delivering to Eagle, within five (5) business days after the execution of this Second Amendment, a letter of credit issued by MDCO's

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principal commercial bank, in the amount of the purchase price for the Finished Product reflected on PO 1284, permitting Eagle to draw on such letter of credit upon (i) MDCO's acceptance of the Finished Product in accordance with the Supply Agreement and Quality Agreement, and (ii) MDCO' s delivery to Eagle as proof of acceptance of Finished Product the approved Incoming Receipt Inspection Record which MDCO provides ICS upon the release of Finished Product. Partial (pro-rated) draws shall be permitted under the letter of credit upon timely delivery and inspection of a portion of the Finished Product in accordance with (i) and (ii) above.

5. Representations and Warranties. Each of the Parties represents and warrants that:

(a) It is duly organized and validly existing under the laws of its jurisdiction of incorporation and has the corporate power and authority to execute and deliver this Second Amendment and to perform its obligations hereunder.

(b) The execution, delivery and performance of this Second Amendment by such Party has been duly and validly authorized and approved by proper corporate action on the part of such Party. Such Party has taken all other action required by applicable law, its certificate of incorporation or by-laws or any agreement to which it is a party or by which it or its assets are bound, to authorize such execution, delivery and performance. Assuming due authorization, execution and delivery on the part of the other Party, this Second Amendment constitutes a legal, valid and binding obligation of such Party.

6. Entire Agreement. The License Agreement, as amended by this Second Amendment, constitutes the entire agreement between the Parties with respect to the subject matter hereof and may not be amended or modified except in writing signed by the Parties hereto. This Second Amendment shall only amend the License Agreement to the extent set forth herein, and all other terms of the License Agreement, and the instruments and agreements executed and delivered in connection therewith, remain in full force and effect.

IN WITNESS WHEREOF, the Parties have executed this Second Amendment as of the date first written above.

EAGLE PHARMACEUTICALS, INC.	THE MEDICINES COMPANY
By: /s/ Scott Tarriff	By: /s/ William O'Connor
Name: Scott Tarriff	Name: William O'Connor
Title: President and CEO	Title: V.P., CAO

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Exhibit I - Financial Settlement

Claims	Reference / Section	Owed to Eagle	Owed to MDCO
Recall-related expenses	3(i)		[*]
Product supply sold to customers in 2011	3(11)	[*]	
Product supply identified in Section 2 (a)	3(iii)	[*]	
Royalties	3(Iv)	[*]	
Validation charges	3(v)	[*]	
Section 7.4.2 of License Agreement	3(vi)	[*]	
Shipping & temperature control study	3(v11)	[*]	
		[*]	[*]
Less: Prepaid by MDCO		[*]	
		[*]	[*]
Net amount owed to Eagle		**$ 471,077**	

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PO 001284

October 12, 2012

Vendor

Eagle Pharmaceuticals, Inc.
470 Chestnut Ridge Road
Woodcliff lake, NJ 07677

The Medicines Company

Accounts Payable
8 Sylvan Way
Parsippany, NJ 07054
United States

Ship To

ICS/MDCO — Reno
5360 Capital Court, Suite 102
Reno, NV 89502

Product	Description	Quantity	Unit Price	Total Price
Argatroban	10 Pack Cartons — Due Date: December 15, 2012	[*]	[*]	[*]
Argatroban	10 Pack Cartons — Due Date: January 15, 2012	[*]	[*]	[*]
			Tax	$ 0.00
			Total	**[*]**

Coding

Cost Center	Account	Sub-Account	Project
00000000000000000000	1600	0	0

Notes

All invoices in reference to this purchase order should be mailed to the address specified above, or emailed to ap@themedco,com Please include the following information on all invoices:

- PO Number
- Care of: Accounts Payable
- Cost Center — If Specified in the PO
- Account — If Specified in the PO
- Sub-Account — If Specified in the PO
- project Code — If Specified in the PO

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/s/ Scott Tarriff

/s/ William O'Connor

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Exhibit 10.15

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DATED 14 DECEMBER 2012

AGREEMENT FOR THE SUPPLY OF ARGATROBAN AND TOPOTECAN

between

CIPLA LIMTED

and

EAGLE PHARMACEUTICALS, INC.

CONTENTS

CLAUSE

1.	Supply of Products	1
2.	Limitation of liability	6
3.	Indemnity	7
4.	Entire Agreement	7
5.	Waiver	8
6.	Payment of Amounts	8
7.	Transfer of Manufacture	9
8.	Term and Termination	9
9.	Consequences of Expiry/Termination	10
10.	Governing law and jurisdiction; miscellaneous	11
Annexure I- Quality Agreement		14

THIS AGREEMENT FOR SUPPLY OF ARGATROBAN AND TOPOTECAN **(Agreement)** is dated 14 December 2012

PARTIES

(1) **CIPLA LIMITED** incorporated and registered in India with company number whose principal place of business is at Mumbai Central, Mumbai, 400 008, India **(Cipla).**

(2) **EAGLE PHARMACEUTICALS, INC.** incorporated and registered in Delaware USA with its principal place of business located at 470 Chestnut Ridge Road, Woodcliff Lake, NJ 07030, USA (**Eagle**).

BACKGROUND

(A) Cipla and Eagle are parties to a Contract Manufacturing and Supply Agreement dated 18 September 2009 **(Supply Agreement),** which covers the supply of Argatroban Product and Topotecan Product.

(B) Cipla provided to Eagle a termination notice dated 21 September, 2012 with respect to the Supply Agreement as regards the supply of Argatroban Product only, with the remainder of the Supply Agreement remaining in force in respect of all other Products.

(C) Eagle has rejected the termination notice provided by Cipla. However, without prejudice to the aforesaid termination notice issued by Cipla, the parties are, by this Agreement, attempting to resolve their disputes.

(D) Cipla and Eagle also wish to terminate the supply of Topotecan Product under the Supply Agreement.

(E) Eagle has requested that Cipla, notwithstanding Cipla's termination notice with respect to the Supply Agreement, continue to supply Argatroban Product for sale in the territory of United States of America (USA) and Topotecan Product for sale in the territory of European Union (EU) to Eagle (for the respective product USA and EU to be referred to as **Territory**) pursuant to clause 8.1.

(F) Accordingly, Cipla is prepared to supply non-exclusively, and Eagle is prepared to be supplied, Argatroban Product and/or Topotecan Product on the terms of this Agreement with effect from the date of this Agreement (**Effective Date**).

AGREED TERMS

1. SUPPLY OF PRODUCTS

1.1 Subject to clause 5.2, the parties agree that, effective on the Effective Date, the Supply Agreement has been terminated with respect to Argatroban Product and Topotecan Product for the territories mentioned therein and that all supply of Argatroban Product

and Topotecan Product by Cipla to Eagle is pursuant to the terms of this Agreement only and in no event shall this Agreement be construed as a continuation of the supply of Argatroban Product or Topotecan Product under the terms of the Supply Agreement. Notwithstanding the foregoing, the Quality Agreement dated 10 June 2011 and entered into between Eagle and Cipla (the **Quality Agreement)** shall, upon execution of this Agreement, automatically stand terminated. Both parties hereby agree to a revised quality agreement, attached hereto as Annexure 1. In case of any inconsistency between the terms of this Agreement and the Quality Agreement, this Agreement shall prevail.

1.2 The following commercial terms shall apply to the supply of Argatroban Product and Topotecan Product on a non-exclusive basis:

(a) Argatroban Product: 50ml vial of 1mg/ml Argatroban.

(b) Topotecan Product: 3mg/mL, in a 1mL and 5mL vial.

(c) Argatroban Product Price: The price per vial of Argatroban Product on FOB/FCA Mumbai basis is US$[*] and US$[*]; provided, that [*], the Argatroban Product Price will be equitably amended (up or down, as applicable). The parties acknowledge and agree that (i) Eagle ordered and pre-paid for Argatroban Product pursuant to this Agreement prior to the date hereof at $[*] per vial, (ii) the [*], (iii) the price per vial is of the Argatroban Product is therefore $[*], and (iv) the parties will mutually agree on an appropriate methodology of [*] by Eagle as soon as practicable after the date hereof.

(d) Topotecan Product Price: The price per vial of Topotecan Product [*] is US$[*] per 1ml vial and US$[*] per 5ml vial, [*], provided, that [*], the Topotecan Product Price will be equitably amended (up or down, as applicable). This price is subject to the exact same formulae (including the packaging material) being used for EU (as was used in the USA under the Supply Agreement).

(e) Argatroban Product Batch Size: [*].

(f) Topotecan Product Batch Size: [*].

(g) Inventory:

(i) Eagle shall supply Cipla with a yearly estimated forecast of its demand for Argatroban Product and Topotecan Product set out on a [*] basis and agrees that Cipla will need to acquire inventories [*] and other raw materials and components in order to meet Eagle's forecasted requirements of Argatroban Product and Topotecan Product notwithstanding that such forecasted requirement is Eagle's

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estimated requirements. In order to assist Cipla to maintain sufficient capacity at the manufacturing facilities of the Argatroban Product and Topotecan Product, Eagle agrees that the [*] of the said forecast shall be considered as firm and binding on Eagle to purchase the quantities mentioned therein.

(ii) Eagle shall pay Cipla the cost incurred by Cipla in respect of any inventories acquired by Cipla in order that Cipla may satisfy such forecasted demand of Eagle that Cipla is unable, for whatever reason, to use in the supply of Argatroban Product and/or Topotecan Product to Eagle, unless Cipla is able to utilize this inventory elsewhere.

(h) Orders: Eagle shall place orders for complete registered batch size (**Batches**) or multiples thereof.

(i) Payment:

(i) Cipla shall invoice Eagle for the quantities of Argatroban Products and/or Topotecan Products, at least [*] prior to the start of a mutually agreed [*], as Eagle shall order pursuant to any purchase order submitted by Eagle, upon acceptance by Cipla of such purchase order. Eagle shall pay such invoice in full by wire transfer to the designated bank account of Cipla within [*] from the date of the invoice.

(ii) Cipla shall have no obligation to commence manufacture or supply of any Argatroban Product and/or Topotecan Product ordered by Eagle pursuant to an accepted purchase order until payment in cleared funds has been received in full by Cipla; provided, however, that once funds have been deposited into Cipla's account, Cipla will use commercial reasonable efforts to commence manufacturing and meet the mutually agreed manufacturing dates. Subject to clause 1.2(j), if such mutually agreed upon date will not be met by Cipla, Cipla will inform Eagle as soon as reasonably practicable and the parties shall agree on a revised delivery schedule. Cipla shall take all commercially reasonable action necessary to deliver product on such revised delivery schedule.

(iii) Cipla shall supply the yield of the Batches ordered by Eagle pursuant to such accepted purchase orders and no refund shall be due to Eagle regardless of the yield of such Batches; provided, however, that Cipla shall use commercially reasonable efforts to improve the yield based on the manufacturing process and specifications of the approved 505(b)(2) regulatory file.

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(j) Delay: The delivery of the Argatroban product and/or Topotecan product shall be [*] basis. In the event of any delay in delivery of any Argatroban Products and/or Topotecan Products such that delivery is, or is likely to be, effected after the delivery date specified in the accepted purchase order and such delay results from any circumstance not within Cipla's direct and sole control or was unforeseeable by Cipla at the time it accepted such purchase order, then:

(i) Cipla shall use commercially reasonable efforts to rectify in a timely manner any delay that is not within its direct and sole control;

(ii) Cipla shall have no liability whatsoever to Eagle in respect of such late delivery;

(iii) Eagle shall not be entitled to adjust payment against future batches or reject or refuse to pay for such Argatroban Products and/or Topotecan Products on the grounds that the delivery is late; and

(iv) any accelerated measures such as [*] required to minimise any such delay in delivery shall be taken solely at Eagle's discretion and cost. For the avoidance of doubt, [*].

(k) Quality Acceptance, Quality Control and Product Release:

(i) Within [*] of the receipt of the product at Eagle's (or Eagle nominated) premises, Eagle shall conduct a review of the Argatroban Product and/or Topotecan Product batch records and confirm whether the product complies with the specifications as set forth in approved regulatory application (**Specifications**). If within the above-mentioned [*] Cipla has not received any notification from Eagle, the shipment will be deemed accepted by Eagle; provided that such acceptance shall not (i) adversely affect or otherwise diminish Eagle's rights to receive shipments in compliance with clause 2.1 or (ii) preclude a subsequent rejection of any shipment of product by Eagle following discovery of an inherent proven manufacturing defect in such product arising out of a non-conformity to the corresponding Specifications provided that such defect is solely attributable to Cipla,

(ii) In case Eagle notifies Cipla that the Argatroban Product and/or the Topotecan Product contain an inherent manufacturing defect, and if such finding is rejected by Cipla, the parties will refer a sample of the subject shipment to a mutually agreed upon U.S independent laboratory or industry expert mutually appointed by the parties. In case such independent laboratory/expert finds that the Argatroban Product and/or the Topotecan Product contains an inherent proven

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manufacturing defect arising solely out of non-conformity to the corresponding Specifications and provided such defect is attributable solely and directly to Cipla, Cipla shall, within a reasonable period, replace the non-conforming product with a conforming product. The report of the independent laboratory will be final and binding. Eagle shall, at Cipla's sole option and expense, either return such non-conforming product within a reasonable period of time, or destroy the same and provide a certificate of destruction to Cipla.

(l) Eagle shall release the Argatroban Product and/or Topotecan Product onto the market in the Territory only after ensuring that the Argatroban Product and/or Topotecan Product materially conforms to the Specifications as agreed between the parties, based on a review of the batch records. Subject to clauses 1.2(k), 1.2(m) and 2.1, once the Argatroban Product and/or the Topotecan Product is released in the Territory, Cipla shall not be held responsible for any reason whatsoever. Cipla shall supply Eagle, as reasonably requested by Eagle, with all manufacturing and packaging records including all test results and release and conformance certifications and a copy of the raw data as needed to assess acceptability of each batch. At the request of Cipla, Eagle shall provide to Cipla such copies of the release records of activities conducted by Eagle.

(rn) Subject to clause 2.3, in the event that the Argatroban Product and/or Topotecan Product under this Agreement contains an inherent proven manufacturing defect arising solely out of non-conformity to the corresponding Specifications provided such defect is attributable solely and directly to Cipla, for the said products, Cipla shall promptly replace said non-eonforming product with a conforming product at its sole cost.

(n) Cipla additionally agrees:

(i) not use the intellectual property provided by Eagle, the formulation work provided by Eagle to Cipla or any of Eagle's confidential information provided by Eagle for any reason other than in performing its obligation hereunder, provided that

Cipla shall be entitled to develop, have developed, manufacture, have manufactured, sell, commercialise or in any manner make available any Argatroban Product and/or Topotecan Product without the use of any intellectual property provided by Eagle;

(ii) Eagle shall have the right, upon reasonable notice to Cipla and during normal business hours, not more than once during any calendar year, unless Eagle reasonably believes that there may be a problem associated with a product or manufacturing facility that makes additional inspection advisable, to audit Cipla's facilities for

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such product to ensure that the products are being manufactured, packaged and stored in compliance with the applicable Specifications, and all applicable laws and regulations, including without limitation, cGMP; and

(o) Eagle agrees that it shall obtain and maintain valid throughout the term and [*] after expiry or earlier termination of the Agreement and/or shelf life of the Products supplied under the Agreement, full and sufficient comprehensive or general commercial liability insurance, including transit insurance from the delivery destination, third party, public and product liability insurance from reputed insurers with 'A' rating, at its own cost, to cover its actual and potential liabilities hereunder and shall name Cipla as additional insured. Eagle shall, upon request by Cipla, provide the certificate (or equivalent confirmation) of such insurance. Any such insurance does not relieve and/or limit Eagle's liability under this Agreement.

2. LIMITATION OF LIABILITY

2.1 Subject to clause 1.2(l), Cipla warrants that finished Argatroban Product and/or Topotecan Product at the time of delivery hereunder shall (i) have been manufactured in accordance with cGMPs and other applicable laws, including the U.S. Federal Food, Drug, and Cosmetic Act, and (ii) conform to product Specifications provided by Eagle. Cipla gives no other warranty nor makes any representation in respect of Argatroban Product and/or Topotecan Product supplied under this Agreement and all implied warranties are excluded to the maximum extent legally permissible.

2.2 Except as expressly provided in clauses 1.2(k), 1.2(m) and 2.1, to the maximum extent legally permissible, Cipla shall have no liability to Eagle (including any liability in tort) under or in connection with this Agreement. In particular, Cipla shall have no liability to Eagle for any:

(i) loss of profits;

(ii) loss of revenue;

(iii) loss of or damage to reputation or goodwill;

(iv) loss of opportunity;

(v) wasted management or other staff time;

(vi) losses or liabilities under or in relation to any other contract; or

(vii) any indirect or special loss or damage.

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2.3 Notwithstanding anything to the contrary in any prior agreements or the provisions of this Agreement, in the event of any claim either by Eagle or a third party that the Argatroban Product and/or Topotecan Product sold prior to or after the Effective Date contains an inherent proven manufacturing defect arising solely out of non-conformity to the corresponding Specifications for the said products provided that such defect is attributable solely and directly to Cipla, Cipla's liability under any circumstance whatsoever is restricted to replacement of the said non-conforming product with a conforming product.

