UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2019

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from ______ to ______ .

Commission File Number 001-36306

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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading symbol**	**Name of each exchange on which registered**
Common stock, $0.001 par value per share	EGRX	The Nasdaq Global Market

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No o

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

Large accelerated filer	☒	Accelerated filer	☐	Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐						

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No x

The aggregate market value of voting Common Stock held by non-affiliates of the registrant was approximately $677,440,631 computed by reference to the last reported sale price of $55.68 per share as reported by The Nasdaq Global Market, as of the last business day of the registrant’s most recently completed second fiscal quarter, June 30, 2019. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

The number of shares outstanding of the registrant’s common stock, $0.001 par value per share, as of February 24, 2020 was 13,679,350 shares.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the definitive proxy statement for our 2020 annual meeting of stockholders, which is to be filed within 120 days after the end of the fiscal year ended December 31, 2019, are incorporated by reference into Part III of this Form 10-K, to the extent described in Part III.

EAGLE PHARMACEUTICALS, INC.

ANNUAL REPORT ON FORM 10-K

For the fiscal year ended December 31, 2019

NOTE REGARDING FORWARD-LOOKING STATEMENTS

The Eagle Pharmaceuticals, Inc. name and logo, and Ryanodex®, are either registered trademarks or trademarks of Eagle Pharmaceuticals, Inc. in the United States and/or other countries. All other trademarks, service marks or other tradenames appearing in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this report may appear without the ® or TM symbols. References to the "Company," "Eagle Pharmaceuticals," "Eagle," "we," "us" or "our" mean Eagle Pharmaceuticals, Inc., a Delaware corporation and its subsidiaries, references to "Eagle Biologics" mean Eagle Biologics, Inc. and references to "Eagle Research Lab" mean Eagle Research Lab Limited.

This Annual Report on Form 10-K includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and Section 27A of the Securities Act of 1933, as amended, or the Securities Act. For this purpose, any statements contained herein regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management, other than statements of historical facts, are forward-looking statements. 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 products and product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product;
- our ability to obtain funding for our operations;
- our plans to research, develop and commercialize our products and product candidates and our ability to successfully commercialize our products and product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- the size and growth potential of the markets for our products and product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our products and product candidates;
- our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators;
- the performance of our strategic collaborators and success of our current strategic collaborations;
- 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 retention of key scientific or management personnel;
- our use of the proceeds from our initial public offering; and subsequent follow-on 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.

Forward-looking statements are statements that are not historical facts. Words such as “believes,” “potential,” “will,” “could,” “would,” “should,” “may,” “intends,” “anticipates,” “plans,” “enables,” “entitles,” “estimates,” “projects,” “predicts,” and similar expressions are intended to identify forward-looking statements.

These forward-looking statements reflect our management’s beliefs and views with respect to future events, are based on estimates and assumptions as of the date of this Annual Report on Form 10-K, and are subject to risks and uncertainties. Additionally, these statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements. 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. Some of these important factors include our “critical accounting estimates” described in Item 7 in Part II of this Annual Report on Form 10-K and the factors set forth under the caption “Risk Factors” in Item 1A in Part I of this Annual Report on Form 10-K. Moreover, we operate in a very competitive and rapidly changing environment. Although we may elect to update forward-looking statements in the future, we specifically disclaim any obligation to do so (unless required by law), even if our estimates change, and readers should not rely on our forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

PART I

Item 1. Business

Company Overview

Organization

We are a pharmaceutical company registered at and with principal offices at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677, we also have a state-of-the-art R&D lab in Cambridge, Massachusetts.

Business

Our business model is to develop proprietary innovations to FDA-approved, injectable drugs, that offer commercial and/or functional advantages to currently available alternatives. We are focused on developing and commercializing injectable drugs, primarily in the Central Nervous System ("CNS") critical care and oncology areas, among other underserved therapeutic areas, using the U.S. Food and Drug Administration ("FDA")'s 505(b)(2) New Drug Application ("NDA") regulatory pathway. We market and/or commercialize our products through marketing partners and/or through our internal direct sales force.

For each of our current and future pre-commercial products, we target market entry no later than the entry of the first generic or as an approved 505(b)(2) NDA drug with the goal of substantially converting 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 applicable law and regulations. 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 505(b)(2) model has been validated by the approval and successful launches of our novel formulations of Ryanodex® (dantrolene sodium) ("Ryanodex") and Eagle's bendamustine ready-to-dilute ("RTD") 500ml solution ("Belrapzo"); marketed by Eagle, and rapidly infused bendamustine RTD ("Bendeka"); marketed by Teva Pharmaceutical Industries Ltd. ("Teva"), licensed to and launched jointly with Teva in 2016.

Our product portfolio now includes three approved products: Ryanodex; Belrapzo; and Bendeka. Our primary commercial partner is Teva, which through its subsidiary Cephalon, Inc. ("Cephalon") markets Bendeka.

On February 10, 2020, we received final approval from the FDA for our novel product PEMFEXY™ (pemetrexed for injection), a branded alternative to ALIMTA®.

We currently have multiple product candidates in advanced stages of development, and/or under review for approval by the FDA. Our advanced product candidates are EP-4104 (dantrolene sodium for exertional heat stroke ("EHS") and nerve agent exposure) ("EP-4104"), and EGL-5385-C-1701 ("fulvestrant"). EP-4104 and EGL-5385-C-1701, both unapproved, may address unmet medical needs in major specialty markets. Vasopressin is our first to file Abbreviated New Drug Application ("ANDA") that references Endo's Vasostrict® indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines. Our ANDA submission was accepted for filing by the FDA in March 2018. These projects and others noted below have the potential to yield 5 product launches in the next 3 years.

In 2019 and in January and February 2020, we accomplished the following with respect to our product portfolio and our development projects:

- On February 21, 2019, the FDA issued a decision in favor of the Company regarding the scope of exclusivity for Bendeka™. Pursuant to the decision, no bendamustine product (including generic versions of TREANDA®) may launch in the United States until December 7, 2022 unless it is clinically superior to Bendeka. Prior to the decision, generic versions of TREANDA were poised to enter the market in November 2019.
- As of March 29, 2019, the Company and TPIG executed an amendment to the Cephalon License Agreement to terminate Teva's obligation to pay future milestones and royalties on Bendeka sales outside of the U.S., which included

an upfront cash payment of $9 million that was recorded as License and other revenue on the consolidated statements of income.

- On April 13, 2019, the Company and Teva Pharmaceutical Industries Ltd. ("Teva") entered into an Amendment to the Cephalon License Agreement ("Cephalon License"), amending the terms of the License Agreement to increase the U.S. royalty paid to the Company and re-allocate certain litigation expenses. Pursuant to the Amendment, beginning on October 1, 2019, the Company's royalty payment will increase from 25% to 30% of Bendeka net United States sales, provided that Bendeka's orphan drug exclusivity has not been rescinded, withdrawn or waived by such date. The royalty rate will increase by one percentage point on each anniversary of October 1, 2019 until it reaches 32%, and it will remain at 32% thereafter. The Amendment also extends the U.S. royalty term for Bendeka until it is no longer sold in the United States. The previous royalty term was set to expire in 2025. The extended term coincides with the bendamustine patents with expiries through 2033. Pursuant to the amendment, Eagle will continue to be responsible for the manufacture of Bendeka for the U.S. market for so long as it is sold in the United States.
- On April 22, 2019, the Centers for Medicare & Medicaid Services ("CMS") granted unique J code for Belrapzo.
- On May 7, 2019, the Company announced positive results of its study to evaluate the neuroprotective effects of Ryanodex secondary to nerve agent exposure, conducted with the United States Army Medical Research Institute of Chemical Defense.
- On August 5, 2019, the Company announced a clinical development plan to support the submission of a NDA for our fulvestrant formulation. Fulvestrant, an estrogen receptor antagonist with no agonist properties, is approved by the FDA for the treatment of advanced hormone-related breast cancers. The therapeutic effect of fulvestrant relies on its ability to inhibit estrogen receptors ("ER") in cancer cells by binding to and downregulating, or blocking, the ER in breast cancer cells. Eagle's original formulation of fulvestrant was studied in a clinical trial conducted in 2018 in healthy post-menopausal women. A detailed review of the study data led to the hypothesis that the unique properties of our formulation would potentially allow for greater inhibition of estrogen receptors. Based on this hypothesis, the Company completed additional work designed to further enhance our proprietary drug formulation. The Company met with the FDA and mutually agreed to a clinical program that could provide an efficient approval pathway for our fulvestrant formulation. The main goal of the clinical research program is to determine if the unique properties of our fulvestrant formulation will result in greater inhibition of estrogen receptors, potentially leading to improved efficacy outcomes, including lower disease progression rates, compared to current treatment options. The Company intends to begin a pilot study shortly in healthy female volunteers to evaluate the pharmacokinetics and safety of our formulation. Once the pilot study results are reviewed, a clinical pivotal trial designed to evaluate fulvestrant exposure and estrogen receptor inhibition based upon the parameters determined with the FDA will be conducted in a target patient population. Depending on recruitment rates and other factors, the Company believes the pivotal study could be completed within approximately 12 months of commencing enrollment.
- On October 7, 2019, we announced that our marketing partner SymBio Pharmaceuticals Limited ("SymBio") has submitted a New Drug Application ("NDA") for TREAKISYM ready-to-dilute ("RTD") liquid formulation in Japan. The NDA covers all indications for which TREAKISYM is currently approved (low-grade non-Hodgkin's lymphoma, mantle cell lymphoma, and chronic lymphocytic leukemia). SymBio expects to launch the TREAKISYM RTD product in the first quarter of 2021, after obtaining marketing authorization. Approval is expected in Q4 2020, which would trigger a $5 million milestone payment to Eagle. Potential payments to Eagle could reach $10 to $25 million per year in royalties and milestones.
- On November 12, 2019, we announced that the Company has recruited a total of 41 patients at the 2015, 2018 and 2019 Hajj pilgrimages. We have submitted a plan to the FDA that proposes reviewing the data collectively for all 41 patients. If FDA agrees with this plan, Eagle plans to resubmit the NDA for EHS in response to the Complete Response Letter received in 2017.
- On December 9, 2019, we announced that the Company has commenced dosing in a pilot clinical study to assess the unique characteristics of its fulvestrant product candidate, which has the potential to enhance ER inhibition and improve patient outcomes. The results of the pilot study will inform the design of the Company's pivotal trial, which Eagle expects to commence in 2020. Fulvestrant, an estrogen receptor antagonist with no agonist properties, is approved by the FDA for the treatment of advanced hormone-related breast cancers. Breast cancer is the most commonly diagnosed cancer in women, with approximately 290,000 women diagnosed in the U.S. annually and more than 2.8 million breast cancer survivors in the U.S. today.
- On December 13, 2019, we reached a settlement agreement with Eli Lilly and Company related to the Company's novel product, PEMFEXY™ (pemetrexed for injection), a branded alternative to ALIMTA®. The agreement provides for a release of all claims by the parties and allows for an initial entry of PEMFEXY™ into the market (equivalent to approximately a three week supply of current ALIMTA®utilization) on February 1, 2022 and a subsequent uncapped entry on April 1, 2022.
- On December 16, 2019, we announced that the FDA granted orphan drug designation (ODD) for Ryanodex® (dantrolene sodium) for the treatment of organophosphate exposure. Organophosphates are a class of chemicals that

include potent pesticides and chemical weapons, known as nerve agents. Acute intoxication with organophospates may result in severe consequences, including brain damage and death. About 2,700 people in the United States are treated for accidental exposure to organophosphate pesticides every year. Eagle is currently evaluating Ryanodex for the treatment of brain damage secondary to nerve agent exposure. If approved, Ryanodex would represent the first product available for this indication.

- On January 6, 2020, we issued a press release announcing a new research agreement with NorthShore University HealthSystem in Evanston, Illinois, focused on studying Ryanodex for traumatic brain injury (TBI) in animal models. TBI can acutely cause brain lesions that result in direct tissue damage that may prompt apoptotic cell mechanisms for several weeks post-injury, which may lead to worsened long-term outcomes. Disruption of certain intracellular mechanisms may affect cell functioning and survival.
- On January 7, 2020, Tyme Technologies, Inc. and Eagle Pharmaceuticals announced a strategic collaboration to advance oral SM-88 for the treatment of patients with cancer. SM-88 is an investigational agent in two Phase 2 studies for pancreatic cancer and in a Phase 2 study for prostate cancer. Data is expected in 2021.
- On January 9, 2020, we announced that the Company has resubmitted its New Drug Application ("NDA") for Ryanodex® (dantrolene sodium for injectable suspension) for the treatment of exertional heat stroke ("EHS"), in addition to body cooling, to the FDA. Eagle believes that this submission addresses the Complete Response Letter received in July 2017. A Prescription Drug User Fee Act ("PDUFA") date of six months is anticipated for this class of resubmissions.
- On January 13, 2020, we issued a press release announcing that the Company and the University of Pennsylvania had agreed on terms of a new exclusive worldwide license agreement for the development of dantrolene sodium for the potential treatment of people living with Alzheimer’s disease, including an agreement to fund additional research and provisions regarding commercialization of products developed under the license.
- On February 10, 2020, we announced that it has received final approval from the FDA for its novel product, PEMFEXY™ (pemetrexed for injection), a branded alternative to ALIMTA®.

We have built an internal commercial team consisting of 47 direct sales representatives, support staff and management who are a part of our independent commercial organization.

Our Competitive Strengths

Our Purpose

We believe that many currently available CNS critical care and oncology injectable drugs and biopharmaceuticals 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 could 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. Likewise the viscosity of many biologic products requires them to be delivered intravenously often in time consuming and sometimes painful treatments for patients. 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.

We have and continue to engage physicians, nurses, pharmacists and key opinion leaders, to identify 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 with injectable pharmaceuticals, and a track record of success in product development, regulatory relations, and quality assurance to develop improved products.

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 before applicable generic drugs, which may be subject to protracted patent litigation that delays 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 holdings include over 30 owned or exclusively-licensed U.S. issued patents and over 10 filed U.S. patent applications, as well as several patents and patent applications that have been filed in various worldwide territories, that we believe protect or will protect, as applicable the market value of our current portfolio of products. We believe that other potential barriers to entry for our competitors consist of the following:

- 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, 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 product portfolio is focused on oncology, CNS critical care, and orphan diseases and includes five approved products, and several distinct product candidates in advanced development. Additionally, we have other exploratory candidates under our collaborative agreement with AMRI.

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 the amount of diluent required to administer the drug;
- reduction in drug waste;
- reduction in drug infusion time; and
- potential label expansion to include additional indications.

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 that represent an improvement over the currently marketed reference drug. Our strategy to achieve this goal includes:

Strengthen our product portfolio. We intend to continue to strengthen our product portfolio in the areas of oncology, CNS 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.

Enter the market no later than the first generic drug. We intend to enter the market no later than the first generic or biosimilar 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. In general, we believe that we can cost-effectively commercialize our products in the United States internally or through a contracted sales force and selected commercial arrangements, and thereby retain the commercial value of these products. We have established a small, contract specialty sales force focusing on GPOs, hospital systems and key stakeholders in acute care settings, primarily hospitals. Outside of the United States, we may utilize partners for the commercialization of our products.

Continue to build a robust intellectual property portfolio. Our patent estate includes over 30 owned or exclusively-licensed U.S. issued patents and over 10 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. 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

Belrapzo and Bendeka (Licensed to Teva and SymBio) for Chronic Lymphocytic Leukemia ("CLL") and Non-Hodgkin's Lymphoma ("NHL")

Overview

Bendamustine is an alkylating agent approved for use in CLL, and indolent B-cell 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).

U.S. Marketed Bendamustine Products

Teva currently markets its lyophilized bendamustine product under the trade name Treanda®. Teva ceased distribution of Treanda® liquid on March 30, 2016.

Limitations of Marketed Bendamustine Products

Treanda® is a lyophilized powder that requires reconstitution in water prior to use. A 500 mL intravenous (IV) administration is used over 30 or 60 minutes for CLL and NHL patients, respectively. The product is sold in single use vials creating an opportunity for product waste in certain applications.

Eagle's Solution: Belrapzo and Bendeka

The Belrapzo and Bendeka liquid formulations eliminate the need to reconstitute the drug prior to use, relative to the lyophilized presentation of Treanda®. As a result, we believe that relative to the lyophilized presentation of Treanda® there is less potential for dosing errors, less exposure to cytotoxic powders and a more efficient work flow.

Additionally, admixtures prepared with Bendeka contain lower sodium as compared with Treanda® which could be of benefit to the predominantly elderly, renally impaired and cardiovascular compromised patients. Also, Bendeka is available in a multi-use vial, which allows infusion centers and hospitals to avoid needless waste of unused drug remaining after procedures with single use vials.

Belrapzo

On May 15, 2018, the FDA granted final approval for Belrapzo, a ready-to-dilute (“RTD”), multi-dose liquid with extended drug stability for use with a 500mL intravenous, or IV, infusion bag.

Teva License- Bendeka

Bendeka is the same RTD, multi-dose liquid formulation as Belrapzo, with extended drug stability, but for use with a 50 mL IV infusion bag, which enables it to be administered in a shorter time-period than current drugs on the market and represents a label expansion from Belrapzo. We received orphan drug designation for Bendeka for CLL and NHL in July 2014. We entered into the Cephalon License to market this product. *See License Agreements - Cephalon License Agreement, below.*

Ryanodex® for Malignant Hyperthermia

Overview

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 ("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 on Accreditation of Healthcare Organizations, (the "Joint Commission") requires that all hospitals stock vials of this product at all times, generally in the operating room area.

Currently-Preexisitng Dantrolene Products for MH

The two preexisting injectable 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 addressable U.S. market opportunity for MH drugs is approximately $75 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 ("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 in adult patients 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 adult 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®

We have developed a differentiated formulation of dantrolene sodium that was approved by the FDA in July 2014 and is currently sold under the brand name, Ryanodex®, for the treatment of MH. The presentation is a 5ml vial containing 250mg of dantrolene sodium in lyophilized powder form.

We believe that the immediate benefits of our Ryanodex® formulation are clinically significant in CNS critical care situations. Specifically, Ryanodex® reduces the amount of time to reconstitute and administer dantrolene from 15 to 20 minutes with Dantrium® and Revonto®, to 1 minute, as the anesthesiologist will be able to mix and administer a dose of 250mg from a single vial of Ryanodex® in contrast to mixing and administering up to 12 or more vials of Dantrium® or Revonto®. 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.

EP-4104 (dantrolene) for Exertional Heat Stroke ("EHS")

EHS is a rare, sudden and unpredictable life-threatening medical condition. It is thought that symptoms and effects are correlated to MH and our research and development efforts suggest dantrolene may be beneficial for treating EHS.

EHS is one of the leading causes of death in athletes, including college and high-school students. EHS 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. EHS typically affects 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. 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.

Limitations of Current EHS Therapies

There are currently no FDA-approved products that treat EHS, and patients continue to die or suffer significant morbidity from the condition. The current treatment regimen for EHS is not directed at the underlying cause of the disease, but is essentially symptomatic therapy. Currently, to treat EHS, the standard treatment includes body surface cooling by water immersion or ice packs and support of organ system function with a goal of accelerating the transfer of heat from the skin to the environment. 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

EP-4104's presentation will initially be a 5mL vial containing 250mg of dantrolene in lyophilized powder form requiring reconstitution. We believe that EP-4104 may provide significant benefits over the current standard of care, which may not be readily available in most settings. Independent market research commissioned by us suggests that the worldwide peak annual revenue for EHS could exceed $400 million.

EP-4104 Clinical Development and Regulatory Status

In February 2016, the FDA granted Fast Track designation to our product candidate EP-4104 (i.e. Ryanodex® for the treatment of EHS). The FDA's Fast Track program facilitates the development and review of drugs intended to treat serious conditions and address an unmet medical need. A drug development program with Fast Track designation is afforded greater access to the FDA for the purpose of expediting the drug's development, review and potential approval to get important new drugs to the patient earlier.

On July 11, 2016, the FDA determined that no additional human safety and efficacy data would be required for the submission of EP-4101. Following the completion of additional animal studies the NDA was submitted on January 20, 2017.

On July 26, 2017, the Company received a Complete Response Letter from the FDA regarding its 505(b)(2) NDA for Ryanodex for the treatment of exertional heat stroke ("EHS"), in conjunction with external cooling methods. Based on a meeting with the FDA, the Company conducted an additional clinical trial in August 2018 during the Hajj pilgrimage, similar to the study conducted during the Hajj in 2015. The Company enrolled additional patients in its controlled clinical study of Ryanodex® (dantrolene sodium for injectable suspension) for the treatment of exertional heat stroke (“EHS”) patients during the 2019 Hajj pilgrimage held from August 9-14 in Saudi Arabia. The Company has recruited a total of 41 patients at the 2015, 2018 and 2019 Hajj pilgrimages. Eagle has submitted a plan to the FDA that proposes reviewing the data collectively for all 41 patients. If FDA agrees with this plan, Eagle plans to resubmit the New Drug Application (“NDA”) for EHS.

EP-4104 Ryanodex®* (dantrolene sodium) for the treatment of organophosphate exposure *(Nerve Agents)

Organophosphates are a class of chemicals that include potent pesticides and chemical weapons, known as nerve agents. Acute intoxication with organophospates may result in severe consequences, including brain damage and death. About 2,700 people in the United States are treated for accidental exposure to organophosphate pesticides every year. Eagle is currently evaluating Ryanodex for the treatment of brain damage secondary to nerve agent (NA) exposure. If approved, Ryanodex would represent the first product available for this indication.

We conducted an initial study in 2017 to evaluate the neuroprotective effects of Ryanodex in a rodent model of NA-induced brain damage. The animal study was conducted in a rat model of acute nerve agent (soman) exposure. Animals were randomized into each of the six study groups, including a positive control and a negative control group. Five groups received standard treatment with HI-6, atropine and midazolam. Four of the groups also received Ryanodex. Surviving animals were evaluated for neuropathology 24 hours post-soman exposure to assess the neuroprotective effects of Ryanodex in this well-established animal model.

In May 2019, we announced positive results of our study to evaluate the neuroprotective effects of Ryanodex®(dantrolene sodium) secondary to nerve agent (NA) exposure, conducted with the United States Army Medical Research Institute of Chemical Defense (USAMRICD), the nation's leading science and technology laboratory in the area of medical chemical countermeasures research and development. The study results show a p-value of 0.04 or less compared to the control group in six critical areas of the brain. We believe these results demonstrate the neuroprotective effects of Ryanodex. It has been hypothesized that nerve agent poisoning triggers intracellular calcium release in the body. The study data supports the proposed mechanism of action of Ryanodex, which modulates intracellular calcium in different organs including the brain.

Limitations of Current Therapies

While the standard treatment of atropine and oxime is essential after exposure to a nerve agent, these drugs are not neuroprotective. There are currently no FDA-approved products that treat acute intoxication with organophospates that may result in severe consequences, including brain damage and death.

Eagle's Solution: Ryanodex

Ryanodex's presentation will initially be an injectable suspension. We believe that Ryanodex may provide significant benefits over the current standard of care, which may not be readily available in most settings.

EP-4104 Clinical Development and Regulatory Status

On December 16, 2019, we announced that the FDA has granted orphan drug designation (ODD) for Ryanodex®(dantrolene sodium) for the treatment of organophosphate exposure. Eagle is currently evaluating Ryanodex for the treatment of brain damage secondary to nerve agent exposure. If approved, Ryanodex would represent the first product available for this indication.

The mission of the FDA’s Office of Orphan Products Development (OOPD) is to advance the evaluation and development of products that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions that affect fewer than 200,000 people in the U.S. In fulfilling that task, the OOPD evaluates scientific and clinical data submissions from sponsors to identify and designate products as promising for rare diseases and to further advance scientific development of such promising medical products. Orphan drug designation provides incentives for sponsors to develop products for rare diseases. These incentives may include a partial tax credit for certain clinical trial expenditures, the waiver of certain FDA user fees, and potential eligibility for seven years of orphan drug marketing exclusivity, if approved.

FDA has recommended that, under the animal rule, an additional study be conducted in a second species. Eagle expects to file a supplement to the current NDA in the second half of 2020.

EP-5101 (PEMFEXY™) for Lung Cancer

EP-5101 is an IV-administered cancer agent indicated for locally advanced or metastatic non-small cell lung cancer and mesothelioma. We have developed EP-5101 as a ready-to-use/dilute liquid form of pemetrexed that will be available in a 25mg/mL per vial. 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 a pemetrexed product is marketed by Eli Lilly and Company ("Lilly") as Alimta. Alimta is approved for use to treat non-small cell lung cancer and mesothelioma. Alimta's lyophilized formulation utilizes pemetrexed disodium. 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, worldwide sales of Alimta for the 2019 calendar year were approximately $2.1 billion.

Limitations of Alimta

Alimta, a lyophilized pemetrexed disodium formulation requiring reconstitution, adds 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. Furthermore, 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, lyophilized formulations are less preferred by the Joint Commission as compared to an RTD product.

Eagle's Solution: EP-5101 (PEMFEXY™)

EP-5101 is an RTD liquid formulation of pemetrexed. As an RTD liquid formulation, EP-5101 will not require additional time for reconstitution and may avoid certain safety concerns to healthcare professionals, including reducing exposure to the drug's cytotoxic vapors during reconstitution by healthcare providers, and potential dosing errors during mixing. This could allow for a more efficient work flow within the infusion clinic and may result in an opportunity to reduce office staff and see more patients each day.

EP-5101 (PEMFEXY™) Development and Regulatory Status

We submitted an NDA for EP-5101 on December 30, 2016 for use in non-small cell lung cancer and mesothelioma. During February 2017, we received confirmation from the FDA that the filing was accepted. On October 27, 2017, we were granted tentative approval for EP-5101 by the FDA. On December 13, 2019, the Company reached a settlement agreement with Lilly related to PEMFEXY. The agreement provides for a release of all claims by the parties and allows for an initial entry of PEMFEXY into the market on February 1, 2022 and a subsequent uncapped entry on April 1, 2022. On February 10, 2020, we received final approval from the FDA for our novel product PEMFEXY™ (pemetrexed for injection), a branded alternative to ALIMTA®.

EGL-5385-C-1701 (fulvestrant) for Breast Cancer

Fulvestrant is an injectable estrogen receptor antagonist. It is used for the treatment of hormone receptor positive advanced breast cancer for post-menopausal women whose disease has progressed following treatment with prior endocrine therapy.

Currently-Marketed Fulvestrant Products

The branded form of fulvestrant is Faslodex, a 500mg injectable product marketed by AstraZeneca plc. Worldwide sales of Faslodex were $1 billion in 2018, which included U.S. sales of $537 million.

Limitations of Faslodex

Faslodex is administered in two deep intramuscular injections of high viscosity product per dose of treatment (5 ml each) over 1-2 minutes into each buttock. The procedure is painful and Faslodex injection reactions have been associated with peripheral nerve adverse reactions, including risk of damaging the sciatic nerve.

Eagle's Solution: EGL-5385-C-1701

On August 5, 2019, the Company announced a clinical development plan to support the submission of a NDA for our fulvestrant formulation. Eagle's original formulation of fulvestrant was studied in a clinical trial conducted in 2018 in healthy post-menopausal women. A detailed review of the study data led to the hypothesis that the unique properties of our formulation would potentially allow for greater inhibition of estrogen receptors. Based on this hypothesis, the Company completed additional work designed to further enhance our proprietary drug formulation. The Company met with the FDA and mutually agreed to a clinical program that could provide an efficient approval pathway for our fulvestrant formulation. The main goal of the clinical research program is to determine if the unique properties of our fulvestrant formulation will result in greater inhibition of estrogen receptors, potentially leading to improved efficacy outcomes, including lower disease progression rates, compared to current treatment options.

On December 9, 2019, we announced that the Company has commenced dosing in a pilot clinical study to assess the unique characteristics of its fulvestrant product candidate, which has the potential to enhance estrogen receptor ("ER") inhibition and improve patient outcomes. The results of the pilot study will inform the design of the Company's pivotal trial, which Eagle expects to commence in 2020.

Additional Products in our Portfolio

Vasopressin

Vasopressin injection is indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines. We filed and ANDA in April 2018 for a generic version of VASOSTRICT® (vasopressin IV solution (infusion), which variously covers either vasopressin-containing pharmaceutical compositions or methods of using a vasopressin-containing dosage form to increase blood pressure in humans. In May 2018, the NDA owner filed a lawsuit against us within the 45-day deadline to invoke a 30-month stay of FDA approval pursuant to the Hatch-Waxman legislative scheme. In August 2018, Eagle filed an answer and a counterclaim for non-infringement and invalidity of asserted patents, and filed an amended answer and counterclaims on October 30, 2019. The court issued a Markman ruling on July 1, 2019. On December 20, 2019, Par dismissed with prejudice claims of three of the patents asserted against Eagle, and the Court entered an Order reflecting that dismissal on December 27, 2019. Mediation is scheduled to take place on March 3, 2020. Trial is scheduled to begin May 18, 2020.

Other Opportunities

We are pursuing several additional potential products and product indications that address broad indications such as oncology, emergency medicine, 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.

In addition to our internal efforts, in January 2016 we entered into an agreement with AMRI to jointly develop and manufacture several select and complex parenteral drug products for registration and subsequent commercialization in the United States.

Under the terms of the agreement, AMRI will develop and initially provide cGMP manufacturing and analytical support for the registration of the new product candidates. We will be responsible for advancing the product candidates through clinical trials and regulatory submissions.

Sales and Marketing

Other than products subject to existing commercialization arrangements, we commercialize our product portfolio in the United States with our commercial organization. Ryanodex and Belrapzo are marketed by our internal commercial team consisting of 47 direct sales representatives, support staff and management.

Major Customer

The Company is dependent on its commercial partner to market and sell Bendeka; therefore, the Company's future revenues are highly dependent on the collaboration and distribution arrangement with Teva.

Teva markets Bendeka through the Cephalon License. Pursuant to that license agreement, Teva pays the Company a royalty based on net sales of the product and also purchases the product from the Company. A disruption in this arrangement, caused by among other things, a supply disruption, loss of exclusivity or the launch of a superior product would have a material adverse effect of the Company’s financial position, results of operations and cash flows.

The total revenues and accounts receivables broken down by major customers as a percentage of the total are as follows:

	Year Ended December 31,		
	2019	**2018**	**2017**
Net revenues			
Cephalon, Inc. (Teva) - See Revenue Recognition	77%	75%	79%
Other	23%	25%	21%
	100%	100%	100%

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.

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 eight issued U.S. patents, and several pending U.S. patent applications, along with foreign counterparts that include both issued patents and pending applications. The issued U.S. patents 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.

We are the sole owner of over 10 issued patents, several pending U.S. patent applications, and multiple patents and/or 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 between 2031 and 2033.

We are the owner of U.S. Patent No. 8,431,539 expiring July 20, 2031 and covering daptomycin.

Eagle also has a patent portfolio of issued and/or pending U.S. patent applications and corresponding foreign patent application in a range of countries that cover its biologics platform technologies. We are the sole owner of U.S. Patent Nos. 9,833,513, 9,913,905 and 9,925,263 expiring between 2034 and 2036.

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., ("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. On August 3, 2016, the Company amended our agreement with Lyotropic Therapeutics, Inc. to reduce future royalties related to Ryanodex net sales to 3% (subject to further reduction upon the occurrence of certain triggering events) in exchange for $15 million.

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

In March 2008 we entered into a development and license agreement with Robert One, LLC ("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 (the "Robert One (bendamustine) Subject Products") and granted us an exclusive, sub-licensable, 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.

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 (i) at 10%, pursuant to an amendment in 2013, for bendamustine products and (ii) at 50% for products, other than bendamustine products, that achieve regulatory approval and are commercialized on the basis of a 505(b)(2) application (provided that we are entitled to recoup all of our expenses related to the development of a product commercialized under a 505(b)(2) application prior to splitting the profits we receive from such product), and (iii) at 30% with respect to products, other than bendamustine 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 (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.

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 ("the Robert One 2009 Subject Products") and granted us an exclusive, sub-licensable, license under Robert One's intellectual property rights to develop make, use, sell and import Robert One 2009 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.

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 2009 Subject Product by us and our affiliates in the Territory (i) at 25% for pemetrexed parental formulation (ii) at 50% for Robert One 2009 Subject Products other than pemetrexed that achieve regulatory approval and are commercialized on the basis of a 505(b)(2) application (provided that we are entitled to recoup all of our expenses related to the development of a product commercialized under a 505(b)(2) application prior to splitting the profits we receive from such product), and (ii) at 30% with respect to Robert One 2009 Subject Products other than pemetrexed 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 2009 Subject Product and the expiration of the last valid claim covering such Robert One 2009 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 2009 Subject Product in a country in the territory.

Cephalon License Agreement

On February 13, 2015, we submitted an NDA to the FDA for Bendeka which was approved by the FDA on December 8, 2015. Also, on February 13, 2015, we entered into the Cephalon License with Cephalon, for U.S. and Canadian rights to Bendeka for treatment of patients with CLL and patients with NHL. Subsequently, with the consent of the Company, Cephalon assigned to Teva Pharmaceuticals International GmbH (“TPIG”) all of Cephalon’s rights and obligations under the Cephalon License. Accordingly, all references to “Cephalon” or to the “Cephalon License” and the related supply agreements for Bendeka should be read and construed as references to TPIG and to the license agreement and supply agreements for Bendeka to which the Company and TPIG are now parties. Pursuant to the terms of the Cephalon License, Cephalon is responsible for all U.S. commercial activities for the product including promotion and distribution, and we are responsible for obtaining and maintaining all regulatory approvals and conducting post-approval clinical studies. Additionally, under the terms of the Cephalon License, the Company received an upfront cash payment of $30 million, received a $15 million milestone payment in January 2016 in connection with the FDA approval of Bendeka in December 2015, received a $40 million milestone in the fourth quarter of 2016 in connection with the receipt of the J-Code for Bendeka and in Q1 of 2017, Bendeka reached $500 million in cumulative net sales, triggering an additional $25 million sales-based milestone payment. In addition, the royalty payments of 20% of net sales of the product that the Company was entitled to receive increased to 25% on receipt of the J-Code. In connection with the Cephalon License, the Company has entered into a supply agreement with Cephalon, pursuant to which the Company is responsible for supplying product to Cephalon. During the quarter-ended September 30, 2016, the Company entered into an amendment to that certain Exclusive License Agreement (the "Cephalon License") with Cephalon and the related supply agreements for Bendeka. The amendment expands the geographical scope of the rights granted under the original agreement to include certain territories outside the US and Canada. In accordance with this amendment, the Company recorded $1.75 million in license and other revenue on the statements of operations for the year-ended December 31, 2016. The Company is also eligible to receive up to $750 thousand on each regulatory approval received in certain additional territories, not to exceed $2.25 million, as well as royalties on future sales.

On April 13, 2019, the Company and Teva entered into an Amendment to the Cephalon License, amending the terms of the License Agreement to increase the U.S. royalty paid to the Company and re-allocate certain litigation expenses. Pursuant to the Amendment, beginning on October 1, 2019, the Company's royalty payment will increase from 25% to 30% of Bendeka net United States sales, provided that Bendeka's orphan drug exclusivity has not been rescinded, withdrawn or waived by such date. The royalty rate will increase by one percentage point on each anniversary of October 1, 2019 until it reaches 32%, and it will remain at 32% thereafter. The Amendment also extends the U.S. royalty term for Bendeka until it is no longer sold in the United States. The previous royalty term was set to expire in 2025. The extended term coincides with the bendamustine patents with expiries through 2033. Pursuant to the amendment, Eagle will continue to be responsible for the manufacture of Bendeka for the U.S. market for so long as it is sold in the United States.

In March 2019, we received an upfront cash payment of $9.0 million upon execution of an amendment to the Cephalon License to terminate Teva's obligation to pay future milestones and royalties on Bendeka sales outside of the U.S.

Cephalon Settlement and License Agreement

On February 13, 2015, we entered into the Cephalon Settlement Agreement with Cephalon, in connection with the Cephalon License, pursuant to which the parties agreed to settle the pending patent infringement claims against each other regarding Cephalon's US Patent No. 8,791,270, under which we agreed to enter into a Consent Judgment regarding the '270 patent. As part of the Cephalon Settlement Agreement, Cephalon has agreed to waive its orphan drug exclusivities for the treatment of patients with CLL and patients with NHL.

SymBio Product Collaboration and License Agreement

On September 20, 2017, we entered into the SymBio License with SymBio for the rights to develop and commercialize EP-3101 and Bendeka (collectively, the "Products") in Japan. Under the SymBio License, SymBio will be responsible for all development of the Products in Japan and for obtaining and maintaining all regulatory approvals of the Products in Japan, with a target for regulatory approval of a Product in Japan in 2020. SymBio will bear all costs of development of the Products in Japan except that, if Japanese regulatory authorities require a certain clinical study to be conducted as a condition for approving one of the Products in Japan, we would share 50% of the out-of-pocket costs of that clinical study up to a specified dollar amount as a reduction to future royalty payments. Based on our assessment of the probability of additional costs, we have not deferred revenue on the SymBio License. SymBio will also be responsible, at its sole cost, for all marketing, promotion, distribution and sales of the Products in Japan and is obligated to launch the Products and meet certain minimum detailing, promotion and marketing commitments in connection with commercialization of the Products in Japan.

SymBio currently markets in Japan TREAKISYM®, a lyophilized powder formulation of bendamustine hydrochloride indicated for CLL, relapsed or refractory low-grade NHL, mantle cell lymphoma ("MCL"), and as a first line treatment of low-grade NHL and MCL. Under the SymBio License, SymBio may continue to market TREAKISYM® in Japan and SymBio will be permitted to develop and market certain other bendamustine hydrochloride products in Japan for limited indications.

Pursuant to the terms of the SymBio License, Eagle and SymBio will enter into a separate supply agreement, under which we will be responsible for manufacturing and supplying the Products to SymBio for development and commercialization in Japan. After a period of time following launch of a Product, SymBio will have the right to assume the responsibility for manufacturing of the Products in and for Japan. Under the SymBio License, we will retain the right to control the prosecution, maintenance and enforcement of our patents covering the Products, both inside and outside of Japan.

Under the SymBio License, we earned an upfront non-refundable cash payment of $12.5 million in the third quarter of 2017, and we are eligible to receive a milestone payment upon approval of a Product in Japan and a milestone payment upon achievement of certain cumulative net sales of the Products in Japan. After regulatory approval of a Product in Japan, we will also receive tiered, low double-digit royalties on net sales of the Products in Japan for so long as there are patents covering the Products in Japan or regulatory exclusivity for the Products in Japan.

On October 7, 2019, we announced that SymBio has submitted a NDA for TREAKISYM RTD liquid formulation in Japan. The NDA covers all indications for which TREAKISYM is currently approved (low-grade non-Hodgkin's lymphoma, mantle cell lymphoma, and chronic lymphocytic leukemia). SymBio expects to launch the TREAKISYM RTD product in the first quarter of 2021, after obtaining marketing authorization. Approval is expected in Q4 2020, which would trigger a $5 million milestone payment to Eagle. Potential payments to Eagle could reach $10 to $25 million per year in royalties and milestones.

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 payors. 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 for Drugs

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug and Cosmetic Act ("FDCA"), and in the case of biologics, the Public Health Service Act (“PHSA”) 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 biologic 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 ("cGLP") regulations;
- submission to the FDA of an Investigational New Drug ("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 ("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 ("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 or BLA;
- satisfactory completion of a potential review by an FDA advisory committee, if applicable; and
- FDA review and approval of the NDA or BLA.

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.

Phase 3: 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 application 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 applications is subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved application is 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 application for filing. In this event, the application 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 application 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 tentative approval is issued to a 505(b)(2) NDA if the sponsor must await the expiration of an Orange Book listed patent covering the reference product. 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 application, 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 or BLA approval, the FDA may require a Risk Evaluation and Mitigation Strategies ("REMS") program to help ensure that the benefits of the drug outweigh the potential risks. If the FDA determines a REMS program is necessary during review of the application, the drug sponsor must agree to the REMS plan at the time of approval. A REMS program 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 program 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 supplements as it does in reviewing original applications.

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. However, companies may share truthful and not misleading information that is otherwise consistent with a product’s FDA approved labeling. 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 the 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 ("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 pharmacological 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.

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.

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, the U.S. Department of Health and Human Services ("HHS") and its various enforcement divisions, such as the Centers for Medicare & Medicaid Services ("CMS"), the Office of Inspector General ("OIG"), the Office for Human Research Protections ("OHRP"), and the Office of Research Integrity ("ORI"), state Attorneys General, state Medicaid Fraud Control Units, or MFCUs, and other state and local government agencies. Healthcare laws and regulations that may govern our business include the following.

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 to induce in return for either the referral of an individual, or the purchase, recommendation, leasing, ordering or furnishing of a 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. 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, which are narrowly drawn, 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 federal 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 Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), among other things, amended the intent standard under the federal Anti-Kickback Statute 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.

Federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalty laws, which prohibit, 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 the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. The "*qui tam*" provisions of the federal civil False Claims Act allow a private individual to bring a civil action 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 federal civil 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 federal civil 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 federal civil 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.

Also, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created several additional federal civil and
criminal statutes that prohibit 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. Like the federal Anti-Kickback Statute, the ACA amended certain of these federal criminal statutes 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.

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 certain healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, which are independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity, 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 the Health Information Technology for Economic and Clinical Health Act ("HITECH"), which expanded certain 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 Payments Sunshine Act created under Section 6002 of the ACA and its implementing regulations require that certain manufacturers of drugs, devices, biologics, and medical supplies 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, physicians and teaching hospitals. Applicable manufacturers and applicable group purchasing organizations must also report annually to the CMS certain ownership and investment interests held by physicians (as defined above) and their immediate family members.

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. Several states have also 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 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 significant administrative, criminal and civil monetary penalties, damages, fines, imprisonment, disgorgement, contractual damages, reputational harm, exclusion from participation in government healthcare programs, integrity obligations, 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. 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.

To the extent that any of our products are sold in a foreign country, we also 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 approved product portfolio, as well as our pre-clinical and clinical 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. In the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. 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/or 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. Further, 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 and administrative proposals. Our results of operations and business could be adversely affected by current and future third-party payor policies as well as healthcare legislative and administrative 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 will likely affect our future 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, improve access, and improve quality.

By way of example, in March 2010, the ACA was passed, which significantly changed health care financing by both governmental and private insurers. The provisions of the ACA of importance to the pharmaceutical and biotechnology industry included, 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;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most 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 now agree to offer 70% 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 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 federal civil False Claims Act and the federal Anti-Kickback Statute, 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;
- new requirements under the federal Physician Payments Sunshine Act for manufacturers to report information related to payments and other transfers of value made to physicians, as defined by such law, 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.

There have been judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the U.S. Presidential administration to repeal or replace certain aspects of the ACA. Since January 2017, the U.S. President has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. For example, the Tax Cuts and Jobs Act of 2017 (the “Tax Act”) included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole”. In December 2018, CMS published a new final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace ACA will impact ACA.

Other healthcare legislative changes have been proposed and adopted since the ACA was enacted. For example, 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 and, following passage of subsequent legislation, including the BBA, will remain in effect through 2029 unless additional Congressional action is taken. Additionally, 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, including hospitals, imaging centers, and cancer treatment centers, 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.

In addition, the Drug Supply Chain Security Act signed into law on November 27, 2013 imposes on manufacturers of certain pharmaceutical products new obligations related to product tracking and tracing, among others, which will be phased in over ten years. Among the requirements of this new legislation, manufacturers subject to this federal law will be required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Covered manufacturers will also be required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this legislation, covered manufacturers will have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

We expect that additional state and federal healthcare reform measures will be adopted in the future. For example, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, the current U.S. Presidential administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. Previously, the current U.S. Presidential administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning on January 1, 2020. The final rule codified a CMS policy change that was effective January 1, 2019. While some of these and other proposed measures may require additional authorization to become effective, Congress and the current U.S. Presidential administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Any additional healthcare reform measures could further constrain our business and/or 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 December 31, 2019, we had a total of 108 employees. 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.

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.

Available Information

Our corporate website address is www.eagleus.com. Information contained on or accessible through our website is not a part of this Annual Report on Form 10-K, and the inclusion of our website address in this Annual Report on Form 10-K is an inactive textual reference only. We make our Annual Reports on Form 10-K, Quarterly reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports available free of charge on our website as soon as reasonably practicable after we file such reports with, or furnish such reports to, the Securities and Exchange Commission, or SEC. You can access our filings through the SEC's internet site: www.sec.gov.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below in addition to the other information included or incorporated by reference in this Annual Report on Form 10-K, as well as our other public filings with the Securities and Exchange Commission. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer. In that case, the trading price of our common stock could fall. In addition to the risk factors identified under the captions below, the operation and results of our business are subject to risks and uncertainties identified elsewhere in this Annual Report on Form 10-K as well as general risks and uncertainties such as those relating to general economic conditions and demand in the market for our products.

Risks Related to Our Financial Condition and Need for Additional Capital

If we cannot sustain profitability, our business, prospects, operating results and financial condition would be materially harmed.

We have focused primarily on developing a broad product portfolio and currently have final regulatory approval for a limited number of 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. Although we had net income of $14.3 million for the year ended December 31, 2019, $31.9 million for the year ended December 31, 2018 and $51.9 million for the year ended December 31, 2017, we incurred significant net losses prior to 2015.

We have devoted most of our financial resources to product development and may not generate significant revenue from sales of our product candidates in the near-term, if ever. As of December 31, 2019, we commercialize the following main products, Ryanodex, Belrapzo and Bendeka.