3. INDEMNITY

3.1 Eagle agrees on demand to indemnify each of Cipla and its directors, officers and employees against any loss, damage, liability, demand, claim, recovery, judgment, execution, fine, penalty, charge and any other cost and expense of any nature or kind whatsoever, including any costs of recovery on a full indemnity basis suffered or incurred by it (**Losses**), from time to time, arising from any third party claim, demand, action or proceeding against any of Cipla and its directors, officers and employees arising out of or in connection with i) Eagle's marketing or putting on the market of Argatroban Product and/or Topotecan Product (including, without limitation, any claim for infringement of any intellectual property rights and any product liability claim); ii) any breach of this Agreement by Eagle; or iii) any negligence of Eagle or its directors, officers and employees, in each case, except to the extent that such Losses result from (a) a breach by Cipla of clause 2.1, (b) the Argatroban Product and/or Topotecan Product under this Agreement containing an inherent proven manufacturing defect arising solely and directly out of nonconformity to the corresponding

Specifications for the said products provided that such defect is attributable solely and directly to Cipla or (c) the gross negligence or wilful wrongful acts of Cipla.

4. ENTIRE AGREEMENT

4.1 This Agreement constitutes the entire agreement between the parties about the subject matter of this Agreement and in relation to such subject matter, supersedes and extinguishes (subject to clause 5.2) all earlier understandings and agreements between the parties and all earlier representations by any party. The parties have not entered into this Agreement in reliance upon any representation, warranty or promise. No representation or warranty or condition or any other term is to be implied in this Agreement whether by virtue of any usage or course of dealing or otherwise except as expressly set out in it.

4.2 Any continuing obligation of either party for any supplies of Argatroban Product and/or Topotecan Product made prior to the Effective Date, shall be exclusively governed by the terms and conditions of this Agreement and nothing contained in the Supply Agreement or the Quality Agreement shall be deemed to survive for the said purpose, except as explicitly provided in Section 5.2 below.

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5. WAIVER

5.1 Subject to clause 5.2, on execution of this Agreement each party hereby irrevocably releases and discharges the other from all claims or demands whatsoever, under or in connection with the Supply Agreement, as it relates to the manufacture of; supply of, purchase of or otherwise relates to Argatroban Product and/or Topotecan Product including without limitation claims for negligence, whether arising before or on the date of this Agreement.

5.2 The release and waiver at clause 5.1 shall not apply to:

(a) Eagle's obligation to pay any amounts validly invoiced by Cipla pursuant to the terms of this Agreement and the Supply Agreement;

(b) Eagle's obligations to make payments of the amounts as mentioned under clause 6.

All payments under this clause 5.2, shall be made within [*] of the receipt of the corresponding invoice raised by Cipla.

Eagle hereby waives its claim against Cipla in respect of Eagle claims related to the recall of the Argatroban Product (batch numbers 1-9).

6. PAYMENT OF AMOUNTS

6.1 Eagle shall pay to Cipla within [*] of the date of this Agreement the sum of [*] in respect of the [*] manufactured by Cipla pursuant to binding purchase orders submitted by Eagle and accepted by Cipla,

6.2 Additionally, within [*] of the date of this Agreement, Eagle shall pay to Cipla the sum of [*] in respect of the [*] carried out by Cipla on the Argatroban Product and/or Topotecan Product as set forth in, and in satisfaction of, Cipla [*].

6.3 Within [*] of date of receipt by Eagle of the invoice raised by Cipla, Eagle shall pay to Cipla

(a) the charges for the terminal sterilization study on Argatroban Product amounting to [*]; and

(b) the charges [*] on the Argatroban Product amounting to [*], provided that in the event Cipla has to incur any further changes for the [*], Eagle shall reimburse Cipla for such charges within [*] of the date of the receipt by Eagle of the invoices in respect thereof.

6.4 Out of Pocket Expenses. Additionally, Eagle shall reimburse Cipla actual expenses incurred, without any mark-up, in relation to any out of pocket expenses incurred by Cipla and consented to by Eagle (such consent not to be unreasonably withhold, conditioned or delayed) in relation to (a) specific equipment or tools procured specifically

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for the Argatroban Product and/or Topotecan Product; and (b) if technology-transfer activity requires Cipla personnel to travel to Eagle, its Affiliate or a third party site.

6.5 Other Expenses.

(a) Eagle shall pay to Cipla stability charges at [*] for complete testing per testing point, per strength, per stability condition, per orientation for sterile products;

(b) Eagle shall pay to Cipla the costs for any additional work required either for the Argatroban Product and/or Topotecan Product (including manufacturing of exhibit batches and any data generation) as shall be mutually discussed and agreed by the parties provided that. Cipla shall not be obliged to commence such additional activity unless the scope of work and the charges for such activity are agreed.

6.6 All payments under this clause 6 shall be made within [*] of the receipt of the corresponding invoice raised by Cipla.

6.7 For the avoidance of doubt it is clarified that, in case Eagle does not make the payment according to the terms of this Agreement, Cipla shall have no obligation to supply the Argatroban Product and/or the Topotecan Product to Eagle. Additionally and without prejudice to any rights that Cipla may have, Cipla shall be entitled to terminate this Aireement with immediate effect.

7. TRANSFER OF MANUFACTURE

7.1 Eagle shall use its commercially best efforts to effect a transfer of the manufacture of Argatroban Product and Topotecan Product to an alternate manufacturer as soon as possible, but [*]. Eagle shall notify Cipla [*] of receiving regulatory approvals to manufacture Argatroban Product and Topotecan Product respectively [*].

7.2 In addition to the above, both parties shall, in good faith, cooperate and negotiate [*] to allow and procure the transfer of such [*] product to [*].

8. **TERM AND TERMINATION**

8.1 This Agreement shall come into effect on the date of execution of this Agreement and shall remain in force until the earlier of:

(a) In respect of Argatroban Product:

(i) Receipt by Eagle of approval from the US FDA for manufacture of Argatroban Product for sale in the Territory at a third party manufacturing site;

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(ii) 31 March 2014 unless the parties agree in writing to extend this Agreement beyond such date;

(iii) Termination of this Agreement by either party in accordance with the terms of clause 8.2.

(b) In respect of Topotecan Product:

(i) Receipt by Eagle of approval for manufacture of Topotecan Product for sale in the Territory at a third party manufacturing site;

(ii) 31 December 2013, unless the parties agree in writing to extend this Agreement beyond such date;

(iii) Termination of this Agreement by either party in accordance with the terms of clause 8.2.

8.2 Without prejudice to any rights that have accrued under this Agreement, either party may terminate this Agreement with immediate effect by giving written notice to the other party if:

(a) the other party fails to pay any amount due under this Agreement on the due date for payment and remains in default not less than [*] after being notified in writing to make such payment; or

(b) the other party commits a material breach of any term of this Agreement and (if such breach is remediable) fails to remedy that breach within a period of [*] after being notified in writing to do so; or

(c) a receiver, or administrative receiver, is appointed over the whole or any part of the other party's assets, or an order is made or a resolution passed for winding-up the other party (unless such order or resolution is part of a voluntary scheme for the reconstruction or amalgamation of the other party as a solvent corporation and the resulting corporation, if a different legal entity, undertakes with the terminating party to be bound by the terms of this Agreement) or the other party otherwise becomes subject to or takes advantage of the bankruptcy or insolvency laws applicable to it.

9. CONSEQUENCES OF EXPIRY/TERMINATION

9.1 Any expiry or termination of this Agreement shall be without prejudice to any rights or remedies that may have accrued under this Agreement as at the date of its expiry or termination. Furthermore, clauses 1.1, 1.2(1, j and k), 2, 3, 4, 5, 6, 9 and 10 shall survive any expiry or termination of this Agreement.

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10. GOVERNING LAW AND JURISDICTION; MISCELLANEOUS

10.1 Confidentiality. Each party agrees to keep, any and all information received by the other party, whether under or in connection with this Agreement (or the Quality Agreement) as confidential and not use or disclose such information to any third party without the prior written consent of the party disclosing such information. This obligation of confidentiality shall survive during the term of this Agreement and for a period of [*] from the earlier of the date of expiry or termination of this Agreement. Notwithstanding any of the foregoing, Eagle shall have the right to the use and disclose Cipla's confidential information (i) to the applicable regulatory authorities and otherwise to the extent required in connection with its marketing, sale and use of Argatroban Product and Topotecan Product; and (ii) if Eagle determines that such information is required to be released pursuant to securities disclosure regulations. If either party is required under applicable law to disclose the other party's confidential information by any court or to any governmental authority, the party required to disclose the other's confidential information shall, prior to such disclosure, notify the other party of such requirement and all particulars related to such requirement. This Agreement does not constitute the conveyance of ownership with respect to or a license to any confidential information.

10.2 Access. Cipla acknowledges that it is essential for Eagle to have periodic access to each Cipla facility at which Argatroban Product and Topotecan Product are manufactured for the purpose of conducting inspections and/or audits under this Agreement, including audits of Cipla's compliance with cGMP and with applicable laws. Eagle shall have the right, upon reasonable notice to Cipla and during normal business hours, not more than [*] unless Eagle reasonably believes that there may be a problem associated with Argatroban Product or Topotecan Product or manufacturing facility that makes additional inspection advisable, to audit Cipla's facilities for such Product to ensure that such Products are being manufactured, packaged and stored in compliance with the Specifications, and all applicable laws and regulations. Cipla shall make available to Eagle, books, records and documents which in any way pertain to the manufacture or quality control, testing and compliance procedures of Argatroban Product and Topotecan Product. If Eagle observes or discovers variances from established standards and methods of production of Argatroban Product and Topotecan Product or any noncompliance with cGMP or any other required standard herein, Eagle shall give written notice thereof to Cipla, and upon receipt of any such notice, Cipla promptly shall take all appropriate remedial or corrective action and give written notice to Eagle describing in reasonable detail such actions taken. If Cipla disagrees with any such advice and direction, the parties shall discuss in good faith an appropriate resolution.

10.3 Record Retention. Cipla will retain copies of all batch documentation, and all other records or documentation generated by it in connection with the processing and testing of Argatroban Product and Topotecan Product under the terms of this Agreement, and all records which may be reasonable necessary to assist Eagle in the event of a product recall or adverse drug event or product complaint, [*] after the expiration date of each Argatroban Product and Topotecan Product to which the documentation relates and, if longer, such period as required by applicable law.

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10.4 This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and interpreted in accordance with the law of England and Wales with courts of England and Wales having jurisdiction in respect of it.

10.5 The parties irrevocably agree that any dispute arising hereunder shall be governed conclusively and exclusively by the rules laid down by the London Court of International Arbitration (LCIA). The arbitration shall be conducted in English. The arbitration shall be conducted in London, United Kingdom.

10.6 No waiver by any party, whether express or implied, of its rights under any provision of this Agreement shall constitute a waiver of such party's rights under such provisions at any other time or a waiver of such party's right under any other provision of this Agreement. For the sake of clarity, this provision shall not affect Article 5 of this Agreement.

10.7 Variation. Any variation of this Agreement shall be in writing and signed by or on behalf of each party.

10.8 Notice. Any notice given under this Agreement shall be in writing and signed by or on behalf of the party giving it and may be served by delivering it personally or sending it by pre-paid recorded delivery or registered post or fax to the address mentioned hereinabove and for the attention of the relevant party.

10.9 This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

[Signature Page Follows]

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This Agreement has been entered into by Eagle and Cipla as of the Effective Date.

CIPLA LIMITED EAGLE PHARMACEUTICLAS, INC.

By: /s/ Abhayan Jawaharial

Name: Abhayan Jawaharial

Position: Chief Legal Officer

By: /s/ Scott Tarriff

Name: Scott Tarriff

Position: CEO

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ANNEXURE 1- QUALITY AGREEMENT

This Quality Agreement forms an integral part of the Agreement. In case of any inconsistency between the terms of this Quality Agreement and the Agreement, the Agreement shall prevail.

THIS QUALITY AGREEMENT (this "**Quality Agreement**") is entered into by and between **Eagle Pharmaceuticals, Inc** (for the purposes of the Quality Agreement shall be hereinafter referred to as "**Company**") and **Cipla Ltd.** (for the purposes of the Quality Agreement shall be hereinafter referred to as "**Supplier**") and replaces all previous versions

RECITALS

WHEREAS, the parties desire to enter into this Quality Agreement, which shall define the responsibilities of Company and Supplier with respect to the quality assurance of the products manufactured for Company by Supplier, subject to the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises and of the mutual covenants of the parties hereinafter contained, the parties hereto agree as follows:

AGREEMENT

1. Purpose: The purpose of this Quality Agreement is to set forth the responsibilities of Company and Supplier. Supplier shall manufacture and supply the Argatroban Product 50 ml vial of 1mg/ml and/or Topotecan Product 3mg/ml in a 1ml and 5m1 (hereinafter for the purpose of the Quality Agreement shall be referred to as the **"Product(s)")** in accordance with the current "Rules Governing Good Manufacturing Practice" in the U.S. Code of Federal Regulations (21 CFR 211) and the current Good Manufacturing Practice Standards as set forth in Europe (e.g. -Annex 1, etc) and the Product specifications and as per the terms of the Agreement. This Quality Agreement provides the methods for implementing the quality assurance and regulatory affairs provisions and the specific responsibilities of each party with respect to product quality in accordance with the Agreement.

2. Definitions. The following terms for the purpose of this Quality Agreement shall have the following respective meanings:

2.1 ANDA shall mean an Abbreviated New Drug Application for the finished Product submitted to the FDA or any other comparable filings submitted by Company to any comparable regulatory authority in the Territory including any amendments or supplements thereto.

2.2 NDA shall mean a New Drug Application for the finished Product submitted to the FDA by Company, or any other comparable filings submitted to any comparable regulatory authority in the Territory by Company, including any amendments or supplements thereto.

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2.3 Active Pharmaceutical Ingredient (API) Specifications shall mean the Bulk Formulated Drug Substance Specifications and requirements contained in or made a part of Company's ANDA/NDA or other regulatory filing for territory.

2.4 Components shall mean all containers, closures, packaging components, labels and labeling necessary for the manufacture of the finished Product as finished goods.

2.5 FDA shall mean the United States Food and Drug Administration.

2.6 EMA shall mean the European Medicines Agency and as a regulatory agency of the European Union can represent any European Regulatory Agency such as the Medicines & Health Care Products Regulatory Agency (MHRA) in the UK etc.

2.7 Materials shall mean all inactive raw materials used in the formulation of the finished Product necessary for the manufacture of the finished Product as finished goods.

2.8 Re-processing shall mean any finished product or intermediate which is sent back through any portion of the formulation or filling process; provided, however, that Re- processing does not include the steps associated with labeling, packaging or re-inspection.

2.9 Specifications shall mean the finished Product description and attributes set forth in the approved Regulatory applications.

2.10 Territory shall have the meaning assigned to it under the Agreement.

2.11 Work in Process shall mean Materials and Bulk Formulated Drug Product from the time of pre-weighing for allocation to a manufacturing lot until satisfactory completion of quality testing for such manufacturing lot.

3. BSE/TSE Warranty. Supplier will certify that all Active Ingredient, Materials and Components used in the manufacture of Product are not of animal origin. If any Active Ingredient, Materials or Components are of animal origin, particularly if they are of ruminant origin, Supplier will certify in writing that the Product is free of Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy. Supplier will also certify that the Product has not come in contact during the manufacturing process with any equipment used with materials of animal origin. Notifications will be provided to Company prior to change in BSE/TSE status at Supplier.

4. Master Formula. The composition of Products to be said in the EU / U.S. will be as stated in the applicable Product DMF / ANDA / NDA and European Regulatory Dossier, as applicable.

5. Manufacturing Conditions. Supplier represents that it has, adequate premises and equipment and sufficient knowledge and experience to carry out activities relating, directly or indirectly, to the manufacture and supply of Product to Company. Supplier represents that it has a formal program to train and document training of its employees. Supplier represents that all employees are fully trained and qualified to perform their duties. As of the date of the execution

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of this Quality Agreement, Supplier is an EMA / FDA approved manufacturer of pharmaceuticals and is, as such, under the inspection of the U.S. Food and Drug Administration and other regulatory agencies.

6. Good Manufacturing Practices. Products will be manufactured and packaged by Supplier in accordance with current Good Manufacturing Practices (**"cGMP"**).

7. Chemical and Packaging Component Inspection and Release. Supplier shall test, inspect and release all Active Ingredient and inspect and release all Materials and Components used in the manufacture of Product. Supplier shall inspect and release all labels, package inserts, and labeling utilized for Product for conformance with approved masters. Supplier shall inspect and release all other packaging components in compliance with Specifications. All Active Ingredients, Components and Material for Product to be sold in the EU / U.S. will be procured, by Company or Supplier, in accordance with the applicable approved U.S. ANDA/NDA and the FDA Act and European Regulatory Dossier. Supplier and Company shall mutually agree upon any proposed change to such suppliers, tests or release requirements, subject to the procedure described herein. Both Supplier and Company agree that either party may participate in quality audits of all Active Ingredient, Material and Component suppliers. Both Supplier and Company shall ensure that manufacturer of Active Ingredient complies with ICH Q7 Guideline, Good Manufacturing Practice for Active Pharmaceutical Ingredients.

8. Documentation. Supplier shall provide to Company complete specifications, written manufacturing and testing procedures and other documentation necessary for the manufacture of the Product. Supplier will update such information to reflect changes in the manufacture and/or packaging of the Product with new information prior to implementing such changes. Master batch record for Company owned products will be reviewed and approved by a Company representative prior to implementation.

9. Labeling.

(a) All labels for Products shall use the Company name. The Company NDC number shall be used for the US market. Supplier shall be permitted to use such labels only on Products delivered to Company. Company shall approve in a timely manner the artwork for labeling for the containers, package inserts and shipping containers in the form specified by Supplier. Company shall have approved all such labeling in writing in advance of initial printing. Unless otherwise agreed, labeling approved by Company shall be the only labeling used by Supplier for Company Products, provided that the labels and package inserts are consistent with EMA / FDA and Supplier's requirements with regard to physical dimensions and specifications relating to the methods of handling and affixing on the container.

(b) All code or product specific printed material or labeling, excluding promotional and advertising material, shall be [*] electronically verified or printed on line for appropriate lot and expiration date. If electronic verification or on-line printing is not available for labels, 200% manual inspection is required.

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(c) Company will monitor the Reference Listed Drug package insert text for Company owned products. Company will comply with all regulatory requirements.

10. Change Control. Company and Supplier will notify the other party in writing of any proposed change, including changes to the Active Ingredients or non-compendial materials and components, process specifications and/or controls, as well as the manufacturing and/or packaging of Product including changes to specifications, in-process specifications and process validation if the proposed change requires Regulatory Agency notification (e.g. —EMA / FDA *Guidance Documents such as Changes to an Approved NDA or ANDA, or SUPAC, etc).* Any such change must be agreed upon and approved in writing

by Company prior to implementation or submission to regulatory authorities for approval. Supplier will submit a change control notification document containing the following elements prior to implementing the change: material affected, description of change, reason/justification for change including impact assessment, signature and date of Supplier representative, anticipated date of change. If the change is agreed to, the parties will develop an agreed upon timeline for implementing the change. Supplier will provide official copies of revised documents to Company [*] after internal Supplier's approval or based on other mutually agreed upon timeframe.

11. Batch Records. Records which include the information relating to the manufacturing, packaging and quality operation for each lot of Product shall be prepared by Supplier for each lot at the time at which such operations occur. The records shall include, but are not limited to, the following documentation: manufacturing, raw materials and components charge-in-records; mixing and filling records; packaging component charge-in records; packaging records; container and component traceability records; in-process and final laboratory testing results; in-process and final product physical inspection results; yield reconciliation for bulk and finished product; label samples; deviations and/or excursions from approved procedure (as well as the Supplier investigation and corrective actions) incurred during the processing and packaging of the lot. Company may review the original documents for each lot at its request when auditing the manufacturing site of Product(s). Supplier shall keep all batch records according to this section [*] after the expiration date of each Product lot.

12. Batch Documents to be provided to Company for Each Lot. The following outlines the minimum batch documentation required to be provided to Company's QA organization for release review of each lot of Product shipped to Company:

- Packaging Bill of Materials.
- Copies of all deviations/ exception reports for each lot (including OOS investigations)
- Copies of Certificate of Analysis for each lot.
- Full Batch Records for initial Lots as agreed between Company and the Supplier.

The certificate of analysis, signed by the responsible quality official, must include the numerical results for each test (chemical, microbiological and bacteriological) as applicable performed to assure results are in compliance with Product Specifications, the date of manufacture and expiration date of the Product, as well as a statement that the subject lot was produced in accordance to the applicable Regulatory Filing and in compliance with all applicable cGMP

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requirements. At Company's request copies of full batch record documentation are to be sent to Company's QA organization.

13. Shipping. Supplier shall assure that Product is handled and shipped until the port at Mumbai under approved storage conditions without damage to Product, until risk of loss has passed to Company Notwithstanding the above, on delivery of the Product at the Mumbai port, the risk of loss, damage passes to the Company with the Supplier having no liability whatsoever. Temperature recorders are to be included with each shipment of Product from Supplier to Company.

14. Retention Samples. Supplier is responsible for storing, annual inspection, and maintaining retention samples of Products from each lot supplied to Company to meet regulatory requirements. Commencing with the inception of manufacturing, Supplier shall keep appropriate retention samples and records [*] after the expiration date of each Product lot. All retention samples shall be made available to Company for inspection at any time during Supplier's normal business hours.

15. Adverse Event Reporting. Any Adverse Event or Serious Adverse Event, as defined in 21 CFR 314 or designated as post-authorization ICSR by Volume 9A of the "Rules Governing Medicinal Products in the European Union: Pharmacovigilance for medicinal products for human use", as appropriate, will be reported to Supplier as soon as possible after receipt of the incident by Company or its designated contract call center so that regulatory reporting requirements can be met. Supplier will report to Company or its designated contract call center any Adverse Event received directly as soon as possible. All Adverse Event investigations and reports will be shared between the parties and parties shall use commercially reasonable efforts to cooperate in investigations as needed, provided however that all Adverse Event regulatory filing as may be required by the FDA/ EMA (or any other regulatory authority shall be the sole responsibility of Eagle.

16. Product Complaint. Company or its designated contract call center shall report all Product complaints to Supplier as soon as possible. Supplier shall assist Company in investigating Product complaints by analyzing Product and Materials to determine the cause, if any, of an alleged Product manufacturing defect or failure. Supplier shall use commercially reasonable efforts to provide a written report of its determination in a timely manner after receipt of Company's written request and samples of the involved Product(s Company shall be responsible to ensure that Supplier receives samples of the Product(s) to be investigated. In the event that Supplier determines that any reasonable additional physical, chemical, biological, or other evaluation should be conducted by Supplier in relation to a product complaint, Supplier shall conduct the necessary evaluation and advise Company of the results. In the event that Company requests that any reasonable additional physical, chemical, biological, or other evaluation be conducted by Supplier in relation to a product complaint, Company shall so advise Supplier. In the event that Supplier determines after evaluation that such testing is reasonable to be done, Supplier shall conduct the necessary evaluation and advise Company of the results. Company shall correspond with complainants on all product complaints associated with Product(s).

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17. **Reprocessing**. No reprocessing is to be performed.

18. Expiration Dates. Company retains the right to approve all changes in expiration dates for the Product.

19. **Validation**. Supplier shall validate, all processes, equipment, utilities, facilities and computers utilized in the manufacture, packaging, storage, testing and release of Products for regulatory submissions and' commercial sale in conformance with all current EMA / FDA guidelines and regulations and other applicable regulatory agencies outside the U.S. as required. Company shall report to Supplier its intentions to sell outside US and assure Supplier is aware of requirements of agencies outside US prior to commencement of production for these territories. Supplier shall be responsible for and shall ensure that all validated systems are maintained according to EMA / FDA guidelines (and, other applicable regulatory agencies outside the U.S., if required) and that all required periodic revalidations are performed according to these guidelines. Company shall reserve the right to review all Master Validation Plans and the corresponding protocols (e.g. - process, equipment, computer validation) during agreed upon audits of such validation and final validation reports. Supplier agrees to allow a Company representative to be present to witness all validation activities. Supplier's method validation activities will include but not be limited to the (a) Validation of analytical methods for API release and for inactive ingredients (if required); (b) validate analytical methods for release and stability testing of the Product; (c) develop and validate equipment cleaning methods; (d) develop and validate micro methods.

20. **Regulatory Visits**. Supplier shall notify Company promptly, through its designee, the Company Vice President of Quality, of any inspections by the EMA / FDA or other regulatory authority inspection which pertain to any or Product (s) or facilities that produce Product (s). Supplier will allow the EMA / FDA to inspect, audit and review the facilities and Products are manufactured and all procedures, practices, books, records, and documents to the extent requested by the EMA / FDA. Supplier shall immediately notify Company in writing of any adverse finding or concern relating to inspections by the EMA / FDA, or other regulatory authority including but not limited to, any 483s or other deficiency report related to the Product or facilities which are used for the Product(s). Supplier shall keep Company informed of the resolution of all matters with the EMA / FDA. Supplier and Company shall consult on any corrective actions that relate to the Product. Company retains right to approve any corrective actions that directly affect Company owned Product(s).

21. **Changes to Specifications**. Specifications of the Products shall not be supplemented, modified or amended in any respect without the prior written agreement of the parties; *such* agreement shall not be unreasonably withheld. In the event that Company desires any change to the Specifications of the Product(s), Company shall deliver written notice to Supplier specifying such change desired by Company and Supplier shall respond to any such notice [*] after Supplier's receipt thereof. The Company and Supplier shall negotiate, in good faith, and amend the Specification as applicable. Supplier shall provide recommended timeline for implementation of specification revisions. Supplier will provide official copies of revised specifications to Company [*] after internal company approval or mutually agreed upon.

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22. **Commercial Stability**. Supplier shall be responsible for the generation of all data and associated reports for all stability studies in support of the approved Regulatory Filing in accordance with the ongoing marketed stability protocol for each of the Products. Supplier shall provide Company on an annual basis with copies of stability data and reports at the time Supplier performs their annual review, for applicable products. If any out of specification result is not resolved [*], Supplier will Notify Company immediately of the situation and consult with Company on any corrective actions.

Supplier shall randomly pull and ship stability samples as requested for Company owned products. Samples shall be shipped under control conditions to the Company designee site if requested.

23. **Annual Report and Annual Quality Review**. Supplier shall supply in a timely manner all process and Product (s) related information to the Company necessary for the Company to file the Annual Report for the Product (s). At the same time the Supplier will provide the Annual Quality Review report for the Product (s) to the Company's Quality representative for review. Company and Supplier will consult on any actions or improvements necessary as a result of these Product reviews and reports concerning process deviations, non-conformities, exceptions, stability and release testing or changes that may have affected the Product (s). Company shall complete and file the Annual Report with the FDA or EMA as appropriate.

24. **Quality Inspections, Monitoring and Audits**. As per the Agreement.

25. **Third-Party Manufacturers**. To the extent that Supplier uses a third-party manufacturer for any of the Products, then Supplier shall monitor and ensure that such third-party manufacturer is in compliance with the manufacturing standards set forth in this Quality Agreement. Subsequent to the execution of this Quality Agreement, Supplier shall comply with the provisions of this Quality Agreement prior to any additional use of third-party manufacturers for any of the Products. Supplier shall ensure that any third-party manufacturer complies with Company's inspection and audit rights as set forth in this Quality Agreement with respect to such third party's manufacturing facilities and records that relate to the Products.

26. **Provision of Documents to Customers**. Supplier will provide, at Company's request, specific documentation relating to the quality of manufacturing operations and regulatory history for the Products as requested by Company's customers when such document request is considered reasonable by Supplier or when such documents would be available under the Freedom of Information Act.

27. **Regulatory Approval**. Supplier represents that prior to the first commercial sale of Product to Company, and at all times thereafter during the Term of this Quality Agreement and the Agreement, it will have all necessary approvals including all permits, registrations, licenses and regulatory approvals to manufacture the Product(s).

28. **Regulatory Contacts**. Company shall be responsible for any regulatory contacts and filings related to Company owned product(s). Supplier agrees to consult with Company prior to any

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material meetings or filing with the EMA / FDA with respect to the Product(s) after the Regulatory Filing approval (e.g. - Compliance inspection related items such as Warning Letter). Supplier shall provide Company in a timely fashion with copies of all material correspondence with the EMA / FDA that relates to the Product(s).

29. **Recall Action**.

Subject to the Agreement, all coordination of any recall or field correction activities involving Company labeled Products shall be handled by Company, provided however that the Supplier shall at all times be informed of any such action involving the Company and the Products.

30. **Recall Records**. Subject to the Agreement, each of the parties shall maintain complete and accurate recall records of Products for such periods as may be required by applicable law, [*].

31. Debarment. Supplier represents that it is not debarred under the Generic Drug Enforcement Act of 1992 and that Supplier does not employ or use the services of any individual who is debarred or has engaged in activity that could lead to debarment.

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APPENDIX I
QUALITY ASSURANCE
RESPONSIBILITIES FOR PRODUCT

Responsibility for:	Cipla	Eagle
PRODUCT INFORMATION PACKAGE (batch record, labeling, etc)		
— prepared by	X	
— signed off by	X	
— approved by		X
MASTER FORMULA AND METHOD		
— prepared by	X	
— approved by	X	X
SPECIFICATIONS		
Active ingredients		
— prepared by	X	
— approved by	X	X
Excipient and Raw Materials		
— prepared by	X	
— approved by	X	X
Package components for transportation of PRODUCT (e.g. boxes)		
— prepared by	X	
— approved by	X	X
Primary packing components (e.g., vial, stopper)		
— prepared by	X	
— approved by	X	X

Responsibility for:	Cipla	Eagle
SPECIFICATIONS (Continued)		
PACKED PRODUCT		
— prepared by	X	
— approved by	X	X
— outer packing components for PACKED PRODUCT (e.g., shipper)		
— prepared by	X	
— approved by	X	X

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BATCH NUMBER		X	
RAW MATERIALS AND EXCIPIENT			
Inspection, testing and release		X	
Retention of CERTIFICATE OF ANALYSIS		X	
Retention of reference sample		X	
MANUFACTURE OF PRODUCT			
—	In-process controls	X	
—	Full analytical testing (Including OOS investigation)	X	
—	Review of testing		X
—	Checking of compliance with SPECIFICATION and Suitability of documentation	X	X
—	Retention of batch manufacturing and control records for PRODUCT	X	
—	Labeling of storage or shipping containers for PRODUCT	X	
—	Retention of record for filling PRODUCT into containers for storage or shipping	X	
—	Approval of PRODUCT for filling	X	
—	Generation of CERTIFICATE OF ANALYSIS	X	
—	Retention of reference samples of PRODUCT	X	
—	Inspection, testing and release of containers	X	
—	Secure storage and handling of PRODUCT	X	
Responsibility for:		**Cipla**	**Eagle**
FILLING, PACKING, INSPECTION AND RELEASE OF PRODUCT			
—	Filling of PRODUCT solution including in-process controls	X	
—	Approval of filled PRODUCT for packing	X	
—	Packing and labeling of PRODUCT including in-process controls	X	
—	Full analytical testing (Including OOS Investigation)	X	
—	Review of Full testing (Including OOS Investigation)	X	X
—	Checking of compliance with SPECIFICATION and suitability of documentation	X	
—	Retention of BATCH DOCUMENTATION for PACKED PRODUCT	X	
—	Generation of CERTIFICATE OF ANALYSIS	X	
—	Retention of reference sample of PACKED PRODUCT	X	
—	Approval of PACKED PRODUCT	X	X
—	Handling of PRODUCT up to delivery to Eagle	X	
—	Audit of all BATCH DOCUMENTATION as requested	X	
—	Final Release of PRODUCT from DC	X	
LABEL DESIGN AND CHANGE **CONTROL FOR CONTAINERS OF BULK PRODUCT**			
—	prepared by	X	X

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—	approved by	X	X
CORE PACKAGING TEXT			
—	prepared by	X	
—	maintained by	X	
—	approved by		X
PACKAGE COMPONENT COPY DESIGN AND CHANGE CONTROL FOR PACKED PRODUCT			
—	prepared by	X	
—	approved by	X	X
DESTRUCTION OF HANDLING OF PROCESS WASTE GENERATED AT SUPPLIER		X	
Responsibility for:		**Cipla**	**Eagle**
PROCESS & PACKING VALIDATION			
—	protocol & report prepared by	X	
—	protocol & report signed off by	X	

— protocol & report approved by	X	X
— protocol executed by	X	
COMPUTER AND OTHER VALIDATION		
— protocol &report prepared by	X	
— protocol & report signed off by	X	
— protocol & report approved by	X	
— protocol executed by	X	
POST-MARKETING STABILITY CONFORMANCE		
Stability protocol for SUPPLIER packing sites		
— prepared by	X	
— approved by	X	X
Stability testing for PACKED PRODUCT		
— performance of testing	X	
— review of stability results	X	
— communication of stability performance **to** EAGLE	X	
COMPLAINTS		
Collection of complaints	X	X
Investigation of complaints	X	
— follow-up manufacturing records	X	
— Testing	X	
— report to EAGLE	X	
— action and documentation	X	X

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— Response to Customer		X
ADVERSE EVENT REPORTING		
— Collection of Adverse Drug Event (ADE) Information	X	X
— Investigation of manufacturing records	X	
— Reporting of Event to Regulatory Authorities		X
— Action, documentation and filing	X	
Responsibility for:	**Cipla**	**Eagle**
ANNUAL PRODUCT REVIEW		
Provision of information on manufacture of PRODUCT (includes rejections, deviations, and process changes)		
— BULK PRODUCT	X	
— PACKED PRODUCT	X	
— Generate report for Eagle	X	
— Approved by	X	X
— filed by		X
Annual Quality Review of PRODUCT		
— prepared by	X	
— approved by	X	X
— action and documentation	X	X
REGULATORY AUTHORITY INSPECTION RECORDS FOR PRODUCT MADE AVAILABLE TO THE PARTIES	X	X
AUDITS		
— supplier of primary packaging components	X	
— API Supplier		X
— Manufacturing facilities		X
— audit reports made available to each party	X	X
HEALTH AND SAFETY AND PROTECTION OF ENVIRONMENT		
— active ingredient	X	
— BULK PRODUCT manufacture	X	

—	packing at SUPPLIER	X	
—	PRODUCT storage and handling up to delivery to EAGLE	X	
—	storage, handling and distribution of PRODUCT after receipt		X
EUROPEAN UNION PRODUCT TESTING AND RELEASE			
—	Establish Methods in EU Lab	X	
—	Assist, as appropriate, in transferring Methods to EU Lab	X	
—	Testing of Finished Product in EU		X
—	QP Release in EU		X

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[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

Amendment No.1

This Amendment No. 1 (**"Amendment"**) is executed as of August 30, 2013 (**"Amendment Effective Date"**) by and between: Cipla Limited, a company registered under the Companies Act, 1913, having registered office at Mumbai Central, Mumbai 400008, Maharashtra, India (**"Cipla"**) and Eagle Pharmaceuticals, Inc., a Delaware corporation with principal place of business at 50 Tice Boulevard, Woodcliff Lake, NJ 07030, USA (**"Eagle"**).