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 may incur losses and negative cash flows in the future. We believe that our existing cash and cash equivalents, together with interest thereon and expected operating cash flows, are sufficient to fund our future operations and debt costs for a minimum of twelve months.

If we fail to obtain additional financing, we could 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, both internally and through our external joint development agreements, such as with AMRI. Changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, our product commercialization or 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 additional 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 additional 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 products and 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 products, or to product candidates that we otherwise would seek to develop or commercialize ourselves; or
- significantly curtail, or cease, operations.

The occurrence 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 results in increased fixed payment obligations. In addition, the incurrence of indebtedness also results 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. On November 8, 2019, the Company entered into the Second Amended and Restated Credit Agreement (the “Revised Credit Agreement”), with JPMorgan Chase Bank, N.A., as administrative agent (the “Agent”) and the lenders party thereto, which replaced the Company’s existing credit agreement, dated as of August 8, 2017 (the "Amended Credit Agreement"). The terms and amounts borrowed under the Revised Credit Agreement includes a drawn term loan of $40 million and a undrawn revolving credit facility of $110 million. The schedule of principal payments for the new term loan facility has been extended until November 8, 2022.

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.

Risks Related to Regulatory Approval

We cannot give any assurance that we will receive regulatory approval for our 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 product candidates. Any delay or setback in the development of any of these product candidates could adversely affect our business. For example, in January 2020, the Company has resubmitted its NDA for Ryanodex® (dantrolene sodium for injectable suspension) for the treatment of EHS, in addition to body cooling, to the FDA. Eagle believes that this submission addresses the Complete Response Letter received in July 2017. Although we believe that this submission addresses the Complete Response Letter received in July 2017, we may receive another Complete Response Letter, rather than approval, for this NDA. Our planned development, approval and commercialization of these product candidates may fail to be completed in a timely manner or at all. The FDA or other foreign regulatory agency may refuse or delay approval of our product candidates for failure to collect sufficient clinical or animal safety data and require us or our collaborators to conduct additional clinical or animal safety studies, which may cause lengthy delays and increased costs to our programs. 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. If we do not obtain regulatory approval of new products or additional indications for existing products, or are significantly delayed or limited in doing so, our revenue growth will be adversely affected, we may experience surplus inventory, or our business may be materially harmed and we may need to significantly curtail operations.

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

Our strategy is to 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 products and 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 products or product candidates against other drugs, the opportunity for our products and 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 products or 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 Federal Food, Drug and Cosmetic Act ("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 products or product candidates 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 products or product candidates. 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 products or product candidates would materially adversely impact our ability to successfully commercialize our product candidates or negatively impact our ability to gain market acceptance and market share for our products.

If the FDA does not conclude that our product candidates satisfy the requirements for the regulatory approval, or if the requirements for approval of any of our product candidates 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 those small molecule product candidates described in this Annual Report on Form 10-K.

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 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 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 such 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 our chosen 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.

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 or its equivalent, 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 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 our products or product candidates containing active ingredients that have already been approved and the side effects arising from the use of the active ingredient or class of drug in our products or product candidates are generally known, our products or product candidates may still cause undesirable 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 five NDA products, but no BLA products, and we have multiple NDA product candidates in advanced stages of development and other exploratory candidates under development. However, 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 or existing biologic drugs meet the criteria for our chosen 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 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. There can be no assurance that the FDA will ultimately approve any submitted NDA by us in a timely fashion. For example, in March of 2016 we received a Complete Response Letter from the FDA stating that while their initial review of our NDA for EP-6101 was complete, they could not approve the application in its present form and requested additional information. We have elected not to pursue the application further or seek to exploit EP-6101 for various reasons including the costs associated with addressing the information request in the FDA's Complete Response Letter and because additional generic bivalirudin products have entered or are entering the market. Additionally, in July of 2017 we received a Complete Response Letter from the FDA regarding our 505(b)(2) NDA for Ryanodex for the treatment of EHS, in conjunction with external cooling methods. On January 9, 2020, we announced that the Company has resubmitted its NDA for RYANODEX® (dantrolene sodium for injectable suspension) for the treatment of EHS, in addition to body cooling, to the FDA. Although we believe that this submission addresses the Complete Response Letter received in July 2017, we may receive another Complete Response Letter, rather than approval, for this NDA.

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 candidates.

Some of 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.

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. However, we may share truthful and not misleading information that is otherwise consistent with our products’ FDA 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 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 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 application. 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 drug application. 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 health care programs and require curtailment or restructuring of our operations;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending application or supplements to an application submitted by us;
- seize product; or
- refuse to allow us to enter into government contracts.

Similar post-market 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 FDA and similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulatory bodies; (2) health care laws and regulations, including 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 health care 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, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, integrity obligations, 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 health care professionals, principal investigators, consultants, customers (actual and potential) and third party payors, in addition to our general business operations, are and will continue to be subject, directly or indirectly, to federal and state health care fraud and abuse 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, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, integrity obligations, 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 civil False Claims Act. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as current, proposed and future sales, marketing and education programs. In addition, we may be subject to patient data privacy and security regulation by the federal government, state governments and foreign jurisdictions in which we conduct our business, as well as transparency requirements. The U.S. healthcare laws and regulations 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 health care program, such as the Medicare and Medicaid programs. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, ACA, among other things, amends the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the ACA provides 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;
- federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalty laws, which prohibit and impose penalties for, among other things, individuals or entities knowingly presenting, or causing to be presented, claims for payment or approval from the federal government including Medicare, Medicaid or certain other governmental health care programs that are false or fraudulent or knowingly making or causing to be made 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 additional federal civil and criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care 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 health care 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, health care benefits, items or services relating to health care 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 health care providers, health plans and health care clearinghouses, known as covered entities, as well as their respective business associates, independent contractors or agents of covered entities 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 Payments Sunshine Act, created under Section 6002 of the ACA, and its implementing regulations, which requires certain 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' Centers for Medicare & Medicare Services, or CMS, 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 such physicians and their immediate family members;

- 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 health care 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 health care 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 health care 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 drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

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 health care laws mentioned above, among other foreign laws.

Efforts to ensure that our business arrangements will comply with applicable health care 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 health care 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, significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, integrity obligations, 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 products and 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 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 products and 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 health care 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 if our commercial partners do not adequately perform, the commercial opportunity for our products may be diminished.

Although we intend to establish a commercial organization to promote certain of our approved products in the United States, we currently have limited experience, and the cost of establishing and maintaining such an organization may exceed the benefit of doing so. We have very limited 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.

We and any other commercialization partner we engage in the future may not be able to attract, hire, train and retain qualified sales and sales management personnel. If we or our future partners, if any, are not successful in maintaining an effective number of qualified sales personnel, our ability to effectively market and promote our products may be impaired. Even if we are able to effectively build and maintain such sales personnel, such efforts may not be successful in commercializing our products.

The efforts of our partners in many instances would likely be outside our control. If any future partner is unsuccessful in their efforts, or we are unable to maintain such commercial partnerships or to effectively establish alternative arrangements for our products, our business could be adversely affected.

A substantial portion of our total revenues is derived from sales of a limited number of products.

We derive a substantial portion of our revenue from royalties derived from the sales of one product: Bendeka. This product is sold by our partner Teva Pharmaceuticals. During the year ended December 31, 2019, Bendeka accounted for approximately 77% of our total revenue. The sale of our products can be significantly influenced by the efforts of our partners, which are out of our control, as well as market conditions and regulatory actions. We may experience decreases in the sale of our products in the future as a result of actions taken by our competitors, such as price reductions or entry into the market for competing products, or as a result of regulatory actions related to our products or competing products, which could have a material impact on our results of operations and financial condition.

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.

We may enter into agreements with third parties to market our products 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;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- 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 or public health issues or pandemics including the coronavirus.

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. Many of our competitors both in the United States and internationally, include major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. For example, Ryanodex, and products with dantrolene sodium as the API, is currently marketed in the United States by, among others, Endo International plc, Impax Laboratories, Inc., Hikma Pharmaceuticals, LLC, US WorldMeds, LLC, Mylan Institutional, LLC, and Elite Laboratories, Inc. While our formulations of this product is distinct, and we believe improvements, compared to those competitors mentioned, competition from these products on factors such as price and availability effect our commercial efforts. Additionally, we must compete with alternative drug treatments (as opposed to alternative formulations) for many of the indications that our products are approved to treat.

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 our products 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 persuade 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 application we submit.

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 health care providers.

If our competitors market products that are more effective, safer or less expensive than our products or product candidates, or that reach the market sooner than our product candidates, 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, products 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 or negatively impact our ability to gain market acceptance and market share for our products.

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 health care programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. In the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. 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. Reimbursement by a third party payor may depend upon a number of factors, including but not limited to, the third party payor’s determination that use of a product is: a covered benefit under its health plan; safe, effective, and medically necessary; appropriate for the specific patient; cost-effective; and/or neither cosmetic, experimental, nor investigational.

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 our products 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 health care 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 could require us to provide scientific, clinical and cost effectiveness 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. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability.

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 commercial products, and our pre-clinical and clinical 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.

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

The United States and some foreign jurisdictions are considering, or have enacted, a number of legislative and regulatory proposals to change the health care 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 health care systems with the stated goals of containing health care 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.

By way of example, in March 2010, the ACA was passed, which significantly changed health care financing by both governmental and private insurers. There have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the U.S. Presidential administration to repeal or replace certain aspects of the ACA.. Since January 2017, the U.S. President has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. For example, the Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the PPACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole”. In December 2018, CMS published a new final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Act. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the PPACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace ACA will impact ACA and our business. We cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, 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 and, following passage of the Bipartisan Budget Act of 2015 as well as other legislative amendments, including the BBA, will remain in effect through 2029 unless additional Congressional action is taken. Additionally, 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.

Further, under the Drug Supply Chain Security Act signed into law on November 27, 2013, certain drug manufacturers will be subject to product identification, tracing and verification requirements, among others, that are designed to improve the detection and removal of counterfeit, stolen, contaminated or otherwise potentially harmful drugs from the U.S. drug supply chain. These requirements will be phased in over several years and compliance with this law will likely increase the costs of the manufacture and distribution of drug products, which could have an adverse effect on our financial condition.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and adopted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, the current U.S. Presidential administration’s budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. Further, the U.S. Presidential administration previously released a “Blueprint”, or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning on January 1, 2020. The final rule codified a CMS policy change that was effective January 1, 2019. While some of these and other proposed measures may require additional authorization to become effective, Congress and the current U.S. Presidential administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have

increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. The full impact of these laws, as well as other new laws and reform measures that may be proposed and adopted in the future remains uncertain, but may result in additional reductions in Medicare and other health care funding, or higher production costs which could have a material adverse effect on our customers and, accordingly, our financial operations.
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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 contract research organizations (each a “CRO”) 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 regulations and other laws regarding current good clinical practice (“ 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 Council for 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.

If any of our current strategic collaborators fail to perform their obligations or terminate their agreements with us, the development and commercialization of the product candidates under such agreements could be delayed or terminated and our business could be substantially harmed.

In 2015, we entered into the Cephalon License, with Cephalon (Teva) for U.S. and Canadian rights to Bendeka for treatment of patients with CLL and patients with NHL. Pursuant to the terms of the Cephalon License, as has been amended from time to time, Cephalon is responsible for all U.S. commercial activities for the product including promotion and distribution, and we are responsible for obtaining and maintaining all regulatory approvals and conducting post-approval clinical studies.

This strategic collaboration may not be scientifically or commercially successful due to a number of important factors, including the following:

- If we fail to maintain any regulatory approvals, or otherwise materially breach the agreement, we may not receive all anticipated royalty payments.
- Cephalon has significant discretion in determining the efforts and resources that it will apply to their strategic collaboration with us. The timing and amount of any cash payments, and royalties that we may receive under such agreements will depend on, among other things, the efforts, allocation of resources and the commercialization of our product by Cephalon under the Cephalon License;
- Cephalon currently markets a competitive bendamustine product, Treanda®, in the United States. In addition, it is possible that Cephalon may develop and commercialize, either alone or with others, or be acquired by a company that has, products that are similar to or competitive with the product candidates that they license from us;
- Cephalon may change the focus of their commercialization efforts or pursue higher-priority programs;
- Cephalon may terminate its strategic collaboration with us on short notice, which could make it difficult for us to attract new strategic collaborators or adversely affect how we are perceived in the scientific and financial communities;
- Cephalon has the right to maintain or defend our intellectual property rights licensed to them in their territories, and, although we may have the right to assume the maintenance and defense of our intellectual property rights if they do not, our ability to do so may be compromised by our strategic collaborators' acts or omissions; and
- Cephalon may not comply with all applicable regulatory requirements, or fail to report safety data in accordance with all applicable regulatory requirements.
- If Cephalon fails to effectively commercialize our product, we may not be able to replace them with another collaborator.
- If our agreement with Cephalon terminates, we are required to pay them a portion of our future profits on the product.

  Any of these events could have a material adverse effect on our business, results of operations and our ability to achieve future profitability, and could cause our stock price to decline.

We rely on third parties to manufacture commercial supplies of our products 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 product 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 to manufacture 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 our products or 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 occurrence 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 products and 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 products and 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 products or product candidates that may not be detectable in final product testing. The development, manufacture, supply, and distribution of our products, 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 products and 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 our products and product candidates, and any disruption in the chain of supply may impact production and sales of our products 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 products and product candidates. Because of the unique equipment and process for manufacturing our products transferring manufacturing activities 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. We may, however, be unable to advance the development of our products and 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. We have entered into collaboration and promotion agreements with third parties, such as the agreement with AMRI, but there is no assurance these arrangements will be successful. If we are unable to enter into any future 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.

On January 7, 2020, Tyme Technologies, Inc. and Eagle Pharmaceuticals announced a strategic collaboration to advance oral SM-88 for the treatment of patients with cancer. If we are able to establish additional collaboration arrangements, any such collaborations, in addition to the collaboration with Tyme, 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 or product candidate, including Tyme, we can expect to relinquish some or all of the control over the future success of that product or 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 may be subject to a number of additional risks associated with our collaborations with third parties, the occurrence of which could cause 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, ("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.

Our approved products may not achieve expected levels of market acceptance.

Even if we are able to obtain regulatory approvals for our product candidates, the success of those products is dependent upon market acceptance. Levels of market acceptance for our product candidates could be affected by several factors, including:

- the availability of alternative products from our competitors;
- the price of our products relative to those of our competitors;
- the timing of our market entry;
- the ability to market our products effectively at the retail level;
- the perception of patients and the healthcare community, including third-party payors, regarding the safety efficacy and benefits of our drug products compared to those of competing products; and
- the acceptance of our products by government and private formularies.

Some of these factors are not within our control, and our products may not achieve expected levels of market acceptance. Additionally, continuing and increasingly sophisticated studies of the proper utilization, safety and efficacy of pharmaceutical products are being conducted by the industry, government agencies and others which may call into question the utilization, safety and efficacy of previously marketed products. In some cases, studies have resulted, and may in the future result, in the discontinuance of product marketing or other risk management programs such as the need for a patient registry.

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, which include our Chief Executive Officer, Chief Financial Officer, Chief Medical Officer, and President and Chief Operating Officer. The loss of these executives' 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 December 31, 2019, we had a total of 108 employees in the United States. 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 and 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 our products 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 our products 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, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products, 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 our products 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. Cybersecurity attacks in particular are evolving and include, but are not limited to, malicious software, attempts to gain unauthorized access to data and other electronic security breaches that could lead to disruptions in systems, misappropriation of our confidential or otherwise protected information and corruption of data. The loss, theft or sabotage 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 any products we may sell.

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 unforeseen 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 may be constrained by our obligations under our Credit Agreement to operate our business to its full potential.

Our Revised Credit Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness and dividends and other distributions. Under the terms of the Revised Credit Agreement, we are required to comply with (a) a maximum senior secured net leverage ratio, (b) a maximum total net leverage ratio and (c) a minimum fixed charge coverage ratio. These terms may restrict our ability to operate our business in the manner we deem most effective or desirable, and may restrict our ability to fund our operations through new public offerings of our common stock or strengthen our candidate development pipeline through acquisitions or licenses which cause us to exceed our maximum senior secured net leverage ratio.

Although we have not currently drawn on the Revised Credit Agreement, failure to comply with the representations and warranties or affirmative and negative covenants could constitute an event of default which, if continued beyond the cure period, would allow the administrative agent, at the request of or with the consent of the lenders holding a majority of the loans and commitments under the facility, to terminate the commitments of the lenders to make further loans and declare all the obligations of the loan parties under the Revised Credit Agreement to be immediately due and payable, either of which could harm our business.

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 United States 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 our products 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 United States 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 our products 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 being issued.

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 our products 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 ingredients in our currently marketed products (Ryanodex, Bendeka, Argatroban and Non-Alcohol Docetaxel Injection) has expired, and there is therefore no composition of matter patent protection available for the active ingredient in such products. 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 our products 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 could be able to commercialize products with the same active ingredients as our 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 our products 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 our products and our product candidates could be significantly harmed if competitors are able to develop and commercialize alternative formulations of our products and our product candidates that are different from ours and do not infringe our issued patents covering our products.

Ryanodex® (dantrolene sodium), Belrapzo, and Bendeka ® among other products have 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.

Ryanodex, Belrapzo, and Bendeka, among other of our products, have been approved by the FDA, and we anticipate that other product candidates will be approved by the FDA in the future. One or more third parties may also challenge the patents that we control covering our products in court or the USPTO, 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 products or 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 products or 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 products and product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business, financial condition and results of operations.

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 products or 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, financial condition and results of operations. 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 products or 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, financial condition and results of operations.

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

Risks Related to Ownership of Our Common Stock

Our stock price may continue to fluctuate significantly.

Our initial public offering was completed in February 2014 at a public offering price of $15.00 per share. The trading price of our common stock has fluctuated significantly in the past and 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 our approved products 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 the structure of healthcare payment systems;
- 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 our products or any of our product candidates;
- adverse regulatory decisions;
- introduction of new products or technologies by our competitors;
- entry into new markets 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;
- the trading volume of our common stock;
- changes in the collective short interest in our common stock; and
- additional repurchases of our common stock, if any, pursuant to our recently announced share repurchase program.

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 listed companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

In addition, the market price of our shares of common stock could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures, collaborations, or capital commitments;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to short interest positions and/or inconsistent trading volume levels of our shares;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- announcement or expectation of additional debt or equity financing efforts;
- sales of our common stock by us, our insiders or our other stockholders; and
- general economic and market conditions.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. For example, in May 2016, we became party to a federal securities class action lawsuit, and although it was dismissed in October 2017, we incurred substantial costs defending such lawsuit. Such lawsuit, as well as similar lawsuits instituted in the future, could result in substantial additional costs to us and could also divert the time and attention of our management.

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 December 31, 2019, our executive officers, directors, 5% or greater stockholders and their affiliates beneficially own a significant percentage of our voting stock. These stockholders will have the ability to influence us through this ownership position. These stockholders may be able to influence all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to influence 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 have incurred significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we are incurring significant legal, accounting and other expenses that we did not incur as a private company.

For example, as a public company, we are now subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition. We have incurred and will continue to incur costs associated with the preparation in filing of these reports. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC, and Nasdaq have imposed various other requirements on public companies and we have incurred and will continue to incur costs associated with compliance with such requirements. 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 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.

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.

As of February 24, 2020 we had 13,679,350 shares of common stock outstanding, all of which, other than shares held by our directors and certain officers, are eligible for sale in the public market, subject in some cases to compliance with the requirements of Rule 144, including volume limitations and manner of sale requirements.

In addition, shares issued upon exercise of vested options are eligible for sale. 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, ("the Securities Act"). 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 expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2014 Equity Incentive Plan, ("the 2014 Plan"), our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares available for future grant under the 2014 Plan will automatically increase each year by 6% of all shares of our capital stock outstanding as of December 31 of the prior calendar year, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. Currently, we plan to register the increased number of shares available for issuance under the 2014 Plan each year. If our board of directors elects to increase the number of shares available for future grant by the maximum amount each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

We are at risk of securities class action and similar 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. On May 31, 2016, a federal securities class action suit was brought against us seeking compensatory damages in connection with, among other things, the EP-6101 Complete Response Letter. Such lawsuit was dismissed with prejudice in August 2017, however, any similar litigation in the future, could result in substantial cost 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 our recently completed initial public offering and follow-on offering and may not use them effectively.

Our management has broad discretion in the application of the net proceeds from our initial public offering and follow-on offering. Because of the number and variability of factors that will determine our use of the net proceeds from these offerings, 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 continue to invest the net proceeds from our public offerings 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 pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited. 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 cash 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 future determinations to pay cash dividends will be made at the discretion of our board of directors, subject to applicable laws, and will depend on a number of factors, including our financial condition, results of operations, capital requirements, contractual restrictions (such as our Credit Facility), general business conditions, and any other factors that our board of directors may deem relevant. Any return to stockholders will therefore be limited to the appreciation of their stock.

There is no assurance that our stock repurchase program will result in repurchases of our common stock or enhance long term stockholder value.

Repurchases of our common stock pursuant to our stock repurchase program could affect our stock price and increase its volatility and will reduce the market liquidity for our stock. The existence of a stock repurchase program could also cause our stock price to be higher than it would be in the absence of such a program. Additionally, any future repurchases would diminish our cash reserves, which could impact our ability to pursue possible future strategic opportunities and acquisitions. There can be no assurance that any stock repurchases will, in fact, occur, or, if they occur, that they will enhance stockholder value.

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.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for any derivative action or proceeding brought on behalf of the Company, any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Company to the Company or the Company's stockholders, any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or any action asserting a claim governed by the internal affairs doctrine. This forum selection provision does not apply to suits brought to enforce a duty or liability created by the Securities Act or the Exchange Act or any claim for which the federal courts have exclusive jurisdiction.

This forum selection provision may limit a stockholder's ability to bring certain claims in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. If a court were to find this forum selection provision to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

Recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, the Tax Act was signed into law, significantly revising the Code. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation on deductibility of executive compensation under regulation 162(m), limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for NOLs to 80% of current year taxable income and elimination of NOL carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

As of December 31, 2019 we conducted all of our commercial operations for Eagle Pharmaceuticals, Inc. at our 20,497 square foot leased office space located at 50 Tice Boulevard, Suite 315, Woodcliff Lake, NJ 07677. The lease will expire in June 2025.

As of December 31, 2019, we conducted all of our non-outsourced operations at a leased space located at 47 Moulton St. Cambridge, MA 02138. The lease will expire in October 2023.

We consider our current facilities suitable and adequate to meet our current needs.

Item 3. Legal Proceedings

The disclosures under Note 13. Legal Proceedings in the Consolidated Financial Statements included in Part IV, Item 15 of this report are incorporated into this Part I, Item 3 by reference.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock has been listed on The Nasdaq Global Market under the symbol "EGRX" since February 12, 2014. Prior to that date, there was no public trading market for our common stock.

Record Holders

As of February 24, 2020, we had 4 holders of record of our common stock. The actual number of shareholders is greater than this number of record holders and includes shareholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include shareholders whose shares may be held in trust by other entities. The closing price per share of our common stock on February 24, 2020 was $51.10.

Dividends

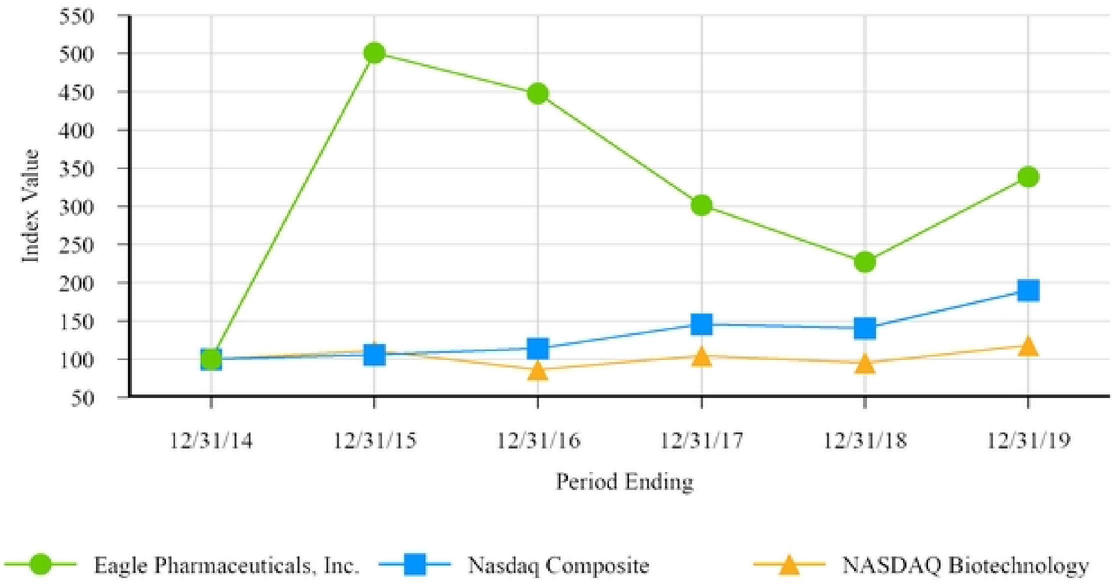
We have never declared or paid a cash dividend on our common stock. We currently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. In addition, our Credit Facility imposes contractual restrictions on us with respect to paying cash dividends. Any future determinations to pay cash dividends will be made at the discretion of our board of directors, subject to applicable laws, and will depend on a number of factors, including our financial condition, results of operations, capital requirements, contractual restrictions, general business conditions, and any other factors that our board of directors may deem relevant.

Stock Performance Graph

The following information shall not be deemed to be "soliciting material" or to be "filed" with the SEC or subject to Regulation 14A or 14C under the Securities Exchange Act of 1934, as amended, ("the Exchange Act"), or to the liabilities of Section 18 of the Exchange Act, and will not be deemed to be incorporated by reference into any filing of Eagle Pharmaceuticals, Inc. under the Exchange Act or the Securities Act of 1933, as amended, ("the Securities Act"), except to the extent we specifically incorporate it by reference into such filing.

The following graph shows a five year comparison from December 31, 2014 through December 31, 2019 of the cumulative total return for our common stock, and the Nasdaq Composite Index and The Nasdaq Biotechnology Index. The graph assumes that $100 was invested at the market close on December 31, 2014 in the common stock of Eagle Pharmaceuticals, Inc, the Nasdaq Composite Index and the Nasdaq Biotechnology Index. The stock price performance of the following graph is not necessarily indicative of future stock price performance.

Comparison of 5 year Cumulative Total Return
Assumes initial investment $100
December 31, 2019



Company / Index	12/31/14	12/31/15	12/31/16	12/31/17	12/31/18	12/31/19
Eagle Pharmaceuticals, Inc	$ 100	$ 501	$ 448	$ 302	$ 228	$ 339
Nasdaq Composite	$ 100	$ 106	$ 114	$ 146	$ 140	$ 190
NASDAQ Biotechnology	$ 100	$ 111	$ 87	$ 105	$ 95	$ 118

Recent Sales of Unregistered Securities

Pursuant to a Warrant to Purchase Common Stock, dated September 2018, the Company issued a warrant to FoxKiser LLP to purchase 7,467 shares of the Company's common stock at an exercise price of $66.96 per share in connection with certain services rendered to the Company. This warrant was issued in reliance on an exemption from registration under Section 4(a)(2) of the Securities Act of 1933, as amended.

Issuer Purchases of Equity Securities

The following table provides information about purchases of our equity securities during the three months ended December 31, 2019:

Period	Total Number of Shares Purchased (1)(2)(3)(4)(5)	Average Price Paid per Share	Total Number of Shares Purchased as Part Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Programs
				(dollars in thousands)
October 1, 2019 to October 31, 2019	—	$ —	—	85,000
November 1, 2019 to November 30, 2019	52,371	$ 56.53	52,371	82,039
December 1, 2019 to December 31, 2019	—	$ —	—	82,039
Total	52,371	$ 56.53	52,371	

(1) All shares repurchased by the Company in this table were repurchased pursuant to the Share Repurchase Program. On October 30, 2018, the Company announced a new repurchase program approved by the Board that included up to $100 million in repurchases, the “2018 Share Repurchase Program”. Under the 2018 Share Repurchase Program, the Company is authorized to repurchase shares through open market purchases, privately-negotiated transactions, accelerated share repurchases or otherwise in accordance with applicable federal securities laws, including through Rule 10b5-1 trading plans and under Rule 10b-18 of the Exchange Act. Under the 2018 Share Repurchase Program, the additional repurchases have no time limit and may be suspended or discontinued completely at any time. The specific timing and amount of repurchases will vary based on available capital resources and other financial and operational performance, market conditions, securities law limitations, and other factors. The repurchases will be made using the Company’s cash resources.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about securities authorized for issuance under our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this annual report on Form 10-K.

Item 6. Selected Financial Data

The following table sets forth our selected financial data for the periods and as of the dates indicated. The following selected financial data should be read in conjunction with our audited financial statements and the related notes thereto included elsewhere in this Annual Report on Form 10-K and the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of this Annual Report on Form 10-K.

The statement of operations data for the years ended December 31, 2019, 2018, 2017, 2016, and 2015 and the balance sheet data as of December 31, 2019, 2018, 2017, 2016 and 2015, are derived from our audited consolidated financial statements. Our audited consolidated financial statements have been prepared in U.S. dollars in accordance with U.S. GAAP.

Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

Statement of Operations Data:	**Year Ended December 31, 2019**	**2018**	**2017**	**2016**	**2015**
	(in thousands except share and per share amounts)				
Total revenue	$ 195,892	$ 213,312	$ 236,707	$ 189,482	$ 66,227
Cost of product sales	47,891	42,374	33,714	35,785	7,762
Cost of royalty revenue	13,006	19,542	23,472	19,521	7,885
Research and development	36,810	44,419	32,607	28,289	27,855
Selling, general and administrative	76,370	60,509	71,416	53,329	20,165
Income from Operations	21,815	36,616	73,990	53,351	2,560
Income tax provision (benefit)	7,685	2,135	21,002	(28,026)	3
Net income attributable to common stockholders	14,313	31,903	51,943	81,453	2,571
Earnings per share- basic	$ 1.04	$ 2.16	$ 3.44	$ 5.24	$ 0.17
Earnings per share- diluted	$ 1.01	$ 2.09	$ 3.27	$ 4.96	$ 0.16
Weighted average common shares outstanding- basic	13,754,516	14,768,625	15,102,890	15,533,681	15,250,154
Weighted average common shares outstanding- diluted	14,138,733	15,278,651	15,908,211	16,434,104	16,253,781

Balance Sheet Data:	**December 31, 2019**	**2018**	**2017**	**2016**	**2015**
	(in thousands)				
Cash and cash equivalents	$ 109,775	$ 78,791	$ 114,657	$ 52,820	$ 79,083
Accounts receivable	48,004	66,486	53,821	42,194	26,267
Total assets	254,554	238,603	270,060	214,320	124,605
Total current liabilities	38,823	39,686	47,302	40,965	34,262
Long-term debt, less current portion	33,557	38,155	42,905	—	—
Retained earnings (Accumulated deficit)	72,500	58,187	26,284	(25,659)	(107,112)
Total stockholders' equity	$ 179,174	$ 160,762	$ 179,144	$ 151,226	$ 90,343

Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of financial condition and results of operations is provided to enhance the understanding of, and should be read in conjunction with, Part I, Item 1, “Business” and Item 8, “Financial Statements and Supplementary Data.” For information on risks and uncertainties related to our business that may make past performance not indicative of future results, or cause actual results to differ materially from any forward-looking statements, see “Special Note Regarding Forward-Looking Statements,” and Part I, Item 1A, “Risk Factors.”

Overview

Our business model is to develop proprietary innovations to FDA-approved, injectable drugs that offer commercial and/or functional advantages to currently available alternatives. We have historically been, and will continue to primarily be, focused on developing and commercializing injectable drugs, primarily in the CNS critical care and oncology areas, using the FDA's 505(b)(2) New Drug Application (“NDA”) regulatory pathway. In addition, we plan to continue to market and/or commercialize our products through marketing partners and/or through our growing internal direct sales force.

Our product portfolio now includes three main approved products: Ryanodex; Belrapzo; and Bendeka. Our primary commercial partner is Teva, which through its subsidiary Cephalon, Inc. ("Cephalon") markets Bendeka.

We have final approval from the FDA for our novel product PEMFEXY™ (pemetrexed for injection), a branded alternative to ALIMTA®.

We currently have multiple product candidates in advanced stages of development, and/or under review for approval by the FDA. Our advanced product candidates are EP-4104 (dantrolene sodium for exertional heat stroke ("EHS")) ("EP-4104"), and EGL-5385-C-1701 (fulvestrant). EP-4104 and EGL-5385-C-1701, both unapproved, may address unmet medical needs in major specialty markets. Vasopressin is our first to file Abbreviated New Drug Application ("ANDA") that references Endo's Vasostrict® indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines. Our ANDA submission was accepted for filing by the FDA in March 2018. These projects and others noted below have the potential to yield 5 product launches in the next 3 years.

In 2019 and in January 2020, we accomplished the following with respect to our product portfolio and our development projects:

- On April 13, 2019, the Company and Teva entered into an Amendment to the Cephalon License, amending the terms of the License Agreement to increase the U.S. royalty paid to the Company and re-allocate certain litigation expenses. Pursuant to the Amendment, beginning on October 1, 2019, the Company's royalty payment will increase from 25% to 30% of Bendeka net United States sales, provided that Bendeka's orphan drug exclusivity has not been rescinded, withdrawn or waived by such date. The royalty rate will increase by one percentage point on each anniversary of October 1, 2019 until it reaches 32%, and it will remain at 32% thereafter. The Amendment also extends the U.S. royalty term for Bendeka until it is no longer sold in the United States. The previous royalty term was set to expire in 2025. The extended term coincides with the bendamustine patents with expiries through 2033. Pursuant to the amendment, Eagle will continue to be responsible for the manufacture of Bendeka for the U.S. market for so long as it is sold in the United States.
- On May 7, 2019, the Company announced positive results of its study to evaluate the neuroprotective effects of Ryanodex secondary to nerve agent exposure, conducted with the United States Army Medical Research Institute of Chemical Defense.
- On August 5, 2019, the Company announced a clinical development plan to support the submission of a NDA for our fulvestrant formulation. Fulvestrant, an estrogen receptor antagonist with no agonist properties, is approved by the FDA for the treatment of advanced hormone-related breast cancers. The therapeutic effect of fulvestrant relies on its ability to inhibit estrogen receptors (ER) in cancer cells by binding to and downregulating, or blocking, the ER in breast cancer cells. Eagle's original formulation of fulvestrant was studied in a clinical trial conducted in 2018 in healthy post-menopausal women. A detailed review of the study data led to the hypothesis that the unique properties of our formulation would potentially allow for greater inhibition of estrogen receptors. Based on this hypothesis, the Company completed additional work designed to further enhance our proprietary drug formulation. The Company met with the FDA and mutually agreed to a clinical program that could provide an efficient approval pathway for our fulvestrant formulation. The main goal of the clinical research program is to determine if the unique properties of our fulvestrant formulation will result in greater inhibition of estrogen receptors, potentially leading to improved efficacy outcomes, including lower disease progression rates, compared to current treatment options. The Company intends to begin a pilot study shortly in healthy female volunteers to evaluate the pharmacokinetics and safety of our formulation. Once the pilot study results are reviewed, a clinical pivotal trial designed to evaluate fulvestrant exposure and estrogen receptor inhibition based upon the parameters determined with the FDA will be conducted in a target patient population. Depending on recruitment rates and other factors, the Company believes the pivotal study could be completed within approximately 12 months of commencing enrollment.
- On December 9, 2019, we announced that the Company has commenced dosing in a pilot clinical study to assess the unique characteristics of its fulvestrant product candidate, which has the potential to enhance estrogen receptor ("ER") inhibition and improve patient outcomes. The results of the pilot study will inform the design of the Company's pivotal trial, which Eagle expects to commence in 2020. Fulvestrant, an estrogen receptor antagonist with no agonist properties, is approved by the FDA for the treatment of advanced hormone-related breast cancers. Breast cancer is the most commonly diagnosed cancer in women, with approximately 290,000 women diagnosed in the U.S. annually and more than 2.8 million breast cancer survivors in the U.S. today.
- On December 13, 2019, we reached a settlement agreement with Eli Lilly and Company related to the Company's novel product, PEMFEXY™ (pemetrexed for injection), a branded alternative to ALIMTA®. The agreement provides for a release of all claims by the parties and allows for an initial entry of PEMFEXY™ into the market (equivalent to approximately a three week supply of current ALIMTA®utilization) on February 1, 2022 and a subsequent uncapped entry on April 1, 2022.

- On December 16, 2019, we announced that the FDA has granted orphan drug designation (ODD) for Ryanodex®(dantrolene sodium) for the treatment of organophosphate exposure. Organophosphates are a class of chemicals that include potent pesticides and chemical weapons, known as nerve agents. Acute intoxication with organophospates may result in severe consequences, including brain damage and death. About 2,700 people in the United States are treated for accidental exposure to organophosphate pesticides every year. Eagle is currently evaluating Ryanodex for the treatment of brain damage secondary to nerve agent exposure. If approved, Ryanodex would represent the first product available for this indication.
- On January 7, 2020, Tyme Technologies and Eagle Pharmaceuticals announced a strategic collaboration to advance oral SM-88 for the treatment of patients with cancer. SM-88 is an investigational agent in two Phase II studies for pancreatic cancer and in a Phase II study for prostate cancer. Data is expected in 2021.
- On January 9, 2020, we announced that the Company has resubmitted its New Drug Application ("NDA") for Ryanodex®(dantrolene sodium for injectable suspension) for the treatment of exertional heat stroke ("EHS"), in addition to body cooling, to the FDA. Eagle believes that this submission addresses the Complete Response Letter received in July 2017. A Prescription Drug User Fee Act ("PDUFA") date of six months is anticipated for this class of resubmissions.

Financial Operations Overview

Revenue

Our revenue consists of product sales, royalty revenue and license and other revenue.

Product Sales. As of December 31, 2019, our primary products were Bendeka, Ryanodex, and Belrapzo. Bendeka is sold to our commercial partner Teva. Argatroban is generally sold directly to our commercial partners Chiesi and Sandoz. Sales to our commercial partners are typically made at little or no profit for resale. Ryanodex and Belrapzo have been sold directly to wholesalers, hospitals and surgery centers through a third party logistics partner. Diclofenac-misoprostol was divested in March 2016. We continued to market diclofenac-misoprostol through the first quarter of 2018 until such time that the purchaser was able to launch the product. As part of a restructuring initiative, we ceased selling Non-Alcohol Docetaxel Injection by September 30, 2018.

We typically enter into agreements with group purchasing organizations acting on behalf of their hospital members, in connection with the hospitals' purchases of our direct commercial products. Based on these agreements, most of our hospital customers have contracted prices for products and volume-based rebates on product purchases. These amounts are estimated and recorded at the time of sale. In the case of discounted pricing, we typically pay a chargeback, representing the difference between the price invoiced to the wholesaler and the customer contract price.

Royalty revenue. We recognize revenue from royalties based on a percentage of Teva's net sales of Bendeka and Sandoz's and Chiesi's gross profit of Argatroban, both net of discounts, returns and allowances incurred by our commercial partners. Royalty revenue is recognized as earned in accordance with contract terms when it can be reasonably estimated and collectability is reasonably assured.

License and other revenue.

Our revenues 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.

The primary factors that determine our revenues derived from Bendeka are:

- the level of orders submitted by our commercial partner, Teva;
- the rate at which Teva can convert the current market to Bendeka;
- the level of institutional demand for Bendeka;
- unit sales prices charged by our commercial partner, net of any sales reserves; and
- the level of orders submitted by wholesalers, hospitals and surgery centers.

The primary factors that may determine our revenues derived from Argatroban are:

- the level of orders submitted by our commercial partners, Sandoz and Chiesi;
- the level of institutional demand for Argatroban; and
- unit sales prices charged by our commercial partners, net of any sales reserves.

The primary factors that may determine our revenues derived from Ryanodex, Belrapzo and our future products are:

- the effectiveness of our sales force;
- the level of orders submitted by wholesalers, hospitals and surgery centers;
- the level of institutional demand for our products; and
- unit sales prices, net of any sales reserves.

Cost of Revenues

Cost of revenue consists of the costs associated with producing our products for our commercial partners. In particular, our cost of revenue includes production costs of our products paid to a contract manufacturing organization coupled with shipping and customs charges, cost of royalty and the amortization of intangible assets. Cost of revenue may also include the effects of product recalls, if applicable.

Research and Development

Costs for research and development are charged to expense as incurred and include: employee-related expenses including salaries, benefits, travel and stock-based compensation expense for research and development personnel, expenses incurred under agreements with contract research organizations, contract manufacturing organizations and service providers that assist in conducting clinical and preclinical studies; costs associated with preclinical activities and development activities, costs associated with regulatory operations; and depreciation expense for assets used in research and development activities.

Costs for certain development activities, such as clinical studies, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by its vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the patterns of costs incurred, and are reflected in the consolidated financial statements as prepaid expenses or accrued expenses as deemed appropriate.

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, sales and operations personnel. Selling, general and administrative expenses also include facility and related costs, professional fees for legal, consulting, tax and accounting services, insurance, selling, marketing, market research, advisory board and key opinion leaders, depreciation and general corporate expenses.

Income Taxes

We account for income taxes using the liability method in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC"), Topic 740, "Income Taxes" ("ASC 740"). Deferred tax assets and liabilities are determined based on temporary differences between financial reporting and tax bases of assets and liabilities and are measured by applying enacted rates and laws to taxable years in which differences are expected to be recovered or settled. Further, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that the rate changes. A valuation allowance is required when it is "more likely than not" that all or a portion of deferred tax assets will not be realized. ASC 740 also prescribes a comprehensive model for how a company should recognize, measure, present and disclose in its financial statements uncertain tax positions that the Company has taken or expects to take on a tax return, including a decision whether to file or not file a return in a particular jurisdiction. We recognize any interest and penalties accrued related to unrecognized tax benefits as income tax expense.

Results of Operations

Comparison of Years Ended December 31, 2019 and December 31, 2018

Revenues

	Year Ended December 31,		Increase /
	2019	2018	(Decrease)
	(in thousands)		
Product sales	$ 73,989	$ 70,385	$ 3,604
Royalty revenue	112,903	142,927	(30,024)
License and other revenue	9,000	—	9,000
Total revenue	$ 195,892	$ 213,312	$ (17,420)

Product sales increased $3.6 million in the year ended December 31, 2019, primarily driven by increases in product sales of Belrapzo of $6.8 million, which was due to volume increases and Bendeka of $6.4 million, which was also due to volume increases. The increased sales were partially offset by decreases in product sales of Ryanodex of $7.2 million due to lower volume on a low reorder cycle period and the discontinuation of Non-Alcohol Docetaxel Injection in September 2018 that resulted in a negative impact to revenues of $2.6 million.

Royalty revenue decreased $30.0 million in the year ended December 31, 2019 as a result of decreases in royalties on Teva's sales of Bendeka of $23.2 million and royalties on sales of Argatroban of $6.8 million.

License and other revenue for the year ended December 31, 2019 represents an upfront cash payment of $9.0 million upon execution of an amendment to the Cephalon License to terminate Teva’s obligation to pay future milestones and royalties on Bendeka sales outside of the U.S.

Cost of Revenue

	Year Ended December 31,		Increase / (Decrease)
	2019	2018	
	(in thousands)		
Cost of product sales	$ 47,891	$ 42,374	$ 5,517
Cost of royalty revenue	13,006	19,542	(6,536)
Total cost of revenue	$ 60,897	$ 61,916	$ (1,019)

Cost of product sales increased $5.5 million in the year ended December 31, 2019, primarily as a result of increased product sales of Belrapzo and Bendeka, partially offset by the discontinuation of Non-Alcohol Docetaxel Injection in September 2018 and decreased product sales of Ryanodex and Argatroban.

Cost of royalty revenue decreased $6.5 million in the year ended December 31, 2019 due to the decrease in royalty revenue for Bendeka and Argatroban.

Research and Development

The table below details the Company’s research and development expenses by significant project for the periods presented.

	Year Ended December 31,		(Decrease) / Increase
	2019	2018	
	(in thousands)		
Fulvestrant “EGL-5385-C-1701”	$ 5,053	$ 21,687	$ (16,634)
Vasopressin	7,779	1,029	6,750
Ryanodex EHS “EP-4104”	5,192	$ 3,845	1,347
All other projects	3,980	$ 4,437	(457)
Salary and other personnel related	$ 14,806	$ 13,421	1,385
Research and development	$ 36,810	$ 44,419	$ (7,609)

The decrease primarily resulted from a decrease in project spending for EGL-5385-C-1701 (the Company’s fulvestrant formulation) relating to the clinical study which completed randomization of 600 subjects in the first half of 2018. This decrease was partially offset by increased spend related to the Company's vasopressin injection ANDA filing and spending on the resubmitted New Drug Application (“NDA”) for Ryanodex® (dantrolene sodium for injectable suspension) for the treatment of exertional heat stroke (“EHS”).

Selling, General and Administrative

	Year Ended December 31,		
	2019	2018	Increase
	(in thousands)		
Selling, general and administrative	$ 76,370	$ 60,509	$ 15,861

This increase is primarily related to an increase of $9.6 million in external legal fees related to ongoing litigation matters, increased compensation costs, including stock compensation expense, of $6.6 million and $0.6 million increase in professional fees. These increases were partially offset by a decrease of $0.9 million in sales and marketing direct costs.