Cipla and Eagle may be referred to, in the singular, as a **"Party"** and jointly as **"Parties"**.

Recitals:

(A) Cipla and Eagle entered into an Agreement dated 14 December 2012 for the supply of Argatroban Product and Topotecan Product (**"Agreement"**) for the territory of USA.

(B) The Parties have now had discussions and wish to amend the Agreement as follows, subject to the terms of this Amendment.

Agreed Terms:

In consideration of the mutual covenants and conditions set forth in this Amendment, the Parties hereby agree as follows:

1. Effective as of the Amendment Effective Date and solely with respect to Argatroban Product, the Parties agree to amend sub-clauses (i) and (ii) of clause 1.2(i) of the Agreement and replace them as follows:

"1.2(i) Payment.

(i) Eagle shall make payment of each shipment of Argatroban Product and Topotecan Product manufactured in terms with this Agreement within [*] of the invoice raised by Cipla ("Payment Due Date")., which shall be raised on the date of the applicable shipment. Such payment shall be made by the Payment Due Date in full by wire transfer to an account as designated by Cipla.

(ii) In the event, at any time during the subsistence of this Agreement, if payment in cleared funds have not been received in full by the Payment Due Date by Cipla of [*] previous batches of Argatroban Product and/or Topotecan Product manufactured by Cipla, Cipla shall have no obligation to commence manufacturing or to supply any Argatroban Product and/or Topotecan Product ordered by Eagle pursuant to a purchase order accepted by Cipla. Additionally, and without prejudice to any other rights of Cipla, for any delay in the payment of the Argatroban Product and/or Topotecan Product, Cipla shall be entitled to [*] on the value of the invoice." Cipla will duly inform Eagle that it is not commencing manufacturing or supply any Argatroban Product and/or Topotecan Product ordered by Eagle

due to non-payment.

2. Solely with respect to the Argatroban Product, the Parties add a new clause 1.2(p) as follows:

"1.2(o) [*]. Cipla shall be responsible to (a) obtain the [*] licenses for the import of [*] the Argatroban Product [*], and (b) make any payments required to obtain and maintain such [*], provided that, (i) at the request of Cipla, Eagle shall provide reasonable assistance to Cipla in [*]; (ii) Eagle shall, promptly upon receipt of invoice, reimburse Cipla for all expenses in obtaining [*]; and (iii) Cipla shall not be responsible for a delay in [*] manufacturing the Argatroban Product for reasons beyond Cipla's control.

Upon Cipla obtaining [*], Cipla shall [*] for the Argatroban Product [*]."

3. Solely with respect to the Argatroban Product, the Parties agree to amend clause 7.1 and replace it as follows:

"7.1 Eagle shall use its commercially reasonable efforts to affect a transfer of manufacture of Argatroban Product to an alternate manufacturer as soon as possible, but [*]. Eagle shall notify Cipla [*] of receiving regulatory approvals to manufacture Argatroban Product at an alternate third party manufacturing site."

4. Solely with respect to the Argatroban Product, the Parties agree to amend clause 8.1 and replace it as follows:

"8.1 Solely with respect of Argatroban Product, and notwithstanding anything to the contrary, this Agreement will come into effect on the execution of the Agreement and shall stand terminated upon the later of (a) receipt by Eagle of approval from the US FDA for manufacture of Argatroban Product for sale in the Territory at a third party manufacturing site; or (b) 31 December 2014."

Unless otherwise defined or provided for herein, all capitalized terms shall have the meaning as set forth in the Agreement.

Except as provided herein, the terms and conditions of the Agreement remain unchanged and continue to remain in full force and effect during the term of its validity. In the event there is any conflict between the terms of each of the Agreement and this Amendment, the terms of this Amendment shall prevail. This Amendment shall constitute the entire agreement between the Parties on the subject matter hereof and shall supersede all other written or oral communication, proposals, drafts, amendments, agreements and representations between the Parties hereto with respect to the subject matter hereof.

Signature Page Follows.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

IN WITNESS HEREOF, the Parties hereto have duly executed this Amendment through their authorised representative to be effective as of the Amendment Effective Date.

CIPLA LIMITED	EAGLE PHARMACEUTICALS, INC.
By: [*]	By: /s/ Scott Tarriff
Name: [*]	Name: Scott Tarriff
Title: [*]	Title: President and CEO

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

Exhibit 10.16

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

SUPPLY AND DISTRIBUTION AGREEMENT

This **SUPPLY AND DISTRIBUTION AGREEMENT** ("Agreement"), dated as of January 28, 2013, is made by and between **Eagle Pharmaceuticals, Inc.**, a Delaware corporation with its principal offices located at 470 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677 ("Eagle"), and **Sandoz AG**, a Swiss corporation with a corporate address at Lichtstraße 35, CH 4056 Basel, Switzerland ("Sandoz").

WHEREAS, Eagle and an Affiliate (as defined below) of Sandoz are currently in a dispute with respect to the manufacture, distribution or sale of the Sandoz ANDA Product (as defined below) and, as of the date hereof, have entered into a mutually agreeable settlement agreement to settle such dispute (the "Settlement Agreement");

WHEREAS, Eagle, pursuant to the terms of this Agreement and the Settlement Agreement, desires to contract manufacture the AG Product (as defined below) at its Contract Manufacturer (as defined below), and supply the AG Product to an Affiliate of Sandoz; and

WHEREAS, Sandoz (or an Affiliate of Sandoz), pursuant to the terms of this Agreement and the Settlement Agreement, would like to (i) purchase AG Product from Eagle and then distribute the AG Product in the Territory, and (ii) distribute the Sandoz Product.

NOW, THEREFORE, in consideration of the mutual promises, covenants and agreements hereinafter set forth, the parties hereto agree as follows:

ARTICLE 1
DEFINITIONS

As used throughout this Agreement and any exhibits, schedules or attachments hereto, each of the following terms will have the respective meaning set forth below:

1.1 **"Act"** means the United States Federal Food, Drug, and Cosmetic Act as amended from time to time.

1.2 **"AG Product"** means an unbranded (generic) form of the Eagle Branded Product as described on Schedule A distributed exclusively by Sandoz under a label not referencing the Eagle Trademark.

1.3 **"Additional Marketing Costs"** means any [*] directly resulting from the [*] the AG Product.

1.4 **"Affiliate"** means, with respect to a party, any other business entity that directly or indirectly controls, is controlled by, or is under common control with, such party. A business entity or party will be regarded as in control of another business entity if it owns directly or indirectly (i) in the case of corporate entities, more than fifty percent (50%) of the equity

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securities in the subject entity entitled to vote in the election of directors, and (ii) in the case of an entity that is not a corporation, more than fifty percent (50%) of the equity securities or other ownership interests in the subject entity with the power to direct the management and policies of such entity by any means whatsoever or entitled to elect the corresponding management authority. Notwithstanding anything to the contrary contained herein, for any and all purposes relating to this Agreement, Sandoz's Affiliates shall be limited solely to [*].

1.5 **"ANDA"** means an abbreviated new drug application pursuant to 21 U.S.C. § 355(j) et seq., and the regulations promulgated thereunder, as such application may be amended or supplemented from time to time.

1.6 **"Applicable Law"** means all applicable provisions of constitutions, statutes, laws, rules, treaties, regulations, guidelines and orders of all governmental authorities and all applicable orders, rules and decrees of courts in the Territory.

1.7 **"Argatroban Patents"** means the United States Patent Nos. 7,589,106 and 7,687,516, and any United States patents resulting from any continuation, continuation-in-part, divisional, reissue or reexamination thereof, and [*] by Eagle or its subsidiaries [*], [*], including but not limited to [*]. For the avoidance of doubt, [*] as provided for in the America Invents Act.

1.8 **"Business Day"** means any day other than a Saturday, Sunday or legal holiday on which banks in New York, New York are closed.

1.9 **"cGMP"** means current Good Manufacturing Practices, as set forth in the United States Code of Federal Regulations (21 CFR part 210 & Part 211), and any other applicable laws, guidelines and regulations.

1.10 **"Commercially Reasonable"** means, with respect to the efforts to be expended or considerations to be undertaken by a party related to any objective, activity or decision to be undertaken hereunder, reasonable, good faith efforts to accomplish a similar objective, activity or decision under similar circumstances. Such efforts will be similar to those efforts, considerations and resources commonly used by a party for a similar product owned by it or to which it has rights, which product is at a similar stage in its product life and is of similar market potential taking into account the competitiveness of alternative products sold by third parties in the marketplace, the regulatory status, market conditions and the profitability of the product.

1.11 **"Contract Manufacturer"** means the current and any future contract manufacturer of the AG Product and Eagle Branded Product.

1.12 **"Convicted Entity"** means a corporation, partnership or association that has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §1320a — 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

1.13 **"Convicted Individual"** means an individual who has been convicted of a

criminal offense that falls within the ambit of 21 U.S.C. §1320a — 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

1.14 **"Damages"** has the meaning given in Section 15.1.

1.15 **"Debarred Entity"** means a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or Affiliate of a Debarred Entity.

1.16 **"Debarred Individual"** means an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335 (a) or (b) from providing services in any capacity to a person that has an approved or pending drug product application.

1.17 **"Eagle Branded Product"** means the drug product Argatroban® 50mg/50m1 that is subject to the Eagle NDA distributed under a label referencing Eagle Trademarks.

1.18 **"Eagle Branded Product Distributor"** means the distributor of the Eagle Branded Product in the Territory.

1.19 **"Eagle Indemnified Parties"** has the meaning given in Section 15.2.

1.20 **"Eagle NDA"** means a new drug application No. 22434 filed with the FDA and all supplements and amendments thereto.

1.21 **"Eagle Trademarks"** means all trade names, trade dress, logos and graphics used by Eagle and/or the Eagle Branded Product Distributor in connection with its branded products or its corporate identity.

1.22 **"Effective Date"** means the date first set forth above.

1.23 **"Excluded Entity"** means an entity (i) that has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General ("OIG/HHS") of the Department of Health and Human Services, or (ii) that has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the United States General Services Administration ("GSA").

1.24 **"Excluded Individual"** means an individual who has been excluded, debarred, suspended or is otherwise ineligible to participate in (i) federal health care programs such as Medicare or Medicaid by the OIG/HHS, or (ii) federal procurement and non-procurement programs, including those produced by the GSA.

1.25 **"FDA"** means the U.S. Food and Drug Administration, and any successor or replacement agency.

1.26 **"Force Majeure Event"** has the meaning given in Article 10.

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1.27 **"Generic Equivalent"** has the meaning given in Section 7.6(i).

1.28 **"Initial Forecast"** has the meaning given in Section 4.3.

1.29 **"Latent Defect"** means any instance where the AG Product fails to conform to the Specifications for such AG Product and such failure would not be discoverable upon reasonable physical inspection of such AG Product or other testing customarily conducted by Sandoz upon receipt by Sandoz in accordance with its standard operating procedures.

1.30 **"Launch at Risk"** has the meaning given in Section 7.6(iv)(B).

1.31 **"Launch Quantities"** means Sandoz's initial purchase order for the quantity of AG Product needed to begin commercial sales of such AG Product by quantity pursuant to Section 4.3.

1.32 **"Licensed Generic Entry Date"** has the meaning given in Section 7.6(i).

1.33 **"Net Profit"** means Net Sales less the sum of (i) Product Cost, (ii) SG&A Costs, and (iii) Additional Marketing Costs.

1.34 **"Net Sales"** means, for any period, the gross sales of the AG Product less the following, as accrued and adjusted: (i) cash discounts [*]; (ii) returns [*] and other similar charges; chargebacks, allowances, discounts, [*], and rebates; (iii) other payments required by law or agreed to be made under [*] (including, but not limited to, payments made under the [*]; (iv) any [*] (as evidenced by written records); and, (v) sales, excise or other similar taxes (excluding income taxes). [*] not covered by this Agreement; provided, however, [*] not covered by this Agreement [*] with respect to such sale. Net Sales shall be determined in accordance with generally accepted accounting principles, consistent with Sandoz's books and records applicable in the Territory.

1.35 **"Notice Letter"** means the notice provided pursuant to 21 U.S.C. § 355(j)(2)(B) that a patent listed in the Orange Book is invalid or will not be infringed by the holder of an ANDA containing a Paragraph IV Certification.

1.36 **"Orange Book"** means the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations, as may be amended from time to time.

1.37 **"Overdue Interest Amount"** means [*] percent per month from the date any unpaid payments are due until paid in full.

1.38 **"Paragraph IV Certification"** means a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(VI).

1.39 **"Pre-Commercial Launch Activities"** means reasonable pre-marketing activities, including [*] under Section 7.5 or Section 7.6, and [*] to such launch date.

1.40 **"Product Cost"** means the "AG Product Cost by Unit Type" as set forth on Schedule A multiplied by the sales volume for the applicable unit type for the applicable Net Sales reporting period, subject to Sections 4.12 and 4.13.

1.41 **"Promotional Materials"** has the meaning set forth in Section 3.5.

1.42 **"Refundable"** means in the event the Triggering Event does not occur within [*] of the Effective Date (other than as a result of a material breach of this Agreement by Sandoz), Eagle shall promptly [*].

1.43 **"Revised Profit Split"** has the meaning given in Section 7.6(iv)(B).

1.44 **"Sandoz ANDA Product"** means the Argatroban 50mg/50m1 product that is the subject of ANDA (as defined in 21 U.S.C. 355(j) *et seq*., and the regulations promulgated thereunder) No. 203743, and any amendments or supplements thereto.

1.45 **"Sandoz Indemnified Parties"** has the meaning given in Section 15.1.

1.46 **"Sandoz Product"** means Argatroban® 125mg/125m1 as described on Schedule A.

1.47 **"Sandoz Trademarks"** has the meaning given in Section 3.6.

1.48 **"Schedule(s)"** means Schedule A attached hereto and any subsequent schedules that the parties may add to this Agreement from time to time.

1.49 **"SG&A Costs"** means Sandoz's total costs for customary sales and distribution expenses (e.g., insurance, transportation and freight outbound charges, VAT tax and duties), which shall be deemed to [*].

1.50 **"Specifications"** means the specifications for the design, composition, manufacture, packaging, and/or quality control of the AG Product as set forth in the NDA.

1.51 **"Supply Failure"** means Eagle's failure to supply AG Product, which has been ordered pursuant to a purchase order submitted by Sandoz in accordance with Sections 4.2, 4.3, 4.4 and 4.5, within [*] after the end of the time period set forth in Section 4.4(iv).

1.52 **"Supply Term"** means the time set forth on Schedule A attached hereto.

1.53 **"Term"** has the meaning given in Section 7.1.

1.54 **"Territory"** means the United States of America, its commonwealths, territories, possessions and U.S. military bases.

1.55 **"Triggering Event"** means the date set forth on Schedule A on which Sandoz will make the first sale of the AG Product to an unaffiliated third party in an arms-length

transaction.

1.56 **"Unlicensed Generic Entry Date"** has the meaning given in Section 7.6(iii).

ARTICLE 2
RIGHT TO USE

2.1 **Rights under Eagle NDA**. Subject to Section 17.8 and the terms of the Settlement Agreement, during the Supply Term, Eagle hereby appoints Sandoz as the exclusive distributor of the AG Product, with the right to market, promote, distribute, offer to sell and sell the AG Product, in the

Territory under the Eagle NDA commencing on the Triggering Event. This [*]. Nothing in this Agreement shall preclude or prevent Eagle or the Eagle Branded Product Distributor from marketing, distributing, offering to sell or selling the Eagle Branded Product through the Eagle Branded Product Distributor. Moreover, nothing in this Agreement shall preclude or prevent Sandoz from marketing, distributing, offering to sell or selling the Sandoz Product.

2.2 **No Rights to Eagle Trademarks and IP**. Eagle grants Sandoz no right to use any Eagle Trademarks or other Eagle intellectual property, except as provided herein or as otherwise required by law or regulation.

2.3 **Sale of AG Product**. During the Supply Term, Sandoz shall not, and shall not permit its Affiliates to, market or sell the AG Product, except as provided herein.

2.4 **Performance through Affiliates**. Notwithstanding anything to the contrary contained herein, each party may discharge any obligations and exercise any right hereunder, or performance hereunder, through any of its Affiliates. Each party hereby guarantees the performance by its Affiliates of such party's obligations under this Agreement, and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance.

ARTICLE 3
SALES AND MARKETING ACTIVITIES

3.1 **Commercial Efforts**. Sandoz will use Commercially Reasonable efforts to (i) market, distribute and sell both the Sandoz Product and the AG Product in the Territory during the Supply Term, and (ii) [*] Net Sales of both the Sandoz Product and the AG Product in the Territory during the Supply Term. Such Commercially Reasonable efforts will include pre-commercial AG Product launch activities to support the AG Product launch and beginning sales on the Triggering Event. Sandoz will provide Eagle an initial sales forecast from such Triggering Event through the end of the following calendar year thirty (30) days prior to the Triggering Event. Thereafter, Sandoz will provide Eagle with a fifteen (15) month sales forecast beginning with January 1 of the following year and a monthly sales forecast for the remaining months of the Supply Term for the AG Product sixty (60) days before the end of each calendar year.

3.2 **Pre-Commercial Launch Activities**. Sandoz will provide Eagle a plan for pre commercial AG Product launch activities no later than five (5) days after the Effective Date.

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Sandoz will take into consideration any reasonable request from Eagle regarding such activities.

3.3 **Pricing**. Sandoz will have independent, sole discretion to determine the pricing, terms of sale, marketing, and selling decisions for the Sandoz Product and AG Product without any consultation with, input from, or prior notice to Eagle. Sandoz [*] the Sandoz Product or the AG Product [*], then [*], the [*] shall [*]. For the avoidance of doubt, Eagle will have independent, sole discretion to determine the pricing, terms of sale, marketing, and selling decisions for the Eagle Branded Product sold through the Eagle Branded Product Distributor without any consultation with, input from, or prior notice to Sandoz.

3.4 **Rebate Processing**.

(i) Sandoz will be solely responsible for all federal, state and local government and private purchasing, pricing or reimbursement programs with respect to the AG Product, including taking all necessary and proper steps to execute agreements and file other appropriate reports and other documents with governmental and private entities and Eagle shall provide reasonable assistance to Sandoz to effectuate same. Sandoz will be solely responsible for payment and processing of all rebates, whether required by contract or local, state or federal law, for the AG Product.

(ii) Eagle is required to refer to AG Product sales made by Sandoz in Eagle's government price reports. As such, Sandoz will provide Eagle with aggregate sales figures for the AG Product sales made by Sandoz and the related Net Profit split by product NDC number. This information will be contained in the NPS Report as set forth in Section 5.2. Eagle shall use any data or information relating to pricing that Sandoz provides under this Section 3.4 or otherwise for the limited purpose of complying with legal price reporting requirements and for no other purpose. Eagle shall not use any such data or information in connection with its sales, marketing or contract operations and will represent and warrant to Sandoz that such data and information is not disclosed among Eagle personnel for any purpose other than for government price reporting.

3.5 **Promotional Materials**. Sandoz will not use any Promotional Materials in connection with the marketing, sale or distribution of the AG Product without Eagle's prior written approval, except that Sandoz may include such AG Product's generic name, launch date, available packaging configurations, and the pricing and delivery terms in its introduction announcements to the trade, bill sheets and product catalog without obtaining Eagle's prior written approval. For purposes of this Agreement, "Promotional Materials" means all labeling and advertising materials as defined in the Act and the regulations of the FDA thereunder. For the avoidance of doubt, Eagle will retain exclusive authority and responsibility for the filing of Promotional Materials with the FDA on Form 2253 (or such other form as required by FDA) or as otherwise required by Applicable Law.

3.6 **Sandoz Trademarks**. All trademarks, trade names and packaging graphics owned or licensed by Sandoz and intended to be used in connection with the AG Product (collectively, the "Sandoz Trademarks") will be chosen by Sandoz in its sole discretion;

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

provided, however, that Sandoz will not be permitted to use any such Sandoz Trademarks to the extent Eagle, in its reasonable judgment, determines that such Sandoz Trademarks will be confusingly similar to those which Eagle uses in connection with any of its own products. Sandoz will provide reasonable

advance written notice to Eagle of any Sandoz Trademarks to permit Eagle to identify any Sandoz Trademark that Eagle reasonably believes is confusingly similar. Eagle will notify Sandoz in writing within fifteen (15) days of receipt of the Sandoz Trademarks if Eagle, in its reasonable judgment, objects to the Sandoz Trademarks. Absent receipt of such notice from Eagle, Sandoz will be free to use the Sandoz Trademarks.

ARTICLE 4
SUPPLY

4.1 **Eagle Supply Obligations**. Subject to the provisions of this Article 4, Eagle will exclusively supply Sandoz's requirements for the AG Product in accordance with Sandoz's forecasts. Eagle's supply of AG Product may not be used for any purpose other than the distribution and sale of AG Product under this Agreement. Eagle will supply the AG Product in the dosage forms and unit types set forth on Schedule A. Sandoz acknowledges that Eagle will, during the Supply Term, have on-going obligations to supply the Eagle Branded Product to the Eagle Branded Product Distributor.

4.2 **Sandoz Purchase Obligations**. Subject to the provisions of this Article 4, Sandoz will exclusively purchase from Eagle Sandoz's requirements for the AG Product for the Supply Term.

4.3 **Sandoz Initial Forecast**.

(i) Within five (5) days after the Effective Date, Sandoz will deliver to Eagle a forecast for the Launch Quantities and all AG Product required for the first twelve (12) months after the Triggering Event (the "Initial Forecast").

(ii) Eagle will accept the forecast or provide an alternative proposal to Sandoz within ten (10) business days after receipt.

(iii) The Initial Forecast will be broken down by unit type and delivery date.

(iv) The first six (6) months of the Initial Forecast (which will include the Launch Quantities) will constitute a binding order and Sandoz will deliver a binding written or electronic purchase order for the first six (6) months of the forecast with the Initial Forecast.

(v) Purchase orders placed shall be based on full batch sizes.

(vi) The balance of the Initial Forecast will be non-binding with respect to the total volume. Sandoz may vary the volume among the remaining delivery dates in the Initial Forecast for each delivery date by up to [*] so long as at the end of the Initial Forecast, Sandoz has purchased all of the AG Product set forth in the Initial Forecast.

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4.4 **On-Going Sandoz Purchase Orders**.

(i) No later than the tenth (10^{th}) Business Day of each month beginning with the first month after the Triggering Event, Sandoz will provide Eagle an updated rolling twelve (12) month forecast for AG Product.

(ii) The first four (4) months of each forecast will be binding upon the parties. With each such rolling forecast, Sandoz will deliver a binding written or electronic purchase order for the fourth (4^{th}) month of each new rolling forecast.

(iii) Without the parties' prior written agreement, no forecast for the rolling twelve (12) month period will vary the amounts set forth in the previous forecast for the same month by more than [*].

(iv) Purchase orders placed shall be based on full batch sizes. The parties acknowledge and agree that except for the Launch Quantities, Eagle will be entitled to [*] lead time to fill AG Product orders placed pursuant to any binding purchase order. Additionally, the parties will work in good faith to fill AG Product orders placed for the Launch Quantities as soon as reasonably practicable.

4.5 **Supplemental Sandoz Purchase Orders**. Sandoz may submit supplemental purchase orders to Eagle for additional quantities of AG Product at any time during the Supply Term set forth on Schedule A attached hereto. Eagle will use Commercially Reasonable efforts to fulfill supplemental purchase orders for up to [*] of the relevant forecast. Sandoz may not submit supplemental purchase orders to Eagle for quantities in excess of [*] without the prior written consent of Eagle. No supplemental purchase orders will be binding upon Eagle unless and until Eagle accepts the quantities and delivery dates in writing after receipt of the supplemental purchase order. Eagle will confirm or reject supplemental purchase orders within ten (10) Business Days after receipt.

4.6 **Conflicts**. To the extent of any conflict or inconsistency between this Agreement and any purchase order, purchase order release, confirmation, acceptance or any similar document, the terms of this Agreement will govern.

4.7 **Shipping Terms**. Eagle shall, or shall cause the Contract Manufacturer to, deliver the AG Product to Sandoz [*] (INCOTERMS 2010) [*]. Title and risk of loss to the Launch Quantity will only pass to Sandoz upon the Triggering Event regardless if such Launch Quantity is in Sandoz's facility (or the facility of its designee). It is agreed and understood that Sandoz shall be responsible for all expenses in connection with carriage of the AG Product from the Contract Manufacturer's facility to Sandoz's facility or the facility of Sandoz's designee (including insurance, freight, VAT tax and duties, if applicable).

4.8 **Delivery**. Delivery by Eagle of at least [*] but no more than [*] of the quantity ordered will be accepted by Sandoz in full satisfaction of Eagle's obligation to supply such firm order. Sandoz will be invoiced for the actual quantities shipped. All charges for packaging are included in the Product Cost unless otherwise agreed to by the parties. Eagle will not be responsible for warehousing finished goods for Sandoz. Eagle will ship all finished goods to

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Sandoz (or its designee) upon completion. All shipments must be accompanied by a packing slip that describes the articles, states the purchase order number and shows the shipment's destination. Deliveries of AG Product will be made in accordance with the delivery schedule set forth in the purchase orders provided, subject to Sections 4.3, 4.4 and 4.5.

4.9 **Meetings**. Eagle and Sandoz shall participate in a supply meeting on a regular but not less frequent than a monthly basis. At each such supply meeting, the parties shall agree on the specific delivery dates during an applicable month for AG Product ordered in the binding purchase order, if any, submitted at such meeting. Participation in any supply meeting may be conducted via teleconference. Within five (5) days after the Effective Date, each of Sandoz and Eagle shall identify an individual whose role will be to manage the relationship between the parties (the "Team Coordinator"). The Team Coordinator for each party shall provide points of contact for such party that will be responsible for functional tasks to include, but not be limited to, supply, ordering and quality obligations.

4.10 **Certificate of Compliance**. Each shipment of AG Product to Sandoz will be accompanied by a certificate of compliance prepared by the Contract Manufacturer confirming that the AG Product has been manufactured in accordance with this Agreement and the Eagle NDA for the AG Product. Any deviations and investigations related to the AG Product will be documented by Eagle in accordance with the Eagle NDA and the Quality Agreement referred to in Section 6.1.

4.11 **Territory**. Sandoz shall only market, distribute, offer to sell and sell the AG Product in the Territory and shall not knowingly distribute the AG Product outside the Territory.

4.12 **Changes**. In the event that either party is required to change the Specifications for the AG Product pursuant to Applicable Law, or in response to a regulatory request, the parties will agree to reasonable and equitable modifications in the Product Cost for the AG Product to reflect any increase in the manufacturing cost caused by this change. To the extent there is an increase in Eagle's cost to acquire the AG Product as a result of an increase in API costs and filling costs at the Contract Manufacturer's facility (as evidenced by written records reasonably acceptable to Sandoz), in any case outside of the control of Eagle, the parties will agree to reasonable and equitable modifications in the Product Cost for the AG Product to reflect any increase in the manufacturing cost caused by such change. If a change is made by either party for any other reason, the party making the change will bear the costs for the change, unless otherwise agreed to by the parties.

4.13 **Technical Transfer to Alternate Manufacturing Facility**. It is understood that Eagle has begun the process of identifying an alternative site for the commercial supply of the AG Product. [*] agrees that after the Triggering Event has occurred, the out-of-pocket costs and expenses (as evidenced by written records reasonably acceptable to [*]) for the technical transfer of the AG Product (the "Tech Transfer Costs") shall initially be borne by [*]; provided, however, that, subject to Section 5.2(ii), beginning [*] after the Triggering Event, [*] may include the [*]. To the extent there is a reduction in [*] to acquire the AG Product as a result of such tech transfer to the alternative site of commercial supply, the parties will agree to reasonable and equitable

modifications in the Product Cost for the AG Product to reflect any decrease in the manufacturing cost caused by such transfer.

ARTICLE 5
CONSIDERATION

5.1 **Product Cost**.

(i) Eagle will send an invoice for the Product Cost by unit type for the AG Product on the date such AG Product is shipped to Sandoz or its designee. Payment will be due from Sandoz within [*] of the end of each calendar month in accordance with Section 5.2. Solely for the Launch Quantity, Sandoz shall pay Eagle, (A) upon the Effective Date, a Refundable milestone payment in an amount equal to [*] of the Launch Quantity purchase order, and (B) the remaining [*] of the Launch Quantity purchase order shall be paid to Eagle by Sandoz within [*] days of Sandoz's receipt of the corresponding invoice.

(ii) In the event Net Sales, on a per-unit basis with respect to each unit of AG Product or Sandoz Product sold by Sandoz, falls below [*] of the Product Cost (for each unit type separately) per customer for any period, as evidenced by written records, Sandoz will promptly inform Eagle of such event.

5.2 **Payment of the Net Profit split**.

(i) Solely for the [*] following the Triggering Event, Sandoz shall, within [*] after the end of each calendar month, provide to Eagle a Net Profit split report for such month ("NPS Report"), a form of which is attached hereto as Exhibit A. This form may be amended from time to time by mutual agreement of the parties. Within [*] of delivery of such NPS Report, Sandoz shall pay Eagle its share of the Net Profit split due. Any payment disputes between the parties shall be resolved within [*] of Eagle's receipt of the NPS Report, or in accordance with Section 16.1 hereof.

(ii) Beginning on the [*] following the Triggering Event and thereafter, Sandoz shall, within [*] after the end of each calendar quarter, provide to Eagle a Net Profit split report for such quarter ("NPS Report"), a form of which is attached hereto as Exhibit A. This form may be amended from time to time by mutual agreement of the parties. Within [*] of delivery of such NPS Report, Sandoz shall pay Eagle its share of the Net Profit split due. Any payment disputes between the parties shall be resolved within [*] of Eagle's receipt of the NPS Report, or in accordance with Section 16.1 hereof. Notwithstanding anything to the contrary contained herein, [*]; thereafter, [*] as set forth on Schedule A.

5.3 **Samples, Coupons and Vouchers**. Sandoz shall not distribute any drug samples of an AG Product or coupons or vouchers for an AG Product to any third party.

5.4 **Late Payment Penalty**. Any payments not made within the specified period of time for payment will incur an interest charge at the rate of the Overdue Interest Amount on such overdue amounts. Any amounts that are not paid because of a bona fide dispute between the

parties that are ultimately paid later will include interest at the time of payment.

5.5 [*]. In the event [*], as evidenced by written records, in any month in which Eagle is supplying AG Product to Sandoz, [*]. This calculation will continue [*] until [*]; provided, however, that if in any such following month [*] as set forth on Schedule A starting with that month [*]. For the avoidance of doubt, any [*].

5.6 **Audit Rights**. Sandoz will keep accurate books and records for purposes of documenting the amount of the Net Sales and product returns for AG Product. Said books and records will be made available at Sandoz's principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey. Upon at least fifteen (15) Business Days notice, Eagle will have the right to have Eagle's independent public accountants obtain access to such books and records during reasonable business hours for the purpose of verifying, at Eagle's expense, the amount of the Net Sales, the calculation of the Net Profit split, and any other information reasonably necessary to verify the above calculations and information; provided, however, that this right may not be exercised more than once in any calendar year. Eagle will solicit or receive from its accountants only information relating to the accuracy of such calculations, and will only have access to information for the most recent [*]. However, if in subsequent audits it is discovered that an error occurred that may have carried back to previous years, Sandoz will provide the information for all previous contract years for purposes of identifying if the error carried back and correcting such error if necessary. Sandoz will be entitled to require such accountants to sign a confidentiality agreement in form and substance reasonably satisfactory to Sandoz, Eagle and such accountant. Eagle and Sandoz will each receive the same report of the audit from the independent accountants which will contain their opinion of whether Sandoz's reports, calculations and payments have been accurate or not and, if not, by how much and for how long and how they arrived at their conclusions. The parties may make inquiries of the independent accountants to clarify the contents of the report and the accountant's response will be provided to both parties. If there is an underpayment of the Net Profit split to Eagle, Eagle will send an invoice to Sandoz for the amount of the underpayment and the Overdue Interest Amount from the original due date. Such invoice will be paid by Sandoz within [*] after its receipt. In the event any such audit reveals a shortfall in amounts paid to Eagle of [*] or more for any calendar year, then the reasonable costs and expenses of the audit including the fees and expenses of the accountant will be reimbursed to Eagle by Sandoz. In the event any such audit report reveals an overpayment of the Net Profit split to Eagle, Sandoz will send an invoice to Eagle for the amount of the overpayment. Eagle will pay such invoice within [*] after its receipt.

ARTICLE 6
QUALITY

6.1 **Quality Agreement**. The parties will enter into a Quality Agreement prior to the Triggering Event. The Quality Agreement will address supply of the AG Product. The Quality Agreement may be amended as necessary to provide for additional products that may be added to this Agreement from time to time. To the extent that any inconsistencies exist between the Quality Agreement and this Agreement, the stipulations and provisions of this Agreement will prevail.

6.2 **Expiration Dating**. All AG Product shipped to Sandoz will have expiration dating as set forth on Schedule A.

6.3 **Stability Testing**. Eagle will maintain a stability testing program for the AG Product. In the event that any results from such program indicate that the AG Product would not meet its expiration date, Eagle will promptly notify Sandoz. Replacement AG Product will be provided to Sandoz at Eagle's expense in the event such AG Product is unsaleable by Sandoz.