Other Income, net

	Year Ended December 31,		Increase / Decrease
	2019	2018	
	(in thousands)		
Interest income	$ 2,169	$ 158	$ 2,011
Interest expense	(2,686)	(2,736)	50
Other income	700	—	700
Total other income, net	$ 183	$ (2,578)	$ 2,761

Interest income increased $2.0 million primarily due to the Company's short term investing initiatives with cash on hand throughout 2019 as compared to 2018.

Interest expense decreased primarily due to lower total long-term debt outstanding due to recurring principal payments required by the Revised Credit Agreement.

Other income represents an amount related to a settlement agreement executed in December 2019 with Eli Lilly and Company ("Lilly") related to the Company's product, PEMFEXY™ (pemetrexed for injection), a branded alternative to ALIMTA®. The agreement provides for a release of all claims by the parties related to an antitrust complaint filed by the Company and an alleged patent infringement based on the filing of the Company's 505(b)(2) NDA. The Settlement also allows for an initial entry of PEMFEXY™ into the market (equivalent to approximately a three week supply of current ALIMTA®utilization) on February 1, 2022 and a subsequent uncapped entry on April 1, 2022.

Provision for income taxes

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Provision for income taxes	$ 7,685	$ 2,135
Effective tax rate	35%	6%

The provision for income taxes was based on the applicable federal and state tax rates for those periods. The effective tax rate for 2019 reflects the impact of certain non-deductible executive compensation partially offset by credits for research and development activity. The effective tax rate for 2018 reflects tax benefits related to stock option exercises in the period as well as credits for research and development activity partially offset by the impact of certain non-deductible executive compensation

Net Income

Net income for the year ended December 31, 2019 was $14.3 million as compared to a net income of $31.9 million for the year ended December 31, 2018, as a result of the factors discussed above.

Comparison of Years Ended December 31, 2018 and December 31, 2017

	Year Ended December 31, 2018	Year Ended December 31, 2017	Increase / (Decrease)
	(in thousands)		
Product sales	$ 70,385	$ 45,327	$ 25,058
Royalty revenue	142,927	153,880	(10,953)
License and other revenue	—	37,500	(37,500)
Total revenue	$ 213,312	$ 236,707	$ (23,395)

Product sales increased $25.1 million in the year ended December 31, 2018, primarily driven by the FDA approval and launch of Belrapzo in May 2018 which generated $22.9 million of 2018 revenues accompanied by increases in product sales of Bendeka of $8.3 million, of which $8.2 million was due to price increases and $0.1 million was due to volume increases. Additionally, product sales for Ryanodex increased by $2.7 million, of which $2.6 million was due to price increases and $0.1 million was due to volume increases. The increases were partially offset by decreases in product sales for Argatroban of $3.7 million, and in Non-Alcohol Docetaxel Injection of $3.8 million due to its discontinuation in September 2018.

Royalty revenue decreased $11.0 million in the year ended December 31, 2018, as a result of lower royalties on Bendeka.

License and other revenue for the year ended December 31, 2017, comprised of a $25.0 million milestone under the Cephalon agreement related to Teva reaching $500 million in cumulative net sales of Bendeka and a $12.5 million upfront cash payment earned under the SymBio License Agreement.

Cost of Revenue

	Year Ended December 31, 2018	Year Ended December 31, 2017	Increase / (Decrease)
	(in thousands)		
Cost of product sales	$ 42,374	$ 33,714	$ 8,660
Cost of royalty revenue	19,542	23,472	(3,930)
Total cost of revenue	$ 61,916	$ 57,186	$ 4,730

Cost of product sales increased $8.7 million in the year ended December 31, 2018, primarily as a result of increased product sales of Belrapzo and Bendeka, offset by decreased product sales of Argatroban, Non-Alcohol Docetaxel Injection, and diclofenac-misoprostol.

Cost of royalty revenue decreased $3.9 million in the year ended December 31, 2018 due to the non-recurrence of both the $25.0 million milestone realized under the Cephalon agreement, related to Teva reaching $500 million in cumulative net sales of Bendeka, and the $12.5 million upfront cash payment earned under the SymBio License Agreement during the year ended December 31, 2017.

Research and Development

	Year Ended December 31, 2018	Year Ended December 31, 2017	Increase / (Decrease)
	(in thousands)		
Fulvestrant “EGL-5385-C-1701”	$ 21,687	$ 10,245	$ 11,442
Ryanodex EHS “EP-4104”	3,845	2,987	858
Vasopressin	1,029	—	1,029
Ryanodex OD / NA	810	971	(161)
Pemetrexed “EP-5101”	290	1,982	(1,692)
All other projects	3,337	4,093	(756)
Salary and other personnel related	13,421	12,329	1,092
Total research and development	**$ 44,419**	**$ 32,607**	**$ 11,812**

The increase primarily resulted from an increase in project spending for EGL-5385-C-1701 relating to the clinical study, which completed randomization of 600 subjects in the first quarter of 2018.

Selling, General and Administrative

	Year Ended December 31,		
	2018	2017	Decrease
	(in thousands)		
Selling, general and administrative	$ 60,509	$ 71,416	$ (10,907)

This decrease is principally related to a $14.5 million decrease in sales and marketing spend prior to an expected launch of Ryanodex for exertional heat stroke that did not occur and the non-recurrence of fees related to a co-promotion agreement during 2017 and $0.8 million decrease in professional fees. These decreases were partially offset by a $2.8 million increase in salary and personnel-related expenses, including stock-based compensation expense, as we build out areas to support the needs of the business.

Restructuring Charge

As part of its ongoing organizational review, the Company engaged in a restructuring initiative to rationalize its product portfolio and focus its physical sites. These measures included the discontinuation of manufacture and distribution of Non-Alcohol Docetaxel Injection in June 2018 and plans to rationalize research and development operations. Charges consist of inventory and related reserves, certain asset impairment charges related to property, plant and equipment, and personnel related costs. The restructuring costs were $7.9 million for the year ended December 31, 2018.

Asset Impairment Charge

On June 30, 2018, we implemented a restructuring initiative resulting in the removal of Non-Alcohol Docetaxel Injection from our product portfolio. Sales for the product ceased entirely at the end of third quarter 2018. We have determined the carrying amount of the asset to no longer be recoverable, resulting in a pre-tax, non-cash asset impairment charge of $2.7 million during the year ended December 31, 2018.

Change in Fair Value of Contingent Consideration

Contingent consideration, which primarily consists of potential milestone payments and royalty obligations, is recorded in our consolidated balance sheets at its estimated fair value at the acquisition date, in accordance with the acquisition method of accounting. The fair value of the acquisition-related contingent consideration is remeasured each reporting period, with changes in fair value recorded in our consolidated statements of income. The fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement as defined in fair value measurement accounting.

Contingent consideration gain of $0.8 million was recorded during the year ended December 31, 2018. This was primarily driven by adjustments to the fair values of the liabilities associated with Non-Alcohol Docetaxel Injection, which was remeasured as a result of the discontinuation of the product and partially offset by accretion for the time value of money.

Other Income and Expense

	Year Ended December 31,		
	2018	2017	Increase
	(in thousands)		
Interest income	$ 158	$ 91	$ 67
Interest expense	(2,736)	(1,136)	(1,600)
Total other income, net	$ (2,578)	$ (1,045)	$ (1,533)

Interest expense increased for the year ended December 31, 2018 related to the amortization of debt issuance costs and interest incurred on long-term debt.

Provision for income taxes

	Year Ended December 31,	
	2018	**2017**
	(in thousands)	
Provision for income taxes	$ (2,135)	$ (21,002)
Effective tax rate	6%	29%

The provision for income taxes were based on the applicable federal and state tax rates for those periods. The effective tax rate for the year ended December 31, 2018 and 2017 reflects tax benefits related to stock option exercises in the period as well as credits for research and development activity (see Note to Consolidated Financial Statements - Note 8. Income Taxes).

As a result of the Tax Act, the federal statutory tax rate was reduced to 21% from 35% beginning in 2018. In addition, the Company's income tax provision for the year ended December 31, 2017 included a charge for the revaluation of net deferred tax assets due to the Tax Act.

Net Income

Net income for the year ended December 31, 2018 was $31.9 million as compared to a net income of $51.9 million for the year ended December 31, 2017, as a result of the factors discussed above.

Liquidity and Capital Resources

Our primary uses of cash are to fund working capital requirements, product development costs, operating expenses as well as strategic business and product acquisitions and repurchases of our common stock. Cash and cash equivalents were $109.8 million, and $78.8 million as of December 31, 2019 and December 31, 2018, respectively.

For the year ended December 31, 2019, we recorded net income of $14.3 million. As of December 31, 2019, we had a working capital surplus of $140.6 million. For the year ended December 31, 2018, we recorded net income of $31.9 million.

We believe that future cash flows from operations will be sufficient to fund our currently anticipated working capital requirements for at least the next twelve months.

We expect to use future loans, if any, under the Credit Facility, for general corporate purposes and any strategic acquisitions.

Operating Activities:

Net cash provided by operating activities for the year ended December 31, 2019 was $56.0 million. Net income for the same period was $14.3 million before non-cash adjustments of approximately $27.3 million from deferred income taxes, depreciation, amortization of intangible assets, stock-based compensation expense, and amortization of debt issuance costs. Net changes in working capital increased cash provided from operating activities by $14.4 million, due to a decrease in accounts receivable of $18.5 million primarily due to Belrapzo launch in 2018, a decrease in inventory of $1.7 million, an increase in accrued expenses and other liabilities of $4.1 million, partially offset by an increase in other assets of $0.6 million, a decrease in prepaid expenses and other current assets of $4.8 million, and a decrease in accounts payable of $4.5 million. The total amount of accounts receivable at December 31, 2019 was approximately $48.0 million. Receivables from our product sales have payment terms ranging from 30 to 75 days with select extended terms to wholesalers on initial purchases of product launch quantities. Our receivables from royalty revenue are due 45-days from the end of the quarter.

Net cash provided by operating activities for the year ended December 31, 2018 was $52.4 million. Net income for the same period was $31.9 million offset by non-cash adjustments of approximately $28.4 million from deferred income taxes, depreciation, amortization of intangible assets, stock-based compensation expense, amortization of debt issuance costs, change in fair value of contingent consideration, asset impairment charge and fair value adjustment related to restructuring. Net changes in working capital decreased cash provided from operating activities by $7.9 million, due to an increase in accounts receivable of $12.7 million, an increase in inventory of $5.6 million, an increase in accrued expenses and other liabilities of $8.1 million, an increase in other assets of $0.6 million partially offset by a decrease in prepaid expenses and other current assets of $4.8 million, and a decrease in accounts payable of $2.1 million. The total amount of accounts receivable at December 31, 2018 was approximately $66.5 million, which included approximately $25.3 million from product sales, $35.7 million from royalty income, and $5.5 million related to cost reimbursements. Receivables from our product sales have payment terms ranging from 30 to 75 days with select extended terms to wholesalers on initial purchases of product launch quantities. Our receivables from royalty revenue are due 45-days from the end of the quarter.

Net cash provided by operating activities for the year ended December 31, 2017 was $58.9 million. Net income for the same period was $51.9 million offset by non-cash adjustments of approximately $36.5 million principally from deferred income taxes, depreciation, amortization of intangible assets, stock-based compensation expense, asset impairment charge, amortization of debt issuance costs, and change in fair value of contingent consideration. Net changes in working capital decreased cash provided from operating activities by $29.6 million, due to an increase in accounts receivable of $11.6 million, an increase in inventory of $2.4 million partially offset by a decrease in prepaid expenses and other current assets of $2.0 million, a decrease in accounts payable of $8.5 million, a decrease in accrued expenses and other liabilities of $9.1 million. The total amount of accounts receivable at December 31, 2017 was approximately $53.8 million, which included approximately $13.3 million from product sales, $36.4 million from royalty income, and $4.1 million related to cost reimbursements, all with payment terms of 45 days. Royalty income is receivable with terms of 45 days and starts at the end of the quarter to which it relates, the immediately preceding quarter.

Investing Activities:

During the years ended December 31, 2019, 2018 and 2017, we invested $0.8 million, $0.1 million, and $4.4 million, respectively, for the purchase of property and equipment.

During the year ended December 31, 2017, we invested $0.8 million related to the purchase of the Ryanodex intangible.

Financing Activities:

Net cash used in financing activities for the year ended December 31, 2019 was $24.2 million, primarily resulting from principal payments for debt required by the Revised Credit Agreement of $6.0 million and payments related to the repurchases of our common stock of $18.0 million.

Net cash used in financing activities for the year ended December 31, 2018 was $88.1 million, primarily resulting from a $15 million payment of contingent consideration in connection with the Arsia Amendment, $73.1 million in cash settlements on repurchases of common stock, $3.7 million payment of debt financing costs and a $4.9 million payment of employee withholding tax for net option exercises. This was offset by the issuance of common stock for stock option exercises of $8.6 million.

Net cash provided by financing activities for the year ended December 31, 2017 was $8.1 million, primarily resulting from $50.0 million in proceeds from debt issuance and the issuance of common stock for stock option exercises of $4.3 million. This was offset by $43.8 million in cash settlements on repurchases of common stock, a $1.2 million payment of debt financing costs, and a $1.3 million payment of debt principal.

Contractual Obligations

Our future material contractual obligations include the following (in thousands):

Obligation	Total	2020	2021	2022	2023	2024	Beyond
Operating leases (1)	$ 6,607	$ 1,345	$ 1,362	$ 1,376	$ 1,291	$ 820	$ 413
Credit facility	39,000	5,000	8,000	26,000	—	—	—
Purchase obligations (2)	18,329	18,329	—	—	—	—	—
Total obligations	$ 63,936	$ 24,674	$ 9,362	$ 27,376	$ 1,291	$ 820	$ 413

(1) We lease our corporate office location. On August 8, 2019, we amended the lease for our corporate office location in order to rent additional office space and extend the term of our existing lease to June 30, 2025. The Company also leases its lab space under a lease agreement that expires on October 31, 2023. Rental expense was $1,146, $571, and $664, for the year ended December 31, 2019, 2018, and 2017, respectively. The remaining future lease payments under the operating leases, exclusive of any renewal option periods, are $6,607 as of December 31, 2019, payable monthly through June 30, 2025 and October 31, 2023.

(2) As of December 31, 2019, the Company has purchase obligations in the amount of $18,329 which represents the contractual commitments under contract manufacturing and supply agreements with suppliers. The obligation under the supply agreement is primarily for finished product, inventory, and research and development.

Recent Accounting Pronouncements

Recent Accounting Pronouncements - Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses which requires financial assets measured at amortized cost basis to be presented at the net amount expected to be collected. The measurement of expected credit losses is based on relevant information about past events, including historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. This standard is effective for fiscal years beginning after December 15, 2019 and we will adopt the standard effective January 1, 2020. We have performed an assessment and determined that adoption will not have a material impact on our consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirement for Fair Value Measurement (“ASU 2018-13”), which amends the disclosure requirements for fair value measurements. The amendments in ASU 2018-13 are effective for fiscal years beginning after December 15, 2019, with early adoption permitted. We have performed an assessment and determined that adoption will not have a material impact on our consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*. The ASU simplifies the accounting for income taxes by removing certain exceptions to the general principles and also clarifies and amends existing guidance. This standard is effective beginning January 1, 2021, with early adoption permitted. We are currently assessing the impact this standard will have on our consolidated financial statements.

Recently Adopted Accounting Pronouncements

The Company adopted FASB ASU No. 2016-02, “Leases (Topic 842)” ("ASU 2016-02") as of January 1, 2019 to increase transparency and comparability among organizations, which included recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. Lessees are required to recognize a lease liability, which represents the discounted obligation to make future minimum lease payments, and a corresponding right-of-use asset on the balance sheet for most leases. The Company adopted ASU 2016-02 using the modified retrospective approach and did not recognized a cumulative-effect adjustment to the opening balance of Retained earnings. The Company elected a number of optional practical expedients permitted under the transition guidance within the new standard, which among other things, allowed us to carry forward the historical lease classification and that permits lease agreements that are twelve months or less to be excluded from the balance sheet. The primary impact upon adoption was the recognition, on a discounted basis, of the Company’s minimum commitments under noncancelable operating leases as right of use assets and obligations on the consolidated balance sheets, in an amount of approximately $3 million as of the adoption date. The Company may enter into future long-term lease agreements or exercise renewal options contained in existing lease agreements that could have a material impact on the right of use assets and obligations reflected on the consolidated balance sheets.

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

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect our reported assets and liabilities, revenues and expenses, and other financial information. Actual results may differ significantly from these estimates under different assumptions and conditions. In addition, our reported financial condition and results of operations could vary due to a change in the application of a particular accounting standard.

We regard an accounting estimate or assumption underlying our financial statements as a “critical accounting estimate” where:

- the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and

- the impact of the estimates and assumptions on financial condition or operating performance is material.

Our significant accounting policies are more fully described in Note 2 to our financial statements included in this Annual Report on Form 10-K. Not all of these significant accounting policies, however, require that we make estimates and assumptions that we believe are “critical accounting estimates.” We have discussed our accounting policies with the audit committee of our board of directors, and we believe that our estimates relating to revenue recognition, share-based compensation, income taxes, other intangibles assets, net and goodwill described below are “critical accounting estimates.”

Revenue Recognition

Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Sales, value add, and other taxes collected on behalf of third parties are excluded from revenue.

Product revenue - The Company recognizes net revenue on sales to its commercial partners and to end users. In each instance, revenue is generally recognized when the customer obtains control of the Company’s product, which occurs at a point in time, and may be upon shipment or upon delivery based on the contractual shipping terms of a contract.

Revenue on sales to commercial partners relates to Argatroban and Bendeka. Sales to our commercial partners are presented gross because the Company is primarily responsible for fulfilling the promise to provide the product, is responsible to ensure that the product is produced in accordance with the related supply agreement and bears risk of loss while the inventory is in-transit to the commercial partner.

Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing the expected value method to which the Company expects to be entitled. As such, revenue on sales to end users for Belrapzo and Ryanodex are recorded net of chargebacks, rebates, returns, prompt pay discounts, wholesaler fees and other deductions. Our products are contracted with a limited number of oncology distributors and hospital buying groups with narrow differences in ultimate realized contract prices used to estimate our chargeback and rebate reserves. The Company has a product returns policy on some of its products that allows the customer to return pharmaceutical products within a specified period of time both prior to and subsequent to the product’s expiration date. The Company's estimate of the provision for returns is analyzed quarterly and is based upon many factors, including historical experience of actual returns and analysis of the level of inventory in the distribution channel, if any. The Company has terms on sales of Ryanodex by which the Company does not accept returns. Variable consideration is included in the transaction price if, in the Company’s judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Estimates of variable consideration are made using the expected value method and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of the Company’s anticipated performance and all information (historical, current and forecasted) that is reasonably available. The Company believes that the estimates it has established are reasonable based upon current facts and circumstances. Applying different judgments to the same facts and circumstances could result in the estimated amounts to vary.

Royalty Revenue — The Company recognizes revenue from license arrangements with its commercial partners' net sales of products. In accordance with ASC 606-10-55-65, royalties are recognized when the subsequent sale of the commercial partner’s products occurs. The Company's commercial partners are obligated to report their net product sales and the resulting royalty due to the Company within 25 days for Bendeka and 60 days for Argatroban 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.

License and other revenue — The Company analyzes each element of its licensing agreements to determine the appropriate revenue recognition. The terms of the license agreement may include payment to us of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. The Company recognizes revenue from upfront payments at a point in time, typically upon fulfilling the delivery of the associated intellectual property to the customer.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. The Company determines standalone selling prices based on the price at which the performance obligation is sold separately. If the standalone selling price is not observable through past transactions, the Company estimates the standalone selling price taking into account available information such as market conditions and internally approved pricing guidelines related to the performance obligations.

The Company recognizes sales-based milestone payments as revenue upon the achievement of the cumulative sales amount specified in the contract in accordance with ASC 606-10-55-65. For those milestone payments which are contingent on the occurrence of particular future events, the Company determined that these need to be considered for inclusion in the calculation of total consideration from the contract as a component of variable consideration using the most-likely amount method. As such, the Company assesses each milestone to determine the probability and substance behind achieving each milestone. Given the inherent uncertainty of the occurrence of these future events, the Company will not recognize revenue from the milestone until there is not a high probability of a reversal of revenue, which typically occurs near or upon achievement of the event.

When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. Applying the practical expedient in paragraph 606-10-32-18, the Company does not assess whether a significant financing component exists if the period between when the Company performs its obligations under the contract and when the customer pays is one year or less. None of the Company’s contracts contained a significant financing component as of December 31, 2019.

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, its allocated overhead, as well as the research and development performed by outside contractors or consultants.

Upon termination of a collaboration agreement, any remaining non-refundable license fees received by the Company, 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 income. 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.

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 and record expense over the employees' service periods, which are generally the vesting period of the equity awards.

The Company accounts 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. The straight-line method is used to allocate compensation cost to reporting periods over each optionee's requisite service period, which is generally the vesting period. The fair value of the Company's stock-based awards to employees and directors is estimated 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, forfeitures and the fair value of the underlying common stock on the date of grant, among other inputs. The risk-free interest rate is 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.

Income Taxes

The Company accounts for income taxes using the liability method in accordance with Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”), Topic 740 - Income Taxes (“ASC 740”). Deferred tax assets and liabilities are determined based on temporary differences between financial reporting and tax bases of assets and liabilities and are measured by applying enacted rates and laws to taxable years in which differences are expected to be recovered or settled. Further, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that the rate changes. A valuation allowance is required when it is "more likely than not" that all or a portion of deferred tax assets will not be realized. ASC 740 also prescribes a comprehensive model for how a company should recognize, measure, present and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return, including a decision whether to file or not file a return in a particular jurisdiction. We recognize any interest and penalties accrued related to unrecognized tax benefits as income tax expense.

Other Intangible Assets, Net

The Company capitalizes and includes in intangible assets the costs of acquired product licenses and developed technology purchased individually or identified in a business combination. Intangible assets are recorded at fair value at the time of their acquisition and stated net of accumulated amortization. The Company amortizes its definite-lived intangible assets using either the straight-line or accelerated method, based on the useful life of the asset over which it is expected to be consumed utilizing expected undiscounted future cash flows. The Company will evaluate the potential impairment of intangible assets if events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Events giving rise to impairment are an inherent risk in our industry and many factors cannot be predicted. Factors that we consider in deciding when to perform an impairment review include significant changes in our forecasted projections for the asset or asset group for reasons including, but not limited to, significant under-performance of a product in relation to expectations, significant changes or planned changes in our use of the assets, significant negative industry or economic trends, and new or competing products that enter the marketplace. The impairment test is based on a comparison of the undiscounted cash flows expected to be generated from the use of the asset group and its eventual disposition to the carrying value of the asset group. If impairment is indicated, the asset is written down by the amount by which the carrying value of the asset exceeds the related fair value of the asset with the related impairment charge recognized within the statements of income.

With respect to determining an asset's fair value and useful life, because this process involves management making certain estimates and these estimates form the basis of the determination of whether or not an impairment charge should be recorded, these estimates are considered to be critical accounting estimates.

Goodwill

Goodwill represents the excess of purchase price over the fair value of net assets acquired in an acquisition. Goodwill is not amortized, but is evaluated for impairment on an annual basis, in the fourth quarter, or more frequently if events or changes in circumstances indicate that the reporting unit's goodwill is less than it's carrying amount. The Company did not identify any impairment to goodwill during the periods presented.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Market risk is the risk of change in fair value of a financial instrument due to changes in interest rates, equity prices, creditworthiness, financing, exchange rates or other factors. We are exposed to market risk related to changes in interest rates. As of December 31, 2019, we had cash and cash equivalents of $109.8 million held primarily in money market mutual funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, however, due to the short-term duration of our money market mutual funds and the low risk profile of our investments, an immediate one percent change in interest rates would not have a material effect on the fair market value of our portfolio.

Our exposure to interest rate risk also relates to our variable-rate indebtedness associated with our Revised Credit Agreement. As of December 31, 2019 and 2018, the aggregate principal amount of such variable-rate indebtedness was $39.0 million and $44.4 million, respectively. Borrowings under the Revised Credit Agreement may from time to time bear interest at variable rates, which rates are further described in Note 6. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of this report. As of December 31, 2019 and 2018, a hypothetical 1% increase in the applicable rate would not have a material effect on the incremental annual interest expense related to our variable-rate debt borrowings.

Item 8. Financial Statements and Supplementary Data

Our Financial Statements and Supplementary Data and Report of Independent Registered Public Accounting Firm appear beginning on page F-1 attached to this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not Applicable.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

As of December 31, 2019, an evaluation was conducted under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act). Based on this evaluation, such officers have concluded that our disclosure controls and procedures were effective as of December 31, 2019. Management has concluded that our consolidated financial statements included in this Annual Report on Form 10-K fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented therein.

Management's Annual Report on Internal Control Over Financial Reporting

The management of Eagle Pharmaceuticals, Inc. ("Eagle") has prepared, and is responsible for, Eagle's financial statements and related footnotes. These financial statements have been prepared in conformity with U.S. generally accepted accounting principles. Eagle's management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of the Company's principal executive and principal financial officers and effected by the Company's board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of Eagle's assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of Eagle are being made only in accordance with authorizations of management and directors of Eagle; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of Eagle's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Eagle's management conducted an assessment of the Company's internal control over financial reporting as of December 31, 2019 based upon the criteria established in "Internal Control - Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework). Based on this assessment, our management has concluded that, as of December 31, 2019, our internal control over financial reporting was effective.

BDO USA, LLP, the independent registered public accounting firm that audits our consolidated financial statements, has issued its attestation report on the Company's internal control over financial reporting as of December 31, 2019. This attestation report appears below.

/s/ Scott Tarriff
Chief Executive Officer and Director
(Principal Executive Officer)

/s/ Pete A. Meyers

Chief Financial Officer

(Principal Accounting and Financial Officer)

Changes in Internal Control Over Financial Reporting

There have been no changes in the Company's internal control over financial reporting during the quarter ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Eagle Pharmaceuticals, Inc.
Woodcliff Lake, NJ

Opinion on Internal Control over Financial Reporting

We have audited Eagle Pharmaceuticals, Inc. (the "Company's") internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of Eagle Pharmaceuticals, Inc. as of December 31, 2019 and 2018, the related consolidated statements of income, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2019, and the related notes, and our report dated March 2, 2020 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Item 9A, Management's Annual Report on Internal Control over Financial Reporting". Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit of internal control over financial reporting in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ BDO USA, LLP

Woodbridge, NJ

March 2, 2020

Item 9B. Other information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item is incorporated by reference to our definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 11. Executive Compensation

The information required by this item is incorporated by reference to our definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item is incorporated by reference to our definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required by this item is incorporated by reference to our definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 14. Principal Accountant Fees and Services

The information required by this item is incorporated by reference to our definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Documents filed as part of this report.

The following documents are filed as part of this report:

1. Financial Statements

See Index to Financial Statements at Item 8 herein.

2. Financial Statement Schedules

Financial statement schedules have been omitted in this report because they are not applicable, not required under the instructions, or the information requested is set forth in the financial statements or related notes thereto.

3. Exhibits

The exhibits listed in the below index to exhibits are filed as part of, or incorporated by reference into, this report.

Exhibit Number		Description
3.1		Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.2 to the Registrant's Registration Statement on Form S-1/A, SEC File No. 333-192984, filed January 28, 2014)
3.2		Amended and Restated Bylaws (incorporated by reference to Exhibit 3.4 to the Registrant's Registration Statement on Form S-1/A, SEC File No. 333-192984, filed January 28, 2014)
4.1		Form of Common Stock Certificate of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1/A, SEC File No. 333-192984, filed January 28, 2014)
4.2		Third Amended and Restated Investor Rights Agreement, dated April 11, 2013, by and among the Registrant and certain of its stockholders (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013)
4.3	(1)	Description of securities registered pursuant to Section 12 of the Securities Exchange Act of 1934.
10.1	†	Form of Indemnification Agreement by and between the Registrant and its directors and officers (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013)
10.2	†	Eagle Pharmaceuticals, Inc. 2007 Incentive Compensation Plan and Form of Stock Option Agreement thereunder (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013), as amended December 15, 2015 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed December 21, 2015)
10.3	†	Eagle Pharmaceuticals, Inc. 2014 Equity Incentive Plan, as amended and restated, and Form of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice thereunder (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed August 10, 2015), as amended with an additional form of Stock Option Agreement (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed December 21, 2015)
10.4	†	Eagle Pharmaceuticals, Inc. 2014 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1/A, SEC File No. 333-192984, filed January 22, 2014)
10.5	†	Eagle Pharmaceuticals, Inc. Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1/A, SEC File No. 333-192984, filed January 22, 2014)
10.6	†	Employment Agreement by and between the Registrant and Scott Tarriff dated March 8, 2007, as amended (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1/A, SEC File No. 333-192984, filed January 28, 2014)

10.7	†	Offer Letter by and between the Registrant and Adrian Hepner dated December 11, 2014 (incorporated by reference to Exhibit 10.7 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed March 15, 2017) as amended by entry into the Eagle Pharmaceuticals, Inc. Officer Severance Benefit Plan on April 29, 2016 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed August 10, 2015)
10.8		Lease Agreement between the Registrant and Mack-Cali Chestnut Ridge L.L.C. dated May 28, 2013, as amended on July 1, 2013 (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013), and as amended on March 16, 2015 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K , SEC File No. 001-36306, filed March 20, 2015)
10.9	*	Development and License Agreement, by and between the Registrant and SciDose, LLC, dated September 24, 2007, as amended March 18, 2008, May 22, 2009 and July 16, 2013 (incorporated by reference to Exhibit 10.11(a) to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013)
10.10	*	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, May 22, 2009 and July 16, 2013 (incorporated by reference to Exhibit 10.11(b) to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013), and as amended on August 5, 2015 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed August 10, 2015)
10.11	*	License and Sublicense Agreement, by and between the Registrant and Lyotropic Therapeutics, Inc., dated October 16, 2008 (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013)
10.12	*	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 (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013)
10.13	*	Supply Agreement, by and between the Registrant and The Medicines Company, dated September 24, 2009 (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013)
10.14	*	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 (incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013)
10.15	*	Supply and Distribution Agreement, by and between the Registrant and Sandoz AG, dated January 28, 2013 (incorporated by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013)
10.16	*	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 (incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013)
10.17	*	Development and License Agreement, by and between the Registrant and Robert One, LLC (pemetrexed), dated February 13, 2009, as amended May 22, 2009, December 23, 2010 and July 16, 2013 (incorporated by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013), and as amended on August 5, 2015 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed August 10, 2015)
10.18	*	Exclusive License Agreement, by and between the Registrant and Cephalon, Inc., dated February 13, 2015 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q/A, SEC File No. 001-36306, filed February 12, 2016)
10.19	*	Settlement and License Agreement, by and between the Registrant and Cephalon, Inc., dated February 13, 2015 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, SEC File No. 001-36306, filed May 15, 2015)
10.20	†	Eagle Pharmaceuticals, Inc. Officer Severance Benefit Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed August 10, 2015), as amended and restated by the Eagle Pharmaceuticals, Inc. Amended and Restated Severance Benefit Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed December 16, 2019).
10.21	†	Form of Letter Agreement (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed December 21, 2015)
10.22	*	License Agreement, by and between the Registrant and Teikoku Pharma USA, Inc., dated October 13, 2015 (incorporated by reference to Exhibit 10.23 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed February 29, 2016)
10.23	*	Co-Promotion Agreement, by and between the Registrant and Spectrum Pharmaceuticals, Inc., dated November 4, 2015 (incorporated by reference to Exhibit 10.23 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed February 29, 2016)
10.24	†	Offer Letter by and between the Registrant and David Pernock dated January 2, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed December 19, 2016)

10.25		Credit Agreement, by and among the Registrant, JPMorgan Chase Bank, N.A., as administrative agent, and the lenders party thereto, dated January 26, 2017 (incorporated by reference to Exhibit 10.26 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed March 15, 2017) as amended and restated by the Amended and Restated Credit Agreement, by and among the Registrant, JPMorgan Chase Bank, N.A., as administrative agent, and the lenders party thereto, dated August 8, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed August 9, 2017), and as amended and restated by the Second Amended and Restated Credit Agreement, by and among the Registrant, JPMorgan Chase Bank, N.A., as administrative agent, and the lenders party thereto, dated November 8, 2019 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, SEC File No. 001-36306, filed November 12, 2019).
10.26		Amendment to License and Sublicense Agreement, by and between the Registrant and Lyotropic Therapeutics, Inc., dated August 3, 2016 (incorporated by reference to Exhibit 10.27 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed March 15, 2017)
10.27	†	Offer Letter between the Registrant and Pete A. Meyers dated May 12, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed May 15, 2017)
10.28	*	Product Collaboration and License Agreement, by and between the Registrant and SymBio Pharmaceuticals Limited, effective as of September 19, 2017 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, SEC File No. 001-36306, filed November 8, 2017)
10.29	†	Form of Restricted Stock Unit Grant Package (2014 Equity Incentive Plan) (incoporated by reference to Exhibit 10.3 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed February 26, 2018)
10.30	†	Form of Performance Stock Unit Grant Package (2014 Equity Incentive Plan) (incoporated by reference to Exhibit 10.3 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed February 26, 2018)
10.31		Stock Purchase Agreement, dated as of November 10, 2016, by and among Eagle Pharmaceuticals, Inc., Arsia Therapeutics, LLC, Arsia Therapeutics, Inc., Amy Schulman, as the Seller Representative, and each person that executed a joinder to the Purchase Agreement (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Commission on November 14, 2016)), as amended by Amendment No. 1 to Stock Purchase Agreement, dated as of February 8, 2018 (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, SEC File No. 001-36306, filed with the Commission on February 14, 2018)
10.32	(1)	Fifth Amendment to Lease Agreement between the Registrant and CAPSTONE TICE BLVD LLC. dated as of August 8, 2019
10.33		Fourth Amendment to Exclusive License Agreement, by and between the Registrant and Teva Pharmaceuticals International GmbH, dated April 12, 2019 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on May 7, 2019).
10.34	(1)+	Settlement Agreement, by and between the Registrant and Eli Lilly and Company, dated December 13, 2019.
10.35	(1)+	Co-Promotion Agreement with Tyme Technologies, Inc., dated January 7, 2020.
10.36		Securities Purchase Agreement, between the Registrant and Tyme Technologies, Inc., dated January 7, 2020 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on January 8, 2020).
21.1	(1)	List of subsidiaries of Eagle Pharmaceuticals, Inc.
23.1	(1)	Consent of BDO USA, LLP, an Independent Registered Public Accounting Firm
24.1		Power of Attorney (incorporated by reference to this signature page of this Annual Report on Form 10-K)
31.1	(1)	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	(1)	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1	(2)	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS		iXBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH		iXBRL Taxonomy Extension Schema
101.CAL		iXBRL Taxonomy Extension Calculation Linkbase
101.DEF		iXBRL Taxonomy Extension Definition Linkbase
101.LAB		iXBRL Taxonomy Extension Labels Linkbase
101.PRE		iXBRL Taxonomy Extension Presentation Linkbase
104		Cover Page Interactive Data File, formatted as Inline XBRL, contained in Exhibit 101 attachments

†Management contract or compensatory plan or arrangement.

*Confidential treatment granted as to certain portions, which portions are omitted and filed separately with the Securities and Exchange Commission.

+Certain portions of the exhibit (indicated by asterisks) have been omitted because they are not material and would likely cause competitive harm to the registrant if publicly disclosed.

(1) Filed herewith.

(2) Furnished (and not filed) herewith pursuant to Item 601 (b)(32)(ii) of Regulation S-K.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 2, 2020.

EAGLE PHARMACEUTICALS, INC.

By: /s/ Scott Tarriff
Scott Tarriff
Chief Executive Officer and Director
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Scott Tarriff and Pete A. Meyers, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this report, and to file the same, with all 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 connection therewith, 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 either of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Signature	Title	Date
/S/ SCOTT TARRIFF Scott Tarriff	Chief Executive Officer and Director (Principal Executive Officer)	March 2, 2020
/S/ PETE A. MEYERS Pete A. Meyers	Chief Financial Officer (Principal Accounting and Financial Officer)	March 2, 2020
/S/ MICHAEL GRAVES Michael Graves	Chairman of the Board of Directors	March 2, 2020
/S/ STEVEN RATOFF Steven Ratoff	Member of the Board of Directors	March 2, 2020
/S/ JENNIFER K. SIMPSON Jennifer K. Simpson	Member of the Board of Directors	March 2, 2020
/S/ ROBERT L. GLENNING Robert L. Glenning	Member of the Board of Directors	March 2, 2020
/S/ RICHARD A. EDLIN Richard A. Edlin	Member of the Board of Directors	March 2, 2020

INDEX TO FINANCIAL STATEMENTS OF EAGLE PHARMACEUTICALS, INC.

APPENDIX A

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Eagle Pharmaceuticals, Inc.
Woodcliff Lake, NJ

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Eagle Pharmaceuticals, Inc. and subsidiaries (the “Company”) as of December 31, 2019 and 2018, the related consolidated statements of income, changes in stockholders’ equity and cash flows for each of the three years in the period ended December 31, 2019, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) and our report dated March 2, 2020 expressed an unqualified opinion thereon.

Change in Accounting Principles

On January 1, 2019, the Company adopted Accounting Standards Update 2016-02, *Leases*. The effects of the adoption are described in Note 2 to the consolidated financial statements.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue Recognition - ***Variable Consideration***

As described in Note 2 to the consolidated financial statements, revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer. To the extent the transaction price includes variable consideration, the Company estimates the amount that should be included in the transaction price to which the Company expects to be entitled. Estimates of variable consideration are made using the expected value method and based largely on an assessment of the Company’s anticipated performance and relevant information (historical, current and forecasted) that is reasonably available. The Company enters into revenue contracts with oncology distributors and hospital buying groups that give rise to variable consideration, including chargebacks, rebates, returns, prompt pay discounts, wholesaler fees and other deductions.

We identified the Company’s estimation of variable consideration related to chargebacks and returns for certain product sales made to oncology supply centers and hospital buying groups as a critical audit matter. These estimates included consideration of: (i) assumptions related to the calculation of the related variable consideration, and (ii) limited historical sales and chargeback information. Auditing these elements involved especially challenging auditor judgment and a high degree of auditor subjectivity.

The primary procedures we performed to address this critical audit matter included:

- Testing the design and operating effectiveness of certain controls relating to management’s calculation and review of the variable consideration.
- Assessing the reasonableness of underlying assumptions through: (i) evaluating historical sales, chargeback activity and returns, (ii) reviewing relevant supporting details including contracts with hospital buying groups, and (iii) performing retrospective reviews utilizing available historical information compared to estimates made in prior periods.
- Testing the completeness and accuracy of management’s calculations by re-performing or independently calculating the variable consideration and reviewing relevant source documents including sales data, chargebacks and assumptions related to returns. Also, on a sample basis, we agreed underlying data used in management’s calculations to the audited trial balances, relevant source documents and revenue contract terms.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2007.

Woodbridge, NJ

March 2, 2020

EAGLE PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share amounts)

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 109,775	$ 78,791
Accounts receivable, net	48,004	66,486
Inventories	6,566	8,304
Prepaid expenses and other current assets	15,104	10,263
Total current assets	179,449	163,844
Property and equipment, net	2,202	2,397
Intangible assets, net	15,583	18,103
Goodwill	39,743	39,743
Deferred tax asset, net	13,669	13,822
Other assets	3,908	694
Total assets	$ 254,554	$ 238,603
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,462	$ 9,917
Accrued expenses and other liabilities	28,361	23,519
Current portion of long-term debt	5,000	6,250
Total current liabilities	38,823	39,686
Other long-term liabilities	3,000	—
Long-term debt, less current portion	33,557	38,155
Total liabilities	75,380	77,841
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of December 31, 2019 and 2018	—	—
Common stock, $0.001 par value; 50,000,000 shares authorized; 16,537,846 and 16,504,283 shares issued as of December 31, 2019 and 2018, respectively	17	17
Additional paid in capital	278,518	256,458
Retained earnings	72,500	58,187
Treasury stock, at cost, 2,907,687 and 2,590,258 shares as of December 31, 2019 and 2018, respectively	(171,861)	(153,900)
Total stockholders' equity	179,174	160,762
Total liabilities and stockholders' equity	$ 254,554	$ 238,603

See accompanying notes to consolidated financial statements

EAGLE PHARMACEUTICALS, INC
CONSOLIDATED STATEMENTS OF INCOME
(In thousands, except share and per share amounts)

	Year Ended December 31,		
	2019	**2018**	**2017**
Revenue:			
Product sales	$ 73,989	$ 70,385	$ 45,327
Royalty revenue	112,903	142,927	153,880
License and other revenue	9,000	—	37,500
Total revenue	195,892	213,312	236,707
Operating expenses:			
Cost of product sales	47,891	42,374	33,714
Cost of royalty revenue	13,006	19,542	23,472
Research and development	36,810	44,419	32,607
Selling, general and administrative	76,370	60,509	71,416
Restructuring charge	—	7,911	—
Asset impairment charge	—	2,704	7,235
Change in fair value of contingent consideration	—	(763)	(7,377)
Legal settlement	—	—	1,650
Total operating expenses	174,077	176,696	162,717
Income from operations	21,815	36,616	73,990
Interest income	2,169	158	91
Interest expense	(2,686)	(2,736)	(1,136)
Other income	700	—	—
Total other income (expense), net	183	(2,578)	(1,045)
Income before income tax	21,998	34,038	72,945
Income tax provision	7,685	2,135	21,002
Net income	$ 14,313	$ 31,903	$ 51,943
Earnings per share:			
Basic	$ 1.04	$ 2.16	$ 3.44
Diluted	$ 1.01	$ 2.09	$ 3.27
Weighted average number of common shares outstanding:			
Basic	13,754,516	14,768,625	15,102,890
Diluted	14,138,733	15,278,651	15,908,211

See accompanying notes to consolidated financial statements

EAGLE PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(In thousands)

	Common Stock					
	Number of Shares	Amount	Additional Paid-In Capital	Treasury Stock	(Accumulated Deficit) Retained Earnings	Total Stockholders' Equity
Balance at December 31, 2016	**15,891**	**$ 16**	**$ 213,872**	**$ (37,003)**	**$ (25,659)**	**$ 151,226**
Stock-based compensation expense	—	—	15,429	—	—	15,429
Issuance of common stock upon exercise of stock option grants	198	—	4,338	—	—	4,338
Common stock repurchases	—	—	—	(43,792)	—	(43,792)
Net income	—	—	—	—	51,943	51,943
Balance at December 31, 2017	**16,089**	**$ 16**	**$ 233,639**	**$ (80,795)**	**$ 26,284**	**$ 179,144**
Stock-based compensation expense	—	—	19,082	—	—	19,082
Issuance of common stock upon exercise of stock option grants	415	1	8,614	—	—	8,615
Payments for employee net option exercises	—	—	(4,877)	—	—	(4,877)
Common stock repurchases	—	—	—	(73,105)	—	(73,105)
Net income	—	—	—	—	31,903	31,903
Balance at December 31, 2018	**16,504**	**$ 17**	**$ 256,458**	**$ (153,900)**	**$ 58,187**	**$ 160,762**
Stock-based compensation expense	—	—	21,998	—	—	21,998
Issuance of common stock upon exercise of stock option grants	34	—	260	—	—	260
Payment of employee withholding tax upon vesting of stock-based awards	—	—	(198)	—	—	(198)
Common stock repurchases				(17,961)		(17,961)
Net income	—	—	—	—	14,313	14,313
Balance at December 31, 2019	**16,538**	**$ 17**	**$ 278,518**	**$ (171,861)**	**$ 72,500**	**$ 179,174**

See accompanying notes to consolidated financial statements

EAGLE PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,		
	2019	2018	2017
Cash flows from operating activities:			
Net income	$ 14,313	$ 31,903	$ 51,943
Adjustments to reconcile net income to net cash provided by operating activities:			
Deferred income taxes	152	(2,468)	17,289
Depreciation expense	2,131	1,155	932
Amortization expense	2,520	2,515	2,815
Stock-based compensation expense	21,998	19,082	15,429
Change in fair value of contingent consideration	—	(763)	(7,377)
Amortization of debt issuance costs	480	376	222
Asset impairment charge	—	2,704	7,235
Non-cash restructuring charge	—	5,769	—
Changes in operating assets and liabilities which provided (used) cash:			
Accounts receivable	18,481	(12,665)	(11,627)
Inventories	1,739	(5,556)	(2,379)
Prepaid expenses and other current assets	(4,841)	4,838	1,993
Other assets	(599)	(570)	—
Accounts payable	(4,455)	(2,064)	(8,460)
Accrued expenses and other liabilities	4,067	8,128	(9,096)
Net cash provided by operating activities	55,986	52,384	58,919
Cash flows from investing activities:			
Purchase of property and equipment	(777)	(133)	(4,436)
Payment for Ryanodex intangible asset	—	—	(750)
Net cash used in investing activities	(777)	(133)	(5,186)
Cash flows from financing activities:			
Repurchases of common stock	(17,961)	(73,105)	(43,792)
Payment of contingent consideration	—	(15,000)	—
Proceeds from long-term debt	—	—	50,000
Payment of debt	(6,000)	(3,750)	(1,250)
Payment of debt financing costs	(326)	—	(1,192)
Payment of employee withholding tax upon vesting of stock-based awards	(198)	—	—
Payments for employee net option exercises	—	(4,877)	—
Proceeds from common stock option exercises	260	8,615	4,338
Net cash (used in) provided by financing activities	(24,225)	(88,117)	8,104
Net increase (decrease) in cash and cash equivalents	30,984	(35,866)	61,837
Cash and cash equivalents at beginning of period	78,791	114,657	52,820
Cash and cash equivalents at end of period	$ 109,775	$ 78,791	$ 114,657

See accompanying notes to consolidated financial statements

EAGLE PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,		
	2019	**2018**	**2017**
Supplemental disclosures of cash flow information:			
Cash paid during the period for:			
Income taxes, net	$ 6,673	$ 2,281	$ 10,542
Interest	2,478	2,084	651
Right-of-use asset obtained in exchange for lease obligation - lease amendment	3,716	—	—

See accompanying notes to consolidated financial statements

1. Organization and Business

Eagle Pharmaceuticals, Inc. (the "Company" or "we") is a specialty pharmaceutical company primarily focused on developing and commercializing injectable products, primarily in the Central Nervous System ("CNS") critical care and oncology areas, using the U.S. Food and Drug Administration's ("FDA's") 505(b)(2) New Drug Application ("NDA") regulatory pathway. The Company's business model is to develop proprietary innovations to FDA-approved injectable drugs, referred to as branded reference drugs, that offer favorable attributes to patients and healthcare providers. The Company has two products currently being sold in the United States under various license agreements in place with commercial partners; a ready-to-use formulation of Argatroban and rapidly infused bendamustine RTD 50ml solution (“Bendeka”). In addition, the Company directly sells two products in the United States; Eagle's bendamustine RTD 500ml solution (“Belrapzo") and Ryanodex®(dantrolene sodium) ("Ryanodex"). The Company has a number of products currently under development and certain products may be subject to license agreements. We view our operation and manage our business as one reporting segment since the majority of our revenues are from royalties.