ARTICLE 7
TERM & TERMINATION

7.1 **Term**. The term of this Agreement will commence on the Effective Date, and subject to the terms of this Article 7, will continue until the expiration of the Supply Term (the "Term"). The Term may be extended by written agreement of the parties.

7.2 **Termination by Eagle**. This Agreement may be terminated by Eagle:

(i) If Sandoz shall fail to pay any amount due under the Agreement within [*] after such amount becomes due and payable, and Sandoz has not cured such breach within [*] after receipt of such written notice from Eagle to cure such breach, in which event termination shall be effective after such [*]; or

(ii) If Sandoz shall be in breach of any material obligation hereunder (other than a payment obligation), and has not cured such breach within [*] after receipt of a notice from Eagle requesting the correction of such breach (unless such breach is by its nature not susceptible of being cured or the giving of such notice would be futile or impracticable, in which event no notice shall be necessary). Such termination shall be effective upon the occurrence of such breach or, if a right to cure exists, upon failure of Sandoz to cure such breach within the specified time period; or

(iii) Upon the filing or institution of any bankruptcy, reorganization, liquidation or receivership proceedings by Sandoz, or upon the failure by Sandoz for more than ninety (90) days to discharge or obtain the dismissal of any such actions filed against it. Such termination shall be effective

upon receipt of notice from Eagle; or

(iv) If a Force Majeure Event affecting the performance of Sandoz specified in Article 10 shall continue for more than [*]. Such termination shall be effective upon receipt of notice from Eagle.

7.3 **Termination by Sandoz**. This Agreement may be terminated by Sandoz:

(i) If Eagle shall be in breach of any material obligation hereunder and has not cured such breach (A) with respect to any Supply Failure within [*] after receipt of a notice from Sandoz requesting the correction of such Supply Failure, or (B) with respect to any other breach of a material obligation within [*] after receipt of a notice from Sandoz requesting the correction of such breach (unless such breach is by its nature not susceptible of being cured or

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the giving of such notice would be futile or impracticable, in which event no notice shall be necessary). Such termination shall be effective upon the occurrence of such breach or, if a right to cure exists, upon failure of Eagle to cure such breach within the specified time period; or

(ii) Upon the filing or institution of any bankruptcy, reorganization, liquidation or receivership proceedings by Eagle, or upon the failure by Eagle for more than ninety (90) days to discharge or obtain the dismissal of any such actions filed against it. Such termination shall be effective upon receipt of notice from Sandoz; or

(iii) If a Force Majeure Event affecting the performance of Eagle specified in Article 10 shall continue for more than [*]. Such termination shall be effective upon receipt of notice from Sandoz.

7.4 **Termination by Either Party**.

(i) Either party may terminate this Agreement by written notice to the other party if no Triggering Event occurs with respect to the AG Product by May 31, 2013; provided, however, that neither party may exercise its rights under this Section 7.4(i) if a Triggering Event shall not have otherwise occurred for any reason provided in subsections (ii), (iii) or (iv) of this Section 7.4.

(ii) Either party may terminate this Agreement by written notice to the other party if the terminating party is advised by the FDA or its outside regulatory legal counsel that marketing, distributing, selling or offering to sell the AG Product under the labeling described in Section 9.3(iii) would likely constitute a violation of the Act or applicable regulations thereunder.

(iii) Subject to the last sentence of this Section 7.4(iii), either party may terminate this Agreement upon reasonable notice to the other party, if any governmental entity determines that this Agreement could violate Applicable Law, including, but not limited to, the United States Federal Trade Commission or either of its Bureau of Competition or Bureau of Economics. In the event a party seeks to trigger this termination right, the parties shall first reasonably consult in good faith with one another for a period of [*] to discuss the potential triggering of this termination right; in the event no mutually agreeable decision is reached within such time period, either party may terminate this Agreement [*].

(iv) Subject to the last sentence of this Section 7.4(iv), either party may terminate this Agreement upon reasonable notice to the other party, if (a) the terminating party, on the advice of legal counsel, determines that this Agreement poses unreasonable legal or economic risks as the result of (1) the enactment or threatened enactment after the Effective Date of any law, decree, rule, regulation or resolution, or (2) any decision of a court or regulatory agency, or (3) any change or threatened change in interpretation of current laws, decrees, rules, regulations or resolutions, and (b) such enactment, decision or change results in the failure to launch, or inability to continue the commercial sale of the AG Product for a [*] period. In the event a party seeks to trigger this termination right, the parties shall first reasonably consult in

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good faith with one another for a period of [*] to discuss the potential triggering of this termination right; in the event no mutually agreeable decision is reached within such time period, either party may terminate this Agreement [*].

(v) Either party may terminate this Agreement upon [*] written notice to the other party if the terminating party determines that it has become commercially unviable to continue sales of the AG Product in the Territory [*].

7.5 **Effect of Expiration or Termination**.

(i) Upon expiration of the Supply Term of this Agreement, Sandoz shall immediately cease all sales, marketing and distribution of the AG Product except that Sandoz shall have the right to market, distribute, offer to sell and sell the remaining AG Product then on hand in its inventory as of the date of such expiration, subject to its obligation to share Net Profits with Eagle pursuant to this Agreement.

(A) In the event that Eagle provides written notice of non-renewal at least [*] prior to the expiration of the Initial Term or any Renewal Term, as applicable, Eagle shall [*].

(B) In the event that Sandoz provides written notice of non-renewal at least [*] prior to the expiration of the Initial Term or any Renewal Term, as applicable, Eagle shall [*].

(ii) Upon termination of this Agreement by Eagle pursuant to Section 7.2(i) (Sandoz failure to pay), Section 7.2(ii) (Sandoz's material breach), Section 7.2(iii) (Sandoz's bankruptcy, etc.), or Section 7.2(iv) (Sandoz's Force Majeure Event), Eagle, in its sole discretion, may either (1) cancel any then outstanding binding purchase order and direct Sandoz to cease all distribution, marketing and sales of the AG Product immediately, or (2) cancel any then outstanding binding purchase order but allow Sandoz a sell-off period, determined by Eagle, which shall not exceed [*] after the effective date of termination, to sell off any inventory of AG Product under Sandoz's control as of the effective date of termination, all in accordance with the terms hereof as in effect prior to the date of such termination (including the obligation of Sandoz to share Net Profits with Eagle in accordance with the terms of this Agreement); provided that Sandoz shall immediately cease all sales, marketing and distribution of the AG Product as of the end of such sell-off period.

(A) In the event of termination of this Agreement by Eagle pursuant to Section 7.2(i) (Sandoz failure to pay), Section 7.2(ii) (Sandoz's material breach), Section 7.2(iii) (Sandoz's bankruptcy, etc.), or Section 7.2(iv) (Sandoz's Force Majeure Event), Eagle shall [*].

(B) In the event of termination of this Agreement by Eagle pursuant to Section 7.2(i) (Sandoz failure to pay) or Section 7.2(ii) (Sandoz's material breach), Sandoz shall be obligated to continue payment of the Net Profit split for the Sandoz Product in accordance with the terms of this Agreement until [*] for all such Sandoz Product sold prior to such date.

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(iii) Upon termination of this Agreement by Sandoz pursuant to Section 7.3(i) (Eagle's material breach), Section 7.3(ii) (Eagle's bankruptcy, etc.), or Section 7.3(iii) (Eagle's Force Majeure Event), Sandoz, shall have the option, in its sole discretion, to cancel all or any portion of any then outstanding binding purchase orders, except that Sandoz will pay Eagle for its share of any amounts (in accordance with Sandoz's Net Profit split) that Eagle is liable to pay its partners or suppliers for the fulfillment of outstanding binding purchase orders (as evidenced by written records reasonably acceptable to Sandoz).

(A) Sandoz shall be entitled to a sell-off period equal to [*] to sell off any inventory of AG Product under Sandoz's control as of the effective date of termination and any AG Product delivered by Eagle and purchased by Sandoz after the effective date of termination, all in accordance with the terms hereof as in effect prior to the effective date of such termination; provided that Sandoz shall immediately cease all sales, marketing and distribution of the AG Product as of the end of such sell-off period.

(B) In the event of termination of this Agreement by Sandoz pursuant to Section 7.3(i) (Eagle's material breach), Section 7.3(ii) (Eagle's bankruptcy, etc.), or Section 7.3(iii) (Eagle's Force Majeure Event), Eagle shall [*].

(iv) Upon termination of this Agreement by either party pursuant to Section 7.4(i) (no Triggering Event), (A) the firm order for the Launch Quantity shall be deemed cancelled (if applicable), (B) Sandoz shall immediately cease all pre-booking activities with respect to AG Product (if applicable), (C) Eagle shall use Commercially Reasonable efforts to cancel all then outstanding binding purchase orders except that Sandoz will pay Eagle for its share of any amounts (in accordance with Sandoz's Net Profit split) that Eagle is liable to pay its partners or suppliers for the fulfillment of outstanding binding purchase orders (as evidenced by written records reasonably acceptable to Sandoz) (if applicable), (D) Sandoz shall immediately cease all sales, marketing and distribution of the AG Product (if applicable), (E) Sandoz shall destroy any remaining inventory of AG Product upon Eagle's written request, such destruction costs and expenses to be borne equally between the parties (if applicable), and (F) Eagle shall [*].

(v) Upon termination of this Agreement by either party pursuant to Section 7.4(ii) (advice by FDA or regulatory counsel of labeling problem), Section 7.4(iii) (agency determination of violation of Applicable Law), or Section 7.4(iv) (determination of unreasonable legal or economic risks), (A) the firm order for the Launch Quantity shall be deemed cancelled (if applicable), (B) Sandoz shall immediately cease all pre-booking activities with respect to AG Product (if applicable), (C) Eagle shall use Commercially Reasonable efforts to cancel all then outstanding binding purchase orders except that Sandoz will pay Eagle for its share of any amounts (in accordance with Sandoz's Net Profit split) that Eagle is liable to pay its partners or suppliers for the fulfillment of outstanding binding purchase orders (as evidenced by written records reasonably acceptable to Sandoz) (if applicable), (D) Sandoz shall immediately cease all sales, marketing and distribution of the AG Product (if applicable), (E) Sandoz shall destroy any remaining inventory of AG Product upon Eagle's written request, such destruction costs and expenses to be borne equally between the parties (if applicable), and (F) Eagle shall [*].

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

(vi) Upon termination of this Agreement by Eagle pursuant to Section 7.4(v) (lack of commercial viability), Sandoz, shall have the option, in its sole discretion, to cancel all or any portion of any then outstanding binding purchase orders, except that Sandoz will pay Eagle for its share of any amounts (in accordance with Sandoz's Net Profit split) that Eagle is liable to pay its partners or suppliers for the fulfillment of outstanding binding purchase orders (as evidenced by written records reasonably acceptable to Sandoz).

(A) Sandoz shall be entitled to a sell-off period equal to [*] to sell off any inventory of AG Product under Sandoz's control as of the effective date of termination and any AG Product delivered by Eagle and purchased by Sandoz after the effective date of termination, all in accordance with the terms hereof as in effect prior to the effective date of such termination; provided that Sandoz shall immediately cease all sales, marketing and distribution of the AG Product as of the end of such sell-off period.

(B) In the event of termination of this Agreement by Eagle pursuant to Section 7.4(v) (lack of commercial viability), Eagle shall [*].

(vii) Upon termination of this Agreement by Sandoz pursuant to Section 7.4(v) (lack of commercial viability), Sandoz, shall have the option, in its sole discretion, to cancel all or any portion of any then outstanding binding purchase orders, except that Sandoz will pay Eagle for its share of any amounts

(in accordance with Sandoz's Net Profit split) that Eagle is liable to pay its partners or suppliers for the fulfillment of outstanding binding purchase orders (as evidenced by written records reasonably acceptable to Sandoz).

(A) Sandoz shall be entitled to a sell-off period equal to [*] to sell off any inventory of AG Product under Sandoz's control as of the effective date of termination and any AG Product delivered by Eagle and purchased by Sandoz after the effective date of termination, all in accordance with the terms hereof as in effect prior to the effective date of such termination; provided that Sandoz shall immediately cease all sales, marketing and distribution of the AG Product as of the end of such sell-off period.

(B) In the event of termination of this Agreement by Sandoz pursuant to Section 7.4(v) (lack of commercial viability), Eagle shall [*].

(viii) Termination of this Agreement for any reason will not release either party hereto from any liability which at such time has already accrued or which thereafter accrues from a breach or default prior to such expiration or termination, nor affect in any way the survival of any other right, duty or obligation of either party hereto which is expressly stated elsewhere in this Agreement to survive such termination.

7.6 **Effect of the Entry of a Third Party's Generic Equivalent**.

(i) In the event that Eagle grants authorization or license in writing to any third party to make, have made, offer to sell, sell, have sold, market, promote, distribute, import or use in or for the Territory any pharmaceutical product that is filed as an application under

Section 505(b)(2) or 505(j) of the Act referencing NDA No. 022434 (hereinafter, a "Generic Equivalent") by a date certain (hereinafter, a "Licensed Generic Entry Date"), Eagle shall provide written notice of such authorization or license to Sandoz, including the Licensed Generic Entry Date and the material terms of such authorization or license, within [*], but in no event later than [*] before the date upon which the Generic Equivalent may be sold in the Territory. The parties agree that the failure of Eagle to provide such notice of such authorization or license or to provide Sandoz with all such relevant information shall be a material breach of this Agreement by Eagle.

(ii) In the event that a Licensed Generic Entry Date occurs during the Term, the parties shall first consult in good faith for a period of [*] (the "Review Period") to discuss potential modifications of this Agreement that may be mutually acceptable to the parties. In the event an agreement is reached at the conclusion of the Review Period, this Agreement will continue in accordance with its mutually agreed upon revised terms. In the event no agreement is reached at the conclusion of the Review Period, this Agreement will continue until expiration or termination, and Eagle shall [*]. For the avoidance of doubt, [*], and [*]

(iii) In the event that (x) a third party files a Notice Letter in respect of a Generic Equivalent; (y) Eagle (or the Eagle Branded Product Distributor) elects not to sue such third party under 35 U.S.C. § 271(e)(2) within forty-five (45) days after Eagle's receipt thereof; and (z) such third party obtains the requisite regulatory approval(s) necessary to market the pharmaceutical product referenced in the Notice Letter, including all applicable product and/or establishment licenses, registrations, permits or other authorizations as may be necessary for the commercial manufacture, commercialization, use, storage, importation, transport, pricing, distribution or sale thereof ("Regulatory Approval"), Eagle shall [*]and to [*] (hereinafter, the "Unlicensed Generic Entry Date"). [*] Eagle shall provide notice of same to Sandoz.

(iv) In the event that a third party files a Notice Letter in respect of a Generic Equivalent and Eagle (or the Eagle Branded Product Distributor) elects to sue such third party within forty-five (45) days after Eagle's receipt thereof as provided by 21 U.S.C. § 355(j)(5)(B)(iii), then the following provisions shall apply:

(A) In the event that Eagle (or the Eagle Branded Product Distributor) has sought a temporary restraining order or preliminary injunction within twenty-one (21) days of the Launch at Risk prohibiting any further offer for sale or sale of said Generic Equivalent, this Agreement shall continue in full force and effect in accordance with its then-applicable terms until a court denies or lifts such temporary restraining order or preliminary injunction;

(B) In the event that Eagle (or the Eagle Branded Product Distributor) has not sought a temporary restraining order or preliminary injunction within twenty-one (21) days of the Launch at Risk prohibiting any further offer for sale or sale of said Generic Equivalent, or the court denies or lifts such temporary restraining order or preliminary injunction, and such third party elects to launch at risk thereafter (hereinafter, a "Launch at Risk"), then the Net Profit split otherwise payable under Schedule A shall be automatically revised upon the Launch at Risk, such that Sandoz will pay to Eagle [*] of the Net Profit of the

AG Product and Sandoz Product (as applicable), and Sandoz will retain the remaining [*] of the Net Profit for the AG Product and Sandoz Product (as applicable) (the "Revised Profit Split");

(C) If, after a Launch at Risk, the court reverses itself and requires such third party to cease selling such Generic Equivalent or Eagle (or the Eagle Branded Product Distributor) obtains an appellate decision requiring such third party to cease selling such Generic Equivalent, the Net Profit split shall immediately revert to the Net Profit split in effect as of the Effective Date upon the issuance of such appellate decision;

(D) In the event of a decision of a United States court from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken, holding the asserted or adjudicated claims of the Argatroban Patents to be invalid, unenforceable or not infringed by a Generic Equivalent, if any third party (i) obtains Regulatory Approval for such Generic Equivalent, and (ii) any third party actually launches such Generic Equivalent, the Net Profit split shall immediately revert to the Revised Profit Split (if not already at such Revised Split) upon the issuance of such court decision, and such court decision date shall be deemed a Licensed Generic Entry Date; and

(E) In the event (1) of a Launch at Risk, and (2) Eagle (or the Eagle Branded Product Distributor) obtains a decision of a United States court from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken, holding the asserted or adjudicated claims of the Argatroban Patents to be valid, enforceable or infringed, then the Net Profit split shall immediately revert to the Net Profit split in effect as of the Effective Date upon the issuance of such court decision.