On February 13, 2015, the Company submitted a NDA to the FDA for Bendeka, which was approved by the FDA on December 7, 2015. Also, on February 13, 2015, the Company entered into an Exclusive License Agreement (the “Cephalon License”) with Cephalon, Inc. (“Cephalon”), a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd. (“Teva”), for U.S. and Canadian rights to Bendeka for treatment of patients with chronic lymphocytic leukemia (“CLL”) and patients with non-Hodgkin’s lymphoma (“NHL”). Subsequently, with the consent of the Company, Cephalon assigned to Teva Pharmaceuticals International GmbH (“TPIG”) all of Cephalon’s rights and obligations under the Cephalon License. Accordingly, all references to “Cephalon” or to the “Cephalon License” and the related supply agreements for Bendeka should be read and construed as references to TPIG and to the license agreement and supply agreements for Bendeka to which the Company and TPIG are now parties. Pursuant to the terms of the Cephalon License, Cephalon will be responsible for all U.S. commercial activities for the product including promotion and distribution, and the Company is responsible for obtaining and maintaining all regulatory approvals and conducting post-approval clinical studies. In connection with the Cephalon License, the Company has entered into a supply agreement with Cephalon, pursuant to which the Company is responsible for supplying product to Cephalon. During the quarter-ended September 30, 2016, the Company entered into an amendment to the Cephalon License and supply agreements for Bendeka. This amendment expanded the geographical scope of the rights granted under the original agreement to include territories outside the U.S. and Canada.

Additionally, under the terms of the Cephalon License, the Company received an upfront cash payment of $30 million in February 2015, earned a $15 million milestone payment related to the FDA approval of Bendeka in December 2015, earned $40 million in November 2016 related to the receipt of a unique, product-specific billing code, J-code (J9034), for Bendeka and earned $25 million in March 2017 for an additional sales-based milestone payment. In addition, the Company was entitled to receive royalty payments of 20% of net sales of the product, which increased to 25% on receipt of the J-code.

On August 9, 2016, the Company announced a share repurchase program approved by the Company’s board of directors authorizing the repurchase of up to $75.0 million of the Company’s common stock (the “Share Repurchase Program”). On August 9, 2017, the Company announced a new share repurchase program approved by the Board, under which the Company may repurchase up to an additional $100 million of its outstanding common stock (the “New Share Repurchase Program”). Under the Share Repurchase Program and the New Share Repurchase Program, the Company is authorized to repurchase shares through open market purchases, privately-negotiated transactions or otherwise in accordance with applicable federal securities laws, including through Rule 10b5-1 trading plans and under Rule 10b-18 of the Exchange Act. The Share Repurchase Programs have no time limit and may be suspended or discontinued completely at any time. The specific timing and amount of repurchases will vary based on available capital resources and other financial and operational performance, market conditions, securities law limitations, and other factors. The repurchases will be made using the Company's cash resources. In any period, cash used in financing activities related to shares repurchased may differ from the comparable change in stockholders' equity, reflecting timing differences between the recognition of share repurchase transactions and their settlement for cash.

On October 30, 2018, the Company announced that its Board of Directors has approved a new share repurchase program providing for the repurchase of up to $150 million of the Company's outstanding common stock, consisting of (i) up to $50 million in repurchases pursuant to an accelerated share repurchase agreement (the “ASR”) with JPMorgan Chase Bank, N.A. (“JPMorgan”), and (ii) up to $100 million in additional repurchases (the “2018 Share Repurchase Program”). In connection with its approval of the 2018 Share Repurchase Program, the Board terminated the Company’s 2016 Share Repurchase Program and 2017 Share Repurchase Program in October 2018. During the fourth quarter of 2018, the Company repurchased 1,000,134 shares of outstanding common stock for $50 million pursuant to the ASR.

The Company repurchased 1,348,563 shares of common stock for $73.1 million during the year ended December 31, 2018 and an aggregate of 2,590,258 shares of common stock for $153.9 million through December 31, 2018.

On February 8, 2018, we entered into an amendment (the “Arsia Amendment”) to the stock purchase agreement dated November 10, 2016 (the “Arsia SPA”), pursuant to which we acquired from Arsia Therapeutics, LLC (the “Seller”) all of the outstanding capital stock of Arsia Therapeutics, Inc. Pursuant to the Arsia Amendment, our obligations to make four separate milestone payments pursuant to the Arsia SPA, which could have aggregated to a total of $48 million, were terminated in exchange for a single payment of $15 million to the Seller.

On November 8, 2019, the Company entered into the Second Amended and Restated Credit Agreement (the “Revised Credit Agreement”), with JPMorgan Chase Bank, N.A., as administrative agent (the “Agent”) and the lenders party thereto, which replaced the Company’s existing credit agreement, dated as of August 8, 2017 (the "Amended Credit Agreement"). Refer to Note 6. "Debt" for further details.

On September 20, 2017, the Company entered into a Product Collaboration and License Agreement, effective as of September 19, 2017, (the “SymBio License Agreement”) with SymBio Pharmaceuticals Limited (“SymBio”) for the rights to develop and commercialize the Company’s bendamustine hydrochloride ready-to-dilute injection product and rapid infusion injection product (collectively, the “Products”) in Japan. Under the License Agreement, SymBio will be responsible for all development of the Products in Japan and for obtaining and maintaining all regulatory approvals of the Products in Japan, with a target for regulatory approval of a Product in Japan in 2020. SymBio will bear all costs of development of the Products in Japan except that, if Japanese regulatory authorities require a certain clinical study to be conducted as a condition for approving one of the Products in Japan, Eagle would share 50% of the out-of-pocket costs of that clinical study up to a specified dollar amount as a reduction to future royalty payments. Based on the Company's assessment of the probability of additional costs, we have not deferred revenue on the Symbio License Agreement. SymBio will also be responsible, at its sole cost, for all marketing, promotion, distribution and sales of the Products in Japan and is obligated to launch the Products and meet certain minimum detailing, promotion and marketing commitments in connection with commercialization of the Products in Japan.

SymBio currently markets in Japan TREAKISYM®, a lyophilized powder formulation of bendamustine hydrochloride indicated for CLL, relapsed or refractory low-grade NHL, mantle cell lymphoma (“MCL”), and as a first line treatment of low-grade NHL and MCL. Under the SymBio License Agreement, SymBio may continue to market TREAKISYM® in Japan and SymBio will be permitted to develop and market certain other bendamustine hydrochloride products in Japan for limited indications.

Pursuant to the terms of the SymBio License Agreement, the Company and SymBio will enter into a separate supply agreement, under which the Company will be responsible for manufacturing and supplying the Products to SymBio for development and commercialization in Japan. After a period of time following launch of a Product, SymBio will have the right to assume the responsibility for manufacturing of the Products in and for Japan. Under the SymBio License Agreement, the Company will retain the right to control the prosecution, maintenance and enforcement of the Company’s patents covering the Products, both inside and outside of Japan.

Under the SymBio License Agreement, the Company earned an upfront non-refundable cash payment of $12.5 million in the third quarter of 2017, and is eligible to receive a milestone payment upon approval of a Product in Japan and a milestone payment upon achievement of certain cumulative net sales of the Products in Japan, which can aggregate to a total of approximately $10.0 million (subject to currency fluctuations). After regulatory approval of a Product in Japan, the Company will also receive tiered, low double-digit royalties on net sales of the Products in Japan for so long as there are patents covering the Products in Japan or regulatory exclusivity for the Products in Japan.

In March 2018, the FDA approved a second manufacturing site for Bendeka.

On April 16, 2018, the Company announced the FDA's acceptance of the Company's ANDA filing for vasopressin injection, 1ml. This product is the generic version of Endo International plc's original Vasostrict® formulation, which is indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines.

On May 15, 2018, the FDA granted final approval for Eagle's ready-to-dilute bendamustine hydrochloride solution in a 500ml admixture for the treatment of patients with chronic lymphocytic leukemia (“CLL”) and patients with indolent B-cell non-Hodgkin lymphoma (“NHL”) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

On March 24, 2016 the FDA denied the Company's request for seven years of orphan drug exclusivity in the U.S., for Bendeka. In April 2016, the Company filed a lawsuit against the FDA arguing that Bendeka is entitled to orphan drug exclusivity as a matter of law (see Note 13. Legal Proceedings). On July 2, 2014, the FDA granted the Company orphan drug designations for Bendeka for the treatment of CLL and indolent B-cell NHL. The designations were based on a plausible hypothesis that Bendeka is “clinically superior” to a drug previously approved for the same indications. Generally, an orphan-designated drug is eligible for seven years of marketing exclusivity for the orphan-designated indications upon approval of the drug for those indications. On June 8, 2018, the U.S. District Court for the District of Columbia (the “Court”) issued a decision requiring the FDA to grant seven years of orphan drug exclusivity (“ODE”) in the U.S., for Bendeka, and on July 8, 2018 the FDA granted such ODE through December 2022. In addition, on July 8, 2018, the FDA submitted a Motion to Alter or Amend the Judgement Pursuant to Rule 59(e), pursuant to which the FDA requested the Court amend its decision to make clear that the decision does not affect any applications referencing TREANDA. The FDA’s motion was denied by the Court on August 1, 2018 on the grounds that FDA was seeking an inappropriate advisory opinion. On February 20, 2019, the FDA issued a decision in favor of the Company, regarding the scope of exclusivity for Bendeka. Pursuant to the decision, no bendamustine product (including generic versions of TREANDA) may launch in the United States until December 7, 2022 unless it is clinically superior to Bendeka. The Company expects to vigorously pursue the scope of its exclusivity grant.

In June 2018, as part of an ongoing organizational review, the Company began a restructuring initiative to rationalize its product portfolio and focus its physical sites. These measures include the discontinuation of manufacture and distribution of Non-Alcohol Docetaxel Injection and plans to rationalize research and development operations. The Company ceased selling the product by September 30, 2018.

On October 3, 2018, the Company announced that it entered into an agreement with the United States Army Medical Research Institute of Chemical Defense, the nation’s leading science and technology laboratory in the area of medical chemical countermeasures research and development, to conduct a study to evaluate the neuroprotective effects of Ryanodex® (dantrolene sodium).

On October 30, 2018, the Company announced that the Company’s fulvestrant formulation has not met the primary pharmacokinetic endpoint evaluating the bioequivalence of the Company’s formulation compared to Faslodex in its open label, randomized, pharmacokinetic and safety study conducted in 600 healthy female volunteers across multiple U.S. sites.

As of March 29, 2019, the Company and Teva Pharmaceutical Industries Ltd. ("Teva") executed an amendment to the Cephalon License Agreement to terminate Teva's obligation to pay future milestones and royalties on Bendeka sales outside of the U.S., which included an upfront cash payment of $9 million that was recorded as License and other revenue on the consolidated statements of income.

On April 13, 2019, the Company and Teva entered into an Amendment to the Cephalon License Agreement ("Cephalon License", amending the terms of the License Agreement to increase the U.S. royalty paid to the Company and re-allocated certain litigation expenses. Pursuant to the Amendment, beginning on October 1, 2019, the Company's royalty payment has increased from 25% to 30% of Bendeka net U.S. sales. The royalty rate will increase by one percentage point on each anniversary of October 1, 2019 until it reaches 32%, and it will remain at 32% thereafter. The Amendment also extends the U.S. royalty term for Bendeka until it is no longer sold in the United States. The previous U.S. royalty term was set to expire in 2025. The extended term coincides with the bendamustine patents with expiries through 2033. Pursuant to the amendment, Eagle will continue to be responsible for the manufacture of Bendeka for the U.S. market for so long as it is sold in the United States.

On May 7, 2019, the Company announced positive results of its study to evaluate the neuroprotective effects of Ryanodex secondary to nerve agent exposure, conducted with the United States Army Medical Research Institute of Chemical Defense.

On December 13, 2019, we reached a settlement agreement with Eli Lilly and Company related to the Company’s novel product, PEMFEXY™ (pemetrexed for injection), a branded alternative to ALIMTA®. The agreement provides for a release of all claims by the parties and allows for an initial entry of PEMFEXY™ into the market (equivalent to approximately a three week supply of current ALIMTA®utilization) on February 1, 2022 and a subsequent uncapped entry on April 1, 2022.

On December 16, 2019, we announced that the FDA has granted orphan drug designation (ODD) for Ryanodex®(dantrolene sodium) for the treatment of organophosphate exposure. Organophosphates are a class of chemicals that include potent pesticides and chemical weapons, known as nerve agents. Acute intoxication with organophospates may result in severe consequences, including brain damage and death. About 2,700 people in the United States are treated for accidental exposure to organophosphate pesticides every year. Eagle is currently evaluating Ryanodex for the treatment of brain damage secondary to nerve agent exposure. If approved, Ryanodex would represent the first product available for this indication.

On January 6, 2020, we issued a press release announcing a new research agreement with NorthShore University HealthSystem in Evanston, Illinois, focused on studying Ryanodex for traumatic brain injury (TBI) in animal models. TBI can acutely cause brain lesions that result in direct tissue damage that may prompt apoptotic cell mechanisms for several weeks post-injury, which may lead to worsened long-term outcomes. Disruption of certain intracellular mechanisms may affect cell functioning and survival.

On January 7, 2020, Tyme Technologies, Inc. and the Company announced a strategic collaboration to advance oral SM-88 for the treatment of patients with cancer. SM-88 is an investigational agent in two Phase 2 studies for pancreatic cancer and in a Phase 2 study for prostate cancer. Data is expected in 2021.

On January 9, 2020, we announced that the Company has resubmitted its New Drug Application ("NDA") for Ryanodex®(dantrolene sodium for injectable suspension) for the treatment of exertional heat stroke ("EHS"), in addition to body cooling, to the FDA. Eagle believes that this submission addresses the Complete Response Letter received in July 2017. A Prescription Drug User Fee Act ("PDUFA") date of six months is anticipated for this class of resubmissions.

On January 13, 2020, we issued a press release announcing that the Company and the University of Pennsylvania had agreed on terms of a new exclusive worldwide license agreement for the development of dantrolene sodium for the potential treatment of people living with Alzheimer’s disease, including an agreement to fund additional research and provisions regarding commercialization of products developed under the license.

On February 10, 2020, we announced that it has received final approval from the FDA for its novel product, PEMFEXY™ (pemetrexed for injection), a branded alternative to ALIMTA®.

2. Summary of Significant Accounting Policies

Use of Estimates

These financial statements are presented in U.S. dollars and are prepared in accordance with U.S. GAAP. The preparation of financial statements in conformity with U.S. GAAP 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.

Reclassifications

Certain reclassifications have been made to prior year amounts to conform with the current year presentation. None of the reclassifications were significant.

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 Measurements

U.S. 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, cash equivalents, accounts receivable and accounts payable approximate fair value due to their life being short term in nature, and are classified as Level 1 for all periods presented.

The fair value of debt is classified as Level 2 for the periods presented and approximates its fair value due to the variable interest rate.

The fair value of the accrued royalty is classified as Level 3 for the period presented.

Intangible Assets

Other Intangible Assets, Net

The Company capitalizes and includes in intangible assets the costs of acquired product licenses and developed technology purchased individually or identified in a business combination. Intangible assets are recorded at fair value at the time of their acquisition and stated net of accumulated amortization. The Company amortizes its definite-lived intangible assets using either the straight-line or accelerated method, based on the useful life of the asset over which it is expected to be consumed utilizing expected undiscounted future cash flows. The Company will evaluate the potential impairment of intangible assets if events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Events giving rise to impairment are an inherent risk in our industry and many factors cannot be predicted. Factors that we consider in deciding when to perform an impairment review include significant changes in our forecasted projections for the asset or asset group for reasons including, but not limited to, significant under-performance of a product in relation to expectations, significant changes or planned changes in our use of the assets, significant negative industry or economic trends, and new or competing products that enter the marketplace. The impairment test is based on a comparison of the undiscounted cash flows expected to be generated from the use of the asset group and its eventual disposition to the carrying value of the asset group. If impairment is indicated, the asset is written down by the amount by which the carrying value of the asset exceeds the related fair value of the asset with the related impairment charge recognized within the statements of income.

With respect to determining an asset’s fair value and useful life, because this process involves management making certain estimates and these estimates form the basis of the determination of whether or not an impairment charge should be recorded, these estimates are considered to be critical accounting estimates.

Goodwill

Goodwill represents the excess of purchase price over the fair value of net assets acquired in the Eagle Biologics acquisition described in Note 11. Goodwill is not amortized, but is evaluated for impairment on an annual basis, in the fourth quarter, or more frequently if events or changes in circumstances indicate that the fair value of the reporting unit’s goodwill is less than it's carrying amount. The Company did not identify any impairment to goodwill during the periods presented.

(In thousands, except share and per share amounts)

Acquisition-Related Contingent Consideration

Contingent consideration related to a business combination is recorded on the acquisition date at the estimated fair value of the contingent payments. The acquisition date fair value is measured based on the consideration expected to be transferred using probability-weighted assumptions and discounted back to present value. The discount rate used is determined at the time of the acquisition in accordance with accepted valuation methods. The fair value of the acquisition-related contingent consideration is re-measured at the estimated fair value at each reporting period with the change in fair value recognized as income or expense in the consolidated statements of income.

Concentration of Major Customers and Vendors

The Company is dependent on its commercial partner to market and sell Bendeka; therefore, the Company's future revenues are highly dependent on the collaboration and distribution arrangement with Teva.

Teva markets Bendeka through a license agreement with the Company. Pursuant to that license agreement, Teva pays the Company a royalty based on net sales of the product and also purchases the product from the Company. A disruption in this arrangement, caused by among other things, a supply disruption, loss of exclusivity or the launch of a superior product would have a material adverse effect of the Company’s financial position, results of operations and cash flows.

The total revenues and accounts receivables broken down by major customers as a percentage of the total are as follows:

	Year Ended December 31,		
	2019	**2018**	**2017**
Net revenues			
Cephalon, Inc. (Teva) - See Revenue Recognition	77%	75%	79%
Other	23%	25%	21%
	100%	100%	100%

	December 31,	
	2019	**2018**
Accounts receivable		
Cephalon, Inc. (Teva) - See Revenue Recognition	80%	61%
Other	20%	39%
	100%	100%

Inventories

Inventories are recorded at the lower of cost or net realizable value, with cost determined on a first-in first-out basis. The Company periodically reviews the composition of its inventories 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 inventories, the Company will record a write-down to net realizable value in the period that the decline in value is first recognized.

Property and Equipment

Property and equipment are stated at cost. Depreciation is recorded 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 for research and development are charged to expense as incurred and include; employee-related expenses including salaries, benefits, travel and stock-based compensation expense for research and development personnel; expenses incurred under agreements with contract research organizations, contract manufacturing organizations and service providers that assist in conducting clinical and preclinical studies; costs associated with preclinical activities and development activities, costs associated with regulatory operations; and depreciation expense for assets used in research and development activities.

Costs for certain development activities, such as clinical studies, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by its vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the patterns of costs incurred, and are reflected in the consolidated financial statements as prepaid expenses or accrued expenses as deemed appropriate. Recoveries of previously recognized research and development expenses from third parties are recorded as a reduction to research and development expense in the period it becomes realizable.

Advertising and Marketing

Advertising and marketing costs are expensed as incurred. Advertising and marketing costs were $2,374, $3,312, and $17,770 for the year ended December 31, 2019, 2018, and 2017, respectively.

Income Taxes

The Company accounts for income taxes using the liability method in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC"), Topic 740 - Income Taxes ("ASC 740"). Deferred tax assets and liabilities are determined based on temporary differences between financial reporting and tax bases of assets and liabilities and are measured by applying enacted rates and laws to taxable years in which differences are expected to be recovered or settled. Further, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that the rate changes. A valuation allowance is required when it is "more likely than not" that all or a portion of deferred tax assets will not be realized. ASC 740 also prescribes a comprehensive model for how a company should recognize, measure, present and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return, including a decision whether to file or not file a return in a particular jurisdiction. We recognize any interest and penalties accrued related to unrecognized tax benefits as income tax expense.

Revenue Recognition

Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Sales, value add, and other taxes collected on behalf of third parties are excluded from revenue.

Product revenue - The Company recognizes net revenue on sales to its commercial partners and to end users. In each instance, revenue is generally recognized when the customer obtains control of the Company's product, which occurs at a point in time, and may be upon shipment or upon delivery based on the contractual shipping terms of a contract. Receivables from our product sales have payment terms ranging from 30 to 75 days with select extended terms to wholesalers on initial purchases of product launch quantities.

Revenue on sales to commercial partners relates primarily to Bendeka. Sales to our commercial partners are presented gross because the Company is primarily responsible for fulfilling the promise to provide the product, is responsible to ensure that the product is produced in accordance with the related supply agreement and bears risk of loss while the inventory is in-transit to the commercial partner.

Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing the expected value method to which the Company expects to be entitled. As such, revenue on sales to end users for Belrapzo and Ryanodex are recorded net of chargebacks, rebates, returns, prompt pay discounts, wholesaler fees and other deductions. Our products are contracted with a limited number of oncology distributors and hospital buying groups with narrow differences in ultimate realized contract prices used to estimate our chargeback and rebate reserves. The Company has a product returns policy on some of its products that allows the customer to return pharmaceutical products within a specified period of time both prior to and subsequent to the product's expiration date. The Company's estimate of the provision for returns is analyzed quarterly and is based upon many factors, including historical experience of actual returns and analysis of the level of inventory in the distribution channel, if any. The Company has terms on sales of Ryanodex by which the Company does not accept returns. Variable consideration is included in the transaction price if, in the Company's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Estimates of variable consideration are made using the expected value method and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of the Company's anticipated performance and all information (historical, current and forecasted) that is reasonably available. The Company believes that the estimates it has established are reasonable based upon current facts and circumstances. Applying different judgments to the same facts and circumstances could result in the estimated amounts to vary.

The Company recorded product sales as follows:

	Year Ended December 31,		
	2019	**2018**	**2017**
	(in thousands)		
Bendeka	$ 31,182	$ 24,568	$ 16,225
Belrapzo	29,665	22,853	—
Ryanodex	13,039	20,195	17,500
Other	103	2,769	11,602
Total Product Sales	$ 73,989	$ 70,385	$ 45,327

Royalty Revenue — The Company recognizes revenue from license arrangements with 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 25 days for Bendeka 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. Our receivables from royalty revenue are due 45-days from the end of the quarter.

License and other revenue — The Company analyzes each element of its licensing agreements to determine the appropriate revenue recognition. The terms of the license agreement may include payment to us of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. The Company recognizes revenue from upfront payments at a point in time, typically upon fulfilling the delivery of the associated intellectual property to the customer.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. The Company determines standalone selling prices based on the price at which the performance obligation is sold separately. If the standalone selling price is not observable through past transactions, the Company estimates the standalone selling price taking into account available information such as market conditions and internally approved pricing guidelines related to the performance obligations.

The Company recognizes sales-based milestone payments as revenue upon the achievement of the cumulative sales amount specified in the contract in accordance with ASC 606-10-55-65. For those milestone payments which are contingent on the occurrence of particular future events, the Company determined that these need to be considered for inclusion in the calculation of total consideration from the contract as a component of variable consideration using the most-likely amount method. As such, the Company assesses each milestone to determine the probability and substance behind achieving each milestone. Given the inherent uncertainty of the occurrence of these future events, the Company will not recognize revenue from the milestone until there is not a high probability of a reversal of revenue, which typically occurs near or upon achievement of the event.

As described above, under the terms of the Cephalon License, the Company received an upfront cash payment of $30 million, received a milestone payment of $15 million for regulatory approval, received a $40 million milestone upon receipt of the J-Code and received $25 million in an additional sales based milestone payment for reaching $500 million in net product sales of Bendeka. In 2015, $30 million upfront payment was allocated between the license issued to Cephalon and obtaining and maintaining regulatory approvals and conducting post-approval clinical studies using the Company's best estimate of selling price for each deliverable. The full $30 million was recognized as income in the first quarter of 2015, as the Company substantially completed its requirements for obtaining regulatory approval, which consisted of filing an NDA, on February 13, 2015, and the remaining obligations were estimated to require minimal effort. On December 7, 2015, the FDA approved Bendeka (50 mL bendamustine hydrochloride) marking the achievement of a milestone which entitled the Company to a $15 million payment which was received in January 2016. The Company received a $40 million milestone payment in November 2016 upon receipt of the unique J-Code. Additionally, this event triggered an increase in the royalty rate from 20% to 25% of Bendeka net sales. In March 2017, the Company received a $25 million sales-based milestone payment for reaching $500 million in net product sales. As discussed above, under the SymBio License Agreement, the Company earned an upfront non-refundable cash payment of $12.5 million during the year ended December 31, 2017. In March 2019, the Company and TPIG executed an amendment to the Cephalon License Agreement to terminate Teva's obligation to pay future milestones and royalties on Bendeka sales outside of the U.S., which include an upfront cash payment of $9 million that was recorded as License and other revenue on the consolidated statements of income.

When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. Applying the practical expedient in paragraph 606-10-32-18, the Company does not assess whether a significant financing component exists if the period between when the Company performs its obligations under the contract and when the customer pays is one year or less. None of the Company's contracts contained a significant financing component as of December 31, 2019.

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, its allocated overhead, as well as the research and development performed by outside contractors or consultants.

Upon termination of a collaboration agreement, any remaining non-refundable license fees received by the Company, 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 income. 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.

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 and record expense over the employees' service periods, which are generally the vesting period of the equity awards.

The Company accounts 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. The straight-line method is used to allocate compensation cost to reporting periods over each optionee's requisite service period, which is generally the vesting period. The fair value of the Company's stock-based awards to employees and directors is estimated 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, forfeitures and the fair value of the underlying common stock on the date of grant, among other inputs. The risk-free interest rate is 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.

(In thousands, except share and per share amounts)

Earnings Per Share

Basic earnings per common share is computed using the weighted average number of shares outstanding during the period. Diluted earnings per share is computed in a manner similar to the basic earnings 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.

The anti-dilutive common shares equivalents outstanding at December 31, 2019, 2018, and 2017 were as follows:

	Year Ended December 31,		
	2019	2018	2017
Options	2,454,077	1,824,728	1,592,548

The following table sets forth the computation for basic and diluted net income per share for December 31, 2019, 2018, and 2017:

	Year Ended December 31,		
	2019	2018	2017
Numerator			
Numerator for basic and diluted earnings per share-net income	$ 14,313	31,903	$ 51,943
Denominator			
Basic weighted average common shares outstanding	13,754,516	14,768,625	15,102,890
Dilutive effect of stock options	384,217	510,026	805,321
Diluted weighted average common shares outstanding	14,138,733	15,278,651	15,908,211
Basic net income per share			
Basic net income per share	$ 1.04	$ 2.16	$ 3.44
Diluted net income per share			
Diluted net income per share	$ 1.01	$ 2.09	$ 3.27

Recent Accounting Pronouncements

Recent Accounting Pronouncements - Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses which requires financial assets measured at amortized cost basis to be presented at the net amount expected to be collected. The measurement of expected credit losses is based on relevant information about past events, including historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. This standard is effective for fiscal years beginning after December 15, 2019 and we will adopt the standard effective January 1, 2020. We have performed an assessment and determined that adoption will not have a material impact on our consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirement for Fair Value Measurement (“ASU 2018-13”), which amends the disclosure requirements for fair value measurements. The amendments in ASU 2018-13 are effective for fiscal years beginning after December 15, 2019, with early adoption permitted. We have performed an assessment and determined that adoption will not have a material impact on our consolidated financial statements.

(In thousands, except share and per share amounts)

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*. The ASU simplifies the accounting for income taxes by removing certain exceptions to the general principles and also clarifies and amends existing guidance. This standard is effective beginning January 1, 2021, with early adoption permitted. We are currently assessing the impact this standard will have on our consolidated financial statements.

Recently Adopted Accounting Pronouncements

The Company adopted FASB ASU No. 2016-02,“Leases (Topic 842)”("ASU 2016-02") as of January 1, 2019 to increase transparency and comparability among organizations, which included recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. Lessees are required to recognize a lease liability, which represents the discounted obligation to make future minimum lease payments, and a corresponding right-of-use asset on the balance sheet for most leases. The Company adopted ASU 2016-02 using the modified retrospective approach and did not recognized a cumulative-effect adjustment to the opening balance of Retained earnings. The Company elected a number of optional practical expedients permitted under the transition guidance within the new standard, which among other things, allowed us to carry forward the historical lease classification and that permits lease agreements that are twelve months or less to be excluded from the balance sheet. The primary impact upon adoption was the recognition, on a discounted basis, of the Company’s minimum commitments under noncancelable operating leases as right of use assets and obligations on the consolidated balance sheets, of approximately $3 million. The Company may enter into future long-term lease agreements or exercise renewal options contained in existing lease agreements that could have a material impact on the right of use assets and obligations reflected on the consolidated balance sheets. Refer to Note 5 - Balance Sheet Accounts for further details.

3. Inventories

Inventories consist of the following:

	December 31,	
	2019	**2018**
Raw materials	$ 2,460	$ 6,303
Work in process	3,243	1,776
Finished products	863	225
	$ 6,566	$ 8,304

4. Property and Equipment, net

Property and equipment consists of the following:

	December 31,		Estimated Useful Life
	2019	**2018**	(years)
Furniture and fixtures	$ 1,188	$ 1,117	7
Office equipment	1,094	546	3
Equipment	3,095	2,952	7
Leasehold improvements	1,144	1,129	2
	6,521	5,744	
Less accumulated depreciation	(4,319)	(3,347)	
Property and equipment, net	$ 2,202	$ 2,397	

Depreciation expense related to property and equipment amounted to $972 and $1,155 for the year ended December 31, 2019 and 2018, respectively. During the year ended December 31, 2018, as part of the restructuring initiative, the Company recorded an asset impairment charge related to property and equipment, primarily related to leasehold improvements.

(In thousands, except share and per share amounts)

5. Balance Sheet Accounts

Prepaid and Other Current Assets

Prepaid and other current assets consist of the following:

	December 31,	
	2019	2018
Advances to commercial manufacturers	$ 2,462	$ 2,700
Prepaid FDA user fee	6,345	1,540
Prepaid insurance	191	150
Prepaid income taxes	4,661	5,739
All other	1,445	134
Total Prepaid expenses and other current assets	$ 15,104	$ 10,263

Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consist of the following:

	December 31,	
	2019	2018
Accrued expenses		
Royalties payable to commercial partners	$ 6,004	$ 7,139
Accrued research & development	1,686	1,245
Accrued professional fees	1,926	2,408
Accrued salary and other compensation	8,083	5,049
Accrued product costs	8,364	5,869
All other	2,298	1,809
Total Accrued expenses and other liabilities	$ 28,361	$ 23,519

Adoption of FASB ASU No. 2016-02, "Leases (Topic 842)" as of January 1, 2019

The Company leases its corporate office under an amended lease agreement that expires on June 30, 2025 (the "Corporate Office Lease"). The Corporate Office Lease was amended on August 8, 2019 to extend the term through such date and to increase the amount of leased office space. The Company also leases lab space under a lease agreement that expires on October 31, 2023 (the "Lab Space Lease"). The Company estimated the right of use asset and the corresponding lease liability, on a discounted basis, as of the adoption date of January 1, 2019. The future minimum lease payments under this Corporate Office Lease are approximately $4.0 million.

For the Company's two operating leases (the Corporate Office Lease and Lab Space Lease), the depreciation and interest expense components are combined and recognized ratably over the remaining term of the lease as research and development and selling, general and administrative in the Company's consolidated statements of operations, respectively.

The Company used its estimated incremental borrowing rate to calculate the present value of the ROU assets and lease liabilities as of the date of adoption date. The implicit interest rate related to the Company's two lease agreements was not known as of the date of adoption. Therefore, the Company calculated an incremental borrowing rate based on the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term and amount equal to the lease payments in a similar economic environment.

(In thousands, except share and per share amounts)

Lease related disclosures consist of the following:

	December 31, 2019
Right of use (ROU) asset, net included in Other assets	$ 3,716
Lease liability included with Other long-term liabilities	$ 3,000
Lease liability included with Accrued expenses and other liabilities	$ 1,101
YTD 2019 depreciation of ROU asset	$ 1,159
YTD 2019 related rent expense	$ 1,146
YTD operating cash flows from operating leases	$ 952
YTD operating lease costs	$ 1,146
Weighted-average remaining lease term - operating leases	5.0 years
Weighted-average discount rate - operating leases	6%

As of December 31, 2019, the future minimum lease commitments for the Company's two leases were as follows:

Total	2020	2021	2022	2023	2024	Beyond
$ 6,607	$ 1,345	$ 1,362	$ 1,376	$ 1,291	$ 820	$ 413

As of December 31, 2018, the future minimum lease commitments for the Company's two leases were as follows:

Total	2019	2020	2021	2022	2023
$ 3,661	$ 1,146	$ 864	$ 583	$ 583	$ 485

6. Debt

On November 8, 2019, the Company entered into the Second Amended and Restated Credit Agreement (the “Revised Credit Agreement”), with JPMorgan Chase Bank, N.A., as administrative agent (the “Agent”) and the lenders party thereto, which replaced the Company’s existing credit agreement, dated as of August 8, 2017 (the "Amended Credit Agreement"). The terms and amounts borrowed under the Revised Credit Agreement includes a drawn term loan of $40 million and a undrawn revolving credit facility of $110 million. The schedule of principal payments for the new term loan facility has been extended until November 8, 2022. The Company classified the current portion of long-term debt of $5 million on the consolidated balance sheet as of December 31, 2019. Per the terms of the Revised Credit Agreement, the Company is limited in its ability to pay dividends. As of December 31, 2019, the Company was in compliance with each of the senior secured net leverage ratio; total net leverage ratio; and fixed charge coverage ratio covenants.

The new term loan facility shall bear interest at the Adjusted LIBOR (equal to (a) the LIBOR for such Interest Period multiplied by (b) the Statutory Reserve Rate as established by Board of Governors of the Federal Reserve System of the United States of America) for the Interest Period in effect for such Borrowing plus the Applicable Rate as described below. The Agent and the Company may amend the Revised Credit Agreement to replace the LIBOR with a Benchmark Replacement, described below.

Loans under the Revised Credit Agreement bear interest at a rate equal to either (a) the LIBOR rate, plus an applicable margin ranging from 2.25% to 3.0% per annum, based upon the total net leverage ratio (as defined in the Revised Credit Agreement), or (b) the Benchmark Replacement which is defined as the greatest of the prime lending rate, or the NYFRB Rate (the rate for a federal funds transaction) in effect on such day plus ½ of 1% or the Adjusted LIBO Rate for a one month Interest Period on such day plus 1% plus an applicable margin ranging from 1.25% to 2.0% per annum, based upon the total net leverage ratio.

(In thousands, except share and per share amounts)

The Company is required to pay a commitment fee on the unused portion of the new revolving credit facility in the Revised Credit Agreement at a rate ranging from 0.35% to 0.45% per annum based upon the total net leverage ratio.

As of December 31, 2019, the Company had $0.4 million of unamortized deferred debt issuance costs and $0.9 million of unamortized prepaid in its consolidated balance sheets.

Debt Maturities		**As of December 31, 2019**
2020	$	5,000
2021		8,000
2022		26,000
Total	$	39,000

On August 8, 2017, the Company entered into an Amended and Restated Credit Agreement (the "Amended Credit Agreement"), with JPMorgan Chase Bank, N.A., as administrative agent (the "Agent") and the lenders party thereto, which amended and restated the Company's then existing credit agreement, dated as of January 26, 2017. The Amended Credit Agreement provided for a 3-year $50 million revolving credit facility and a 3-year $100 million term loan facility (which are collectively referred to as the "Amended Credit Facility"). The Amended Credit Facility was subject to certain financial covenants.

On the date of the amendment, $50 million of the term loan facility was drawn, and none of the revolving credit facility had been drawn. The Amended Credit Facility included a $5 million letter of credit subfacility. Loans under the Amended Credit Facility bore interest, at the Company's option, at a rate equal to either (a) the LIBOR rate, plus an applicable margin ranging from 2.25% to 3.0% per annum, based upon the total net leverage ratio (as defined in the Amended Credit Agreement), or (b) the prime lending rate, plus an applicable margin ranging from 1.25% to 2.0% per annum, based upon the total net leverage ratio. The Company was required to pay a commitment fee on the unused portion of the Amended Credit Facility at a rate ranging from 0.35% to 0.45% per annum based upon the total net leverage ratio. The Company was permitted to terminate or reduce the revolving commitments or term commitments of the lenders and to make voluntary prepayments at any time subject to break funding payments. The Company was required to make mandatory prepayments of outstanding indebtedness under the Amended Credit Agreement (a) upon receipt of proceeds from certain sales, transfers or other dispositions, casualty and other condemnation events and the incurrence of certain indebtedness other than indebtedness permitted, subject to customary reinvestment exceptions and (b) in the case that the aggregate amount of all outstanding loans and letters of credit issued under the Amended Credit Facility exceed the aggregate commitment of all lenders under the Amended Credit Facility. The Company was obligated to repay the term loan facility on the last day of each March, June, September and December in an aggregate principal amount equal to 2.5% during the term of the loan.

7. Common Stock and Stock-Based Compensation

Common Stock

On October 30, 2018, the Company announced a new repurchase program approved by the Board pursuant to which the Company may repurchase of up to $150 million of the its outstanding common stock, consisting of (i) up to $50 million in repurchases pursuant to an accelerated share repurchase agreement (the "ASR"), with JPMorgan Chase Bank, N.A. ("JPMorgan"), and (ii) up to $100 million in additional repurchases (collectively, the "2018 Share Repurchase Program"). In connection with its approval of the 2018 Share Repurchase Program, the Board terminated the Company's 2016 Share Repurchase Program and 2017 Share Repurchase Program in October 2018. Under the 2018 Share Repurchase Program, the Company is authorized to repurchase shares through open market purchases, privately-negotiated transactions, accelerated share repurchases or otherwise in accordance with applicable federal securities laws, including through Rule 10b5-1 trading plans and under Rule 10b-18 of the Exchange Act. Under the 2018 Share Repurchase Program, the additional repurchases have no time limit and may be suspended or discontinued completely at any time. The specific timing and amount of repurchases will vary based on available capital resources and other financial and operational performance, market conditions, securities law limitations, and other factors. The repurchases will be made using the Company's cash resources.

(In thousands, except share and per share amounts)

In connection with the 2018 Share Repurchase Program, on October 30, 2018, the Company entered into the ASR with JPMorgan to repurchase an aggregate of $50 million of the Company's common stock. Under the terms of the ASR, the Company paid $50 million to JP Morgan on November 1, 2018, and received 702,988 shares, representing approximately 80% of the notional amount of the ASR, based on the closing price of $56.90 on October 29, 2018. Upon settlement of the ASR, the final number of shares repurchased were trued up based on the average of the daily volume weighted average share prices of the Company's common stock, less a discount, during the term of the ASR. The Company received 297,146 shares on December 6, 2018, the termination date.

On August 9, 2016, the Company announced a share repurchase program approved by the Company's board of directors authorizing the repurchase of up to $75.0 million of the Company's common stock (the "Share Repurchase Program"). On August 9, 2017, the Company announced a new share repurchase program approved by the Board, under which the Company may repurchase up to an additional $100 million of its outstanding common stock (the "New Share Repurchase Program"). Under the Share Repurchase Program and the New Share Repurchase Program, the Company was authorized to repurchase shares through open market purchases, privately-negotiated transactions or otherwise in accordance with applicable federal securities laws, including through Rule 10b5-1 trading plans and under Rule 10b-18 of the Exchange Act.

We repurchased the following shares of common stock with cash resources:

	Year Ended December 31,		
	2019	2018	2017
Shares of common stock repurchased	317,429	1,348,563	674,857
Value of common stock repurchased	$ 17,961	$ 73,105	$ 43,792

Stock-Based Compensation

In December 2007, the Company's board of directors approved the 2007 Incentive Compensation Plan (the "2007 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. In November 2013, the Company's board of directors approved the 2014 Equity Incentive Plan (the "2014 Plan") which became effective on February 11, 2014. The 2007 Plan was terminated upon the effectiveness of the 2014 Plan and all shares available for issuance under the 2007 Plan were made available under the 2014 Plan. The 2014 Plan provides for the awards of incentive stock options, non-qualified stock options, restricted stock, restricted stock units and other stock-based awards. Awards generally 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. At the Company's annual meeting of stockholders held on August 4, 2015, the stockholders approved an amendment to the 2014 Plan to, among other things, increase the number of shares of common stock authorized for issuance thereunder by 500,000 shares. After accounting for such increase, and as of such amendment, the Company has reserved and made available 1,934,193 shares of common stock for issuance under the 2014 Plan.

During the year ended December 31, 2018, the Company introduced a new long-term incentive program with the objective to better align the share-based awards granted to management with the Company's focus on improving total shareholder return over the long-term. The share-based awards granted under this long-term incentive program consist of time-based stock options, time-based restricted stock units ("RSUs") and performance-based stock units ("PSUs"). PSUs are comprised of awards that vest upon achievement of certain share price appreciation conditions.

(In thousands, except share and per share amounts)

Stock Options

The fair value of stock options granted to employees, directors, and consultants is estimated using the following assumptions:

	Year Ended December 31,		
	2019	**2018**	**2017**
Risk-free interest rate	1.42% - 2.61%	2.30% - 3.07%	1.70% - 2.42%
Volatility	40.83% - 50.73%	43.76%	28.56% - 37.63%
Expected term (in years)	1.51 - 9.41 years	5.50 - 6.08 years	5.50 - 7.0 years
Expected dividend yield	0.0%	0.0%	0.0%

The following table summarizes information about stock option activity related to the 2014 Plan:

	Number of Stock Option Shares	**Weighted Average Exercise Price (Per Share)**	**Non-Exercisable**	**Exercisable**
Outstanding at December 31, 2017	**2,786,568**	**$ 57.13**	**1,349,339**	**1,437,229**
Granted	672,092	59.17		
Exercised	(502,322)	17.19		
Forfeited or expired	(399,973)			
Outstanding at December 31, 2018	**2,556,365**	**$ 62.78**	**1,074,456**	**1,481,909**
Granted	**628,133**	$ 44.28		
Exercised	**(23,032)**	$ 10.33		
Forfeited or expired	**(65,305)**			
Outstanding at December 31, 2019	**3,096,161**	**$ 59.29**	**1,070,054**	**2,026,107**

The weighted-average grant-date fair value of options granted during the year ended December 31, 2019, 2018, and 2017 was $22.18, $26.73, and $32.83, respectively. As of December 31, 2019, there was $19,051 of unrecognized stock-based compensation expense related to stock options that is expected to be recognized over a weighted average period of 2 years. The total intrinsic value of options exercised during the year ended December 31, 2019 was $1,068.

The weighted average contractual terms of options outstanding as of December 31, 2019, 2018, and 2017 was 6.8, 7.3, and 7.0 years, respectively.

The aggregate pre-tax intrinsic value of options outstanding as of December 31, 2019, 2018, and 2017 was $31.9 million, $10.7 million, and $33.7 million, respectively.

RSUs

Each vested time-based RSU represents the right of a holder to receive one of the Company’s common shares. The fair value of each RSU granted was estimated based on the trading price of the Company’s common shares on the date of grant.

(In thousands, except share and per share amounts)

The following table summarizes information about RSU activity related to the 2014 Plan:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value (Per Share)
Non-vested at December 31, 2017	**—**	**$ —**
Granted	64,080	59.04
Vested	—	—
Forfeited	(9,861)	$ 59.14
Non-vested at December 31, 2018	**54,219**	**$ 59.02**
Granted	211,829	$ 42.17
Vested	(13,555)	$ 59.02
Forfeited	(1,278)	$ 52.19
Non-vested at December 31, 2019	**251,215**	**$ 44.84**

As of December 31, 2019, there was $7,028 of unrecognized stock-based compensation expense related to non-vested RSUs that is expected to be recognized over a weighted average period of 3 years.

PSUs

The fair value of PSUs granted to employees was estimated using a monte carlo simulation model. Inputs used in the calculation include a risk-free interest rate of 2.06%, an expected volatility of 47%, contractual term of 3 years, and no expected dividend yield.

The following table summarizes information about PSU activity related to the 2014 Plan:

	Number of Performance Stock Units	Weighted Average Grant Date Fair Value (Per Share)
Non-vested at December 31, 2017	**—**	**$ —**
Granted	127,080	90.19
Vested	—	—
Forfeited	(9,861)	$ 90.19
Non-vested at December 31, 2018	**117,219**	**$ 90.19**
Granted	—	$ —
Vested	—	$ —
Forfeited	(1,038)	$ 90.19
Non-vested at December 31, 2019	**116,181**	**$ 90.19**

As of December 31, 2019, there was $3,098 of unrecognized stock-based compensation expense related to non-vested PSUs that is expected to be recognized over a weighted average period of 2 years.

(In thousands, except share and per share amounts)

The Company recognized stock-based compensation in its consolidated statements of income for the year ended December 31, 2019, 2018, and 2017 as follows:

	Year Ended December 31,		
	2019	2018	2017
Stock options	$ 16,394	$ 15,333	$ 15,429
PSUs	3,062	3,059	—
RSUs	2,542	690	—
Stock-based compensation expense	$ 21,998	$ 19,082	$ 15,429
Selling, general and administrative	$ 17,556	$ 15,068	$ 11,486
Research and development	4,442	4,014	3,943
Stock-based compensation expense	$ 21,998	$ 19,082	$ 15,429

8. Income Taxes

The components of our provision from income taxes is as follows:

	Year Ended December 31,		
	2019	2018	2017
Current:			
Federal	$ 6,689	$ 4,137	$ 1,304
State	844	466	2,409
	$ 7,533	$ 4,603	$ 3,713
Deferred:			
Federal	392	(2,565)	18,045
State	(240)	97	(756)
	$ 152	$ (2,468)	$ 17,289
Provision for income taxes	$ 7,685	$ 2,135	$ 21,002

The reconciliation of the statutory U.S. Federal income tax rate to the Company's effective income tax rate is as follows;

	Year Ended December 31,		
	2019	2018	2017
Federal statutory tax rate	21 %	21 %	35 %
State income taxes, net of federal benefit	2 %	1 %	3 %
Tax benefit on stock option exercises, net of forfeitures	1 %	(11)%	(4)%
R&D tax credits and Orphan Drug credits	(2)%	(7)%	(10)%
Limitation on executive compensation	10 %	3 %	N/A
Revaluation of net deferred tax assets due to U.S. tax reform	— %	— %	5 %
Change in valuation allowance	4 %	— %	— %
Other	(1)%	(1)%	— %
Effective tax rate	35 %	6 %	29 %

(In thousands, except share and per share amounts)

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:

	December 31, 2019	December 31, 2018
Deferred tax assets		
Net operating loss carryforward	$ 243	$ —
Stock based compensation	10,647	7,934
Research and development and other tax credit carryforwards	—	3,251
Inventories	1,539	1,767
Employee-related expenses	51	732
Prepaid R&D expenses	620	761
Intangible assets	662	—
ROU asset	925	—
Other	1,017	64
Total deferred tax assets	15,704	14,509
Deferred tax liabilities		
Intangible assets	—	280
Prepaid expenses	43	34
Fixed assets	203	282
Lease liability	838	—
Other	—	91
Total deferred tax liabilities	1,084	687
Valuation allowance	(951)	—
Net deferred tax assets	$ 13,669	$ 13,822

The Tax Cuts and Jobs Act (the "Tax Act") enacted on December 22, 2017, significantly revised U.S. corporate income tax law by, among other things, reducing the corporate income tax rate to 21% and implementing a modified territorial tax system. In response to the Tax Act, the SEC issued SAB 118 which allows issuers to recognize provisional estimates of the impact of the Tax Act in their financial statements and adjust in the period in which the estimate becomes finalized, or in circumstances where estimates cannot be made, to disclose and recognize within a one year measurement period.

Implementation of the Tax Act resulted in an approximate $3.4 million charge for the revaluation of the Company's net deferred tax assets during the year ended December 31, 2017. In reaching these estimates, the Company utilized all available guidance and notices issued by the U.S. Department of the Treasury. During 2018, the Company finalized the impact of the Tax Act. An immaterial adjustment was recorded in the year ended December 31, 2018.

As a result of attaining profitability and the expectation that substantially all net operating loss carryforwards would be utilized in 2017, the Company performed a formal tax evaluation to determine maximum research and development credits that are available based on current law. As a result of the evaluation of historical records and data, our tax filings, and various tax law interpretations related to the R&D credit availability, additional tax credits were identified. The Company recorded an adjustment of such tax credits of $5.5 million resulting in a reduction of income tax expense in 2017.

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.

The Company files income tax returns in the U.S. federal jurisdiction and several states. Given that the company has incurred tax losses in most years since its inception, all of the Company's tax years are effectively open to examination. The Company is under audit by three states tax jurisdiction as of December 31, 2019. The Company has no amount recorded for any unrecognized tax benefits as of December 31, 2019. The Company regularly evaluates its tax positions for additional unrecognized tax benefits and associated interest and penalties, if applicable. There are many factors that are considered when evaluating these tax positions including: interpretation of tax laws, recent tax litigation on a position, past audit or examination history, and subjective estimates and assumptions.

9. License Agreements of Development and Commercialization Rights

Development

On February 13, 2015, the Company submitted a New Drug Application or NDA to the FDA for Bendeka, which was approved by the FDA on December 7, 2015. Also, on February 13, 2015, the Company entered into the Cephalon License for U.S. and Canadian rights to Bendeka for treatment of patients with CLL and patients with NHL. Pursuant to the terms of the Cephalon License, Cephalon will be responsible for all U.S. commercial activities for the product including promotion and distribution, and the Company is responsible for obtaining and maintaining all regulatory approvals and conducting post-approval clinical studies. Additionally, under the terms of the Cephalon License, the Company received an upfront cash payment of $30 million, in January 2016, received a $15 million milestone payment related to the FDA approval of Bendeka in December 2015, received $40 million related to the receipt of the J-code for Bendeka and is currently eligible to receive up to $25 million in an additional sales-based milestone payment. In addition, the Company was entitled to receive royalty payments of 20% of net sales of the product which increased to 25% on receipt of the J-code in November 2016. In connection with the Cephalon License, the Company has entered into a supply agreement with Cephalon, pursuant to which the Company is responsible for supplying product to Cephalon. As of March 29, 2019, the Company and TPIG executed an amendment to the Cephalon License Agreement to terminate Teva's obligation to pay future milestones and royalties on Bendeka sales outside of the U.S., which included an upfront cash payment of $9 million that was recorded as License and other revenue on the consolidated statements of income. On April 13, 2019, we announced an expansion of our Cephalon License. Under the terms of the revised agreement, beginning on October 1, 2019, Eagle's royalty payment has increased from 25% to 30% of Bendeka net U.S. sales. The royalty rate will increase by one percentage point on each anniversary of October 1, 2019 until it reaches 32%, and it will remain at 32% thereafter. The revised agreement also extends the U.S. Bendeka royalty term until it is no longer sold in the United States. The previous U.S. royalty term was set to expire in 2025.

On September 20, 2017, the Company entered into a Product Collaboration and License Agreement, effective as of September 19, 2017, (the "SymBio License Agreement") with SymBio Pharmaceuticals Limited ("SymBio") for the rights to develop and commercialize the Company's bendamustine hydrochloride ready-to-dilute injection product and rapid infusion injection product (collectively, the "Products") in Japan. Under the License Agreement, SymBio will be responsible for all development of the Products in Japan and for obtaining and maintaining all regulatory approvals of the Products in Japan, with a target for regulatory approval of a Product in Japan in 2020. SymBio will bear all costs of development of the Products in Japan except that, if Japanese regulatory authorities require a certain clinical study to be conducted as a condition for approving one of the Products in Japan, Eagle would share 50% of the out-of-pocket costs of that clinical study up to a specified dollar amount as a reduction to future royalty payments. Based on the Company's assessment of the probability of additional costs, we have not deferred revenue on the SymBio License Agreement. SymBio will also be responsible, at its sole cost, for all marketing, promotion, distribution and sales of the Products in Japan and is obligated to launch the Products and meet certain minimum detailing, promotion and marketing commitments in connection with commercialization of the Products in Japan.

SymBio currently markets in Japan TREAKISYM®, a lyophilized powder formulation of bendamustine hydrochloride indicated for CLL, relapsed or refractory low-grade NHL, mantle cell lymphoma ("MCL"), and as a first line treatment of low-grade NHL and MCL. Under the SymBio License Agreement, SymBio may continue to market TREAKISYM® in Japan and SymBio will be permitted to develop and market certain other bendamustine hydrochloride products in Japan for limited indications.

Pursuant to the terms of the SymBio License Agreement, the Company and SymBio will enter into a separate supply agreement, under which the Company will be responsible for manufacturing and supplying the Products to SymBio for development and commercialization in Japan. After a period of time following launch of a Product, SymBio will have the right to assume the responsibility for manufacturing of the Products in and for Japan. Under the SymBio License Agreement, the Company will retain the right to control the prosecution, maintenance and enforcement of the Company's patents covering the Products, both inside and outside of Japan.

(In thousands, except share and per share amounts)

Under the SymBio License Agreement, the Company earned an upfront non-refundable cash payment of $12.5 million in the third quarter of 2017, and is eligible to receive a milestone payment upon approval of a Product in Japan and a milestone payment upon achievement of certain cumulative net sales of the Products in Japan. After regulatory approval of a Product in Japan, the Company will also receive tiered, low double-digit royalties on net sales of the Products in Japan for so long as there are patents covering the Products in Japan or regulatory exclusivity for the Products in Japan.

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.

10. Commitments

Our future material contractual obligations include the following:

Obligation	Total	2020	2021	2022	2023	2024	Beyond
Operating leases (1)	$ 6,607	$ 1,345	$ 1,362	$ 1,376	$ 1,291	$ 820	$ 413
Credit facility	39,000	5,000	8,000	26,000	—	—	—
Purchase obligations (2)	18,329	18,329	—	—	—	—	—
Total obligations	$ 63,936	$ 24,674	$ 9,362	$ 27,376	$ 1,291	$ 820	$ 413

(1) We lease our corporate office location. On August 8, 2019, we amended the lease for our corporate office location in order to rent additional office space and extend the term of our existing lease to June 30, 2025. The Company also leases its lab space under a lease agreement that expires on October 31, 2023. Rental expense was $1,146, $571, and $664, for the years ended December 31, 2019, 2018, and 2017, respectively. The remaining future lease payments under the operating leases, exclusive of any renewal option periods, are $6,607 as of December 31, 2019, payable monthly through June 30, 2025 and October 31, 2023.

(2) As of December 31, 2019, the Company has purchase obligations in the amount of $18,329 which represents the contractual commitments under contract manufacturing and supply agreements with suppliers. The obligation under the supply agreement is primarily for finished product, inventory, and research and development.

11. Acquisitions

Acquisition of Docetaxel-Injection, Non-Alcohol Formula

On October 13, 2015, the Company entered into the Teikoku Agreement with Teikoku to market, sell and distribute Non-Alcohol Docetaxel Injection, an investigational product intended for the treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma, and head and neck cancer. The NDA for Non-Alcohol Docetaxel Injection for these indications was approved by the FDA on December 22, 2015. Under the terms of the agreement, the Company paid $4,850 upon FDA approval and NDA transfer to the Company, which occurred on January 12, 2016. The Company also paid 25% royalties on gross profits to Teikoku. The Company accounted for the transaction as a purchase of a business in 2016, in accordance with ASC 805 *Business Combinations*.

The Company has measured the fair value of the future royalty payment using its own assumptions of future profitability of Non-Alcohol Docetaxel Injection. Acquisition contingent consideration is measured at fair value on a recurring basis using unobservable inputs; which accordingly represents a Level 3 measurement within the fair value hierarchy. Any change in fair value of the contingent consideration subsequent to the acquisition date is recognized in operating income within the statement of operations.

(In thousands, except share and per share amounts)

During the year ended December 31, 2017, the Company recorded a change in the fair value of contingent consideration of $6.2 million. This was primarily driven by adjustments to the fair values of the liabilities associated with Non-Alcohol Docetaxel Injection, which was remeasured due to the loss of a customer and other market conditions identified during the third quarter of 2017 for the product and partially offset by accretion for the time value of money.

During the year ended December 31, 2018, the Company recorded an adjustment to the remaining contingent consideration to reflect the Company's decision to discontinue sales of Non-Alcohol Docetaxel Injection.

The following table represents a reconciliation of the change in the fair value measurement of the contingent consideration liability, which was recorded in the Company's consolidated statements of income:

Closing Balance December 31, 2016	Changes in fair value	Payment of contingent consideration	Closing Balance December 31, 2017	Changes in fair value	Payment of contingent consideration	Closing Balance December 31, 2018
$ 6,940	$ (6,176)	$ —	$ 764	$ (763)	$ (1)	$ —

Total consideration of $11,220, which is comprised of the $4,850 cash paid on FDA approval and NDA transfer to the Company and the fair value of contingent consideration has been attributed to the intangible asset for Non-Alcohol Docetaxel Injection product rights.

Eagle Biologics Acquisition

On November 16, 2016, the Company entered into a stock purchase agreement (“Arsia SPA”) to acquire Arsia Therapeutics (“Arsia” “Seller”), an early-stage biotechnology firm with proprietary viscosity-reducing technology and formulation know-how and subsequently renamed the subsidiary Eagle Biologics, Inc. ("Eagle Biologics"). Under the terms of the stock purchase agreement, we paid approximately $27.2 million in cash and 40,200 shares of Eagle common stock worth $3.0 million at closing. We also agreed to pay up to $48 million in additional payments upon the completion of certain milestones, for aggregate potential payments of $78 million.

On February 8, 2018, the Company entered into an amendment (the “Arsia Amendment”) to the Arsia SPA. Pursuant to the Arsia Amendment, the Company's obligation to make four separate milestone payments pursuant to the Arsia SPA, which could have aggregated to a total of $48 million, were terminated in exchange for a single payment of $15 million to the Seller.

The acquisition was accounted for as a business combination in accordance with ASC 805, which requires the assets acquired and liabilities assumed from Eagle Biologics to be recorded on the acquisition date at their respective fair values. Eagle Biologics’ results of operations are included in the financial statements from the date of acquisition.

The following table summarizes the consideration transferred to acquire Eagle Biologics at the date of acquisition:

The aggregate consideration consisted of:	Final fair value
Cash consideration paid	$ 27,209
Common stock issued *(i)*	3,046
Fair value of contingent consideration payable to seller (long term) *(ii)*	15,000
Total consideration	$ 45,255

(i) Under the stock purchase agreement, the number of common shares to be issued to the seller is equal to $2.7 million divided by the average of the closing day price per share for the 30 trading days prior to the Closing Date. The average price of the common stock of 30 days prior to closing was $68.18. Accordingly, the number of common stock to be issued

(In thousands, except share and per share amounts)

to the seller was determined at 40,200 shares ($2.7 million divided by $68.18 per share). The fair value of the common stock issued was determined based on the closing price of Eagle's common stock on November 16, 2016.

(ii) Under the Arsia SPA, the contingent consideration includes four separate milestone payments which could aggregate to a total of $48 million payable to the Seller upon achievement of certain clinical, regulatory and development milestones. In accordance with the provisions of ASC 805-30-25-5, each unit of contingent consideration is recognized at the acquisition date fair value. The acquisition date fair value of the contingent consideration was $16.1 million. Such fair values are determined based on a probabilistic model with weights assigned on the likelihood of the Company achieving the clinical, regulatory and development milestones as well as an acceleration event in the future. Each unit of contingent consideration is classified as a liability in the balance sheet and would be subsequently measured at fair value on each reporting date. Any future change in fair value would be recognized in the statement of operations. As described above, on February 8, 2018, the Company entered into the Arsia Amendment, pursuant to which the Company's obligations to make four separate milestone payments under the Arsia SPA were terminated in exchange for a single payment of $15 million to the Seller.

During the year ended December 31, 2017, the Company recorded a change in the fair value of contingent consideration of $1.2 million related to the Arsia Amendment.

The following table represents a reconciliation of the change in the fair value measurement of the contingent consideration liability, which was recorded in the Company's consolidated statements of income:

Closing Balance December 31, 2016	Changes in fair value	Payment of contingent consideration	Closing Balance December 31, 2017	Changes in fair value	Payment of contingent consideration	Closing Balance December 31, 2018
$ 16,201	$ (1,201)	$ —	$ 15,000	$ —	$ (15,000)	$ —

12. Intangible Assets, Net

The gross carrying amounts and net book value of our intangible assets are as follows:

		December 31, 2019			
	Useful Life (In Years)	Gross Carrying Amount	Accumulated Amortization	Accumulated Impairment Charges	Net Book Value
Ryanodex intangible	20	$ 15,000	$ (2,454)	$ —	$ 12,546
Developed technology	5	8,100	(5,063)	—	3,037
Total		$ 23,100	$ (7,517)	$ —	$ 15,583

		December 31, 2018			
	Useful Life (In Years)	Gross Carrying Amount	Accumulated Amortization	Accumulated Impairment Charge	Net Book Value
Docetaxel product rights	10	$ 11,220	$ (1,281)	$ (9,939)	$ —
Ryanodex intangible	20	15,000	(1,554)	—	13,446
Developed technology	5	8,100	(3,443)	—	4,657
Total		$ 34,320	$ (6,278)	$ (9,939)	$ 18,103

(In thousands, except share and per share amounts)

Amortization expense amounted to $2,520, $2,515, and $2,815, for the year ended December 31, 2019, 2018, and 2017, respectively.

Intangible Asset Impairment

During the year ended December 31, 2017, the Company experienced a decline in customer contracts and saw a drop in market pricing for Non-Alcohol Docetaxel Injection. Accordingly, the Company estimated the fair value of our Non-Alcohol Docetaxel Injection product and determined the carrying amount of the intangible asset was no longer fully recoverable, resulting in a pre-tax, non-cash asset impairment charge of $7.2 million during the year ended December 31, 2017.

On June 30, 2018, the Company implemented a restructuring initiative based on its assessment of the current product portfolio and made a decision to discontinue manufacture and distribution of Non-Alcohol Docetaxel Injection. The Company ceased selling the product by September 30, 2018. As a result, the Company recognized a pre-tax, non-cash asset impairment charge of $2.7 million during the year ended December 31, 2018.

Estimated Amortization Expense for Intangible Assets

Based on definite-lived intangible assets recorded as of December 31, 2019, and assuming that the underlying assets will not be impaired and that the Company will not change the expected lives of the assets, future amortization expenses are estimated as follows:

	Estimated Amortization Expense	
Year Ending December 31,		
2020	$	2,666
2021		2,623
2022		1,369
2023		1,570
2024		1,570
All other		5,785
Total estimated amortization expense	$	15,583

13. Legal Proceedings

In addition to the below legal proceedings, from time to time, the Company may be a party to litigation and subject to claims incident to the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, the Company currently believes that the final outcome of these ordinary course matters, or matters discussed below, will not have a material adverse effect on the Company's business nor has the Company recorded any loss in connection with these matters because the Company believes that loss is neither probable nor estimable. Regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources and other factors.

Commercial Litigation

In Re: Taxotere (Docetaxel)

On February 1, 2017, the Company was named as a defendant, among various other manufacturers, in several product liability suits that are consolidated in the U.S. District Court for the Eastern District of Louisiana as part of MDL 2740 (Civil Action No 2:16 md-2740). The claims are for personal injuries allegedly arising out of the use of docetaxel.

In March 2017, the Company reached agreements in principle with the Plaintiffs’ Steering Committee in this matter to voluntarily dismiss the Company from all of the lawsuits in which it was named and from the master complaint. The Company is in the process of working with the other parties in this matter to have it removed from the Multidistrict litigation entirely. As part of the agreement, in the event a case is brought in the future with facts that justify the Company’s inclusion, the plaintiffs reserved the right to include the Company in such matter. The plaintiffs have filed several additional lawsuits since the parties’ agreement in principle to dismiss, and the Company is in the process of working with plaintiffs to explore the possibility of dismissing those lawsuits.

Eagle v. Burwell

On April 27, 2016, the Company filed an action in the U.S. District Court for the District of Columbia against the FDA and other federal defendants seeking an order requiring the FDA to recognize orphan drug exclusivity for Bendeka for the treatment of CLL and indolent B-cell NHL. On June 8, 2018, the Court issued a decision requiring the FDA to recognize seven years of orphan drug exclusivity in the U.S. for Bendeka, and on July 6, 2018 the FDA recognized such ODE until December 7, 2022. In addition, on July 6, 2018, the FDA submitted a Motion to Alter or Amend the Judgement Pursuant to Rule 59(e), pursuant to which the FDA requested that the Court amend its decision to make clear that the decision does not affect any applications referencing TREANDA. The FDA’s motion was denied by the Court on August 1, 2018 on the grounds that the FDA had not satisfied the standard for altering or amending the judgment. The FDA and two intervenors have appealed the Court’s final judgment to the U.S. Court of Appeals for the District of Columbia Circuit. Oral arguments occurred on October 17, 2019 and a decision is not expected until the Spring of 2020. On February 20, 2019, the FDA issued a decision in favor of the Company, regarding the scope of exclusivity for Bendeka. Pursuant to the FDA’s decision, and unless the district court is reversed on appeal, no bendamustine product used to treat the same indications (including generic versions of TREANDA) may launch in the United States until December 7, 2022 unless it is clinically superior to Bendeka.

Eagle v. Eli Lilly

On August 24, 2017, the Company filed an antitrust complaint in the United States District Court for the District of New Jersey (“New Jersey District Court”) against Eli Lilly and Company (“Lilly”). The complaint alleges that Lilly engaged in anticompetitive conduct which restrained competition by delaying and blocking the Company's launch of a competing pemetrexed injection product (to compete with Lilly's Alimta). Lilly accepted service and answered the complaint on October 27, 2017. Lilly also filed a motion to transfer this case to Delaware on October 27, 2017. The Company filed a motion to oppose such transfer on November 6, 2017. On July 20, 2018, the New Jersey District Court transferred the case to Delaware. On November 27, 2018, the Delaware Court stayed the case at least until conclusion of the PEMFEXY™ patent trial described below. On December 16, 2019, the Delaware Court entered the Company and Lilly's stipulation dismissing this case with prejudice.

Patent Litigation

Eli Lilly and Company. v. Eagle Pharmaceuticals, Inc. (PEMFEXY™ (Pemetrexed))

On August 14, 2017, Lilly filed suit against the Company in the United States District Court for the Southern District of Indiana (the "Indiana Suit"). Lilly alleged patent infringement based on the filing of the Company's 505(b)(2) NDA seeking approval to manufacture and sell the Company's EP-5101. EP-5101, if finally approved by FDA, will be a branded alternative to Alimta®.

On September 8, 2017, Eagle moved to dismiss the Indiana Suit for improper venue. On September 11, 2017, Lilly voluntarily dismissed the Indiana Suit. It then filed a complaint in the United States District Court for the District of Delaware, alleging similar patent infringement claims (the "Delaware Suit"). Eagle answered and filed various counterclaims in the Delaware Suit on October 3, 2017. Lilly answered Eagle's counterclaims on October 24, 2017. The Court held a scheduling conference on December 11, 2017 and set trial in the Delaware Suit to begin on September 9, 2019, but later rescheduled trial to begin October 28, 2019. On May 31, 2018, Eagle filed a Motion for Judgment on the Pleadings, which the Court denied on October 26, 2018. On January 23, 2019, the Court held a Markman hearing. Trial took place from October 28, 2019 to October 31, 2019 and is scheduled to continue on December 12, 2019 through December 13, 2019. On December 13, 2019, the Company and Lilly settled this litigation. The agreement provides for a release of all claims by the parties and allows for an initial entry of PEMFEXY™ into the market (equivalent to approximately a three week supply of current ALIMTA® utilization) on February 1, 2022 and a subsequent uncapped entry on April 1, 2022. On December 16, 2019, the District Court entered the Company and Lilly's stipulation dismissing this case with prejudice.

Eagle Pharmaceuticals, Inc., et al. v. Slayback Pharma Limited Liability Company; Eagle Pharmaceuticals, Inc., et al. v. Apotex Inc. and Apotex Corp.; Eagle Pharmaceuticals, Inc., et al. v. Fresenius Kabi USA, LLC; Eagle Pharmaceuticals, Inc., et *al. v. Mylan Laboratories Limited; Eagle Pharmaceuticals, Inc. et al. v. Hospira, Inc; Eagle Pharmaceuticals, Inc. et al. v. Lupin, Ltd. And Lupin Pharmaceuticals, Inc.. - (Bendeka®)*

Bendeka, which contains bendamustine hydrochloride, is an alkylating drug that is indicated for the treatment of patients with chronic lymphocytic leukemia, as well as for the treatment of patients with indolent B-cell non-Hodgkin's lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. Five companies - Slayback Pharma Limited Liability Company (“Slayback”), Apotex Inc. and Apotex Corp. (“Apotex”), Fresenius Kabi USA, LLC (“Fresenius”), Mylan Laboratories Limited (“Mylan”), and Lupin, Ltd. And Lupin Pharmaceuticals, Inc. (“Lupin”)- have filed Abbreviated New Drug Applications (“ANDA’s”) referencing Bendeka® that include challenges to one or more of the Bendeka® Orange Book-listed patents. Hospira, Inc. (“Hospira”) filed a 505(b)(2) NDA.

The Company, Cephalon, Inc. and/or Teva Pharmaceuticals International GMBH (together the “Patentees”), filed separate suits against Slayback, Apotex, Fresenius, Mylan, Hospira, and Lupin in the United States District Court for the District of Delaware on August 16, 2017 (Slayback (“Slayback I”)), August 18, 2017 (Apotex), August 24, 2017 (Fresenius), December 12, 2017 (Mylan), January 19, 2018 (Slayback (“Slayback II”)), July 19, 2018 (Hospira), and July 2, 2019 (Lupin). In these Complaints, the Patentees allege infringement of the challenged patents, namely U.S. Patent Nos. 8,791,270 and 9,572,887 against Slayback (Slayback I and Slayback II), and of U.S. Patent Nos. 8,609,707, 8,791,270, 9,000,021, 9,034,908, 9,144,568, 9,265,831, 9,572,796, 9,572,797, 9,572,887, 9,579,384, 9,597,397, 9,597,398, 9,597,399 against Fresenius, Apotex, and Mylan, and of U.S. Patent Nos. 9,572,887, 10,010,533, 9,034,908, 9,144,568, 9,597,397, 9,597,398, 9,597,399, 9,000,021, 9,579,384 against Hospira, and of U.S. Patent Nos. 8,609,707, 9,000,021, 9,034,908, 9,144,568, 9,265,831, 9,572,796, 9,572,797, 9,572,887, 9,579,384, 9,597,397, 9,597,398, 9,597,399, 10,010,533, and 10,052,385 against Lupin. The parties stipulated to dismiss without prejudice U.S. Patent No. 8,791,270 as to Apotex, Fresenius and Mylan on July 24, 2018, August 2, 2018, and August 3, 2018, respectively. Slayback, Apotex, Fresenius, and Mylan answered their Complaints and some filed various counterclaims on September 29, 2017 (Slayback I), February 12, 2018 (Slayback II), November 27, 2017, September 15, 2017, and February 14, 2018, respectively. The Patentees answered the Slayback I, Slayback II, Fresenius, and Apotex counterclaims on October 20, 2017, March 5, 2018, October 6, 2017, and December 18, 2017, respectively. On October 15, 2018, the Patentees filed a suit against Fresenius and Mylan in the United States District Court for the District of Delaware, alleging patent infringement of U.S. Patent Nos. 10,010,533 and 10,052,385. The Slayback I, Slayback II, Apotex, Fresenius and Mylan cases have been consolidated for all purposes, and a bench trial in these cases began September 9, 2019 and concluded September 19, 2019. Hospira filed a motion to dismiss the case, which was fully briefed on November 16, 2018. On December 16, 2019, the United States District Court for the District of Delaware denied Hospira’s motion to dismiss with respect to U.S. Patent No. 9,572,887 and granted that motion with respect to the remaining patents. Trial is set for November 15, 2021. All cases are pending.

The FDA is stayed from approving Apotex’s, Fresenius’, Mylan’s, and Lupin’s ANDA’s, and Hospira’s 505(b)(2) application, until the earlier of (1) January 7, 2020, January 14, 2020, April 30, 2020, November 21, 2021, and December 20, 2020 respectively (the “30-month stay dates”); and (2) a court decision that each of the challenged patents is not infringed, invalid, or unenforceable. The 30-month stay dates may be shortened or lengthened if either party to the action fails to reasonably cooperate in expediting the action. The FDA cannot approve Slayback’s ANDA until March 2031.

Eagle Pharmaceuticals, Inc. v. Slayback Pharma Limited Liability Company

Slayback filed an ANDA referencing Eagle's Belrapzo NDA. Slayback’s ANDA includes challenges to one or more of the Belrapzo Orange Book-listed patents. On September 20, 2018, the Company filed a suit against Slayback in the United States District Court for the District of Delaware, alleging patent infringement of U.S. Patent Nos. 8,609,707, 9,265,831, 9,572,796, 9,572,797 and 10,010,533. On October 10, 2018, Slayback answered the Complaint and filed various counterclaims. On October 31, 2018, the Company answered Slayback’s counterclaims. This case is currently stayed.

Eagle Pharmaceuticals, Inc. v. Slayback Pharma Limited Liability Company

Slayback filed a 505(b)(2) NDA referencing Eagle’s Belrapzo NDA. Slayback’s NDA includes challenges to one or more of the Belrapzo Orange Book-listed patents. On December 11, 2018, the Company filed a suit against Slayback in the United States District Court for the District of Delaware, alleging patent infringement of U.S. Patent Nos. 9,265,831, 9,572,796, 9,572,797, and 10,010,533. On January 4, 2019, Slayback filed a motion for judgment on the pleadings. On May 9, 2019, the United States District Court for the District of Delaware granted Slayback’s motion for judgment on the pleadings. On July 23, 2019, the Company filed an appeal of this decision with the United States Court of Appeals for the Federal Circuit. The Federal Circuit scheduled oral argument on March 4, 2020. That appeal is pending.

Par Pharmaceutical, Inc. et al. v. Eagle Pharmaceuticals, Inc. (Vasopressin)

On May 31, 2018, Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (together "Par") filed suit against the Company in the United States District Court for the District of Delaware. Par alleged patent infringement based on the filing of the Company's ANDA seeking approval to manufacture and sell the Company's vasopressin product. The Company's vasopressin product, if approved by FDA, will be an alternative to Vasostrict, which is indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines. The Company answered the complaint on August 6, 2018, and filed an amended answer and counterclaims on October 30, 2019. The court issued a Markman ruling on July 1, 2019. On December 20, 2019, Par dismissed with prejudice claims of three of the patents asserted against Eagle, and the Court entered an Order reflecting that dismissal on December 27, 2019. Mediation is scheduled to take place on March 3, 2020. Trial is scheduled to begin May 18, 2020. This suit is pending.

Eagle Pharmaceuticals, Inc. et al.v. Accord (Argatroban)

On March 27, 2019, the Company and Chiesi filed suit against Accord Healthcare, Inc. ("Accord") in the United States District Court for the District of New Jersey (the "New Jersey suit") and in the United States District Court for the Middle District of North Carolina (the "North Carolina suit") (together "the suits"). The suits alleged patent infringement based on Accord's 505(b)(2) NDA seeking approval to manufacture and sell Accord's proposed argatroban product. On May 21, 2019, the Company and Chiesi voluntarily dismissed the North Carolina suit. On July 10, 2019, Accord moved for judgment on the pleadings in the New Jersey suit. The New Jersey suit is pending.

14. Selected Quarterly Financial Data - Unaudited

A summary of quarterly financial information for the year ended December 31, 2019 and 2018 is as follows:

	For the Quarter Ended				
	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019	Total Fiscal Year 2019
	(in thousands except share and per share amounts)				
Revenue	$ 49,785	$ 56,702	$ 41,147	$ 48,258	$ 195,892
Gross Profit	$ 36,685	$ 35,418	$ 26,225	$ 36,667	$ 134,995
Income (loss) from operations	$ 12,169	$ 9,233	$ (2,484)	$ 2,897	$ 21,815
Net income (loss)	$ 8,973	$ 6,725	$ (2,390)	$ 1,005	$ 14,313
Earnings (loss) per share- basic	$ 0.64	$ 0.49	$ (0.17)	$ 0.08	$ 1.04
Earnings (loss) per share- diluted	$ 0.62	$ 0.48	$ (0.17)	$ 0.08	$ 1.01

	For the Quarter Ended				
	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018	Total Fiscal Year 2018
	(in thousands except share and per share amounts)				
Revenue	$ 46,626	$ 59,296	$ 51,337	$ 56,053	$ 213,312
Gross Profit	$ 34,818	$ 40,737	$ 38,346	$ 37,495	$ 151,396
Income from operations	$ 2,305	$ 183	$ 18,402	$ 15,726	$ 36,616
Net income	$ 2,616	$ 2,659	$ 14,040	$ 12,588	$ 31,903
Earnings per share- basic	$ 0.18	$ 0.18	$ 0.94	$ 0.86	$ 2.16
Earnings per share- diluted	$ 0.17	$ 0.17	$ 0.91	$ 0.84	$ 2.09

15. Restructuring

As part of its ongoing organizational review, the Company engaged in a restructuring initiative to rationalize its product portfolio and focus its physical sites. These measures included the discontinuation of manufacture and distribution of Non-Alcohol Docetaxel Injection in June 2018 and plans to rationalize research and development operations. Charges consist of inventory and related reserves, certain asset impairment charges related to property and equipment, and personnel related costs. The restructuring costs of $7,911 for the year ended December 31, 2018 has been recorded to Restructuring charge on the Consolidated Statements of Income. The Company also recorded an asset impairment charge for the remaining Intangible asset for Non-Alcohol Docetaxel Injection of $2,704 as well as an adjustment to remove the contingent consideration of $790 on the related line items in the Statements of Income for the year ended December 31, 2018. The Company does not expect to incur additional expenses related to this restructuring initiative. There is no liability remaining for the restructuring as of December 31, 2018.

16. Related Party Transactions

During the year ended December 31, 2018, the Company obtained legal services from Greenberg Traurig, LLP in exchange for $0.2 million. Richard A. Edlin, a member of the Company's Board, is an attorney and shareholder of Greenberg Traurig, LLP.

On May 10, 2019, Hudson Executive Capital LP ("Hudson Capital") sold 100,000 shares of the Company's common stock and the Company purchased those100,000 shares in a block trade at a price of $56.14 per share. Douglas Braunstein is the Managing Partner of Hudson Capital and was a member of Eagle’s Board of Directors at the time of the transaction.

17. Subsequent Event

On January 7, 2020, Tyme Technologies, Inc. ("Tyme") and the Company announced a strategic collaboration to advance oral SM-88 for the treatment of patients with cancer. SM-88 is an investigational agent in two Phase II studies for pancreatic cancer and in a Phase II study for prostate cancer. Data is expected in 2021. Under the terms of the securities purchase agreements,

Tyme is entitled to receive up to a total $40 million as follows; (a) an initial $20 million upfront. In return, we will receive 10 million restricted shares of Tyme’s common stock at $2.00 per share; (b) a second $20 million milestone payment upon achieving primary endpoints in pivotal trial results or approval of a cancer indication in the U.S. for SM-88. This payment will be split into a $10 million milestone cash payment and a $10 million investment in Tyme at a 15% premium to the then prevailing market price. Under the terms of the co-promotion agreement, we will be responsible for 25% of the promotional sales effort of SM-88 and will receive 15% of net revenues of SM-88 in the U.S. Tyme retains all commercial rights to SM-88 outside the U.S. and reserves the right to repurchase our U.S. co-promotion right for $200 million.

Exhibit 4.3

DESCRIPTION OF SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description sets forth certain material terms and provisions of the securities of Eagle Pharmaceuticals, Inc. (the "Company") that are registered under Section 12 of the Securities Exchange Act of 1934, as amended, and is based on the provisions of our amended and restated certificate of incorporation, or certificate of incorporation, and amended and restated bylaws, or bylaws, and the applicable provisions of the Delaware General Corporation Law ("Delaware Law"). The following summary does not purport to be complete and is subject to, and is qualified in its entirety by reference to, the applicable provisions of Delaware law and our certificate of incorporation and bylaws, copies of which are incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Exhibit 4.3 is a part. We encourage you to read our amended and restated certificate of incorporation, our amended and restated bylaws and the applicable provisions of Delaware Law for additional information.

General

Our authorized capital stock consists of 50,000,000 shares of common stock, $0.001 par value per share, and 1,500,000 shares of preferred stock, $0.001 par value per share.

Common Stock

Holders of our common stock are 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. 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.

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. All of our outstanding shares of common stock are fully paid and nonassessable.

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.

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company LLC. Its address is 6201 15th Ave., Brooklyn, NY 11219. Its phone number is (718) 921-8200.

Our common stock is listed on the Nasdaq Global Market under the symbol "EGRX."

Preferred Stock

Under our certificate of incorporation, our board of directors has the authority, without further action by the stockholders (unless such stockholder action is required by applicable law or the rules of any stock exchange or market on which our securities are then traded), to designate and issue up to 1,500,000 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.

We will fix the designations, voting powers, preferences and rights of the preferred stock of each series, as well as the qualifications, limitations or restrictions thereof, in a certificate of designation relating to that series that describes the terms of the series of preferred stock we are offering before the issuance of that series of preferred stock. This description will include:

- the title and stated value;
- the number of shares we are offering;
- the liquidation preference per share;
- the purchase price;
- the dividend rate, period and payment date and method of calculation for dividends;
- whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;
- the procedures for any auction and remarketing, if any;
- the provisions for a sinking fund, if any;
- the provisions for redemption or repurchase, if applicable, and any restrictions on our ability to exercise those redemption and repurchase rights;
- any listing of the preferred stock on any securities exchange or market;
- whether the preferred stock will be convertible into our common stock, and, if applicable, the conversion price, or how it will be calculated, and the conversion period;
- whether the preferred stock will be exchangeable into debt securities, and, if applicable, the exchange price, or how it will be calculated, and the exchange period;
- voting rights, if any, of the preferred stock;
- preemptive rights, if any;
- restrictions on transfer, sale or other assignment, if any;
- whether interests in the preferred stock will be represented by depositary shares;

- a discussion of any material U.S. federal income tax considerations applicable to the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs;
- any limitations on the issuance of any class or series of preferred stock ranking senior to or on a parity with the series of preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs; and
- any other specific terms, preferences, rights or limitations of, or restrictions on, the preferred stock.

Delaware Law provides that the holders of preferred stock will have the right to vote separately as a class (or, in some cases, as a series) on an amendment to our certificate of incorporation if the amendment would change the par value or, unless the certificate of incorporation provided otherwise, the number of authorized shares of the class or change the powers, preferences or special rights of the class or series so as to adversely affect the class or series, as the case may be. This right is in addition to any voting rights that may be provided for in the applicable certificate of designation.

Our board of directors may authorize the issuance of preferred stock with voting, exchange 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.

Anti-Takeover Effects of Provisions of Our Amended and Restated Certificate of Incorporation and Bylaws

Our certificate of incorporation and bylaws provide for our board of directors to be divided into three classes, with staggered three-year terms. Only one class of directors is elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, our stockholders representing a majority of the shares of common stock outstanding will be able to elect all of our directors due to be elected at each annual meeting of our stockholders. In addition, our certificate of incorporation provides that subject to any limitations imposed by applicable law and subject to the rights of the holders of any series of Preferred Stock that may be designated from time to time, any vacancies on our Board of Directors resulting from death, resignation, disqualification, removal or other causes and any newly created directorships resulting from any increase in the number of directors, shall, unless the Board of Directors determines by resolution that any such vacancies or newly created directorships shall be filled by the stockholders and except as otherwise provided by applicable law, be filled only by the affirmative vote of a majority of the directors then in office, even though less than a quorum of the Board of Directors, and not by the stockholders. Our bylaws provide that all stockholder action must be effected at a duly called meeting of stockholders and not by written consent or electronic transmission, and that only the chairman of our board, our chief executive officer, or a majority of the authorized directors may call a special meeting of stockholders. Our certificate of incorporation requires a 66-2/3% stockholder vote for the amendment, repeal or modification of certain provisions of our certificate of incorporation relating to, among other things, the classification of our Board of Directors and filling of vacancies on our Board of Directors. Our certificate of incorporation and bylaws also require a 66-2/3% stockholder vote for the stockholders to adopt, amend or repeal certain provisions of our bylaws relating to stockholder proposals at annual meetings, director nominees and the number and term of office of directors.

The combination of the classification of our Board of Directors, the lack of cumulative voting and the 66-2/3% stockholder voting requirements will make it more difficult for our existing stockholders to replace our Board of Directors as well as for another party to obtain control of us by replacing our Board of Directors. Since our Board of Directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our Board of Directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to effect a change of our control.

These provisions may have the effect of deterring hostile takeovers or delaying changes in our control or in our management. These provisions are intended to enhance the likelihood of continued stability in the composition of our Board of Directors and in the policies they implement, and to discourage certain types of transactions that may involve an actual or threatened change of our control. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal. The provisions also are intended to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they also may inhibit fluctuations in the market price of our shares that could result from actual or rumored takeover attempts.

Section 203 of Delaware Law

We are subject to Section 203 of Delaware Law, or Section 203, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that 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 began, 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
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, lease, transfer, pledge or other disposition of 10% or more of the assets of the corporation to or with the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines interested stockholder as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation or any entity or person affiliated with or controlling or controlled by such entity or person.

Exhibit 10.32

FIFTH AMENDMENT TO LEASE

1. **PARTIES**

1.1 THIS FIFTH AMENDMENT TO LEASE (this "5th Amendment") made the 8th day of August, 2019 is between **CAPSTONE TICE BLVD LLC** ("Landlord") whose address is c/o Capstone Realty Group, LLC, 411 Hackensack Avenue, 8th Floor, Suite 800, Hackensack, New Jersey 07601 and **EAGLE PHARMACEUTICALS, INC.** ("Tenant"), whose address is 50 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

2. **STATEMENT OF FACTS**

2.1 Landlord's predecessor in interest, Mack-Cali Chestnut Ridge L.L.C. and Tenant previously entered into a Lease Agreement dated May 28, 2013 (the **"Initial Lease"**), as amended by a First Amendment to Lease dated July 1, 2013, a Second Amendment to Lease dated March 16, 2015, a Third Amendment to Lease dated May 5, 2015 and a Fourth Amendment to Lease Commencement Date Agreement dated February 10, 2016 (hereinafter collectively referred to as the **"Lease"**) covering 20,497 gross rentable square feet on the third (3rd) floor ("**Existing Premises**") consisting of (i) 9,906 gross rentable square feet on the third (3rd) floor ("**Initial Premises**"), (ii) 5,267 gross rentable square feet on the third (3rd) floor ("**1st Expansion Premises**") as set forth in the Second Amendment to Lease, and (iii) 5,324 gross rentable square feet on the third (3rd) floor ("**2nd Expansion Premises**") as set forth in the Third Amendment to Lease, all in the building located at 50 Tice Boulevard, Woodcliff Lake, New Jersey (**"Building"**); and

2.2 The Term of the Lease expires on June 30, 2020; and

2.3 Tenant desires to expand the Existing Premises by leasing 6,596 gross rentable square feet on the third (3rd) floor of the Building ("**3rd Expansion Premises**"), as shown on Exhibit A attached hereto and made a part hereof, being suites 360 and 363; and

2.4 The parties desire to extend the Term of the Lease as to the Existing Premises for a period to commence on July 1, 2020; and

2.5 The parties desire to amend certain terms of the Lease as set forth below.

3. **AGREEMENT**

NOW, THEREFORE, in consideration of the terms, covenants and conditions hereinafter set forth, Landlord and Tenant agree as follows:

3.1 The above recitals are incorporated herein by reference.

3.2 All capitalized and non-capitalized terms used in this 5th Amendment which are not separately defined herein but are defined in the Lease shall have the meaning given to any such term in the Lease.

3.3 The Term applicable to the 3rd Expansion Premises shall commence on the Effective Date (as defined below) and shall terminate at 11:59 p.m. on June 30, 2025 ("Expiration Date").

3.4 The effective date applicable to the 3rd Expansion Premises (the "Effective Date") shall be the earlier of: (i) the day Landlord substantially completes The Work (defined in Section 3 of Exhibit B hereof) pursuant to Exhibit B, attached hereto and made part hereof, but subject to The Work passing inspection to allow for occupancy of the 3rd Expansion Premises by Tenant (such date, the "Completion Date") provided that if full occupancy is legally permitted prior to the issuance of a temporary or final certificate of occupancy the same may be issued subsequent to the Completion Date provided Landlord pursues issuance of the same in a commercially reasonable manner, or (ii) the date Tenant or anyone claiming under or through Tenant shall occupy the 3rd Expansion Premises (provided that it is understood that Tenant's entry into the 3rd Expansion Premises under Sections 13.a.-b. of Exhibit B shall not constitute occupancy of the 3rd Expansion Premises by Tenant).