(v) Notwithstanding anything to the contrary contained herein, in the event this Agreement has been terminated by either party or this Agreement expires, effective as of the first Licensed Generic Entry Date or Unlicensed Generic Entry Date (as applicable), Eagle shall [*]. For the avoidance of doubt, [*], and [*]

7.7 [*]. As of [*], Eagle, [*], in each case [*]. Eagle, [*] to the extent permitted under the terms of this Agreement.

ARTICLE 8
DEFECTIVE AG PRODUCT/INSPECTIONS/TESTING

8.1 **Disposition of Defective AG Product**. Eagle will replace, at its own cost and expense, including reimbursement of reasonable freight and disposition costs incurred by Sandoz, AG Product that fails to comply with the Specifications for such AG Product. Eagle will not, however, replace any AG Product which fails or ceases, prior to the applicable expiration date, to conform to the Specifications as a result of improper storage or mishandling after delivery thereof to Sandoz. Sandoz will, within sixty (60) days after receipt of any shipment of AG Product, notify Eagle of the existence and nature of any patent (obvious) non-compliance or defect. If such notice is not provided within the sixty (60) day period, then all such AG Product will be deemed to be in compliance with this Agreement and Eagle will bear no further

responsibility for such AG Product non-compliance except in accordance with the provisions of Section 8.3. If Sandoz notifies Eagle within such sixty (60) day period of the receipt of defective AG Product, then, subject to this Article 8, Eagle will have a reasonable opportunity, not to exceed thirty (30) days from the date of notice, to inspect such claimed defective AG Product and agree with or dispute Sandoz's disposition. If Eagle agrees, it will provide Sandoz with detailed written instructions to return or dispose of such defective AG Product at Eagle's sole cost and expense. If Eagle disputes the defect, then both parties shall agree to work together to resolve the dispute in accordance with Section 8.2. If Eagle accepts Sandoz's disposition and fails to instruct Sandoz as to the disposition of such defective AG Product within sixty (60) days from the date of notice, Sandoz may dispose of such defective AG Product as it sees fit (and at Eagle's expense).

8.2 **Dispute Resolution and Independent Testing**. If, after Eagle's inspections of the AG Product and the analysis of the corresponding sample kept by Eagle as part of the stability testing program provided for in Section 6.3, the parties disagree as to the AG Product's conformance to the Specifications or whether the AG Product has such a defect that is Eagle's responsibility, either party may deliver the AG Product to an independent qualified third-party laboratory or third party expert who is mutually and reasonably acceptable to both parties, to confirm the AG Product's conformance to the Specifications or the presence or absence of defects. The parties will make reasonable efforts to work with each other and the independent third-party to identify any reasons for non-conformance or the presence of defects. This may include Eagle supplying the independent laboratory with a sample kept by Eagle as part of the stability testing program, or any other relevant storage or manufacturing information kept by either party. All costs associated with such third-party testing will be at Sandoz's expense unless the tested AG Product is deemed by such third-party not to be in compliance with the Specifications, in which case all such costs, including reimbursement of freight and disposition costs, will be promptly paid by Eagle. The findings of the independent laboratory or expert will be binding upon both parties.

8.3 **Latent Defects**. As soon as either party becomes aware of a Latent Defect in any AG Product lot, it will promptly notify the other party of such event (including reasonable details and the lot involved). If an AG Product accepted by Sandoz becomes non-conforming by virtue of the later discovery of a Latent Defect, Sandoz may place the lot on quality assurance hold pending Eagle's investigation and a final resolution of the claimed Latent Defect pursuant to Section 8.1 and 8.2 above. In the event that such AG Product is found to contain a Latent Defect, such AG Product will be deemed rejected pursuant to Sections 8.1 and 8.2 as of the date of the notice, and the rights and obligations of the parties with respect to the rejected AG Product will thereafter be governed by Sections 8.1 and 8.2.

8.4 **Sandoz Damage to AG Product**. Eagle shall not be liable to Sandoz in the event AG Product is damaged by Sandoz (or by Sandoz's designee) after delivery pursuant to Section 4.7.

ARTICLE 9
REGULATORY MATTERS

9.1 **Reporting**. Sandoz will have the responsibility in the Territory for complying with all regulatory requirements and other matters which relate solely to Sandoz's acting as a distributor of the AG Product in the Territory. All other regulatory reporting matters (including adverse event and product

complaint reporting) will be Eagle's responsibility for the AG Product. Prior to the Triggering Event, the parties will enter into a separate Pharmacovigilence Agreement that will cover the parties' responsibilities with respect to any report(s) of adverse events.

9.2 **FDA Communications**. Sandoz and Eagle agree to promptly notify the other party in the event they receive any communication or notice from FDA with respect to the AG Product and each party will promptly provide a copy of such communications to the other. The parties will cooperate in good faith in responding to any such FDA inquiry or in making any report to FDA with respect to the AG Product. Notwithstanding the foregoing, Eagle will have final authority for regulatory decisions and responsibility for all communications with FDA concerning the AG Product.

9.3 **Labeling Configuration**.

(i) The parties agree to cooperate in procedures designed to ensure that the AG Product is properly labeled and that appropriate standard operating procedures are in place to ensure that the labeling and printed packaging components for the AG Product comply with Applicable Law.

(ii) Subject to paragraph (iii) of this Section 9.3, all final decisions regarding labeling of AG Product shall be made by Eagle in Eagle's sole discretion as the holder of the NDA.

(iii) Unless otherwise required by Applicable Law, the parties agree that the text comprising the labeling for the AG Product will be substantially identical to the labeling for the Eagle Branded Product with the following exceptions: (A) the name of Sandoz will appear as a distributor, (B) the NDC Numbers of Sandoz will be listed in the "How Supplied" section of the physicians circular (or insert), (C) in the "How Supplied" section, information will be provided about the AG Product as manufactured by Eagle for the purpose of providing complete information concerning all dosage strengths and formulations of Eagle Branded Product available under the Eagle NDA as included in the FDA approved labeling for the Eagle Branded Product, (D) the appearance and design of the AG Product label will be sufficiently different from the label for Eagle Branded Product so as to avoid confusion between the two, and (E) any other exceptions mutually agreed to by the parties. Eagle shall submit AG Product listing information to the FDA after receipt of all required information and documentation (including required information and documentation from Sandoz) as reasonably determined by Eagle. Sandoz shall obtain NDC Numbers for the AG Product as set forth on Schedule A and shall distribute and sell only the AG Product bearing the applicable NDC Numbers set forth on Schedule A. Eagle shall promptly submit to the FDA the AG Product label under the Eagle NDA and a drug listing form showing Sandoz as the private label distributor of the AG Product.

9.4 **Recalls**. Eagle and Sandoz will each notify the other party promptly, and in any event within twenty-four (24) hours, if any batch of AG Product is the subject of a recall or market withdrawal, and the parties will reasonably cooperate in the handling and disposition of such recall or market withdrawal; provided, however, in the event of a disagreement as to any matters related to such recall or market withdrawal, other than the determination of who will bear the costs as set forth in the immediately following sentence, Eagle will have the final authority with respect to any product recall relating to the AG Product. Sandoz will bear the cost of all recall or market withdrawals of AG Product purchased by Sandoz pursuant to this Agreement unless such recall or market withdrawal will have been the result of (i) the failure of such AG Product to meet the Specifications for such AG Product at the time of delivery, or (ii) Eagle's breach of any of its covenants, obligations, representations or warranties set forth in this Agreement (either of the foregoing clause (i) or (ii), an "Eagle Recall Event"), then in each such case Eagle will bear the entire cost of such recall. Sandoz will maintain records of all sales of AG Product and all customers sufficient to adequately administer a recall or market withdrawal for the longer of one (1) year after termination or expiration of this Agreement or the period required by Applicable Law. Sandoz will, in all events and regardless of who bears the cost, be responsible for administering the physical aspects of any recalls or market withdrawals with respect to the AG Product, provided, however, that upon the occurrence of an Eagle Recall Event, any reasonable external costs and expenses incurred by Sandoz relating to the Eagle Recall Event (including, but not limited to reasonable recall destruction costs) will be borne by Eagle. AG Product and inventory held by Sandoz (or its designee) that is subject to a recall will [*] and, upon an Eagle Recall Event, Eagle will provide AG Product to Sandoz at Eagle's expense to replace the recalled AG Product. For the avoidance of doubt, AG Product that is recalled [*].

9.5 **Complaints**. Sandoz will collect complaint files for the AG Product in accordance with the provisions of the Quality Agreement as provided for in Section 6.1 and cGMP. AG Product complaint reports received by Sandoz will be sent to Eagle by e-mail within twenty-four (24) hours of receipt to the attention of Eagle Quality Assurance drohrbach@eagleus.com), with an original sent promptly by U.S. mail to David Rohrbach, Eagle Pharmaceuticals, Inc., 470 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677 (office: 201-326-5333; fax: 201-391-2430; with a back-up to Chris Butler, office: 201-326-5398; fax: 201-391-2430). Sandoz and Eagle will each notify the other of any product complaints made by customers that will or could cause an FDA "field alert" to be issued, within twenty-four (24) hours of the decision to file a field alert and will thereafter reasonably cooperate with each other relative to any investigation or inquiry that may be initiated by FDA with respect thereto. For purposes of clarification, the parties acknowledge that the foregoing complaint handling procedures will only apply to complaints which implicate the manufacturing, packaging, testing or storage of the AG Product.

9.6 **Inspections.** In the event Eagle's or Eagle's Contract Manufacturer's manufacturing, packaging, testing or storage facility (or facilities) producing AG Product is/are inspected by representatives of any federal agency in connection with Eagle's Contract Manufacturer's manufacture of the AG Product, Eagle will notify Sandoz promptly upon learning of such inspection, and will supply Sandoz with redacted copies of any correspondence

or communications or portions thereof which relate to the AG Product.

9.7 **Regulatory Letter**. In the event Sandoz is inspected or receives a regulatory letter or comments from any federal agency or authority in connection with the distribution of the AG Product, Sandoz will notify Eagle promptly upon learning of such inspection or receiving such documentation. Eagle may participate in that portion of such inspection relating to the AG Product (and will be required to participate if requested by Sandoz at Sandoz's

expense). If Sandoz requests Eagle to participate as described above, Eagle and Sandoz will mutually agree on the response with respect to the AG Product and Sandoz will be responsible for submitting any such responses to the regulatory authorities.

9.8 **Inquiries from Health Care Professionals**. Eagle shall provide reasonable assistance to Sandoz in its preparation and filing with appropriate regulatory agencies (both federal and state agencies) related to reimbursement and health care insurance filings required for the marketing and distribution of AG Product in the Territory by Sandoz. Eagle and Sandoz will work together in good faith to develop such necessary regulatory strategies, which may be required for purposes of this Agreement. In addition, Eagle will provide Sandoz with copies (in electronic format if available) of those materials, which Eagle uses to respond to inquiries regarding applicable products from consumers and health care professionals.

ARTICLE 10
FORCE MAJEURE

If either party is prevented from performing any of its obligations hereunder (except for any financial payments due hereunder) due to any cause which is beyond the non-performing party's reasonable control, including fire, explosion, flood, or other acts of God; acts, regulations, or laws of any government; court injunction or other court order; war, terrorist act or civil commotion; strike, lock-out or labor disturbances; or failure of public utilities or common carriers (each, a "Force Majeure Event"), such non-performing party will not be liable for breach of this Agreement with respect to such non-performance to the extent any such non-performance is due to a Force Majeure Event. Such non-performance will be excused for as long as such event will be continuing, provided that the non-performing party gives written notice to the other party of the Force Majeure Event within three (3) Business Days. Such non-performing party will exercise all reasonable efforts to eliminate the Force Majeure Event and to resume performance of its affected obligations as soon as practicable. In the event such Force Majeure Event continues unabated for a period of [*], then the party which is not subject to such Force Majeure Event may terminate this Agreement consistent with Article 7.

ARTICLE 11
INSURANCE

Each party agrees to procure and maintain in full force and effect during the Term of this Agreement, at its sole cost and expense, statutory worker's compensation insurance and employer's liability insurance. The parties further agree to procure and maintain in full force and effect during the Term of this Agreement, at its sole cost and expense, (i) commercial general

liability and umbrella liability insurance, and (2) product liability insurance each with limits of not less than [*] per occurrence and [*] in the aggregate annually. Each party will, on request, provide to the other party evidence of such insurance coverage (an email from the employee responsible for such insurance coverage setting forth the names of the insurance companies and the coverage provided therein will be acceptable). Notwithstanding anything to the contrary contained herein, [*] hereunder.

ARTICLE 12
CONFIDENTIALITY

12.1 **Definition.** As used herein, the term "Confidential Information" means information which relates to the AG Product and/or Sandoz Product, or its respective development, manufacture, testing, marketing, sale or support and which is disclosed by one party hereto to the other, including, but not limited to, technical and business information, samples of compounds, the structure or chemical identity of compounds, the properties and utilities of compounds, manufacturing procedures, manufacturing processes, manufacturing equipment, plant layouts, product volumes, quality control procedures, quality control standards, know-how, scientific information, clinical data, efficacy and safety data, formulas, methods and processes, specifications, pricing information (including discounts, rebates and other price adjustments), the terms and conditions of this Agreement, and other terms and conditions of sales, customer information, business plans, and all other intellectual property. Notwithstanding anything to the contrary contained herein, at any time after execution of this Agreement by both parties, [*].

12.2 **Exceptions**. The obligations of confidentiality and nondisclosure shall not apply to Confidential Information which

(i) at the time of disclosure is in the public domain;

(ii) as shown by written records was in the possession of the receiving party prior to disclosure or development under this Agreement;

(iii) is rightly received by the receiving party, without obligation of secrecy, from a third party who was entitled to receive and transfer such;

(iv) as shown by written records was independently developed by employees of the receiving party who did not have access to Confidential Information; or

(v) a party hereto is compelled to disclose by a court, tribunal or regulatory agency of competent jurisdiction. In such case, to the extent permitted by applicable law, the compelled party shall give the disclosing party prompt notice so that the disclosing party can seek a protective order, and shall exercise reasonable efforts to ensure that the information is accorded confidential treatment by the court, tribunal or regulatory agency.

12.3 **Use and Disclosure**. Each party shall retain Confidential Information of the other party in strict confidence and shall not, directly or indirectly, publish or disclose it to any third

party, or use Confidential Information for any purpose other than the purposes of this Agreement without the prior written consent of the disclosing party. Each party agrees it shall not communicate Confidential Information of the other party except to its employees, advisors, representatives and contractors who have a need to know such Confidential Information. Termination or expiration of this Agreement between Sandoz and Eagle shall not affect the secrecy and restrictions on use obligations under this Article 12, which shall survive for a period of [*] after such termination or expiration.

12.4 **Effect of Termination**. Upon termination or expiration of this Agreement, the receiving party shall return to the disclosing party or destroy any Confidential Information in tangible form in its possession, except that the receiving party shall not destroy Confidential Information required to be retained in order to comply with applicable law, rule or regulation.

12.5 **Injunctive Relief**. Each party shall be entitled, in addition to any other right or remedy it may have, at law or in equity, to an injunction, without the posting of any bond or other security, enjoining or restraining any other party from any violation or threatened violation of this Article 12.

ARTICLE 13
PUBLIC ANNOUNCEMENTS; ETC.

13.1 **Public Announcements**. The parties hereto covenant and agree that, except as provided for herein below, each will not from and after the date hereof make, issue or release any public announcement, press release, statement or acknowledgment of the existence of, or reveal publicly the terms, conditions and status of, the transactions contemplated herein, without the prior written consent of the other party as to the content and time of release of and the media in which such statement or announcement is to be made; provided, however, that in the case of announcements, statements, acknowledgments or revelations which either party is required by law to make, issue or release, the making, issuing or releasing of any such announcement, statement, acknowledgment or revelation by the party so required to do so by law will not constitute a breach of this Agreement if such party will have given, to the extent reasonably possible, not less than five (5) Business Days prior notice to the other party, and will have attempted, to the extent reasonably possible, to clear such announcement, statement, acknowledgment or revelation with the other party (including any Q&A and other similar materials).

13.2 **Use of Eagle Name**. Sandoz will not use the name of Eagle or any of its Affiliates for advertising, promotion or other purposes without the prior written consent of Eagle, other than in discussions with its customers pursuant to the last sentence of Section 12.1.

13.3 **Use of Sandoz Name**. Eagle will not use the name of Sandoz or any of its Affiliates for advertising, promotion or other purposes without the prior written consent of Sandoz.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

ARTICLE 14
REPRESENTATIONS AND WARRANTIES

14.1 **Eagle Warranties**. Eagle represents and warrants to Sandoz that it will:

(i) cause the Eagle Contract Manufacturer to manufacture and supply all AG Product in accordance and in conformity with the Specifications, as also set forth in the applicable Eagle NDA for such AG Product;

(ii) comply with all applicable statutes, laws, ordinances and regulations relating to the manufacture and supply of any AG Product being provided hereunder, including, without limitation, those enforced by the FDA (including compliance with cGMP's);

(iii) timely file the AG Product label for the relevant Eagle NDA;

(iv) timely file a drug listing form showing Sandoz as the private label distributor of the AG Product; and

(v) have in place systems and resources for tracking and reporting all complaints and adverse events with respect to the AG Product in accordance with the Quality and Pharmacovigilence Agreements as provided in Sections 9.1 and 9.5 respectively.