Landlord estimates that the Completion Date shall be on or about one hundred fifty (150) days from the later of: (a) the issuance of permits by applicable governmental entities for The Work, to the extent so required ("Issuance of Permits")' and (b) Tenant's approval of final plans and Tenant's completion of final selections for The Work, subject to: (i) Force Majeure; (ii) delays attributable solely to Tenant, including changes to The Work or plans requested by Tenant and/or interference by Tenant and/or Tenant's employees, agents, contractors or invitees with The Work; (iii) delays attributable to waiting for governmental inspections and approvals or other municipal delays; and (iv) Punch List items as set forth in Exhibit B. Landlord agrees to use commercially reasonable efforts to cause The Work to be substantially completed within one hundred fifty (150) days from the Issuance of Permits, subject to the foregoing.

Notwithstanding the foregoing sentence, in the event that Landlord's Work is not substantially completed within one hundred fifty (150) days from the Issuance of Permits, subject to the conditions in the previous paragraph, Landlord shall not be in default of the Lease or this 5th Amendment and the Lease, there shall be no penalties in connection therewith and this Fifth Amendment shall remain in full force and effect.

Landlord, however, shall exercise reasonable commercial efforts to advise Tenant, either in writing or orally, of Landlord's good faith estimate of the Completion Date at least ten (10) days before such estimated Completion Date. Landlord's failure to comply with the immediately preceding sentence shall neither be a breach, default or violation of the Lease by Landlord nor postpone, delay or defer the Effective Date, it being understood that Landlord's willingness to provide such estimate to Tenant is merely a courtesy and Tenant shall have no recourse against Landlord if the estimate is not furnished or if the estimate is inaccurate.

3.5 From and after the Effective Date, the following shall be effective:

a. Landlord shall lease to Tenant and Tenant shall hire from Landlord the 3rd Expansion Premises, subject to the next sentence, in its "AS-IS" condition, as shown on Exhibit A attached hereto and made part hereof. Landlord shall have no obligation to perform any tenant improvement work or grant any tenant allowance, except as set forth in Exhibit B hereof.

b. The Premises shall be defined as 27,093 gross rentable square feet on the third (3rd) floor of the Building and Paragraph 5 of the Basic Lease Provisions to the Lease shall be deemed amended accordingly.

c. Tenant shall pay to Landlord an additional Security Deposit applicable to the 3rd Expansion Premises in the amount of $31,331.00, which shall be due and payable upon Tenant's execution and delivery of this Fifth Amendment. Landlord acknowledges that it is presently holding a Security Deposit in the amount of $93,542.08.

d. In addition to the Fixed Basic Rent payable applicable to the Existing Premises, Tenant shall pay Landlord Fixed Basic Rent applicable to the 3rd Expansion Premises which shall accrue as follows and Paragraph 7 of the Basic Lease Provisions to the Lease shall be deemed amended accordingly:

Term	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

If the Effective Date is a day other than the first day of a calendar month, then the first Monthly Installment of Fixed Basic Rent payable by Tenant for the calendar month in which occurs the Effective Date shall be prorated.

e. Tenant's Percentage applicable to the 3rd Expansion Premises shall be 2.81% (6,596/235,000=2.81%).

f. Tenant shall pay Landlord, as Additional Rent, Tenant's Percentage applicable to the 3rd Expansion Premises of the increased cost to Landlord for each of the categories set forth in Exhibit G of the Initial Lease (Tax and Operating Cost Rider) over the Base Period Costs, as modified by Section 3.5g. hereof.

g. The Calendar Year for the Base Period Costs applicable to the 3rd Expansion Premises shall be the calendar year 2020 and Paragraph 3 of the Basic Lease Provisions to the Lease shall be deemed amended accordingly.

h. Tenant shall pay Landlord the cost of electricity consumed within the 3rd Expansion Premises in accordance with Exhibit H of the Initial Lease (Electricity Rider).

i. The number of parking spaces as set forth in Paragraph 10 of the Basic Lease Provisions to the Lease shall be increased by twenty-six (26) unassigned parking spaces. Landlord and Tenant acknowledge and agree that Tenant is currently entitled to use a total of eight (8) covered parking spaces in the Building's garage pursuant to the Lease and separate agreements (spaces in the Building's garage are referred to as the "Covered Parking Spaces"). Tenant's existing rights to the Covered Parking Spaces are hereby consolidated into the Lease, the number of Tenant's Covered Parking Spaces as set forth in Paragraph 10 of the Basic Lease Provisions to the Lease is hereby amended to be eight (8), and all other agreements between Landlord and Tenant for use of Covered Parking Spaces are hereby terminated. In consideration for such Covered Parking Spaces, Tenant shall pay Landlord, as Additional Rent, $150.00 per space per month. Such Additional Rent shall be paid together with and in the same manner as the Fixed Basic Rent.

3.6 The Term applicable to the Existing Premises shall be extended for a period ("Extension Term") commencing on July 1, 2020 and expiring at 11:59 p.m. on the Expiration Date, and Paragraph 6 of the Basic Lease Provisions and Paragraph 11 of the Definitions to the Initial Lease shall be deemed amended accordingly.

3.7 Landlord shall have no obligation to perform any tenant improvement work in the Existing Premises or grant any tenant allowance with respect to the Existing Premises in connection with the Extension Term and Tenant hereby hires from Landlord the Existing Premises in its "AS-IS" condition for the Extension Term under the terms and conditions set forth herein.

3.8 Commencing on July 1, 2020, the following shall be effective:

a. The Fixed Basic Rent applicable to the Existing Premises shall be as follows and Paragraph 7 of the Basic Lease Provisions to the Initial Lease shall be deemed amended accordingly:

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

b. Tenant shall continue to pay Landlord, as Additional Rent, Tenant's Percentage applicable to the Existing Premises of the increased cost to Landlord for each of the categories set forth in Exhibit G of the Initial Lease (Tax and Operating Cost Rider) over the Base Period Costs, as modified by Section 3.8d. hereof.

c. Tenant shall continue to pay Landlord the cost of electricity consumed within the Existing Premises in accordance with Exhibit H of the Initial Lease (Electricity Rider).

d. The Calendar Year applicable to the Existing Premises shall be the calendar year 2020 and Paragraph 3 of the Basic Lease Provisions to the Initial Lease shall be deemed amended accordingly. Prior to July 1, 2020, the Calendar Year shall continue to be the calendar year 2015.

3.9 As of the date hereof, Section 3.11 of the Initial Lease, as amended by Section 3.9 of the Second Amendment to Lease (together, the "Amended Section 3.11"), shall be deemed deleted in its entirety.

Notwithstanding the foregoing, subject to the provisions of this Section 3.9, Tenant shall have the option to lease from Landlord solely the following space on the third (3rd) floor (each such space defined individually as "Additional Space") at the expiration of the existing space lease for such Additional Space, subject to Landlord's right to renew and/or extend each such lease and/or to enter into direct leases with existing subtenants and subject to the rights of any existing tenant with respect to each such Additional Space: (a) Unit 317 leased by Par-Four Investment Management, LLC covering approximately 4,297 gross rentable square feet; and (b) Unit 317B leased by Sapphire Marketing L.L.C. covering approximately 2,410 rentable square feet.

If the Term of this Lease shall be in full force and effect on the expiration or termination date of the existing space lease for such Additional Space and the date upon which Tenant shall exercise the option hereinafter referred to, then, subject to Landlord's right to renew and/or extend such lease and/or enter into a direct lease with existing subtenants and subject to the rights of any existing tenant with respect to each such Additional Space, Tenant shall have the option to lease all, but not less than all of such Additional Space then being offered to Tenant on an "as-is" basis, provided Tenant gives Landlord written notice of such election to lease such additional space within ten (10) days after Tenant shall receive Landlord's notice that such Additional Space is available for leasing to Tenant ("Landlord's Availability Notice").

Landlord and Tenant shall use their best efforts, during the ten (10) day period after Tenant receives Landlord's Availability Notice to agree upon the Fixed Basic Rent to be paid by Tenant for said Additional Space. If Landlord and Tenant shall agree upon the Fixed Basic Rent during such ten (10) day period, the parties shall promptly execute an amendment to this Lease stating the Fixed Basic Rent for the Additional Space, confirming Tenant's election to lease said Additional Space and the incorporation of said Additional Space into the Premises.

If the parties are unable to agree on the Fixed Basic Rent for said Additional Space within ten (10) days after Tenant receives Landlord's Availability Notice and Tenant thereby fails or refuses to exercise this option within such ten (10) day time period (time being of the essence), then Tenant will be deemed to have declined the right to lease the subject Additional Space and in such event Tenant shall have no further rights under this Section 3.9 with respect to the Additional Space which was the subject of Landlord's Availability Notice.

If Tenant shall elect to lease said Additional Space: (w) said Additional Space shall be deemed incorporated within and part of the Premises on the date that Landlord shall notify Tenant that such Additional Space is ready for occupancy by Tenant and shall expire on the Expiration Date of the Lease, (x) the Fixed Basic Rent payable under the Lease shall be increased by the agreed amount for said Additional Space as determined in the manner set forth above, (y) Tenant's Percentage shall be proportionately increased, and (z) all other terms and provisions set forth in this Lease shall apply, except that Landlord not be required to perform any work with respect to said Additional Space or provide any tenant improvement allowance.

The option granted to Tenant under this Section 3.9 may be exercised only by Tenant, its permitted successors and assigns, and not by any subtenant or any successor to the interest of Tenant by reason of any action under the

Bankruptcy Code, or by any public officer, custodian, receiver, United States Trustee, trustee or liquidator of Tenant or substantially all of Tenant's property.
Notwithstanding the foregoing, Tenant shall have no right to exercise the option granted to Tenant hereunder if, at the time Landlord gives Tenant notice of such availability of Additional Space: (i) Tenant shall not be in occupancy of substantially all of the Premises; or (ii) the Premises or any part thereof shall be the subject of a sublease, except pursuant to a “Permitted Transfer” as defined and set forth under Section 3.11B of this 5th Amendment.

If Tenant shall have elected to exercise its option hereunder, such election shall be (at Landlord’s option) deemed withdrawn if, at any time after the giving of notice of such election and prior to the occupancy of the Additional Space, Tenant shall sublease all or any part of the Premises or assign Tenant’s interest in this Lease, except pursuant to a “Permitted Transfer” as defined and set forth under Section 3.11B of this 5th Amendment. Tenant shall have no right to exercise any of such options (and Landlord shall not be required to give Tenant the Landlord’s Availability Notice) subsequent to the date Landlord shall have the right to deliver a notice of termination under the Lease or if Tenant has delivered the “Termination Notice” as defined and set forth under Section 3.10 of this 5th Amendment.

3.10 **<u>TERMINATION OPTION</u>**:

Notwithstanding anything to the contrary contained herein, Tenant shall have the option to terminate the Lease (“Termination Option”) in accordance with the following terms and conditions:

a. If Tenant desires to exercise the Termination Option, Tenant shall give Landlord irrevocable written notice (“Termination Notice”) of Tenant’s exercise of this Termination Option, which shall be delivered by certified mail which Termination Notice must be received by Landlord no later than the date that is two hundred and seventy (270) days prior to the Termination Date (as defined below) elected by Tenant in such Termination Notice, and which Termination Notice may be delivered to Landlord no earlier than July 1, 2023. **TIME IS OF THE ESSENCE** with respect to Landlord’s receipt of the Termination Notice and all other deadlines in this Article.

b. If Tenant gives the Termination Notice and complies with all the provisions in this Article, the Lease shall terminate at 11:59 p.m. on the date specified by Tenant in the Termination Notice (the “Termination Date”), but in no event shall the Termination Date be earlier than March 31, 2024 regardless of the date that the Termination Notice is delivered.

c. Tenant’s obligations to pay Fixed Basic Rent, Additional Rent, and any other costs or charges under this Lease, and to perform all other Lease obligations for the period up to and including the Termination Date, shall survive the termination of this Lease.

d. Notwithstanding the foregoing, if at any time during the period on or after the date on which Tenant shall exercise its Termination Option, up to and including the Termination Date, Tenant shall be in default of this Lease, beyond any applicable notice and cure periods, then Landlord may elect, but is not obligated, to cancel and declare null and void Tenant’s exercise of the Termination Option and this Lease shall continue in full force and effect for the full Term hereof unaffected by Tenant’s exercise of the Termination Option.

e. In the event Tenant exercises the Termination Option, Tenant covenants and agrees to surrender full and complete possession of the Premises to Landlord on or before the Termination Date vacant, broom-clean, in good order and condition, and, in accordance with the provisions of this Lease, and thereafter the Premises shall be free and clear of all leases, tenancies, and rights of occupancy of any entity claiming by or through Tenant.

f. If Tenant shall fail to deliver possession of the Premises on or before the Termination Date in accordance with the terms hereof, Tenant shall be deemed to be a holdover Tenant from and after the Termination Date, and in such event all covenants and terms of Article 19 of the Lease shall apply, except that the 150% figure in Article 19 of the Lease shall be increased to 200%. Tenant shall also be liable to Landlord for all costs and expenses incurred by Landlord in securing possession of the Premises. Landlord may accept any such sums from Tenant without prejudice to Landlord’s right to evict Tenant from the Premises by any lawful means.

g. Subject to Landlord’s right to cancel and declare null and void Tenant’s exercise of the Termination Option pursuant to Section 3.10 d. above, if Tenant properly and timely exercises the Termination Option, the Lease shall cease and expire on the Termination Date with the same force and effect as if said Termination Date were the date originally provided in this Lease, as modified by this 5th Amendment, as the Expiration Date of the Term hereof.

h. If the Tenant under the Lease assigns its interest in the Lease: then, from and after the date of such assignment, the Termination Option shall be deemed null and void, and neither Tenant nor the assignee shall have the right to exercise such Termination Option, provided, however, that Landlord and Tenant agree that an event that is deemed to be a Permitted Transfer pursuant to Section 6(c) of the Original Lease (as amended as provided in Section 3.11B below), shall not result in the loss of the Termination Option, which Termination Option shall continue in full force and effect and may be exercised at any time following any such occurrence.

3.11 As of the date hereof: (i) Article 31 of the Original Lease (defined in Section 2.1 of the Initial Lease dated May 28, 2013), titled “Option to Renew”, which was reinstated by the Second Amendment to Lease, shall be amended so that all references to the Expiration Date in said Article 31 shall mean June 30, 2025 and all references to the Renewal Term in said Article 31 shall mean the five (5) year period beginning on July 1, 2025 and ending on June 30, 2030.

3.11A Landlord confirms that Landlord's right to terminate the Lease or recapture any space set forth in Section 6(a) of the Original Lease does not apply to Permitted Transfers.

3.11B The first sentence of the second paragraph of Section 6(c) of the Original Lease is hereby deleted and replaced with the following:

> Notwithstanding anything contained in this Lease to the contrary, Tenant may assign this Lease or sublet all or any portion of the Premises to (i) any corporation or other Entity directly or indirectly controlling or controlled by Tenant or under common control with Tenant, or (ii) any successor by merger, consolidation, corporate reorganization or acquisition of all or substantially all of the assets of Tenant (any transaction referred to in clauses (i) or (ii) hereof will be a "Permitted Transfer") provided that the net worth of any transferee of a Permitted Transfer will not be less than $100,000,000 immediately preceding the Permitted Transfer. Any other assignment or subleasing of Tenant's interest under this Lease will be subject to Landlord's approval, which approval will not be unreasonably withheld, conditioned or delayed.

3.11C Landlord shall secure for Tenant a subordination, non-disturbance and attornment agreement recognizing Tenant's rights under the Lease (a "SNDA") from the holder of any mortgage, deed of trust or lease encumbering the Building or the property on which it is located as of the date of this 5th Amendment (which parties Landlord represents and warrants to be BVFL I FI LLC), in the form attached hereto as Exhibit D, provided that Tenant shall execute and deliver to Landlord concurrently with Tenant's execution and delivery of this 5th Amendment such SNDA. Landlord shall also secure for Tenant a SNDA from all future holders of any mortgage, deed of trust, or lease encumbering the Building or the property on which it is located at the time the same comes into existence on such holder's standard form subject to Tenant's reasonable review and comment. From and after the date of this 5th Amendment, the effectiveness of the provisions of Section 12 of the Original Lease as to any mortgage, deed of trust, or lease are subject to Landlord's compliance with the preceding requirements to deliver an SNDA for the same.

3.12 **<u>NOTICE ADDRESSES</u>** for the Landlord shall mean the following and Paragraph 9 of the Basic Lease Provisions to the Lease shall be deemed amended accordingly:

If to Landlord:
c/o Capstone Realty Group, LLC
411 Hackensack Avenue, 8th Floor, Suite 800
Hackensack, New Jersey 07601
Attention: Brad Gillman – Manager

3.13 No later than thirty (30) days after the determination of the Effective Date, the parties shall memorialize the Effective Date in writing.

3.14 Landlord and Tenant represent and warrant to the other that it has dealt with no broker in connection with this transaction, except for Savills Studley, Inc., and Landlord and Tenant agree to indemnify and hold the other harmless from any and all claims of any other broker arising out of or in connection with negotiations of, or entering into of, this 5th Amendment based upon any dealings that the other broker had with the indemnifying party. Landlord shall pay the commission owed to Savills Studley, Inc. pursuant to a separate written agreement between Landlord and Savills Studley, Inc.

3.15 Tenant agrees not to disclose the terms, covenants, conditions or other facts with respect to the Lease, including the Fixed Basic Rent and Additional Rent, to any person, corporation, partnership, association, newspaper, periodical or other entity, except: (i) to Tenant's accountants, advisors, or attorneys, (ii) to actual or potential investors, purchasers, acquirers, providers of financing, acquisition targets, or business counterparties of Tenant, and each of their accountants, advisors, or attorneys, or (iii) as required by law. Tenant agrees that said accountants, advisors, or attorneys (except to the extent necessary to handle any litigation concerning the Lease) shall be required to keep the terms of the Lease confidential. This non-disclosure and confidentiality agreement will be binding upon Tenant without limitation as to time, and a breach of this paragraph will constitute a material breach by Tenant under this 5th Amendment and the Lease. In addition, Tenant's employees, contractors, etc. shall keep all of the terms and conditions of the Lease, including any billing statements and/or any backup supporting those statements, confidential, subject to the same exceptions set forth in the first sentence of this Section 3.15.

3.16 Tenant, to the best of its knowledge, information and belief, as of the date hereof, hereby represents to Landlord that (i) there exists no default under the Lease either by Landlord or Tenant; (ii) Tenant is entitled to no credit, free rent or other offset or abatement of the rents due under the Lease; and (iii) there exists no offset, defense or counterclaim to Tenant's obligations under the Lease. Landlord, to the best of its knowledge, information and belief, as of the date hereof, hereby represents to Tenant that there exists no default under the Lease either by Landlord or Tenant.

3.17 Section 3.10 of the Initial Lease, Section 29 of the Original Lease, and Section 3.16 of the Second Amendment to Lease, which give the Landlord the right, subject to certain conditions, to relocate the Premises, are hereby deleted.

3.18 Except as expressly amended herein, the Lease shall remain in full force and effect as if the same had been set forth in full herein, and Landlord and Tenant hereby ratify and confirm all of the terms and conditions thereof.

3.19 This 5th Amendment shall be binding upon and inure to the benefit of the parties hereto and their respective legal representatives, successors and permitted assigns.

3.20 Each party agrees that it will not raise or assert as a defense to any obligation under the Lease or this 5th Amendment or make any claim that the Lease or this 5th Amendment is invalid or unenforceable due to any failure of this document to comply with ministerial requirements including, but not limited to, requirements for corporate seals, attestations, witnesses, notarizations, or other similar requirements, and each party hereby waives the right to assert any such defense or make any claim of invalidity or unenforceability due to any of the foregoing.

This 5th Amendment may be executed in multiple counterparts, each of which, when assembled to include an original signature for each party contemplated to sign this 5th Amendment, will constitute a complete and fully executed original. All such fully executed counterparts will collectively constitute a single agreement. Tenant expressly agrees that if the signature of Landlord and/or Tenant on this 5th Amendment is not an original, but is a digital, mechanical or electronic reproduction (such as, but not limited to, a photocopy, fax, e-mail, PDF, Adobe image, JPEG, telegram, telex or telecopy), then such digital, mechanical or electronic reproduction shall be as enforceable, valid and binding as, and the legal equivalent to, an authentic and traditional ink-on-paper original wet signature penned manually by its signatory.

[Signature page(s) follows.]

IN WITNESS WHEREOF, Landlord and Tenant have hereunto set their hands the date and year first above written, and acknowledge one to the other that they possess the requisite authority to enter into this transaction and to sign this 5th Amendment.

LANDLORD: TENANT:

CAPSTONE TICE BLVD LLC **EAGLE PHARMACEUTICALS, INC.**

By: AFG Capstone Tice Blvd LLC - Manager
By: Capstone Realty Holdings LLC - Manager

By: /s/ Brad Gillman

By: /s/ Pete A. Meyers
Name: Pete A. Meyers
Title: Chief Financial Officer

and

By: /s/ Brian Cahill
Name: Brian Cahill
Title: Vice President, Finance

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKLEY CAUSE COMPETITIVE HARM TO EAGLE PHARMACEUTICALS, INC. IF PUBLICLY DISCLOSED.

CONFIDENTIAL **EXECUTION VERSION**

SETTLEMENT AGREEMENT

This SETTLEMENT AGREEMENT (this "Agreement") is hereby entered into and made effective as of the date it has been executed by all parties hereto (the "Effective Date") by and between Eli Lilly and Company ("Lilly") and Eagle Pharmaceuticals, Inc. ("Eagle"). Lilly and Eagle are referred to herein individually as a "*Party*" and collectively, as the "*Parties.*"

WHEREAS, Lilly owns Orange Book listed United States Patent No. 7,772,209 (the "Asserted Lilly Patent") and, in the Orange Book, the Asserted Lilly Patent has the Patent Use Code, U-1296;

WHEREAS, Lilly is the holder of New Drug Application ("NDA") No. 021462, which is approved by the Food and Drug Administration ("FDA") for the manufacture and sale of pemetrexed for injection in 100 mg/vial and 500 mg/vial dosage strengths which Lilly has marketed in the United States under the brand name ALIMTA®;

WHEREAS, Eagle is the holder of 505(b)(2) New Drug Application ("505(b)(2) NDA") No. 209472, submitted to FDA seeking approval for the manufacture and sale in the United States of generic pemetrexed for injection in a 25 mg/mL, 500 mg vial product, and containing a certification pursuant to 21 U.S.C. §355(b)(2)(A)(iv) alleging that the Asserted Lilly Patent is invalid, unenforceable and/or not infringed;

WHEREAS, Lilly contends that the Asserted Lilly Patent is valid and enforceable and that the manufacture, use, sale, offering for sale, or importation of the Eagle Product (as defined below) in the United States would infringe the Asserted Lilly Patent;

WHEREAS, Lilly and Eagle are involved in litigation in the United States District Court for the District of Delaware (the "District Court"), namely Civil Action No. 1:17-cv-01293-MSG (the "Patent Infringement Lawsuit"), concerning the alleged infringement by Eagle of the Asserted Lilly Patent resulting from the filing by Eagle of the Eagle NDA (as defined below), the related certification pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), and a related Eagle allegation that the Patent Use Code U-1296 is incorrect;

WHEREAS, Lilly and Eagle are involved in litigation in the United States District Court for the District of Delaware (the "District Court"), namely Civil Action No. 1:18-cv-01121-MSG (the "Antitrust Lawsuit"), concerning an alleged antitrust violation by Lilly with respect to the Asserted Lilly Patent and its Patent Use Code listing in the Orange Book (together with the Patent Infringement Lawsuit collectively referred to herein as the "Lawsuits");

WHEREAS, the Parties desire and agree to enter into this Agreement to avoid the costs, uncertainty, and risk associated with continued litigation of these matters and to permit entry of the Eagle Product prior to the expiration of the Asserted Lilly Patent and its pediatric exclusivity upon the terms and subject to the conditions set forth herein;

WHEREAS, this Agreement is the only agreement between the Parties related to the settlement of the Lawsuits relating to the alleged infringement of the Asserted Lilly Patent with respect to the Eagle NDA and the Eagle Product and the alleged anti-competitive behavior by Lilly with respect to the Asserted Lilly Patent;

WHEREAS, no Party has received any consideration from the other Party for its entry into this Agreement other than that which is described in this Agreement; and

NOW, THEREFORE, in consideration of the mutual agreements herein contained and the consideration described herein, the sufficiency and receipt of which are hereby acknowledged, the Parties hereto, intending to be legally bound hereby, agree as follows:

1. DEFINITIONS

1.1 "Affiliate" means, with respect to a Party, any entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such Party. For purposes of this definition, "control" (including the terms "controlled by" and "under common control with") of a business entity means the direct or indirect ownership of more than fifty percent (50%) of the voting stock or other ownership interest in such entity; or the direct or indirect ownership of the power to direct the management and policies of the other entity by any means whatsoever.

1.2 "<u>ALIMTA®</u>" means pemetrexed for injection in 100 mg/vial and 500mg/vial dosage strengths that is the subject of Lilly's NDA No. 021462, and any other dosage strengths added to NDA No. 021462.

1.3 "<u>ALIMTA® Generic Product</u>" means a Generic Pharmaceutical Product, other than the Eagle Product, whose RLD is ALIMTA®, or any Authorized Generic Product.

1.4 "<u>Authorized Generic Product</u>" means a pharmaceutical product sold in the Territory pursuant to and under the Lilly NDA, but marketed without the ALIMTA® trademark or any successor trademark thereto.

1.5 "<u>Calendar Year</u>" means each successive period of twelve months commencing on January 1 and ending on December 31.

1.6 "<u>Control</u>" means, with respect to any patent right or regulatory exclusivity, the possession (whether by ownership or license) by Lilly or its Affiliates of the ability to grant to Eagle a license, waiver or other access as provided herein to such patent right or regulatory exclusivity, without violating the terms of any agreement or other arrangement with any Third Party or Eagle being obligated to pay any royalties or other consideration therefor.

1.7 "<u>Eagle NDA</u>" means Eagle's 505(b)(2) NDA No. 209472, submitted to FDA seeking approval for the manufacture and sale in the United States of generic pemetrexed for injection in a 25 mg/mL, 500 mg vial product, and any amendments and supplements thereto including any additional indications that are approved by the FDA for the Lilly NDA, whether approved before or after the Effective Date but not including any amendment or supplement that converts Eagle's 505(b)(2) NDA to an ANDA under 505(j).

1.8 "<u>Eagle Product</u>" means the NDA product that is the subject of the Eagle NDA.

1.9 "<u>Eagle Quarter</u>" means each of the four (4) thirteen (13) week periods with respect to the United States, commencing on January 1 of any calendar year.

1.10 "<u>Final Court Decision</u>" means a decision (i) by a court of competent jurisdiction, or (ii) by the United States Patent and Trademark Office in an *inter partes* review, post grant review, or other similar proceeding proceeding, in each of clauses (i) and (ii) on the merits (e.g., after a trial or summary judgment motion) of the asserted patent claims, whereby such court enters final judgment of invalidity, unenforceability and/or non-infringement (as applicable) from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken. For the avoidance of doubt, any settlement, consent judgment entered as part of any settlement, withdrawal or dismissal of any action or dispute without a decision on the merits of the asserted patent claims (whether such settlement, consent judgment, withdrawal or dismissal is with or without prejudice, and whether or not such claims may be relitigated) shall not be deemed a Final Court Decision.

1.11 "<u>Generic Pharmaceutical Product</u>" means any product that is the subject of an ANDA and/or any product that is the subject of a 505(b)(2) NDA.

1.12 "<u>License Effective Date</u>" means the earliest to occur of the following:

(a) February 1, 2022; and

(b) [***]; and

(c) the date that Lilly authorizes a Third Party to sell an ALIMTA® Generic Product in the Territory, other than an Authorized Generic Product as described in subsection (e) of this Section 1.12, [***]; and

(d) the date of a Final Court Decision in favor of a Third Party holding all of the then adjudicated claims of the Asserted Lilly Patent to be invalid, not infringed and/or unenforceable; and

(e) the date on which a Third Party (under license or authorization from Lilly), or Lilly or a Lilly Affiliate, first sells in the Territory an Authorized Generic Product. Lilly shall provide Eagle with written advance notice, not less than 120 days prior to the date a Third Party (under license or authorization from Lilly), or Lilly or a Lilly Affiliate is authorized to sell an Authorized Generic Product, if such date is prior to February 1, 2022. For the avoidance of doubt, this subsection shall not apply in the event of a launch of an Authorized Generic Product by Lilly in response to an at-risk Third Party launch as described in Section 3.12; and

(f) the date of expiration, disclaimer, abandonment, cancellation, or dedication to the public of all the claims of the Asserted Lilly Patent subject to the Appeals.

1.13 "Licensed Patents" means the Asserted Lilly Patent and any continuations, continuations-in-part, divisionals, reissues and reexaminations thereof, and any other patents owned or Controlled by Lilly or its Affiliates that are listed now or in the future in the Orange Book as covering the Lilly NDA products.

1.14 "Lilly NDA" means Lilly's NDA No. 021462 and any amendments or supplements thereto.

1.15 "Net Sales" means, with respect to the Eagle Product, the gross amount invoiced by Eagle, its Affiliates or its Sublicensee of such Product to Third Parties ("Gross Sales"), less (a) bad debts related to such Product, (b) sales returns and allowances actually paid, granted or accrued, including, trade, quantity and cash discounts, and other adjustments, including, those granted on account of price adjustments, billing errors, rejected goods, damaged or defective goods, recalls, returns, rebates, chargeback rebates, reimbursement, fees or similar payments granted or given to wholesalers or other distributors, buying groups, health care insurance carriers, pharmacy benefit management companies, health maintenance organizations, Governmental Authorities, or other institutions or health care organizations, (c) prompt pay discounts, and (d) adjustments arising from consumer discount programs or other similar programs or arising in connection with any Eagle discount or savings program. Net Sales shall be determined from books and records maintained in accordance with GAAP, as consistently applied by Eagle with respect to sales of all its drug products; for the sake of clarity, any charge or allowance identified under this Section shall be counted once. Sales and other transfer of Eagle Product between Eagle and its Affiliates will not give rise to Net Sales.

1.16 "Orange Book" means FDA's publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations*.

1.17 "Other Lilly Patents" means, other than the Licensed Patents, any other patents or patent applications owned or Controlled or licensed, now or in the future, by Lilly or any of its Affiliates that claim or cover the making, using, selling, offering for sale or importation of the Eagle Product in or for the Territory.

1.18 "Pediatric Exclusivity" means the period of Regulatory Exclusivity awarded to a drug product during which FDA may not approve another drug product pursuant to 21 U.S.C. 355a(b)-(c).

1.19 "Regulatory Exclusivity" means any grant by the FDA with respect to an NDA or ANDA that precludes final FDA approval of another application during the term of the exclusivity.

1.20 "RLD" means Reference Listed Drug, i.e., a drug that an ANDA or 505(b)(2) NDA references for investigations to show that the drug that is the subject of the ANDA or 505(b)(2) is approvable by the FDA.

1.21 "Royalty Term" means the period commencing on the License Effective Date and ending upon the earliest of the following:

(a) the date of a Final Court Decision in favor of a Third Party holding all of the then adjudicated claims of the Asserted Lilly Patent to be invalid, non-infringed and/or unenforceable;

(b) the date of expiration, disclaimer, abandonment, cancellation, or dedication to the public of the Asserted Lilly Patent with surviving patent term and any regulatory exclusivity attached thereto; and

(c) May 24, 2022.

1.22 "Territory" means the United States of America, its territories, possessions, protectorates, and the Commonwealth of Puerto Rico.

1.23 "Third Party" means any entity or person that is not a Party or an Affiliate of a Party.

2. SETTLEMENT; DISMISSAL; RELEASE

2.1 All of the terms and conditions set forth in this Agreement shall be binding on the Parties as of the Effective Date.

2.2 The Parties are entering into this Agreement in an effort to avoid the costs, uncertainty, and risk associated with the continued litigation of these matters.

2.3 Dismissal of Litigation. Within three (3) business days after the Agreement Effective Date, the Parties shall file the Stipulations of Dismissal attached as Exhibits A and B. The Stipulations of Dismissal shall dismiss all claims and defenses with prejudice, with each Party to bear its own fees and costs. If for any reason the District Court raises an objection to either or both of the Stipulations of Dismissal as drafted or requires that the Parties modify either or both of the Stipulations of Dismissal, the Parties agree to confer promptly and in good faith in order to take action consistent with this Agreement to secure entry of the Stipulations of Dismissal as drafted or with agreed-upon modifications; provided that nothing contained herein shall be deemed to require a Party to agree to a modification of this Agreement or the Stipulations of Dismissal that materially affects the economic value of the transactions contemplated hereby.

2.4 FTC Review. Each Party shall submit this Agreement (including all attachments hereto) to federal antitrust agencies, *i.e.*, the U.S. Federal Trade Commission ("FTC") and U.S. Department of Justice ("DOJ") within ten (10) business days of its execution. The Parties hereby agree that they will work in good faith to resolve any related issues and endeavor to modify this Agreement in view of any objections from such federal antitrust agencies, but no Party shall be required to accept any terms that materially change or modify the purposes of this Agreement. Each Party reserves the right to communicate separately with the FTC and/or DOJ regarding such filings as it believes appropriate, provided, however, that each Party will keep the other Party reasonably informed of such communications.

2.5 Release. In consideration of the mutual execution of this Agreement and the mutual agreement to be legally bound by the terms hereof, Lilly and Eagle each on behalf of itself and its predecessors, successors, assigns, shareholders, officers, directors, employees, trustees, agents, representatives, licensees, licensors, parents, subsidiaries and Affiliates and all others claiming by, through and under them, hereby fully, finally, irrevocably and forever releases, relinquishes, acquits and discharges the other Party and its predecessors, successors, assigns, shareholders, officers, directors, employees, trustees, agents, representatives, licensees, licensors, parents, subsidiaries, Affiliates, customers, suppliers, importers, attorneys, manufacturers, distributors and insurers, if any, from any and all claims, demands, causes of action, liabilities, losses, all manner of actions, judgments, settlements, interest, damages, punitive damages and other damages or costs of whatever nature (including costs, expenses, and attorneys' fees), whether known or unknown, foreseen or unforeseen, certain or contingent, accruing on or before the Effective Date, arising out of, derived from, predicated upon, or relating to the Eagle Product and the Eagle NDA or its filing, the Licensed Patents and Other Lilly Patents, or the Patent Infringement Lawsuit; provided, however, that nothing herein shall prevent or impair the right of either Party to bring a proceeding in the forum set forth in Section 8.2 of this Agreement for a breach of this Agreement or any representation, warranty, or covenant herein, or with respect to any product other than the Eagle Product.

2.6 Unknown Claims. Each Party, on behalf of itself and its Affiliates, hereby expressly waives and relinquishes any and all provisions, rights and benefits conferred by Section 1542 of the California Civil Code, which provides as follows:

> A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN TO HIM OR HER MUST HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR.

Further, each Party, on behalf of itself and its Affiliates, expressly waives and relinquishes all rights and benefits afforded by any law in any other jurisdiction similar to Section 1542 of the California Civil Code.

2.7 No Assignment of Claims. Each Party represents, warrants and covenants that it has not heretofore assigned or transferred, and will not assign or otherwise transfer, to any person or entity any matters released by such Party in Section 2.5, and each such Party agrees to indemnify and hold harmless the other Party and the other persons and entities released under Section 2.5 from and against all such released matters arising from any such alleged or actual assignment or transfer.

2.8 Reliance on Agreement. Neither Party shall seek to rely upon or enter this Agreement or any admission herein into evidence in any proceeding other than a proceeding related to a claimed breach of this Agreement.

3. LICENSE AND COVENANT NOT TO SUE

3.1 Lilly and its Affiliates hereby grant to Eagle and its Affiliates a non-transferable (except as permitted under Section 8.10), non-exclusive license under the Licensed Patents to manufacture, have manufactured, use, sell, offer to sell, and import the Eagle Product in the Territory as of and following the License Effective Date provided that such foregoing license to sell shall be limited to not more than nineteen thousand two hundred (19,200) vials of the Eagle Product in the Territory prior to April 1, 2022, but shall be unlimited thereafter. Eagle and its Affiliates shall not have any right to sublicense its rights under the foregoing license except to an exclusive (even as to Eagle) sublicensee ("Sublicensee"). Eagle and its Affiliates shall not have any right to otherwise transfer or assign any of its rights under the foregoing license, except for any assignment expressly permitted under Section 8.10.

3.2 The license rights under Section 3.1 as to the Eagle Product will begin on the License Effective Date. Eagle will not, and will cause its Affiliates not to, directly or indirectly, sell, have sold, offer to sell, or have offered for sale any of the Eagle Product in the Territory prior to the License Effective Date except as expressly permitted under Section 3.3 or 3.5.

3.3 Limited License. Subject to the terms and conditions of this Agreement, effective as of the dismissal set forth in Section 2.3, Lilly hereby grants to Eagle and its Affiliates a non-exclusive limited license (which may be sublicensed to the Sublicensee) in the Territory under the Licensed Patents, and any foreign counterparts thereto, and any other Lilly-owned patent, patent application, or intellectual property right, whether arising and/or acquired in the future or now-existing, sufficient to allow Eagle, prior to, as of and following the License Effective Date, to make, have made, import, have imported, have stored, and store the Eagle Product and otherwise take such steps in each case solely as reasonably necessary to develop inventory of, and obtain and maintain regulatory approval for, the Eagle Product for sale in the Territory as of and following the License Effective Date.

3.4 Covenant not to sue. Lilly and its Affiliates covenant not to sue, assert any claim or otherwise participate in any action or proceeding against or take any action to interfere with, Eagle and its Affiliates, the Sublicensee, and their importers, suppliers, distributors, and customers, or support or encourage any Third Party to sue, for infringement of the Licensed Patents or Other Lilly Patents with respect to Eagle's or its Affiliates' or its Sublicensee (i) making, having made, using, selling, offering for sale, distributing and importation of the Eagle Product in or for the Territory as of and following the Effective Date pursuant to the terms of this Agreement, and (ii) maintaining with FDA a "Paragraph IV Certification" for the Eagle NDA under 21 U.S.C. § 355(b)(2)(A)(iv).

Lilly shall impose the foregoing covenant not to sue on its Affiliates and any Third Party to which Lilly or any of its Affiliates may assign, license or otherwise transfer any rights to enforce the applicable Licensed Patents or Other Lilly Patents. Lilly will ensure that any and all of its Licensees also comply with this provision.

3.5 Pre-marketing Rights. Subject to the terms and conditions of this Agreement, including Sections 3.1 – 3.4, Eagle or its Sublicensee may engage in discussions with potential customers to make them aware of the upcoming availability of the Eagle Product in the Territory, engage in customary pre-launch marketing activities, other than entry into contracts with potential customers and distributors, beginning not earlier than sixty (60) days prior to the commencement of the Royalty Term, so long as such communications and other activities with potential customers and distributors make explicit that Eagle's Product will not be available for sale in the Territory prior to the License Effective Date ("Pre-Marketing"). Eagle or its Sublicensee may enter into contracts with potential customers and distributors beginning not earlier than January 2, 2022.

3.6 Covenant not to challenge Licensed Patents. Except to the extent required by law or order of a court or administrative agency of competent jurisdiction, only to the extent of any license contained in this Agreement and solely with respect to the Eagle Product, Eagle shall not, and shall cause its Affiliates (and Sublicensee, as applicable) not to: (i) challenge, dispute or contest the validity, enforceability, patentability, priority of invention or other claim to priority, or patent term adjustment of the Licensed Patents or assert non-infringement of the Licensed Patents, in any proceeding in the United States Patent and Trademark Office ("USPTO") (*e.g.*, reexamination, *inter partes* proceeding, protest, observation, comment, opposition, third-party submission, post-grant proceeding, i*nter panes* review, post grant review, covered business method review, derivation proceeding, interference or other action) or any United States court proceedings, and (ii) knowingly assist or join any proceeding with any Third Party challenging, disputing or contesting the validity, enforceability, patentability, priority of invention or other claim to priority, or patent term adjustment, or asserting non-infringement of any of the Licensed Patents. For the avoidance of doubt, nothing herein shall prevent Eagle (or its Sublicensee as applicable) (a) from maintaining a "Paragraph IV Certification" under 21 U.S.C. § 355(b)(2)(A)(iv) for the Eagle NDA, or (b) from challenging, disputing or contesting the validity, enforceability, patentability, priority of invention or other claim to priority, or patent term adjustment of the Licensed Patents or asserting non-infringement of the Licensed Patents, in the event that Lilly or its Affiliates breach this Agreement (and fail to cure such breach as set forth in this Agreement) or assert that the Eagle Product or the Eagle NDA infringes any of the Licensed Patents.

3.7 Waiver of Lilly Regulatory Exclusivity. Lilly waives, as to the Eagle NDA only, any Regulatory Exclusivity awarded to Lilly relating to pemetrexed, whether existing now or in the future, including any Pediatric Exclusivity in effect for the Lilly NDA. If requested, Lilly shall promptly provide to Eagle and the FDA a letter waiving Regulatory Exclusivity. The written consent shall be suitable for submission to the FDA and be in substantially the form set forth in Exhibit C.

3.8 Waiver of 30-month stay. Lilly acknowledges that the entry of the Parties' Stipulation of Dismissal in the Patent Infringement Lawsuit will terminate the 30-month stay of approval of the Eagle NDA that was put into effect pursuant to 21 U.S.C. § 355(c)(3)(C). For clarity, to the extent necessary, Lilly waives the 30-month stay. If requested, Lilly shall promptly provide to Eagle and the FDA a letter waiving any 30-month stay. The written consent shall be suitable for submission to the FDA and be in substantially the form set forth in Exhibit C.

3.9 Lilly Consent to Approval of Eagle NDA. Lilly hereby consents to the final FDA approval of the Eagle NDA, and the entry of the Parties' Stipulation of Dismissal shall permit the FDA to grant final regulatory approval to the Eagle NDA (subject to the Eagle NDA meeting other regulatory requirements), pursuant to 21 U.S.C. § 355(c)(3)(C)(ii)(I)(bb) and 21 C.F.R. §§ 314.107(b)(3)(iii)(B). If requested by the FDA, Lilly shall promptly provide to Eagle and the FDA written consent, pursuant to 21 C.F.R. § 314.50(i)(3), that the FDA may grant final regulatory approval to the Eagle NDA, pursuant to 21 C.F.R. §§ 314.107(b)(3)(vi). The written consent shall be suitable for submission to the FDA and be in substantially the form set forth in Exhibit D. Lilly shall promptly submit this correspondence to the FDA in connection with the Lilly NDA, and promptly confirm to Eagle that it has done so. Eagle shall then, in connection with the Eagle NDA, also submit to the FDA a copy of Lilly's correspondence to Eagle.

3.10 Lilly Regulatory Covenants. Except as required by law, directly requested by FDA or for reasons that relate to the safety and/or efficacy of any pharmaceutical product, Lilly and its Affiliates shall not: (a) initiate any activity in the Territory against the Eagle NDA or the Eagle Product for the purpose of: (i) interfering with Eagle's efforts to obtain or maintain FDA approval of the Eagle Product and the Eagle NDA or (ii) interfering with Eagle's or its Sublicensee's efforts to launch the Eagle Product in the Territory as of the License Effective Date under the terms provided by this Agreement; (b) delist ALIMTA® with the FDA; or (c) delete, remove, designate as "obsolete" or cancel any National Drug Code(s) or any other relevant code(s) for ALIMTA® from the applicable National Drug Data File maintained by First Databank (or any successor or equivalent organization) prior to the License Effective Date. Nothing in this Agreement shall be interpreted as Lilly or its Affiliates consenting to the accuracy or sufficiency of any scientific, medical, bioequivalence, regulatory, or other information contained in the Eagle NDA, and no action or activities of the FDA or any Third Party with respect to any regulatory exclusivity held by a Third Party shall be deemed a breach by Lilly or any of its Affiliates of this Section 3.11, unless Lilly initiated, supported or assisted such activity.

3.11 Eagle Covenant. Other than as expressly set forth in this Agreement, including Sections 3.3, 3.5 and 3.12, neither Eagle nor its Affiliates nor its Sublicensee shall market, offer for sale, sell, take orders for or distribute the Eagle Product in the Territory before the License Effective Date, and Eagle shall not authorize a Third Party to do the same. The Parties agree that any violation of the foregoing by Eagle or its Affiliates would cause irreparable harm to Lilly and understanding this, Eagle hereby irrevocably and unconditionally consents to immediate entry of a temporary restraining order, preliminary injunction and permanent injunction in the event such relief is needed to prevent such harm in the event of a violation or imminent threat of a violation of the foregoing by Eagle or its Affiliates or the Sublicensee or any Person acting on their behalf.

3.12 At Risk Launch by Third Party. If, prior to the License Effective Date, a Third Party, without the assistance, aid, or encouragement of Eagle, launches an ALIMTA® Generic Product in the Territory without license or authorization from Lilly, then Eagle or its Sublicensee may launch the Eagle Product in the Territory "at risk". The Parties agree that in the event of an "at risk" launch by Eagle as provided for in this paragraph, the Licenses for the Eagle Product granted in paragraphs 3.1 and 3.3 shall remain in place and the "at risk" launch by Eagle or its Sublicensee pursuant to this provision shall not be deemed a breach of this Agreement. It is expressly agreed that any sales by Eagle or its Sublicensee pursuant to any such launch would not be licensed by Lilly and that Eagle would be liable to Lilly for damages as a result of such launch in the amount of Eagle's profits on the "at risk" sales of the Eagle Product as described in this Section. It is further agreed that if, after the launch of the Eagle Product pursuant to this provision, but prior to the License Effective Date, Lilly is successful by order, agreement or otherwise in having the Third Party cease sales of its ALIMTA® Generic Product in the Territory, then Eagle or its Sublicensee shall cease sales of the Eagle Product as of the business day after the Third Party is required to cease sales of its product as notified to Eagle by Lilly (provided that Lilly also ceases sales of any Authorized Generic Product launched in response to the Third Party launch as of the same date).

3.13 [***]

4. PAYMENTS

4.1 Royalty Payment. During the Royalty Term, Eagle shall pay to Lilly a royalty of 1.0 % of the Net Sales of the Eagle Product (“Royalty Rate”) during each Eagle Quarter (“the Net Sales Royalty”). The Net Sales Royalty calculation will be delivered in writing by Eagle to Lilly within 45 days of each applicable Eagle Quarter, and will include the Gross Sales of the Eagle Product in the Territory during such Eagle Quarter, royalty rate applied, and the Net Sales Royalty payable with respect to such Net Sales (each, a “Net Sales Statement”). Within 45 days following the end of each applicable Eagle Quarter, Eagle will pay the Net Sales Royalty in United States dollars by wire transfer to an account designated in writing by Lilly.

4.2 Right to audit.

4.2.1 During the Royalty Term and for a period one year after expiration of the Royalty Term, Lilly will have the right, a single time, to engage an independent nationally recognized public accounting firm chosen by Lilly and reasonably acceptable to Eagle (which accounting firm will not be the external auditor of Lilly, will not have been hired or paid on a contingency basis and will have experience auditing generic pharmaceutical companies) (a “CPA Firm”) to conduct an audit of Eagle for the purposes of confirming Eagle’s compliance with the Net Sales Royalty provisions of this Agreement. The fees charged by the CPA Firm will be paid by Lilly unless any additional royalties owed exceed 5% of the royalties paid for the royalty period subject to the audit, in which case Eagle will pay the reasonable fees of the CPA Firm.

4.2.2 The CPA Firm will be given access to and will be permitted to examine such books and records of Eagle relating to sale of the Eagle Product as it will reasonably request, upon prior written notice having been given to Eagle, during regular business hours, for the sole purpose of determining compliance with the Net Sales Royalty provisions of this Agreement. Prior to any such examination taking place, the CPA Firm will enter into a confidentiality agreement reasonably acceptable to Eagle with respect to the information to which it is given access and will not contain in any report or otherwise disclose to Lilly or any Third Party any information labeled by Eagle as being confidential customer information regarding pricing or other competitively sensitive proprietary information.

4.2.3 If the CPA Firm concludes that Eagle has complied with the Net Sales Royalty Provisions of this Agreement, it shall confirm Eagle’s compliance to Lilly and not provide a report to Lilly regarding its audit. If the CPA Firm concludes that Eagle has not complied with the Net Sales Royalty Provisions of this Agreement, Lilly and Eagle will be entitled to receive a full written report of the CPA Firm with respect to its findings and Lilly will provide, without condition or qualification, Eagle with a copy of the report, or other summary of findings, prepared by such CPA Firm promptly following Lilly’s receipt of same. In the event of any dispute between Lilly and Eagle regarding the findings of any such inspection or audit, the Parties will initially attempt in good faith to resolve the dispute amicably between themselves, and if the Parties are unable to resolve such dispute within 4 weeks of delivery to both Parties of the CPA Firm’s report, the Parties will agree on an internationally recognized independent certified public accounting firm (other than the CPA Firm) to resolve the dispute, and such accounting firm’s determination will be binding on both Parties, absent manifest error by such accounting firm.

4.2.4 Within 60 days after completion of the CPA Firm’s audit, Eagle will pay to Lilly any deficiency in the Net Sales Royalty amount determined by the CPA Firm. If the report of the CPA Firm shows that Eagle overpaid, then Eagle will be entitled to off-set such overpayment against any Net Sales Royalty then owed to Lilly. If no royalty is then owed to Lilly, then Lilly will remit such overpayment to Eagle.

4.3 Taxes. Where required by law, Eagle shall have the right to withhold applicable taxes from any payments to be made by Eagle to Lilly pursuant to this Agreement. Eagle shall provide Lilly with receipts from the appropriate taxing authority for all payments of taxes withheld and paid by Eagle to such authorities on behalf of Lilly within 60 days. Lilly shall have the right to appeal to the appropriate taxing authority any such withholding and payment of such taxes. Notwithstanding the foregoing, if Eagle assigns its payment obligations to an Affiliate or a Third Party, and such assignment results in a greater amount of withholding tax which may be subtracted from payments to Lilly than if Eagle had fulfilled its payment obligations to Lilly directly, such Affiliate or Third Party shall increase the payment to Lilly such that the amount received by Lilly after such income tax withholding is equal to the amount Lilly would have received if Eagle had fulfilled such payment obligations to Lilly directly.

4.4 No other compensation. Other than as explicitly set forth (and as applicable) in this Agreement, Eagle will not be obligated to pay any additional fees, royalties or other payments of any kind to Lilly under this Agreement.

5. TERM / TERMINATION

5.1 Term. Unless earlier terminated in accordance with the terms of this section, the term of this Agreement will commence on the Effective Date and will remain in effect until the expiration of the last to expire of the Licensed Patents and Other Lilly Patents and the waived regulatory exclusivities.

5.2 Termination for Cause. The Parties agree that the sale or distribution of the Eagle Product in the Territory prior to the License Effective Date, other than as set forth in Section 3.12, shall constitute a material breach, and Lilly may terminate this Agreement if Eagle fails to cure such a breach within seven (7) days of written notice thereof. In addition, Lilly or Eagle may terminate this Agreement at any time in the event that the other Party has materially breached this Agreement for any other reason and fails to cure such material breach within fifteen (15) days of written notice thereof. In the event that either Party contests the other Party's termination of this Agreement under this Section 5.2, the Parties shall both continue to perform their respective obligations under this Agreement until the resolution of any such contested termination. The Parties further agree that any breach by Eagle of their covenants set forth in Section 3.6 and Section 3.11 is a material breach of this Agreement, that any such breach must be cured by Eagle within (7) days of written notice thereof, and that in the absence of a cure, Lilly shall be entitled, in its sole discretion, to immediately terminate this Agreement.

5.3 Effect of Expiration or Termination. Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination.

6. CONFIDENTIALITY

6.1 Except to enforce this Agreement or unless otherwise agreed to by the Parties in writing or as required by law, the Parties, their Affiliates and their respective employees, officers, directors and other representatives shall not publish or otherwise disclose the contents of this Agreement or confidential information shared pursuant to this Agreement, except that (a) each Party may disclose this Agreement (i) to its attorneys, advisors, consultants, agents, and representatives who are subject to obligations of confidentiality consistent with this Agreement and (ii) if either Party becomes required to disclose this Agreement by law, subpoena, regulation or order of a court or administrative agency, or as otherwise required by law, including reporting requirements to the U.S. Securities and Exchange Commission or by the rules or regulations of any stock exchange to which the Parties are subject, (b) Eagle may communicate with FDA on a confidential basis as of the Effective Date concerning approval of the Eagle NDA and the covenants and waivers provided for herein and, if necessary to effectuate this Agreement, provide a copy of this Agreement. In the event disclosure is required under the foregoing clause (a)(ii), the Party making such disclosure shall (1) provide the other Party with as much advance notice as reasonably practicable of the required disclosure, (2) cooperate with the other Party in an attempt to prevent or limit the disclosure, and (3) limit any disclosure to the specific purpose at issue. Notwithstanding anything contrary in this Agreement (and not subject to the limitations in the immediately preceding sentence), either Party may disclose without limitation a copy of this Agreement, including any exhibits, schedules, ancillary agreements, and amendments thereto in response to a valid request by a U.S., foreign, state, provincial, or local tax authority and the Party making such disclosure shall limit any disclosure to the specific purpose at issue and take all reasonable steps to maintain confidentiality.

6.2 Eagle shall issue a press release consistent with Exhibit E attached hereto.

7. REPRESENTATION / WARRANTIES

7.1 Each Party represents and warrants to the other, as of the Effective Date, that:

(a) Such Party is duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

(b) Such Party has taken all corporate action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;

(c) This Agreement has been duly executed by such Party and constitutes a valid and legally binding obligation of such Party, enforceable in accordance with its terms;

(d) The execution, delivery, and performance of this Agreement does not conflict with any agreement, instrument, or understanding, oral or written, to which such Party is bound nor violate any law or regulation of any court, governmental body, or administrative or other agency having jurisdiction over it;

(e) Such Party represents and warrants that it has been advised by its counsel of its rights and obligations under this Agreement and enters into this Agreement freely, voluntarily, and without duress; and

(f) Such Party represents and warrants that it is not relying on any promises, inducements, or representations other than those provided herein.

7.2 Eagle's Representations and Warranties. As of the Effective Date, Eagle represents and warrants that Eagle is the true owner of the Eagle NDA, and has received no notice or claim and knows of no reason for the assertion of any notice or claim contesting its ownership of the Eagle NDA. For any breach of this Section 7.2, Lilly shall have the immediate right to terminate this Agreement.

7.3 Lilly's Representations and Warranties. As of the Effective Date, Lilly represents and warrants that:

(a) it is the owner of each of the Licensed Patents (to the extent in existence as of the Effective Date) and has not assigned them. Any assignment by Lilly of its rights in any of the Licensed Patents will be subject to all obligations and terms of this Agreement, and the assignee will be bound by the terms of this Agreement. Lilly has not received any written communication challenging Lilly's ownership of any Licensed Patents;

(b) it has the authority to grant to Eagle the covenant not to sue set forth in this Agreement;

(c) it is the owner of the Lilly NDA and has full control over the Pediatric Exclusivity pertaining to the Lilly NDA;

(d) it has sole authority to waive with respect to the Eagle NDA, pursuant to Sections 3.8-3.9, any and all Regulatory Exclusivities in effect for the Lilly NDA or any other Lilly NDA relating to pemetrexed, including Lilly's NDA No. 021462, and any 30-month stay which are required to be waived to enable full approval of the Eagle NDA; and

(e) during the relevant License term and subject to Eagle's compliance with this Agreement, it will not initiate any legal, administrative, regulatory or other action against Eagle, any person involved in the production, and/or supply of any Eagle Product, or any Eagle customer or other person obtaining Eagle Product, to interfere with Eagle's ability to secure supply of, or otherwise make, use, offer to sell or sell, Eagle Product. Nothing in this section shall be construed to limit Lilly's ability to communicate with the FDA or any other regulatory or other government authority in relation to the Lilly NDA regarding health, safety or efficacy matters.

7.4 Disclaimer. EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, NO PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF APPLICABLE LAW.

8. GENERAL PROVISIONS

8.1 Waiver. None of the provisions of this Agreement will be considered waived by any Party unless such waiver is agreed to, in writing, by authorized agents of such Party. The failure of a Party to insist upon strict conformance to any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law will not be deemed a waiver of any rights of any Party.

8.2 Choice of Law and Remedies. This Agreement and any dispute arising out of or related to this Agreement shall be governed and interpreted in accordance with the laws of the State of Delaware without regard to conflicts of law principles. This Agreement does not limit or restrict the remedies available to any Party for the breach of another Party, and the Parties expressly reserve any and all remedies available to them, at law or in equity, for breach of this Agreement or otherwise.

8.3 Costs. Each Party shall each bear its own costs and legal fees associated with the negotiation and preparation of, and performance under, this Agreement and any activities related to the implementation of this Agreement.

8.4 Entire Agreement. This Agreement constitutes the entire agreement between the Parties relating to the subject matter hereof and supersedes all previous agreements and understandings, oral or written, with respect to such matters.

8.5 Notice. All notices or other communications hereunder shall be deemed to have been duly given and made if in writing and if served by personal delivery upon a Party, if delivered by a reputable overnight express courier service (charges prepaid), or if sent by facsimile to the person at the address set forth below, or such other address as may be designated in writing hereafter, in the same manner, by such person as follows:

If to **Lilly**:	Eli Lilly and Company Lilly Corporate Center Indianapolis, Indiana, 46285, USA Attention: General Counsel
with a copy to:	Eli Lilly and Company Lilly Corporate Center Indianapolis, Indiana, 46285 USA [***]
with a copy to:	[***] Williams & Connolly LLP 725 12th Street, NW Washington, DC 20005 Fax: [***]
If to **Eagle**:	Eagle Pharmaceuticals, Inc. 50 Tice Blvd, Suite 315 Woodcliff Lake, NJ 07677 Attention: [***] With copy to: [***]

with a copy to (with such copy not constituting notice):

[***]
Kirkland & Ellis LLP
300 North LaSalle
Chicago, IL 60654

with a copy to (with such copy not constituting notice):

[***]
Kirkland & Ellis LLP
601 Lexington Avenue
New York, NY 10022

Such notices will be deemed to have been given on the date delivered in the case of personal delivery or overnight courier or on the date actually received in the case of facsimile delivery.

8.6 Severability. When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law. If, however, any provision of this Agreement is held to be invalid, illegal, or unenforceable for any reason, the Parties shall negotiate in good faith for a substitute provision to continue the intent and purpose of such invalid provisions, and the validity, legality, and enforceability of the remaining provisions shall not be in any way impaired thereby.

8.7 Amendments. No amendment, modification or supplement of any provisions of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

8.8 Descriptive Headings. The captions and descriptive headings of this Agreement are for convenience only and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.

8.9 Third-Party Benefit. None of the provisions of this Agreement shall be for the benefit of, or enforceable by, any Third Party.

8.10 Assignment. Neither Party will assign this Agreement or any part hereof or any interest herein (whether by operation of law or otherwise) without prior written notice to the other Party not less than 60 days prior to such assignment becoming effective; provided, however, that either Party may assign this Agreement without such prior notice (a) to any Affiliate of such assigning Party (for as long as such assignee remains an Affiliate of such Party); or (b) to any successor entity in the case of a merger, consolidation, change in control or sale of all or substantially all of the assets related to this Agreement. No assignment will be valid unless the permitted assignee(s) assumes all obligations of its assignor under this Agreement. No assignment will relieve any assigning Party of responsibility for the performance of its obligations hereunder. Any purported assignment in violation of this Section 8.10 will be void. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the Parties and their respective heirs, successors and permitted assigns.

8.11 Counterparts; Electronic Delivery. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement and any signed agreement or instrument entered into in connection with this Agreement, and any amendments hereto or thereto, to the extent delivered by means of a telecopy machine or electronic mail (any such delivery, an "Electronic Delivery"), shall be treated in all manner and respects as an original agreement or instrument and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person.

SIGNATURES FOLLOW ON NEXT PAGE

IN WITNESS WHEREOF, each of the Parties has caused this Agreement to be executed by its duly authorized representative as of the Effective Date.

ELI LILLY AND COMPANY	EAGLE PHARMACEUTICALS, INC.
By:	By:
/s/ Michael J. Harrington	/s/ Pete A. Meyers
Name: Michael J. Harrington	Name: Pete A. Meyers
Title: Senior Vice President and General Counsel	Title: CFO
Date: 12/13/19	Date: 12/13/19

EXHIBIT A

Patent Infringement Lawsuit Stipulation of Dismissal

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ELI LILLY AND COMPANY, Plaintiff v. EAGLE PHARMACEUTICALS, INC., Defendant.	Civ. A. No. 17-cv-01293-MSG

STIPULATION OF DISMISSAL

Pursuant to Rules 41(a)(1) and 41(c) of the Federal Rules of Civil Procedure, Plaintiff Eli Lilly and Company ("Lilly") and Defendant Eagle Pharmaceuticals, Inc. ("Eagle") hereby stipulate and agree that Lilly's action against Eagle and Eagle's action against Lilly, including all claims and defenses asserted by Lilly against Eagle and all claims and defenses asserted by Eagle against Lilly, are hereby dismissed with prejudice. All parties shall bear their own costs, disbursements and attorneys' fees.

Respectfully submitted,

EXHIBIT B

Antitrust Lawsuit Stipulation of Dismissal

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELA WARE

EAGLE PHARMACEUTICALS, INC., Plaintiff v. ELI LILLY AND COMPANY, Defendant.	Civ. A. No. 18-cv-01121-MSG

STIPULATION OF DISMISSAL

Pursuant to Rule 41(a)(1) of the Federal Rules of Civil Procedure, Plaintiff Eagle Pharmaceuticals, Inc. ("Eagle") and Defendant Eli Lilly and Company ("Lilly") hereby stipulate and agree that Eagle's claims against Lilly are hereby dismissed with prejudice. All parties shall bear their own costs, disbursements and attorneys' fees.

Respectfully submitted,

EXHIBIT C

EXCLUSIVITY CORRESPONDENCE
RELINQUISHMENT OF ANY EXCLUSIVITY AS TO EAGLE NDA NO. 209472

Food and Drug Administration
[insert applicable address]

RE: NDA No. 021462
PRODUCT: ALIMTA® (pemetrexed disodium) Injection 100 mg/vial and 500 mg/vial

Dear Sir or Madam:

Eli Lilly and Company ("Lilly") submits this Relinquishment of Exclusivity solely as to Eagle's 505(b)(2) NDA No. 209472 ("Eagle NDA") for pemetrexed for injection in a 25 mg/mL, 500 mg vial product. The Reference Listed Drug for the Eagle NDA is Lilly's ALIMTA® product.

The Eagle NDA was previously blocked from final FDA approval at least due to a 30-month stay, expiring on February 8, 2020, in effect by virtue of Lilly's filing of a Complaint for patent infringement against the Eagle NDA within 45 days of receipt of Eagle's Notice of Paragraph IV Certification for the Eagle NDA. On ______, this litigation was terminated pursuant to a Stipulation of Dismissal submitted by the parties to the litigation and entered by the U.S. District Court for the District of Delaware. The parties submitted the Stipulation of Dismissal pursuant to a Settlement Agreement entered into between Lilly and Eagle. A copy of the Stipulation of Dismissal is enclosed.

Pursuant to the terms of the license, Lilly also granted to Eagle a selective waiver of any unexpired periods of pediatric and/or other statutory or regulatory exclusivities that might be listed in the Orange Book in connection with NDA 021462 for ALIMTA with respect to Eagle NDA No. 209472. Accordingly, Lilly hereby selectively waives its right to any unexpired periods of pediatric and/or other statutory or regulatory exclusivities listed in connection with NDA 021462, including any pediatric exclusivity associated with U.S. Patent No. 7,772,209, and/or any other patent(s) listed in the Orange Book in connection with NDA 021462 as such exclusivities would otherwise apply to Eagle NDA No. 209472.

For the avoidance of doubt, Lilly waives neither any 30-month stay nor any exclusivity as to any NDA or ANDA other than the Eagle NDA.

EXHIBIT D

CONSENT TO FINAL REGULATORY APPROVAL AS TO EAGLE NDA NO. 209472

Food and Drug Administration
[insert applicable address]

RE: NDA No. 021462
PRODUCT: ALIMTA® (pemetrexed disodium) Injection 100 mg/vial and 500 mg/vial

Dear Sir or Madam:

Eli Lilly and Company (“Lilly”), the owner of U.S. Patent No. 7,772,209 listed in the Food and Drug Administration’s (“FDA’s”) *Approved Drug Products with Therapeutic Equivalence Evaluations* (“Orange Book”) for ALIMTA®, approved under NDA No. 021462 and also held by Lilly, is writing to provide FDA with consent to grant final regulatory approval of the 505(b)(2) NDA 209472 submitted by Eagle Pharmaceuticals, Inc. (the “Eagle NDA”).

The Eagle NDA was previously blocked from final FDA approval at least due to a 30-month stay, expiring on February 8, 2020, in effect by virtue of Lilly’s filing of a Complaint for patent infringement against the Eagle NDA within 45 days of receipt of Eagle’s Notice of Paragraph IV Certification for the Eagle NDA. On XXX, this litigation was terminated pursuant to a Stipulation of Dismissal submitted by the parties to the litigation and entered by the U.S. District Court for the District of Delaware. The parties submitted the Stipulation of Dismissal pursuant to a Settlement Agreement entered into between Lilly and Eagle. A copy of the Stipulation of Dismissal is enclosed.

FDA’s regulation at 21 C.F.R. § 314.50(i)(3) provides that if a company has submitted a 505(b)(2) application to the Agency containing a Paragraph IV certification to a patent listed in the Orange Book for the Listed Drug, here ALIMTA, and “[i]f the patent owner consents to [final] approval of the 505(b)(2) application (if otherwise eligible for approval) as of a specific date, the 505(b)(2) application must contain a written statement from the patent owner that it has a licensing agreement with the applicant and that it consents to approval of the 505(b)(2) application as of a specific date.” Similarly, FDA’s regulation at 21 C.F.R. § 314.107(b)(3)(vi) concerning 505(b)(2) application approval provides that “[i]f before the expiration of the 30-month period . . . the patent owner or the exclusive patent licensee (or their representatives) agrees in writing that the 505(b)(2) application. . . may be approved any time on or after the date of consent, approval may be granted on or after that date.”

Consistent with the Consent to Approval regulations identified above, as well as 21 C.F.R. § 314.107(e)(2), which requires prompt submission of such consent by the 505(b)(2) applicant to FDA, Lilly, the owner of U.S. Patent No. 7,772,209, hereby consents to the approval of Eagle NDA No. 209472 as of the date of this letter.

Exhibit E

[SEE PRESS RELEASE OF EAGLE PHARMACEUTICALS, INC. DATED DECEMBER 13, 2019]

Exhibit 10.35

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKLEY CAUSE COMPETITIVE HARM TO EAGLE PHARMACEUTICALS, INC. IF PUBLICLY DISCLOSED.

EXECUTION VERSION

CO-PROMOTION AGREEMENT

by and between

TYME TECHNOLOGIES, INC.
And

EAGLE PHARMACEUTICALS, INC.

January 7, 2020

CO-PROMOTION AGREEMENT

This Co-Promotion Agreement (this "**Agreement**") is entered into and dated as of January 7, 2020 (the "**Effective Date**") by and between Tyme Technologies, Inc., a Delaware corporation ("**TYME**"), and Eagle Pharmaceuticals, Inc., a Delaware corporation ("**Eagle**"). TYME and Eagle are each referred to individually as a "**Party**" and together as the "**Parties**".

RECITALS

WHEREAS, TYME is an emerging biotechnology company developing cancer metabolism-based therapies and owns or otherwise controls certain intellectual property rights, clinical data and regulatory filings related to the compound SM-88 (racemetyrosine) (defined below), which is the subject of clinical development;

WHEREAS, Eagle is in the business of developing and commercializing drugs, primarily in the critical care and oncology areas, including through collaboration agreements;

WHEREAS, the Parties believe that it would be mutually beneficial to collaborate on promotional activities for the Product (defined below) and, accordingly, TYME desires that Eagle conduct certain promotional activities, and Eagle desires to conduct such activities, for the Product in the Territory;

WHEREAS, simultaneously with the execution and delivery of this Agreement, the Parties have entered into that certain Securities Purchase Agreement, providing for, among other things, the issuance and sale by TYME of shares of TYME common stock to Eagle in return for Eagle's upfront payment of $20 million in cash and TYME's right to receive additional milestone payments upon the achievement of certain milestones as provided therein;

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1DEFINITIONS

Unless otherwise defined in this Agreement, the following terms shall have the meanings provided hereunder:

1.1 "**Act**" shall mean the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., as it may be amended from time to time, and the regulations promulgated thereunder.

1.2 "**Adverse Event**" shall mean any untoward medical occurrence in a patient or clinical investigation subject who is administered the Product, but which does not necessarily have a causal relationship with the treatment for which the Product is used. An "Adverse Event" can include any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of the Product, whether or not related to the Product. A pre-existing condition that worsened in severity after administration of the Product would be considered an "Adverse Event".

1.3 "**Affiliate**" shall mean, with respect to any Person, any other Person that directly or indirectly controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses the power to direct or cause the direction of the management, business and policies of such Person, whether through the ownership of fifty percent (50%) or more (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting securities of such Person, by contract or otherwise.

1.4 "**Agreement**" shall have the meaning set forth in the preamble to this Agreement.

1.5 "**Alliance Managers**" shall have the meaning set forth in Section 4.1.5.

1.6 "**Applicable Laws**" shall mean all applicable statutes, ordinances, regulations, codes, rules, or orders of any kind whatsoever of any Governmental Authority in the Territory pertaining to any of the activities and obligations contemplated by this Agreement, including, as applicable, the Act, the Generic Drug Enforcement Act of 1992 (21 U.S.C. § 335a et seq.), the Anti-Kickback Statute (42 U.S.C. § 1320a-7b et seq.), the Health Insurance Portability and Accountability Act of 1996, the Federal False Claims Act (31 U.S.C. §§ 3729-3733) (and applicable state false claims acts), the Physician Payments Sunshine Act, the Code, the Department of Health and Human Services Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, released April 2003, the Antifraud and Abuse Amendment to the Social Security Act, the American Medical Association guidelines on gifts to physicians, generally accepted standards of good clinical practices adopted by current FDA regulations, as well as any state laws and regulations (i) impacting the promotion of pharmaceutical products, (ii) governing the provision of meals and other gifts to medical professionals, including pharmacists, or (iii) governing consumer protection and deceptive trade practices, including any state anti-kickback/fraud and abuse related laws, all as amended from time to time.

1.7 "**Business Day**" means each day of the week, excluding Saturday, Sunday or a day on which banking institutions in New York, New York, USA are closed.

1.8 "**Buyout Amount**" means $200 million.

1.9 "**Claims**" shall mean all charges, complaints, actions, suits, proceedings, hearings, investigations, claims, demands, judgments, orders, decrees, stipulations or injunctions, in each case of a Third Party (including any Governmental Authority).

1.10 "**Code**" shall mean the Code on Interactions with Healthcare Professionals promulgated by the Pharmaceutical Research and Manufacturers of America (PhRMA)/BIO, as it may be amended.

1.11 "**Commercialize**," "**Commercializing**," and "**Commercialization**" means activities directed to manufacturing, obtaining pricing and reimbursement approvals for, marketing, promoting, distributing, importing, and/or selling the Product.

1.12 "**Commercially Reasonable Efforts**" means, with respect to a Party's obligations under this Agreement, a measure of effort and resources consistent with the exercise of prudent scientific and business judgment and the reasonable practices that would typically be exerted by a similarly situated pharmaceutical or biotechnology company of comparable size and capabilities as such company for the Development or Commercialization of a pharmaceutical product with similar characteristics owned by such company at a similar stage of development or commercialization as the Product, taking into account efficacy and safety considerations, and other relevant scientific, technical, and commercial factors, including product profile, the regulatory environment, competitiveness of the marketplace and market potential, and price and reimbursement status.

1.13 "**Compensation Report**" shall have the meaning set forth in Section 4.2.2(b).

1.14 "**Compliance Manager**" shall have the meaning set forth in Section 4.3.10.

1.15 "**Compliance Report**" shall have the meaning set forth in Section 4.2.2(c).

1.16 "**Confidential Information**" shall mean all secret, confidential, non-public or proprietary Know-How, whether provided in written, oral, graphic, video, computer or other form, provided by or on behalf of one Party to the other Party pursuant to this Agreement, including information relating to the disclosing Party's existing or proposed research, development efforts, promotional efforts, regulatory matters, patent applications or business and any other materials that have not been made available by the disclosing Party to the general public. All such information related to this Agreement disclosed by or on behalf of a Party (or its Affiliate) to the other Party (or its Affiliate) pursuant to the Confidentiality Agreement shall be deemed to be such Party's Confidential Information disclosed hereunder. For purposes of clarity, (i) TYME's Confidential Information shall include all Product Materials unless and until made available by TYME to the general public (including through Eagle) and (ii) the terms of this Agreement shall be considered Confidential Information of both Parties.

1.17 "**Confidentiality Agreement**" shall have the meaning set forth in Section 8.1.1.

1.18 "**Detail(s)**" shall mean the Product presentation during a face-to-face sales call between a Target Professional and a Sales Representative, during which a presentation of the Product's attributes, benefits, prescribing information and safety information are orally presented, for use in the Field in the Territory. Neither e-details, nor presentations made at conventions, exhibit booths, a sample drop, educational programs or speaker meetings, or similar gatherings, shall constitute a Detail.

1.19 "**Detail Report**" shall have the meaning set forth in Section 4.2.2.

1.20 "**Development**" shall mean non-clinical, pre-clinical and clinical drug discovery, research, and/or development activities, including without limitation quality assurance and quality control development, and any other activities reasonably related to or leading to the development and submission of information to a Regulatory Authority. When used as a verb, "**Develop**" means to engage in Development.

1.21 "**Dispute**" shall have the meaning set forth in Section 12.6.

1.22 "**Dollar**" or "**$**" shall mean United States dollar.

1.23 "**Eagle Activities**" shall mean any and all promotional activities (including Detailing) conducted by Eagle with respect to the Product in the Territory, as set forth in the Sales Plan or otherwise mutually agreed upon by the Parties in writing, in each case, in accordance with the terms of this Agreement.

1.24 "**Eagle Property**" shall have the meaning set forth in Section 7.1.1.

1.25 "**Eagle Quarterly Minimum Details**" for an applicable Fiscal Quarter shall mean the number established by the Operating Parameters Schedule as in effect from time to time.

1.26 "**Effective Date**" shall have the meaning set forth in the preamble to this Agreement.

1.27 "**Exclusive Detail**" shall mean a Detail for which the Product is the sole product detailed on the call.

1.28 "**Exhibit**" shall mean an exhibit attached to this Agreement.

1.29 "**FDA**" shall mean the United States Food and Drug Administration or any successor agency performing comparable functions.

1.30 "**Field**" shall mean the treatment of any and all indications for which the Product is approved in humans in the Territory.

1.31 "**Field Force Personnel**" shall mean collectively, the Sales Representatives, and any other employees of Eagle engaged in the Eagle Activities.

1.32 "**First Commercial Sale**" shall mean the first commercial sale of the Product for monetary value by TYME, one or more of its Affiliates or one or more of its licensees in an arm's length transaction to a Third Party that is not a licensee, including without limitation any final sale to a distributor or wholesaler under any non-conditional sale arrangement, of the Product in the Field in the Territory after Regulatory Approval of the Product has been granted in the Field in the Territory. For the avoidance of doubt, sales or transfers of the Product for clinical and non-clinical research and trials (including studies reasonably necessary to comply with Applicable Law or requests by a Regulatory Authority), early access programs or for compassionate or similar use, shall not be considered a First Commercial Sale.

1.33 "**Fiscal Quarter**" shall mean each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1.

1.34 "**Fiscal Year**" shall mean each successive period of (12) twelve months commencing on April 1 and ending on March 31st.

1.35 "**GAAP**" shall mean United States generally accepted accounting principles.

1.36 "**Governmental Authority**" shall mean any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or any supranational organization of which any such country is a member, which has competent and binding authority to decide, mandate, regulate, enforce, or otherwise control the activities of the Parties contemplated by this Agreement.

1.37 "**Indemnified Party**" shall have the meaning set forth in Section 10.3.

1.38 "**Indemnifying Party**" shall have the meaning set forth in Section 10.3.

1.39 "**Intellectual Property**" shall have the meaning set forth in Section 7.1.2.

1.40 "**Inventions**" shall have the meaning set forth in Section 7.1.2.

1.41 "**Know-How**" shall mean information, whether or not in written form, including biological, chemical, pharmacological, toxicological, medical or clinical, analytical, quality, manufacturing, research, or sales and marketing information, including processes, methods, procedures, techniques, plans, programs and data.

1.42 "**License**" shall mean any agreement pursuant to which TYME grants to a Third Party (a "**Licensee**") a license, sublicense, or other right to any TYME Patent Rights or Regulatory Filings or Regulatory Approvals relating to the Product; *provided, however*, that a License shall not include (a) any agreement with any distributor or wholesaler that obtains solely the right to distribute the Product after purchase from TYME and (i) serves as a logistics services provider or (ii) otherwise distributes the Product to pharmacies, group purchasing organizations or similar entities, but in each case of (i) and (ii), without the right to co-market or co-promote the Product, or (b) any agreement pursuant to which TYME or any of its Affiliates grants a license or sublicense of any of its intellectual property rights (i) solely to conduct research, (ii) solely to manufacture the Product, or (iii) otherwise to service providers solely on a non-exclusive basis in the ordinary course of Development or Commercialization of the Product (e.g., material transfer agreements, distribution agreements, and consulting agreements).

1.43 "**Licensee**" has the meaning set forth in the definition of License.

1.44 "**Losses**" shall mean any and all amounts paid or payable to Third Parties with respect to a Claim (including any and all losses, damages, obligations, liabilities, fines, fees, penalties, awards, judgments, interest), together with all documented out-of-pocket costs and expenses, including attorney's fees, reasonably incurred.

1.45 "**Minimum Sales Representatives Requirement**" has the meaning set forth in the definition of Operating Parameters Schedule.

1.46 "**Multidisciplinary Detail**" shall mean a Detail call to a sales account with a multidisciplinary oncology practice, as determined by TYME.

1.47 "**Net Sales**" shall mean, for an applicable period, with respect to the Product, commencing with the First Commercial Sale, net sales as determined in accordance with GAAP, which, for the avoidance of doubt, shall comprise the gross amounts received by TYME, its Affiliates and Licensees for arm's length sales of the Product in the Field in the Territory to a Third Party (excluding any sales among TYME, its Affiliates and any Licensee), less the following deductions solely to the extent incurred or allowed with respect to such sales, and solely to the extent such deductions are in accordance with GAAP, and which are not already reflected as a deduction from the invoiced price: (a) discounts (to the extent not previously applied to such amounts received), charge-back payments, and rebates; (b) credits or allowances for damaged goods, rejections, recalls or returns of the Product; (c) freight, insurance, postage, and shipping charges for delivery of the Product, to the extent separately billed on the invoice as well as any bona fide service fee specifically incurred for the distribution of the Product; (d) taxes, customs, or duties levied on, absorbed, or otherwise imposed on the sale of the Product, as adjusted for rebates and refunds, to the extent not paid by the Third Party and only to the extent such taxes, customs, or duties are not reimbursed to the paying party, but excluding all income taxes; (e) allowances for doubtful or uncollectible amounts (provided that, such amounts shall be included in the computation of "Net Sales" to the extent subsequently collected or earned) and (f) that portion of the annual fees due under Section 9008 of the United States Patient Protection and Affordable Care Act of 2010 (Pub. L. No. 111-48) and any other fees imposed by Applicable Law. If the Product is sold by TYME, its Affiliates or Licensees through intermediaries such as agents, consignees or co-promoters who do not purchase and take title to the Product, the promotion fee will be due only on sales to those Third Parties who actually purchase and take title to the Product through such intermediaries.

If the Product is transferred to Third Parties in connection with clinical and non-clinical research and trials (including studies reasonably necessary to comply with Applicable Law), Product samples, charitable purposes, promotional purposes, early access programs, compassionate sales or use, or an indigent program or similar *bona fide* arrangements for which TYME or any of its Affiliates or Licensees for good faith business reasons receives consideration in respect thereof that is less than the average cost of goods for this Product, such consideration shall not be included in Net Sales.

1.48 "**NDA**" means a New Drug Application filed with the FDA that is required for approval for the Product in the United States, or its foreign equivalent in the Territory.

1.49 "**Operating Parameters Schedule**" means the requirements set forth in Schedule 4.1 to this Agreement, as such may, subject to the provisions of Section 3.4.2, be revised from time to time by TYME in consultation with the SOC. The Operating Parameters Schedule shall be updated no less than annually with the minimum required number of Sales Representatives (the "**Minimum Sales Representatives Requirement**") and the Eagle Quarterly Minimum Details.

1.50 "**Party**" shall have the meaning set forth in the preamble to this Agreement.

1.51 "**Patent Rights**" means (a) patents and patent applications, and any foreign counterparts thereof, (b) all divisionals, continuations, continuations-in-part of any of the foregoing, and any foreign counterparts thereof, and (c) all patents issuing on any of the foregoing, and any foreign counterparts thereof, together with all registrations, reissues, re-examinations, supplemental protection certificates, substitutions or extensions thereof, and any foreign counterparts thereof.

1.52 "**Person**" shall mean any individual, corporation, partnership, limited liability company, association, joint-stock company, trust, unincorporated organization or other entity, or government or political subdivision thereof.

1.53 "**Pivotal Clinical Study**" shall mean a human clinical study of the Product in any country on a sufficient number of subjects that is designed to establish that the Product is safe and efficacious for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with the Product in the dosage range to be prescribed, which trial is intended to support Regulatory Approval of the Product, as described in 21 C.F.R. § 312.21(c), or equivalent clinical study in a country other than the United States.

1.54 "**Primary Multidisciplinary Detail**" shall mean a Multidisciplinary Detail call where the Product (i) is the first product Detailed, (ii) is emphasized more than any other product and (iii) is the primary focus of such Detail, primary focus meaning greater than [***]% of the total call time during the Detail is spent on promoting the Product.

1.55 "**Product**" shall mean any product that contains SM-88 (racemetyrosine).

1.56 "**Product Labeling**" shall mean the labels and other written, printed or graphic matter upon (a) any container or wrapper utilized with the Product or (b) any written material accompanying the Product, including Product package inserts, in each case as approved by the FDA.

1.57 "**Product Materials**" shall have the meaning set forth in Section 4.4.1(a).

1.58 "**Product Training Materials**" shall have the meaning set forth in Section 4.4.1(a).

1.59 "**Professionals**" shall mean health care practitioners, consisting of physicians, nurse practitioners, physician assistants, pharmacists and any other medical professionals in the Territory with prescribing, formulary or dispensing authority (as authorized under Applicable Law) in the Territory for the Product.

1.60 "**Promotional Materials**" shall have the meaning set forth in Section 4.4.1(a).

1.61 "**Promotional Program**" shall mean an educational program regarding the Product conducted by a Third Party healthcare provider within TYME's approved speakers bureau for SM-88 (racemetyrosine), located in a healthcare provider office or an outside venue, all in accordance with TYME speakers bureau guidelines.

1.62 "**Quarterly Average Sales Force Size**" shall have the meaning set forth in Section 4.2.2.

1.63 "**Regulatory Approval**" shall mean any and all necessary approvals, licenses, registrations or authorizations from any Governmental Authority, in each case, necessary to Commercialize the Product in the Territory.

1.64 "**Regulatory Authority**" means any national or supranational Governmental Authority, including without limitation the FDA, that has responsibility for granting any licenses or approvals or granting pricing and/or reimbursement approvals necessary for the development, marketing, and sale of the Product in any country.

1.65 "**Regulatory Exclusivity**" means any exclusive marketing rights or data exclusivity rights conferred by any Governmental Authority under Applicable Law with respect to the Product in a country or jurisdiction in the Territory to prevent Third Parties from Commercializing the Product in such country or jurisdiction, other than a Patent Right, including without limitation orphan drug exclusivity, pediatric exclusivity and rights conferred in the U.S. under the Hatch-Waxman Act or the FDA Modernization Act of 1997.

1.66 "**Regulatory Filings**" means any and all regulatory applications, filings, modifications, amendments, supplements, revisions, reports, submissions, authorizations, and Regulatory Approvals, and associated correspondence required to Develop and Commercialize the Product in the Territory, including without limitation any reports or amendments necessary to maintain Regulatory Approvals.

1.67 "**Restricted Period**" shall have the meaning set forth in Section 2.3.1.

1.68 "**Schedule**" shall mean a schedule attached to this Agreement.

1.69 "**Sales Forecast**" shall have the meaning set forth in Section 4.1.3.

1.70 "**Sales Plan**" shall mean the written sales plan relating to promotion and Detailing of the Product in the Field in the Territory by the Sales Representatives, which shall include, without limitation, the Eagle Quarterly Minimum Details and other commercial activities geared towards achieving the Sales Forecast, that is prepared by the SOC and approved by TYME as provided in Section 3.

1.71 "**Sales Representative**" shall mean an individual employed and compensated by Eagle as a full-time employee as part of its sales forces and who engages in Detailing of the Product in the Territory, and who is also trained with respect to the Product in accordance with this Agreement (including the Product Labeling and the use of the Promotional Materials) to deliver Details for the Product in the Field in the Territory.

1.72 "**Senior Officer**" shall mean, with respect to TYME, its Chief Executive Officer and Chief Operating Officer (or such officer's designee), and with respect to Eagle, its President and Chief Operating Officer (or such officer's designee). From time to time, each Party may change its Senior Officer by giving written notice to the other Party.

1.73 "**SM-88 (racemetyrosine)**" means TYME's SM-88 (racemetyrosine) novel oral therapy. SM-88 (D,L-alpha-metyrosine; racemetyrosine [USAN]) is a proprietary modified dysfunctional tyrosine derivative.

1.74 "**Specialty**" means a sales account's primary oncology specialty designation, as reasonably determined by TYME.

1.75 "**SOC**" shall have the meaning set forth in Section 3.1.

1.76 "**Target Launch Date**" shall mean the date selected by TYME, in its sole discretion, and of which TYME has provided notice to Eagle in writing at least nine (9) months in advance thereof, for the initial Commercialization of the Product in the Territory.

1.77 "**Target Professionals**" shall mean, with respect to the Product, one of the specifically identified community and/or hospital-based Professionals to be called upon by a Sales Representative based upon the Sales Plan. "Target Professionals" shall exclude key thought leaders as identified on Schedule 1.77 to this Agreement, which Schedule shall be prepared and provided by TYME prior to the Target Launch Date.

1.78 "**Term**" shall have the meaning set forth in Section 11.1.

1.79 "**Territory**" shall mean the United States of America and its territories and possessions.

1.80 "**Third Party(ies)**" shall mean any person or entity other than TYME and Eagle and their respective Affiliates.

1.81 "**TYME Trademarks and Copyrights**" shall mean the logos, trade dress, slogans, domain names and housemarks of TYME or any of its Affiliates as may appear on any Product Materials or Product Labeling, in each case, as may be updated from time to time by TYME.

ARTICLE 2 RIGHTS AND OBLIGATIONS

2.1 **Engagement; Grant of Rights**. During the Term, subject to the terms and conditions of this Agreement, TYME hereby grants to Eagle the non-exclusive right to Detail and promote the Product in the Territory in the Field, and to conduct the Eagle Activities in accordance with the terms and conditions of this Agreement. Notwithstanding the foregoing, TYME retains and reserves the right for TYME and its Affiliates to promote the Product in the Territory and to grant the non-exclusive right to Detail and/or promote the Product in the Territory to any other Third Party in its sole discretion. Eagle shall have no other rights relating to the Product, except as specifically set forth in this Agreement. Eagle's rights and obligations under this Section 2.1 are non-transferable, non-assignable, and non-delegable. Eagle shall not subcontract the Eagle Activities with any Third Party (including any contract sales force). For clarity, Eagle shall not have any other license rights hereunder except as expressly set forth in this Section 2.1, nor any rights to sublicense any rights hereunder.

2.2 **Retention of Rights**. Except with respect to the limited rights granted to Eagle to conduct the Eagle Activities for the Product in the Territory in the Field pursuant to Section 2.1, TYME retains all rights in and to the Product. TYME shall have the sole right, as between the Parties, to Develop and Commercialize the Product, including without limitation, determining the marketing and regulatory strategies for seeking (if and when appropriate) Regulatory Approvals and Regulatory Exclusivity in the Territory for Product in the Field, filing for such Regulatory Approvals and Regulatory Exclusivity for Product in the Territory, preparing, submitting, and maintaining any and all Regulatory Filings and Regulatory Approvals for Product in the Field in the Territory, and seeking any necessary Regulatory Approvals of Regulatory Authorities for Product Labeling and Promotional Materials to be used in connection with Commercializing Product in the Field in the Territory. TYME shall solely own and control any and all Regulatory Approvals and any and all other Regulatory Filings submitted in connection with seeking and maintaining Regulatory Approvals for the Product in the Field in the Territory. As between the Parties, TYME shall be responsible for all costs and expenses incurred by TYME in connection with the foregoing activities. Without limiting the generality of the foregoing (and without limiting TYME's retained rights set forth in Section 2.1), TYME specifically retains the following rights (and Eagle and its Affiliates shall have no rights to the following, except as set forth below in this Section 2.2):

2.2.1 responsibility for all decisions regarding regulatory submissions and for all communications that relate to any Regulatory Approvals or other Regulatory Filings prior to and after any Regulatory Approval with respect to the Product in the Field in the Territory;

2.2.2 responsibility for the manufacture and distribution of the Product, and any future development of the Product;

2.2.3 responsibility, except as expressly set forth herein, for interactions with any Governmental Authority, including but not limited to FDA, with respect to the Product (provided that, Eagle shall retain the right to respond to communications or inquiries from Governmental Authorities in connection with the conduct of any Eagle Activities);

2.2.4 responsibility for creation and final approval of all Product Materials content (including submission of Promotional Materials to FDA's Office of Prescription Drug Promotion) with respect to the conduct of the Eagle Activities for the Product, except as expressly set forth herein;

2.2.5 selling and booking all sales of the Product;

2.2.6 responsibility for the Product's overall commercial strategy, including marketing, payer strategy, pricing, regulatory and other government affairs; and

2.2.7 responsibility for handling all safety related activities related to the Product as set forth in ARTICLE 5 (including submitting all safety reports and interacting with Governmental Authorities with respect thereto) and initiating and managing any Product recalls.

For clarity, except as provided in Sections 2.1 or 2.4, Eagle shall not acquire any license or other intellectual property interest, by implication or otherwise, in any technology, Know-How or other Intellectual Property owned or controlled by TYME or any of its Affiliates, and TYME is not providing any such technology, Know-How or other Intellectual Property, or any assistance related thereto, to Eagle for any use other than for the mutual benefit of the Parties as expressly contemplated hereby.