14.2 **Sandoz Warranties**. Sandoz represents and warrants to Eagle that it will:

(i) discharge its obligations pursuant to this Agreement in accordance with all applicable statutes, laws, ordinances and regulations including those enforced by the FDA (including compliance with cGMP's);

(ii) maintain the AG Product pending sale to its customers in a facility that is properly equipped to store such AG Product in accordance with the applicable AG Product labeling; and

(iii) have in place systems and resources for tracking and reporting all complaints and adverse events with respect to the AG Product in accordance with the Quality and Pharmacovigilence Agreements as provided in Sections 9.1 and 9.5 respectively.

14.3 **Debarment**. The parties each hereby represent and warrant to the best of their knowledge after reasonable investigation, that neither it, nor any of its employees or agents who will participate in the performance of this Agreement, have been, are currently, or are the subject of a proceeding that could lead to their or such employees or agents becoming, as applicable, a Debarred Entity, Debarred Individual, Excluded Entity, Excluded Individual, Convicted Entity, or Convicted Individual. The parties further covenant, represent and warrant that, to the best of their knowledge after reasonable investigation, if during the Term of this Agreement, it, or any of its employees or agents participating in the performance of their obligations hereunder, become or are the subject of a proceeding that could lead that party, employee or agent becoming, as applicable, a Debarred Entity, Debarred Individual, Excluded Entity, Excluded Individual, Convicted Entity or Convicted Individual, then it will immediately notify the other party. In the event of such a notice, the parties will promptly discuss necessary measures to avoid such a

circumstance from affecting a party's performance under this Agreement.

14.4 **LIMITATION ON LIABILITY OF PARTIES**. EXCEPT (A) AS PROVIDED IN SECTION 15.1 AND SECTION 15.2 HEREIN AND/OR (B) WITH RESPECT TO A BREACH OF A PARTY'S OBLIGATIONS IN ARTICLE 12, THE PARTIES MAKE NO WARRANTY OF ANY KIND, EXPRESS OR IMPLIED INCLUDING WITHOUT LIMITATION ANY WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES RESULTING FROM THIS AGREEMENT.

14.5 **Execution and Performance of Agreement**. Eagle and Sandoz each represents and warrants to the other that it has the full right, power and authority to enter into and perform its obligations under this Agreement. Eagle and Sandoz each further represents and warrants to the other that the performance of its obligations under this Agreement will not result in a violation or breach of, and will not conflict with or constitute a default under any agreement, contract, commitment or obligation to which such party or any of its Affiliates is a party or by which it is bound.

ARTICLE 15
INDEMNIFICATION

15.1 **Indemnification by Eagle**. Eagle will indemnify and hold harmless Sandoz, its Affiliates, and each of their respective current or former directors, officers, employees, agents and representatives (the "Sandoz Indemnified Parties") from and against any and all damages, liabilities, claims, costs, charges, judgments and expenses (including all reasonable attorneys' fees and expenses) (collectively "Damages") from third parties that may be sustained, suffered or incurred by the Sandoz Indemnified Parties, arising from or in connection with (i) the breach by Eagle of any warranty, representation, covenant or agreement made by Eagle in this Agreement, or (ii) the intentional misconduct or gross negligence of any Eagle Indemnified Party in connection with this Agreement or the AG Product, or (iii) a breach of Eagle's responsibilities pursuant to the Quality Agreement as provided for in Section 6.1, or (iv) Eagle's (or any of Eagle's Affiliates') and/or the Eagle Branded Product Distributor's distribution, marketing or sales activities related to the Eagle Branded Product, or (v) [*], or (vi) Eagle or any of Eagle's subsidiaries' infringement of the intellectual property rights of a third party where such alleged [*], except, in the case of clauses (i)-(vi) immediately above, for Damages for which Sandoz has an obligation to indemnify the Eagle Indemnified Parties pursuant to Section 15.2 as to which Damages each of Eagle and Sandoz shall indemnify the other party to the extent of its respective liability for such Damages.

15.2 **Indemnification by Sandoz**. Sandoz will indemnify and hold harmless Eagle, its Affiliates, and each of their respective current or former directors, officers, employees, agents and representatives (the "Eagle Indemnified Parties") from and against any and all Damages from third parties that may be sustained, suffered or incurred by the Eagle Indemnified Parties, arising from or in connection with (i) the breach by Sandoz of any warranty, representation, covenant or agreement made by Sandoz in this Agreement, or (ii) the intentional misconduct or

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gross negligence of any Sandoz Indemnified Party in connection with this Agreement or the AG Product, or (iii) a breach of Sandoz's responsibilities pursuant to the Quality Agreement as provided for in Section 6.1, or (iv) [*], or (v) [*], or (vi) Sandoz or any of Sandoz's Affiliates' infringement of the intellectual property rights of a third party where such alleged [*], except, in the case of clauses (i)-(vi) immediately above, for Damages for which Eagle has an obligation to indemnify the Sandoz Indemnified Parties pursuant to Section 15.1 as to which Damages each of Sandoz and Eagle shall indemnify the other party to the extent of its respective liability for such Damages.

15.3 **Claims.** Each Eagle Indemnified Party and Sandoz Indemnified Party ("Indemnified Party") agrees to give the indemnifying party prompt written notice of any matter upon which such Indemnified Party intends to base a claim for indemnification (an "Indemnity Claim") under this Article 15. In the event that an Indemnity Claim is brought or made against both parties, then each party will have the right to be represented by counsel at its own expense. Notwithstanding the foregoing, in the event that such Indemnity Claim relates solely to causes covered by Section 15.1 hereof, then Eagle will assume full control of the defense of such Indemnity Claim including without limitation the settlement thereof All expenses of such suit, claim or proceeding, including the settlement and the payment of any damages thereof, will be borne solely by Eagle. Notwithstanding the foregoing, in the event that such Indemnity Claim relates solely to causes covered by Section 15.2 hereof, then Sandoz will assume full control of the defense of such Indemnity Claim including without limitation the settlement thereof All expenses of such suit, claim or proceeding, including the settlement and the payment of any damages thereof, will be borne solely by Sandoz. The Indemnified Party will make available to the indemnifying party and its counsel, at all reasonable times during normal business hours, all books and records of the other party relating to such suit, claim or proceeding, and each party will render to the other party such assistance as it may reasonably require in order to ensure proper and adequate defense of any such suit, claim or proceeding. The indemnifying party will obtain the written consent of the Indemnified Party prior to settling, ceasing to defend or otherwise disposing of any Indemnity Claim if as a result thereof the Indemnified Party would become subject to injunctive or other equitable relief or the business of the Indemnified Party would be adversely affected in any manner whatsoever.

ARTICLE 16
INFORMAL DISPUTE RESOLUTION; EXCLUSIVE JURISDICTION

16.1 **Informal Dispute Resolution**. Unless otherwise expressly provided for herein, any claim or controversy between the parties arising out of or relating to the execution, interpretation and performance of this Agreement (including the validity, scope and enforceability of this provision) will be identified in writing and presented to the other party. Within [*] after delivery of such notice of dispute, the Chief Executive Officer of Eagle and the President of Sandoz (or another executive of a party or an Affiliate designated by such Chief Executive Officer or President, as applicable) (the "Designated Officers") will meet (either in person or via telephone conference) at a mutually acceptable time and place, and thereafter as often as they reasonably deem necessary, to attempt to resolve the dispute in good faith. All reasonable requests for information made by one party to another will be honored. All

negotiations pursuant to this clause are confidential and will be treated as compromise and settlement negotiations for purposes of applicable rules of evidence. If such Designated Officers cannot resolve such dispute within [*] after such initial meeting, then each party reserves its right to any and all remedies available under law or equity with respect to any other dispute. Notwithstanding anything to the contrary herein, each party may seek immediate or other equitable relief against the other party at any time to enforce their proprietary rights in confidential information or other intellectual property rights.

16.2 **Exclusive Jurisdiction and Governing Law**. This Agreement will be governed by and construed in accordance with the laws of the State of New Jersey, without regard to the conflict of law principles thereof. The parties agree that any action arising out of this Agreement will be commenced in the federal or state courts of New Jersey, as appropriate, and that such court is a proper venue for such action, that effective process may be served to a party at the address set forth in Section 17.6, and that A RIGHT TO TRIAL BY JURY IS HEREBY WAIVED. Each party hereto agrees that any such proceeding will be conducted solely in the English language.

ARTICLE 17
MISCELLANEOUS

17.1 **Amendment**. The parties may add additional products to this Agreement from time to time. The parties will prepare a Schedule and attach the new Schedule as an amendment to the Agreement, signed and dated by both parties. No modification, change or amendment to this Agreement will be effective unless in writing signed by each of the parties hereto.

17.2 **Relationship of the Parties**. The relationship of Sandoz and Eagle established by this Agreement is that of independent contractors, and nothing contained herein will be construed to (i) give either party any right or authority to create or assume any obligation of any kind on behalf of the other, or (ii) constitute the parties as partners, joint venturers, co-owners or otherwise as participants in a joint or common undertaking.

17.3 **Third Party Rights.** Nothing in this Agreement will be deemed to create any third party beneficiary rights in or on behalf of any other person.

17.4 **Entire Agreement**. It is the mutual desire and intent of the parties to provide certainty as to their respective future rights and remedies against each other by defining the extent of their mutual undertakings as provided herein. The parties have, in this Agreement (including the Schedules and Exhibits hereto), and the Quality and Pharmacovigilence Agreements referred to herein, incorporated all representations, warranties, covenants, commitments and understandings on which they have relied in entering into this Agreement, and, except as provided for herein, neither party makes any covenant or other commitment to the other concerning its future action. Accordingly, this Agreement and the Schedules and Exhibits hereto and the Quality and Pharmacovigilence Agreements referred to herein (i) constitute the entire agreement and understanding between the parties with respect to the subject matter hereof and there are no promises, representations, conditions, provisions or terms related thereto other

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than those set forth in this Agreement, and (ii) supersedes all previous understandings, agreements and representations between the parties, written or oral.

17.5 **Headings and Examples**. The Article and Section headings contained in this Agreement and any examples attached hereto are for reference purposes only and will not affect in any way the meaning and interpretation of this Agreement.

17.6 **Notices**. All notices and other communications hereunder will be in writing. All notices hereunder of an Indemnity Claim as defined in Section 15.3, a Force Majeure Event, default or breach hereunder, or, if applicable, termination or renewal of the Term hereof, or any other notice of any event or development material to this Agreement taken as a whole, will be delivered personally, or sent by national overnight delivery service or postage pre-paid registered or certified U.S. mail, and will be deemed given: when delivered, if by personal delivery or overnight delivery service; or if so sent by U.S. mail, five (5) Business Days after deposit in the mail, and will be addressed:

If to Sandoz:

Sandoz AG
Lichtstraße 35
CH 4056 Basel, Switzerland
Attention: Peter Rupprecht, Authorized Signatory
Fax: +41 61 324 5372

With a copy to:
Sandoz Inc.
506 Carnegie Center, Suite 400
Princeton, New Jersey 08540
Attention: General Counsel
Fax: 609-627-8684

If to Eagle:
Eagle Pharmaceuticals, Inc.

470 Chestnut Ridge Road
Woodcliff Lake, New Jersey 07677
Attention: President/CEO
Fax: 201-391-2430

With a copy to:
Orrick, Herrington & Sutcliffe LLP
51 West 52nd Street
New York, New York 10103
Attention: R. King Milling, Esq.
Fax: 212-506-5151

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

or to such other place as either party may designate by written notice to the other in accordance with the terms hereof.

17.7 **Failure to Exercise**. The failure of either party to enforce at any time for any period any provision hereof will not be construed to be a waiver of such provision or of the right of such party thereafter to enforce each such provision, nor will any single or partial exercise of any right or remedy hereunder preclude any other or further exercise thereof or the exercise of any other right or remedy. Remedies provided herein are cumulative and not exclusive of any remedies provided at law.

17.8 **Assignment**. This Agreement may not be assigned by either party without the prior written consent of the other, except that (i) either party may assign its rights and/or obligations hereunder to any of its Affiliates, and (ii) either party may assign its rights and/or obligations hereunder to any successor in interest by way of merger, acquisition or sale of all or substantially all of its business or assets to which this Agreement relates. Subject to the foregoing, this Agreement will bind and inure to the benefit of the parties hereto and their respective permitted successors and assigns.

17.9 **Severability**. In the event that any one or more of the provisions (or any part thereof) contained in this Agreement or in any other instrument referred to herein, will, for any reason, be held to be invalid, illegal or unenforceable in any respect, the remaining provisions of this Agreement will remain in full force and effect. If any of the terms or provisions of this Agreement are in conflict with any applicable statute or rule of law, then such terms or provisions will be deemed inoperative to the extent that they may conflict therewith and will be deemed to be modified to conform with such statute or rule of law. In the event that the terms and conditions of this Agreement are materially altered as a result of this Section 17.9, the parties will renegotiate the terms and conditions of this Agreement to resolve any inequities.

17.10 **Counterparts**. This Agreement may be executed in one or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

17.11 **Expenses**. Each party will pay all of its own fees and expenses (including all legal, accounting and other advisory fees) incurred in connection with the negotiation and execution of this Agreement and the arrangements contemplated hereby, except as specifically provided herein.

17.12 **Survival**. Articles 1, 5, 8, 9, 11, 12, 13, 15, 16 and 17 and Sections 3.3, 3.4, 7.5, [*], 14.1, 14.2, 14.4 and Schedule A will survive the termination of this Agreement in accordance with the respective terms thereof.

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IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized respective representatives as of the day and year first above written.

Eagle Pharmaceuticals, Inc.

By: /s/ Scott Tarriff
Name: Scott Tarriff
Title: President/CEO

Sandoz AG

By: _____
Name:
Title:

Sandoz AG

By: _____
Name:
Title:

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IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized respective representatives as of the day and year first above written.

Eagle Pharmaceuticals, Inc.

By: _____
Name: Scott Tarriff
Title: President/CEO

Sandoz AG

By: /s/ Georg Rieder
Name: Georg Rieder
Title: CFO

Sandoz AG

By: /s/ Peter Rupprecht
Name: Peter Rupprecht
Title: Member of the Board

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Exhibit A
Form of NPS Report

For Section 5.2(i): a monthly breakdown of (i) gross sales, (ii) gross to net items and units, (iii) Net Sales for AG Product and Sandoz Product, and (iv) the volume of units of Sandoz Product sold.

For Section 5.2(ii): a quarterly breakdown of (i) gross sales, (ii) gross to net items and units, (iii) Net Sales for AG Product and Sandoz Product, and (iv) the volume of units of Sandoz Product sold.

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Schedule A
Argatroban®

AG Product means Argatroban® 50mg/50m1 vial, as approved by the FDA under new drug application Number 22434.

Sandoz Product means Argatroban® 125mg/125m1 vial in finished, packaged form that is sold by Sandoz in the Territory under the applicable Sandoz Trademarks, in Sandoz trade dress and under Sandoz NDC numbers.

Net Profit split

Subject to Section 5.2(ii), during the Supply Term, Sandoz will pay to Eagle [*] of the Net Profit of the AG Product. Sandoz will retain the remaining [*] of the Net Profit of the AG Product.

During the Supply Term, Sandoz will pay to Eagle [*] of the Net Profit of the Sandoz Product (and for purposes of computing the Net Profit for the Sandoz Product, any references to "AG Product" in the applicable definitions will be replaced with "Sandoz Product"). Sandoz will retain the remaining [*] of the Net Profit of the Sandoz Product.

Supply Term means the Initial Term and any Renewal Term. "Initial Term" means three (3) years from the Triggering Event (subject to any other termination rights set forth in the Agreement). Upon the expiration of the Initial Term, this Agreement will automatically renew for additional one (1) year periods (each, a "Renewal Term") unless either party gives notice of non-renewal at least six (6) months prior to the expiration of the Initial Term or any Renewal Term, as applicable.

Triggering Event means the date that Eagle provides email notice to Sandoz that Sandoz is authorized to begin commercial sales of the AG Product in the Territory.

Shelf Life means [*] or such longer period of time as approved by the FDA.

Eagle Supply of Launch Quantities to Sandoz: Transfer of the Launch Quantities will occur after the Effective Date but no later than [*].

Expiry Dating: All AG Product shipped to Sandoz will have expiration dating of no less [*] of the Shelf Life at the time of shipment by Eagle to Sandoz (or its designee); provided, that, upon the approval by the FDA of a Shelf Life equal to [*] expiration dating, then (i) all AG Product shipped to Sandoz will have expiration dating of no less than [*] remaining at the time of shipment by Eagle to Sandoz (or its designee), (ii) Eagle will use Commercially Reasonable efforts to supply AG Product with up to [*] expiration dating, and (iii) Eagle may request to ship specific lots to Sandoz with less than [*] dating, but only with the prior written approval of Sandoz.

Table 1: AG Product Cost by Unit Type

The Product Cost in this table represent Eagle's transfer price and is as follows:

NDC Number	Product	Unit Type	Product Cost
4236720384	Argatroban®	50mg/50m1	[*]

For purposes of calculation of the Net Profit split, Product Cost, as defined in Table 1 above, will be used during the entire Supply Term, [*].

Sandoz Product Cost

NDC Number	Product	Unit Type	Product Cost
00781328512	Argatroban®	125mg/125m1	[*]

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