2.3 **Non-Competition; Non-Solicitation**.

2.3.1 **Non-Competition**. During the Term of this Agreement and through and including the first anniversary of the date of Termination of this Agreement (the "**Restricted Period**"), neither Eagle nor its Affiliates shall, directly or indirectly, market, detail, offer for sale, sell, or promote any oncology product in the Territory that is targeting an indication for which SM-88 (racemetyrosine) is approved other than the sales of the Product in accordance with the terms and conditions of this Agreement without TYME's prior written consent, which shall be given or withheld within its sole discretion.

2.3.2 **Non-Solicitation**. During Restricted Period, neither Eagle nor TYME (nor any of their respective Affiliates) shall directly or indirectly solicit for hire or employ as an employee, consultant or otherwise, any employee, consultant or other professional personnel of the other Party who has had direct involvement with the SOC, Eagle Activities under this Agreement or TYME's Commercialization activities for the Product, without the other Party's prior written consent, which shall not be unreasonably withheld; provided, however, that this restriction shall not apply to: (a) conducting any general solicitation not specifically targeted at any such employee; or (b) hiring any employee who responds to such general advertising or who approaches such Party or its Affiliates without any solicitation or inducement to leave the employ of such other Party or its Affiliates.

2.4 **TYME Trademarks and Copyrights**.

2.4.1 Eagle shall have the non-exclusive right to use the TYME Trademarks and Copyrights solely on Product Materials in order to perform the Eagle Activities and solely in accordance with the terms and conditions of this Agreement. TYME shall promptly notify Eagle of any updates or changes to the TYME Trademarks and Copyrights on the Product Materials, and Eagle shall thereafter solely use such updated Product Materials in performing its obligations under this Agreement. Eagle shall promptly notify TYME upon becoming aware of any violation of this Section 2.4.1.

2.4.2 Eagle shall follow all instructions and guidelines of TYME (of which TYME shall provide Eagle copies) in connection with the use of any TYME Trademarks and Copyrights, and, if TYME reasonably objects to the manner in which any such TYME Trademarks and Copyrights are being used, Eagle shall immediately cease the use of any such TYME Trademarks and Copyrights in such manner upon written notice from TYME thereof. Without limiting the foregoing, Eagle shall also adhere to at least the same quality control provisions as companies in the pharmaceutical industry adhere to for their own trademarks and copyrights. In all cases, Eagle shall use the TYME Trademarks and Copyrights with the necessary trademark (and copyright, as applicable) designations, and shall use the TYME Trademarks and Copyrights in a manner that does not derogate from TYME's rights in the TYME Trademarks and Copyrights. Eagle shall not at any time during the Term knowingly do or allow to be done any act or thing which will in any way impair or diminish the rights of TYME in or to the TYME Trademarks and Copyrights. All goodwill and improved reputation generated by Eagle's use of the TYME Trademarks and Copyrights shall inure to the benefit of TYME, and any use of the TYME Trademarks and Copyrights by Eagle shall cease at the end of the Term. Eagle shall have no rights under this Agreement in or to the TYME Trademarks and Copyrights except as specifically provided herein. During the Term, Eagle shall not contest the ownership of the TYME Trademarks and Copyrights, their validity, or the validity of any registration therefor. During the Term, Eagle shall not knowingly register and/or use any marks (including in connection with any domain names) that are confusingly similar to the TYME Trademarks and Copyrights.

ARTICLE 3 JOINT SALES OPERATIONS COMMITTEE

3.1 **Formation of the Joint Sales Operations Committee**. As soon as practicable, but no later than nine (9) months prior to the Target Launch Date, the Parties shall form a joint sales operations committee ("**SOC**") whose responsibilities during the Term shall be to oversee the activities set forth in Section 3.3. The SOC shall consist of no more than seven (7) members, with four (4) members designated by TYME and three (3) members designated by Eagle, each with suitable seniority and relevant experience and expertise to enable such person to address matters falling within the purview of the SOC; provided, that each Party may also have up to three (3) observers present at any SOC meeting. All meetings of the SOC shall be chaired by one of the four representatives from TYME. From time to time, each Party may change any of its representatives on the SOC by giving written notice to the other Party. The SOC shall determine a meeting schedule; provided that in any event, meetings shall be conducted no less frequently than quarterly by teleconference or in person, or as otherwise agreed by the Parties. In person meetings shall occur at such places as mutually agreed by the Parties. Employees or consultants of either Party that are not representatives of the Parties on the SOC may attend meetings of the SOC as one of a Party's designated observers; provided that, such attendees (i) shall not participate in the decision-making process of the SOC, and (ii) are bound by obligations of confidentiality and non-disclosure equivalent to those set forth in ARTICLE 8.

3.2 **Meetings and Minutes**. Meetings of the SOC may be called by either Party on no less than thirty (30) days' prior notice during the Term. Each Party shall make all proposals for agenda items and shall provide all appropriate information with respect to such proposed items at least ten (10) days in advance to the applicable meeting; provided that under exigent circumstances requiring input by the SOC, a Party may provide its agenda items to the other Party within a shorter period of time in advance of the meeting, or may propose that there not be a specific agenda for that particular meeting, so long as the other Party consents to such later addition of such agenda items or the absence of a specific agenda for such meeting, such consent not to be unreasonably withheld. Members may participate in a meeting of the SOC by means of a conference telephone or other communications equipment allowing all persons participating in the meeting to hear each other. Participation by such means shall constitute presence in person at the meeting. The chairperson shall prepare and circulate for review and approval of the Parties minutes of each meeting within thirty (30) days after the meeting. Each Party shall bear its own costs for its members to attend such meetings.

3.3 **Purpose of the SOC**. The purposes of the SOC shall be to, subject to Section 3.4:

3.3.1 provide a forum to discuss and coordinate the Parties' activities under this Agreement, in particular sales performance and metrics, and, subject to Section 3.4.2, develop, update, amend and approve the Sales Plan, including the identification of sales accounts;

3.3.2 provide a forum to discuss and coordinate the promotion of the Product in the Territory;

3.3.3 provide a forum to discuss Product Materials (it being understood that the SOC shall not have the right to approve such Product Materials);

3.3.4 provide a forum for discussing the annual Sales Forecast and revisions thereto (it being understood that TYME retains the right to update the Sales Forecast as described in Section 4.1.3);

3.3.5 provide a forum for reviewing, updating and agreeing on revisions to the Operating Parameters Schedule, including without limitation, to update the Eagle Quarterly Minimum Details and the Minimum Sales Representatives Requirement;

3.3.6 facilitate the flow of information and otherwise promote the communications and collaboration within and among the Parties relating to this Agreement and the promotion of the Product;

3.3.7 discuss planning and implementation of all Eagle Activities, including but not limited to training of Sales Representatives and development and implementation of policies and procedures for conduct of Promotional Programs and Details and Sales Representatives' interactions with sales accounts;

3.3.8 decide on the acceptable form of and review and discuss the Detail Reports and reports of Net Sales;

3.3.9 review and discuss the Compensation Reports and the incentive compensation matters described in Section 4.1.4, including any applicable adjustments to Product-related sales goals and targets of the Sales Representatives proposed by TYME (it being understood that Eagle shall retain final decision-making authority with respect to such matters but shall give good faith consideration to TYME's feedback with respect thereto);

3.3.10 review and discuss any matters brought to its attention by either Party's Alliance Manager;

3.3.11 discuss the Promotional Materials matters described in Section 4.4.1(a);

3.3.12 discuss supply or distribution issues relating to the Product;

3.3.13 act as a first level escalation to address disagreements or disputes between the Parties;

3.3.14 form and oversee any sub-committee or working group in furtherance of the activities contemplated by this Agreement;

3.3.15 decide on the acceptable form of and review and discuss the Compliance Reports; and

3.3.16 perform such other responsibilities as may be mutually agreed upon by the Parties in writing from time to time; provided, however, for clarity the SOC shall have no authority to amend or modify any provisions of this Agreement and no authority to waive or definitively interpret the provisions of this Agreement.

In connection with the SOC meetings contemplated under Section 3.2 (but in any event, no less frequently than each Fiscal Quarter), Tyme shall provide Eagle with a written summary of its material Development and Commercialization strategies and activities with respect to the Product in the Territory since the last SOC meeting or Fiscal Quarter, as applicable, including the results of such activities, and a description of its then-current marketing plans, marketing campaigns and Product-related messaging with key opinion leaders, except and to the extent such information is subject to confidentiality or similar restrictions on disclosure imposed by contractual, regulatory or similar requirements.

3.4 **Decision Making**.

3.4.1 **Quorum; Voting**. Meetings of the SOC shall occur only if at least one (1) representative of each Party is present at the meeting. Each Party shall have one (1) vote. The SOC shall use good faith efforts to reach consensus on all matters properly brought before it. If the SOC does not reach unanimous consensus on an issue at a meeting, or within a period of 30 days thereafter, then the SOC shall submit in writing the respective positions of the Parties to the Senior Officers of the Parties. Such Senior Officers shall use good faith efforts to resolve promptly such matter, which good faith efforts shall include at least one (1) teleconference between such Senior Officers within 30 days after the SOC's submission of such matter to them. Any final decision mutually agreed to in writing by the Senior Officers shall be conclusive and binding on the Parties. If the Senior Officers are not able to agree on the resolution of any such issue within 30 days after such issue was first referred to them, then, except with respect to those disputes that are expressly subject to arbitration pursuant to Section 12.6: (i) Eagle shall have the right to conclusively determine all matters related to the incentive compensation of the Sales Representatives and (ii) subject to Section 3.4.2, TYME shall have the right to conclusively determine all other matters; provided, however, for clarity, that such determination and any related activities comply with the terms and conditions of this Agreement. Notwithstanding anything to the contrary in the foregoing, for the avoidance of doubt, any such determination shall not amend, modify or waive any provisions of this Agreement or definitively interpret the provisions of this Agreement.

3.4.2 **Eagle Approvals**. Any proposed change or amendment to the (a) Operating Parameters Schedule or (b) Sales Plan that would (i) increase Eagle's percentage of the sales force requirements above the percentage provided in the Operating Parameters Schedule (as may be subsequently amended by mutual agreement of the Parties), (ii) increase the number of Eagle Quarterly Minimum Requirements (as such requirements may be updated by mutual agreement of the Parties), (iii) increase the number of Sales Representatives from the number agreed to prior to the Target Launch Date (or as otherwise agreed by mutual agreement of the Parties) or (iv) without duplication of items (i) – (iii) hereof, materially increase Eagle's costs associated with conducting any Eagle Activities other than Detailing shall, in each case of (a) and (b), require the written approval of Eagle (which approval shall not be unreasonably withheld). The initial Sales Plan developed by the SOC to be in effect at the Target Launch Date, which shall set forth the commercial activities geared towards achieving the Sales Forecast, including, without limitation the Eagle Quarterly Minimum Details and the target number of Promotional Programs, shall be developed by the SOC, approved by TYME and require the written approval of Eagle (which Eagle approval shall not be unreasonably withheld).

ARTICLE 4 EAGLE ACTIVITIES FOR THE PRODUCT

4.1 **Eagle Activities**.

4.1.1 **General**. Eagle shall conduct the Eagle Activities for the Product in the Field in the Territory in accordance with this Agreement, including, without limitation, in accordance with the then-current Sales Plan.

4.1.2 **Sales Representatives**. Without limiting the generality of the foregoing, Eagle shall hire, and continuing throughout the remainder of the Term, shall maintain, a sales force with responsibility to Detail the Product in the Territory in accordance with the terms of the Operating Parameters Schedule. Eagle shall have such sales force in place by such time specified in the Operating Parameters Schedule in order to appropriately train on the Product prior to Target Launch Date. The Sales Representatives and their managers shall have the qualifications and meet the criteria set forth in Schedule 4.1.2 hereto, which schedule shall be jointly developed and mutually agreed by TYME and Eagle within 180 days of the execution and delivery of this Agreement.

4.1.3 **Sales Forecast**.

(a) No later than three (3) months prior to the Target Launch Date, TYME shall develop a forecast of reasonably expected Net Sales of the Product in the Territory in the Field for a one (1) year period, including projected quarterly Net Sales (the "**Sales Forecast**"). Thereafter, each Fiscal Year of the Term, TYME shall prepare an annual Sales Forecast for such period. The Sales Forecast shall be updated by TYME from time to time as appropriate, discussed at the SOC, and comprise part of the Sales Plan.

(b) On a quarterly basis, the SOC shall review actual Fiscal Year-to-date Net Sales performance compared to the Sales Forecast.

4.1.4 **Target Incentive Compensation**. Prior to the Target Launch Date, Eagle shall develop an incentive compensation package for each Sales Representative that derives an appropriate portion of target incentive compensation from achieving target sales of the Product, subject to TYME's review and comment prior to implementation of the incentive plan. On at least a quarterly basis, the Parties shall meet, through the SOC, to review the target incentive compensation and the actual incentive compensation paid out to the Sales Representatives to discuss, in good faith, any appropriate adjustments to the sales targets and goals related to the Product.

4.1.5 **Alliance Managers**. Each Party shall appoint a person who shall oversee interactions between the Parties for all matters related to this Agreement, and any related agreements between the Parties (each an "**Alliance Manager**"). The Alliance Managers shall endeavor to ensure clear and responsive communication between the Parties and the effective exchange of information, and shall serve as a single point of contact for all matters arising under this Agreement. The Alliance Managers shall have the right to attend all SOC meetings and, if applicable, subcommittee meetings as non-voting participants and may bring to the attention of the SOC or, if applicable, the subcommittee, any matters or issues either of them reasonably believes should be discussed, and shall have such other responsibilities as the Parties may mutually agree in writing. Each Party may designate different Alliance Managers by notice in writing to the other Party.

4.2 **Detailing**.

4.2.1 **Detail Requirements**. Commencing promptly upon completion of training of the Field Force Personnel that are engaged in Detailing the Product as described in Section 4.4.1 (but on the condition that Promotional Materials have been approved and delivered), Eagle shall deploy its Field Force Personnel that are engaged in Detailing to Detail the Product in accordance with the terms of this Agreement, including without limitation, the requirements for reach, frequency and position of the Product in the Detail provided in the Operating Parameters Schedule and the requirements of the then-current Sales Plan as updated from time to time. From time to time, Field Force Personnel shall organize and coordinate on the presentation of Promotional Programs as developed by the SOC and included in the then-current Sales Plan; however, except as set forth in this Agreement, without the prior written consent of TYME (not to be unreasonably withheld, delayed or conditioned), Eagle shall not conduct any Eagle Activities, other than Detailing, with respect to any Product. The Promotional Program requirements, guidelines and TYME approved speaker bureau will be provided to Eagle prior to initiation of the Promotional Programs.

4.2.2 **Records and Reports**.

(a) Eagle shall keep accurate and complete records, consistent with pharmaceutical industry standards, of each Detail and its obligations hereunder in connection therewith. Such records shall be kept for the longer of (i) five (5) years after the end of the Fiscal Year to which they relate and (ii) such period of time as required by Applicable Laws. Within 15 days following the end of each Fiscal Quarter during the Term, Eagle shall provide TYME with a written report (each a "**Detail Report**"), setting out (1) the quarterly average number of Sales Representatives during such Fiscal Quarter (calculated by taking the sum of the number of Sales Representatives employed by Eagle (or its affiliates) that have incentive compensation packages that comply with the terms of Section 4.1.4 on each Business Day of the Fiscal Quarter divided by the number of Business Days in such Fiscal Quarter) (the "**Quarterly Average Sales Force Size**"), (2) the aggregate actual number of Details for the Product made by its Sales Representatives during such Fiscal Quarter, (3) the aggregate number of Exclusive Details, (4) the aggregate number of Multidisciplinary Details, (5) the number of Primary Multidisciplinary Details, and (6) the number of Details broken down by the name of the Target Professionals and such professional's Specialty. Through the SOC, the Parties shall agree on a mutually acceptable form of Detail Report.

(b) Within 30 days following the end of each Fiscal Quarter during the Term, Eagle shall provide TYME with a written report (each a "**Compensation Report**"), which describes (i) the details of the incentive compensation package of each Sales Representative as it relates to the Product and (ii) the actual incentive compensation payouts for each Sales Representatives as described in Section 4.1.4. Through the SOC, the Parties shall agree on a mutually acceptable form of Compensation Report.

(c) Within 30 days following the end of each Fiscal Quarter during the Term, Eagle shall provide TYME with a written report (each a "**Compliance Report**"), which sets out a summary of any compliance-related disciplinary actions relating to any Field Force Personnel that are engaged in Detailing and any associated remedial actions. Through the SOC, the Parties shall agree on a mutually acceptable form of Compliance Report.

(d) TYME shall have the right, at its own expense, during normal business hours and upon reasonable prior notice, through an independent third party, reasonably acceptable to Eagle, and upon execution of a confidentiality agreement reasonably satisfactory to Eagle in form and substance, to inspect the applicable records and books maintained by Eagle relating to the Eagle Activities solely for purposes of verifying Eagle's compliance with the terms of this Agreement. For purposes of clarity, any such inspection right described in this Section 4.2.2(d) shall be limited to only those books and records of Eagle that are applicable to Eagle's performance of its obligations under this Agreement and may be conducted no more than once per calendar year. Where necessary, on reasonable request, TYME's inspection rights shall include interviewing Sales Representatives and other employees of Eagle. Eagle shall reasonably cooperate in any such inspection conducted by TYME. TYME shall treat all information subject to review under this Section 4.2.2(d) in accordance with the confidentiality provisions of this Agreement.

4.3 **Compliance with Applicable Law**.

4.3.1 In conducting the Eagle Activities hereunder, Eagle shall, and shall require all Field Force Personnel to, comply in all respects with Applicable Laws. In addition, TYME shall, and shall require all of its sales representatives to, comply in all respects with Applicable Laws in connection with its Development or Commercialization (including promotion and Detailing) of the Product in the Territory.

4.3.2 Neither Eagle or Field Force Personnel, nor TYME, its Affiliates or their respective licensees, shall offer, pay, solicit or receive any remuneration to or from any Professionals (including Target Professionals), in order to induce referrals of or purchase of the Product.

4.3.3 In performing the activities contemplated by this Agreement, neither Eagle or Field Force Personnel, nor TYME, its Affiliates or their respective licensees, shall make any payment, either directly or indirectly, of money or other assets to government or political party officials, officials of international public organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing where such payment would constitute violation of any Applicable Law. In addition, neither Eagle nor TYME shall make any payment, either directly or indirectly, to officials if such payment is for the purpose of unlawfully influencing decisions or actions with respect to the subject matter of this Agreement.

4.3.4 No employee of Eagle or its Affiliates shall have authority to give any direction, either written or oral, relating to the making of any commitment by TYME or its agents to any Third Party in violation of terms of this or any other provision of this Agreement

4.3.5 Neither Eagle nor TYME shall undertake any activity under or in connection with this Agreement which violates any Applicable Law.

4.3.6 TYME shall ensure that any patient assistance program used in connection with the Product (and the services performed thereby in connection with the Product) shall be operated in accordance with Applicable Law. Notwithstanding the immediately preceding sentence, TYME shall have no liability with respect to any breach or non-compliance with Applicable Law relating to any patient assistance program used in connection with the Product to the extent caused by the act or omission of any Field Force Personnel, which act or omission is not in compliance with the terms of this Agreement, Applicable Law or instructions of TYME.

4.3.7 TYME shall ensure that government-insured patients do not receive co-pay support from TYME with respect to the Product.

4.3.8 TYME shall ensure that its donations to, and interactions with, any 501(c)(3) charitable foundation that provides co-pay assistance to government-insured patients with respect to the Product are in full compliance with all Applicable Laws.

4.3.9 If, during the Term, Eagle becomes aware of a material violation or failure to comply with Applicable Law or the terms of this Agreement by a member of the Field Force Personnel that are engaged in Detailing, it shall promptly, but no later than two (2) Business Days after it becomes aware, notify TYME of such violation and, as promptly as possible thereafter, shall notify the steps it has taken or intends to take to remediate such violation.

4.3.10 As soon as practicable, but no later than six (6) months prior to the Target Launch Date, each Party shall appoint a representative to act as its compliance manager under this Agreement, each of which shall be routinely responsible for advising such Party on compliance matters and has suitable seniority and other relevant experience and expertise (each, a "**Compliance Manager**"). From time to time, each Party may change its Compliance Manager by giving written notice to the other Party. The Compliance Managers shall serve as a key point of contact between the Parties for compliance-related matters. Each Compliance Manager shall facilitate the resolution of any compliance issue with the Compliance Manager of the other Party. The Compliance Managers shall use good faith efforts to reach consensus on all compliance matters. If the Compliance Managers do not reach consensus on an issue promptly, then such issue shall be submitted to dispute resolution process described in Section 12.6. Upon the reasonable request of TYME from time to time, Eagle shall deliver to TYME copies of Eagle's compliance program policies and compliance training materials which are applicable to the Field Force Personnel's promotion of the Product. Other than as expressly stated herein, Eagle shall not be required to modify its compliance policies or practices in connection with the compliance-related provisions herein.

4.4 **Field Force Personnel Training; Product Materials**.

4.4.1 **Training, Training Materials and Promotional Materials**.

(a) Subject to the terms of this Section 4.4.1, TYME shall prepare and control the content of (i) all Product training materials for Field Force Personnel (the "**Product Training Materials**") and (ii) all Product marketing and educational materials (the "**Promotional Materials**") (the Product Training Materials and the Promotional Materials, collectively, the "**Product Materials**"). TYME shall be solely responsible for ensuring that the Product Materials prepared and approved by it are in compliance with the Regulatory Approval for the Product, the Product Labeling and Applicable Law. Once approved by TYME, the content of the Product Materials shall be provided by TYME to Eagle in advance of the Eagle Activities to allow for Eagle to review such content and provide verbal feedback to TYME in advance of use of the Product Materials. Within 15 days of receipt of such Product Materials, Eagle shall verbally provide to TYME any comments and/or proposed revisions to such Product Materials, which comments and revisions TYME shall reasonably consider so long as TYME deems such suggestions are acceptable in the promotion of the Product; provided that in any event, to the extent that TYME reasonably believes that such changes are not in compliance with Applicable Law, the Regulatory Approval for the Product or the applicable Product Labeling, then TYME shall not be required to incorporate any such suggestions from Eagle in the Product Materials. In the event of any disagreement between the Parties regarding any feedback received from Eagle with respect to the Product Materials, TYME shall have the right to conclusively determine such matter; provided that, Eagle shall not be required to use any Product Materials that it reasonably believes violate Applicable Law. If Eagle has provided comments to TYME on the Product Materials and TYME accepts some or all of such comments, then, once revised, TYME shall provide to Eagle the revised versions of such Product Materials for further review by Eagle, in accordance with the terms and timelines of this Section 4.4.1(a) above. Eagle shall use only Product Materials approved by TYME in the performance of Eagle Activities under this Agreement. The content of Product Materials shall not be modified or changed by Eagle or Field Force Personnel at any time without the prior written approval of TYME in each instance. TYME shall be responsible for the costs and expenses of creation and development of the Product Materials and Eagle shall be responsible for the costs and expense of reproduction, printing and delivery of the Product Materials to and for Eagle. The information regarding the Product that is provided by Eagle or Field Force Personnel as part of the Eagle Activities shall not deviate from the Product Materials. The Parties shall coordinate the production and delivery of Product Materials to allow sufficient internal and field force review time to accommodate scheduled training meetings and distribution to Field Force Personnel that are engaged in Detailing. In the event that TYME incurs costs and expenses for which Eagle is responsible under this Section 4.4.1, TYME may deduct such amounts from the payments due under Section 6.1 and shall include a description thereof in the applicable report under Section 6.2. The Parties shall collaborate to finalize the Product Materials in accordance with this Section 4.4.1(a) in advance of the Target Launch Date.

(b) By no later than six (6) months prior to the Target Launch Date, the Parties shall collaborate to plan and schedule training for the Sales Representatives at a mutually acceptable time(s) and date(s), including a launch meeting for the Sales Representatives at a mutually acceptable location. TYME shall lead such initial training and Eagle shall cooperate with any reasonable requests of TYME in order to support such training. The costs and expenses of such launch meeting shall be the responsibility of Eagle. All other training costs and expenses shall be the responsibility of Eagle. After the initial training, the Parties shall collaborate to provide additional training at such frequency, times and places as the circumstances warrant and the Parties mutually agree, but no less frequently than quarterly with at least three (3) live, in-person training sessions annually. Eagle shall have the right, but not the obligation, to conduct such additional training itself, provided that the Eagle trainers have been trained by TYME, and provided further that TYME shall have the right to attend such training upon reasonable notice by TYME to Eagle. Eagle shall certify in writing to TYME that all Field Force Personnel have completed the training described in this Section 4.4.1(b).

(c) Eagle and all Field Force Personnel that are engaged in Eagle Activities shall comply with the applicable provisions of the Code, and shall be trained on Eagle's compliance policies, including those that are consistent with the applicable provisions of Sec. 1128B(b) of the Social Security Act and the American Medical Association Ethical Guidelines for Gifts to Physicians from Industry (which such training may have been accomplished prior to the Term), prior to commencing any Eagle Activities. Eagle agrees that it shall train any employee or agent of Eagle who is involved in performing the activities contemplated by this Agreement on anti-corruption and anti-bribery at its own expense.

(d) Field Force Personnel that are engaged in Detailing shall conduct the Eagle Activities only after having undergone the training described in this Section 4.4 and, without limiting the foregoing, no Field Force Personnel member shall Detail the Product without having undergone such training. Subject to the foregoing, Eagle shall have the responsibility for on-going training of its Field Force Personnel that are engaged in Detailing in accordance with customary practice in the pharmaceutical industry, provided that TYME shall be entitled to approve all such training objectives and content.

4.4.2 **Ownership of Product Materials**. As between the Parties, TYME shall own all right, title and interest in and to any Product Materials (and all content contained therein) and any Product Labeling (and all content contained therein), including applicable copyrights and trademarks (other than any name, trademark, trade name or logo of Eagle or its Affiliates that may appear on such Product materials or Product Labeling), and to the extent Eagle (or any of its Affiliates) obtains or otherwise has a claim to any of the foregoing, Eagle hereby assigns (and shall cause any applicable Affiliate to assign) all of its right, title and interest in and to such Product Materials (and content) and Product Labeling (and content) (other than any name, trademark, trade name or logo of Eagle or its Affiliates that may appear on such Product materials or Product Labeling) to TYME and Eagle agrees to (and shall cause its applicable Affiliate to) execute all documents and take all actions as are reasonably requested by TYME to vest title to such Product Materials (and content) and Product Labeling (and content) in TYME (or its designated Affiliate).

4.5 **Provisions Related to Field Force Personnel**.

4.5.1 **Activities of Field Force Personnel**. Eagle hereby agrees and acknowledges that the following shall apply with respect to itself and the Field Force Personnel that are engaged in Detailing:

(a) Eagle shall instruct and cause the Field Force Personnel that are engaged in Detailing to use only the Product Labeling and, subject to the terms of Section 4.4, Product Materials approved by TYME for the conduct of the Eagle Activities for the Product and consistent with

Applicable Laws. Eagle shall instruct the Field Force Personnel that are engaged in Detailing to, and shall monitor (in accordance with Eagle's standard practice) the Field Force Personnel that are engaged in Detailing, in order to ensure that such Field Force Personnel limit their claims of efficacy and safety for such Product to those claims which are consistent with and do not exceed the Product Labeling and any Promotional Materials.

(b) Eagle shall instruct the Field Force Personnel that are engaged in Detailing to conduct the Eagle Activities for the Product, and shall monitor and audit (in accordance with Eagle's standard practice) the Field Force Personnel that are engaged in Detailing so that such personnel conduct the Eagle Activities for such Product in adherence in all respects with Applicable Laws.

(c) Eagle shall instruct the Field Force Personnel that are engaged in Detailing regarding provisions of this Agreement applicable to Details of the Product, including Section 4.2 and this Section 4.5.1.

(d) Eagle acknowledges and agrees that TYME will not maintain or procure any worker's compensation, healthcare, or other insurance for or on behalf of the Field Force Personnel, all of which shall be Eagle's sole responsibility.

(e) Eagle acknowledges and agrees that all Field Force Personnel are employees of Eagle and are not, and are not intended to be treated as, employees of TYME or any of its Affiliates, and that such individuals are not, and are not intended to be, eligible to participate in any benefits programs or in any "employee benefit plans" (as such term is defined in section 3(3) of the Employee Retirement Income Security Act of 1974, as amended) that are sponsored by TYME or any of its Affiliates or that are offered from time to time by TYME or its Affiliates to their own employees. All matters of compensation, benefits and other terms of employment for any such Field Force Personnel shall be solely a matter between Eagle and such individual. TYME shall not be responsible to Eagle, or to the Field Force Personnel, for any compensation, expense reimbursements or benefits (including vacation and holiday remuneration, healthcare coverage or insurance, life insurance, severance or termination of employment benefits, pension or profit-sharing benefits and disability benefits), payroll-related taxes or withholdings, or any governmental charges or benefits (including unemployment and disability insurance contributions or benefits and workmen's compensation contributions or benefits) that may be imposed upon or be related to the performance by Eagle or such individuals of this Agreement, all of which shall be the sole responsibility of Eagle, even if it is subsequently determined by any Governmental Authority that any such individual may be an employee or a common law employee of TYME or any of its Affiliates or is otherwise entitled to such payments and benefits.

(f) Eagle shall be solely responsible for the acts or omissions of the Field Force Personnel that are not in compliance with Applicable Law and the terms of this Agreement while performing any of the activities under this Agreement. Eagle shall be solely responsible and liable for all probationary and termination actions taken by it, as well as for the formulation, content and dissemination (including content) of all employment policies and rules (including written probationary and termination policies) applicable to its employees.

4.5.2 **Termination of Employment; Cessation of Eagle Activities**. If any Field Force Personnel leaves the employ of Eagle (or any of its Affiliates), or otherwise ceases to conduct the Eagle Activities for the Product, Eagle shall, to the extent consistent with, and in a manner similar to, its practices with respect to departures of the sales representatives or other field force personnel, as applicable, promoting, marketing or detailing other products for Eagle, account for, and shall cause such departing Field Force Personnel to return to Eagle and delete from his/her computer files (to the extent such materials or information have been provided in, or converted into, electronic form) all materials relating to the Product that have been provided to such individual, including the Product Materials and account level information, including all copies of the foregoing.

4.5.3 **Discipline**. If TYME has a reasonable basis for believing any member of the Field Force Personnel that are engaged in Detailing has violated any Applicable Laws, or failed to comply with this Agreement, then TYME shall notify Eagle of the alleged violation and Eagle shall promptly investigate the matter and, if the allegation turns out to be true, shall take the appropriate remedial action. Subject to the foregoing, Eagle shall be solely responsible for taking any disciplinary actions in connection with its Field Force Personnel that are engaged in Detailing. If, at any time, TYME has any other compliance-related concerns regarding any Field Force Personnel Detailing, TYME's Compliance Manager shall notify Eagle's Compliance Manager of such concerns in writing and the Compliance Managers shall discuss and resolve such matters pursuant to Section 4.3.10.

4.6 **Responsibility for Eagle Activity Costs and Expenses**. Other than as expressly set out herein, Eagle shall be solely responsible for any and all costs and expenses incurred by Eagle or any of its Affiliates in connection with the conduct of the Eagle Activities for the Product hereunder, including all costs and expenses in connection with Sales Representatives, including salaries, bonuses, employment benefits, travel expenses and other expenses, credentialing, licensing, providing benefits, deducting federal, state and local payroll taxes, and paying workers' compensation premiums, unemployment insurance contributions and any other payments required by Applicable Laws to be made on behalf of employees.

4.7 **Data Sharing**. Without limiting the information that Eagle shall provide to TYME hereunder, including, without limitation, the reports deliverable under Section 4.2 hereof, TYME shall provide to Eagle certain information relating to the sale, Commercialization, marketing and promotion of the Product, as may be mutually agreed by the Parties from time to time, for use by Eagle and the Field Force Personnel in connection with the Eagle Activities. The timing of the delivery of such information shall be mutually agreed upon by the Parties, acting reasonably.

4.8 **Material Changes**. Eagle acknowledges no Product is available for Commercialization as of the date hereof and that the service levels and requirements of Eagle and its personnel under this Article IV and the accompanying

Schedules are based on the Parties' current expectations regarding SM-88 (racemetyrosine)'s approval pathway in pancreatic cancer. Should SM-88 (racemetyrosine) be approved in additional or different indications, a new Product or class of Product becomes available for Commercialization, or there is otherwise a material change in TYME's requirements hereunder, the Parties agree to amend the Operating Parameters Schedule in good faith to address such development. For the avoidance of doubt, the Parties agree that any such amendment will be made in good faith to preserve the spirit and service levels established hereunder for such new indications or changes. Any disputes arising from this Section 4.8 or amendments to the Operating Parameters Schedule incident thereto that are not resolved by the Senior Officers pursuant to Section 3.4.1 shall be governed by Section 12.6.

ARTICLE 5 REGULATORY, SAFETY AND SURVEILLANCE, COMMERCIAL MATTERS

5.1 **TYME Responsibility**. As between the Parties, except as expressly set out herein, all regulatory matters regarding the Product shall be the responsibility of TYME, including responsibility for all communications with Governmental Authorities, including but not limited to the FDA, related to the Product, and TYME shall have sole responsibility to seek and/or obtain any necessary approvals of any Product Labeling and the Promotional Materials used in connection with the Product, and for determining whether the same requires approval. As between the Parties, TYME shall be responsible for any reporting of matters regarding the manufacture, sale or promotion of the Product (including Adverse Events) to or with the FDA and other relevant Regulatory Authorities, in accordance with Applicable Laws. TYME shall maintain, at its cost, the Regulatory Approvals for the Product and shall comply with all

Applicable Law relevant to the conduct of TYME's business with respect to the Product or pursuant to this Agreement, including, without limitation, all applicable requirements under the Act.

5.2 **Eagle Involvement**. Except as expressly permitted herein, Eagle shall not, without TYME's prior written consent, correspond or communicate with the FDA or with any other Governmental Authority concerning the Product, or otherwise take any action concerning any Regulatory Approval or other authorization under which the Product is marketed or sold. If not prohibited by any Government Authority or Applicable Law, Eagle shall provide to TYME, promptly upon receipt, copies of any communication from the FDA or other Governmental Authority related to the Product. If not prohibited by any Government Authority or Applicable Law, TYME has the right to review and comment on Eagle's draft responses to any Governmental Authorities relevant to Detail of the Product prior to Eagle's issuance of such response; and Eagle agrees to consider any comments or suggestions from TYME in good faith.

5.3 **Inspections**.

5.3.1 If not prohibited by any Government Authority or Applicable Law, Eagle shall notify TYME immediately upon receipt of any notice of inspection or investigation by any Governmental Authority related to or that Eagle reasonably believes may impact any aspect of the Eagle Activities. If not prohibited by any Government Authority or Applicable Law, TYME shall have the right to have a representative present at any such portion of the inspection involving any Eagle Activities. In such cases, Eagle shall (i) keep TYME fully informed of the progress and status of any such inspection or investigation, (ii) prior to undertaking any action pursuant to this Section 5.3.1, notify TYME of the inspection or investigation, and disclose to TYME in writing the Governmental Authorities' assertions, findings and related results of such inspection or investigation pertaining to the Eagle Activities, and (iii) provide full disclosure to TYME with respect to any action undertaken or proposed to be undertaken pursuant to this Section 5.3.1 prior to acting as it pertains to the Eagle Activities. In addition, if such findings or the Governmental Authority requests or suggests that Eagle should change any aspect of the Eagle Activities, the Parties shall work together to make any such modification; provided, however, that notwithstanding anything to the contrary herein, Eagle shall not be required to engage in any Eagle Activities to the extent any finding or Government Authority has requested or suggested that Eagle may not engage in such activity.

5.3.2 If not prohibited by any Government Authority or Applicable Law, TYME shall notify Eagle immediately upon receipt of any notice of inspection or investigation by any Governmental Authority related to or that TYME reasonably believes may impact any aspect of the Eagle Activities. In such cases, TYME shall (i) keep Eagle fully informed of the progress and status of any such inspection or investigation, (ii) disclose to Eagle in writing the Governmental Authorities' assertions, findings and related results of such inspection or investigation pertaining to the Product or its promotion, and (iii) provide full disclosure to Eagle with respect to any action undertaken or proposed to be undertaken pursuant to this Section 5.3.2 prior to acting as it pertains to the Eagle Activities. In addition, if such findings or the Governmental Authority requests or suggests that Eagle should change any aspect of the Eagle Activities, the Parties shall work together to make any such modification; provided, however, that notwithstanding anything to the contrary herein, Eagle shall not be required to engage in any Eagle Activities to the extent any finding or Government Authority has requested or suggested that Eagle may not engage in such activity.

5.4 **Pharmacovigilance**. Subject to the terms of this Agreement, no later than six (6) months prior to the Target Launch Date, TYME and Eagle (under the guidance of their respective pharmacovigilance departments, or equivalent thereof) shall identify and finalize the responsibilities the Parties shall employ to protect patients and promote their well-being in a separate safety data exchange agreement ("**Pharmacovigilance Agreement**"). These responsibilities shall include mutually acceptable guidelines and procedures for the receipt, investigation, recordation, communication and exchange (as between the Parties) of safety information, such as Adverse Events, lack of efficacy, misuse/abuse, and any other information concerning the safety of the Product. Such guidelines and procedures will be in accordance with, and enable the Parties and their Affiliates to fulfill, regulatory reporting obligations to Governmental Authorities. For the avoidance of doubt, such guidelines and procedures shall provide that any Eagle Sales Representative, Field Force Personnel or Eagle Affiliate that becomes aware of an Adverse Event shall follow all TYME policies and procedures regarding Adverse Event reporting, including TYME's Adverse Event Reporting standard operating procedure, which shall be provided to Eagle for training prior to the Target Launch Date. The Pharmacovigilance Agreement shall provide that: (i) TYME shall be responsible for all pharmacovigilance activities regarding the Product, including signal detection, medical surveillance, risk management, medical literature review and monitoring, Adverse Event reporting and responses to Governmental Authority requests or enquiries, and shall provide information related thereto to Eagle, and (ii) in the event Eagle receives safety information regarding the Product, or information regarding any safety-related regulatory request or inquiry, Eagle shall notify TYME as soon as practicable, but, in any event, within the timelines set forth in the Pharmacovigilance Agreement.

5.5 **Unsolicited Requests for Medical Information**. Eagle shall direct to TYME any unsolicited requests for off-label medical information from health care professionals with respect to the Product promptly following receipt by Eagle (but in no event later than two (2) days after receipt). TYME shall, within two (2) days following receipt of any such request from Eagle, address any such requests directly.

5.6 **Recalls and Market Withdrawals**. As between the Parties, TYME shall have the sole right to determine whether to implement, and to implement, a recall, field alert, withdrawal or other corrective action related to the Product. TYME shall bear the cost and expense of any such recall, field alert, withdrawal or other corrective action. Each Party shall promptly (but in any case, not later than one (1) day after) notify the other Party in writing of any order, request or directive of a court or other Governmental Authority to recall or withdraw the Product.

5.7 **Certain Reporting Responsibilities**. Notwithstanding the foregoing provisions of this ARTICLE 5, each Party shall be responsible for its own federal, state and local government pricing reporting and payment transparency reporting in the Territory arising from its Product promotional activities and related expenditures pursuant to Applicable Law. It is the intention of the Parties that any payments or transfer of value by a Party as it relates to the Product shall constitute transfers of value by that Party and such Party shall be responsible for the reporting described in the immediately preceding sentence. However, if a Party is deemed to have provided any payments or transfers of value to a Third Party on behalf of the other Party as it relates to the Product, then such Party shall provide to the other Party, in a format reasonably acceptable to such other Party, the data and other information on a timely basis (i.e., in the case of manual reporting of such data and other information, within 30 days following the end of each Fiscal Quarter, and, in the case of automated reporting of such data and other information, on a periodic basis during each Fiscal Quarter as reasonably requested by such other Party) for such other Party's reporting under the Physician Payments Sunshine Act and other Applicable Laws.

5.8 **Booking of Sales Revenues**. TYME shall retain ownership of the rights to the Product and record on its books all revenues from sales of the Product. TYME shall be exclusively responsible for accepting and filling purchase orders, billing, and returns with respect to the Product. If Eagle receives an order for the Product, it shall promptly transmit such order to TYME (or its designee) for acceptance or rejection. TYME shall have sole responsibility for shipping, distribution and warehousing of the Product, and for the invoicing and billing of purchasers of the Product and for the collection of receivables resulting from the sales of the Product in the Territory.

5.9 **Returns**. Eagle is not authorized to accept any Product returns. Eagle shall advise any customer who attempts to return any Product to Eagle (or its Affiliates) that such Product must be shipped by the customer to the facility designated by TYME from time to time (and in accordance with other instructions provided by TYME). TYME shall provide to Eagle written instructions as to how Eagle should handle any Product that is actually physically returned to Eagle. Eagle shall take no other actions with respect to such return without the prior written consent of TYME.

5.10 **Development; Manufacturing; Distribution**; **Marketing**. TYME shall have the sole authority to Develop, Commercialize, manufacture, package, label, warehouse, sell and distribute the Product in the Territory. TYME shall use Commercially Reasonable Efforts to Develop and Commercialize at least one (1) Product in the Field in the Territory. Following the acceptance of the NDA for SM-88 (racemetyrosine) by the FDA and no later than 90 days prior to the Target Launch Date, TYME shall use Commercially Reasonable Efforts to cause sufficient quantities of Product to be available in inventory to promptly fill orders throughout the Territory and otherwise meet the forecasted demand for Product in the Territory. If, despite such efforts, there is insufficient supply of Product to meet demand, then TYME shall use Commercially Reasonable Efforts to promptly address such insufficiency. TYME shall contractually require (and shall use commercially reasonable efforts to enforce such contractual provisions) that all Product is manufactured, shipped, sold and distributed in accordance with all Product specifications and all Applicable Law and that its contract manufacturers and/or suppliers of Product operate their facilities in accordance with Applicable Law. TYME shall ensure that all Product Labeling complies with the applicable Regulatory Approval for the Product and Applicable Law. Other than as set forth in this Agreement, TYME shall be responsible for all marketing of the Product in the Territory.

ARTICLE 6 FINANCIAL PROVISIONS

6.1 **Promotion Fee**.

6.1.1 **Calculation of Promotion Fee**.

(a) Subject to Section 6.1.2, commencing with the Fiscal Quarter following the First Commercial Sale, as consideration for the Eagle Activities performed by Eagle, TYME shall pay Eagle a promotion fee based on Net Sales during the Term, calculated by multiplying fifteen percent (15%) by Net Sales of all Product in the Territory in each Fiscal Quarter.

(b) At any time after the date hereof, TYME shall have the right to terminate Eagle’s right to Detail and Promote the Product in the Territory in the Field upon a payment to Eagle of all accrued, earned but unpaid promotion fee amounts plus the Buyout Amount.

6.1.2 **Adjustment of Promotion Fee**. In the event that Eagle fails to satisfy the Eagle Quarterly Minimum Details for the Product or fails to demonstrate Commercially Reasonable Efforts to execute on other aspects of the Sales Plan then in effect for a period of two (2) consecutive Fiscal Quarters, the promotion fee payable by TYME pursuant to Section 6.1.1(a) shall be reduced to twelve percent (12%) for subsequent Fiscal Quarters and Eagle shall continue to receive such reduced promotion fee until such Fiscal Quarter in which Eagle satisfies the Eagle Quarterly Minimum Details for the Product or demonstrates Commercially Reasonable Efforts to execute on other aspects of the Sales Plan, as the case may be. Eagle’s failure to meet the Eagle Quarterly Minimum Details or to demonstrate Commercially Reasonable Efforts to execute on other aspects of the Sales Plan then in effect for the Product for a period of four (4) consecutive Fiscal Quarters shall be deemed a material breach of this Agreement (it being understood that a failure to meet the Eagle Quarterly Minimum Details or to demonstrate Commercially Reasonable Efforts to execute on other aspects of the Sales Plan then in effect for the Product for any period less than four consecutive Fiscal Quarters shall not alone be deemed a material breach of this Agreement). For the avoidance of doubt, notwithstanding anything to the contrary herein, such material breach of this Agreement shall give rise to TYME’s immediate ability to terminate the Agreement pursuant to Section 11.2.2 and shall not be subject to any cure period.

6.2 **Reports; Payments**.

6.2.1 **Quarterly Reports and Payments**. Within fifteen (15) Business Days after the end of each Fiscal Quarter during the Term, TYME shall provide to Eagle a written report setting forth in reasonable detail the calculation of the Net Sales for such Fiscal Quarter and the promotion fee payable in respect of such Net Sales in accordance with Section 6.1, including the number of units of the Product shipped to patients in the Territory during such Fiscal Quarter, together with an itemized list of such units by Target Professional writing the applicable prescription. Within sixty (60) days after the end of each Fiscal Quarter during the Term, TYME shall pay to Eagle the undisputed portion of the promotion fee payable in respect of such Net Sales in accordance with Section 6.1. If this Agreement terminates or expires during a Fiscal Quarter, the promotion fee payable to Eagle under Section 6.1 shall be calculated only on the Net Sales that occurred during prior to the effective date of such termination or expiration in such Fiscal Quarter.

6.2.2 **Monthly Estimate Reports**. Within fifteen (15) Business Days of the end of each month within each Fiscal Quarter, TYME shall provide to Eagle a written report setting forth TYME’s good faith estimate of the Net Sales and the estimated promotion fee payable in respect of such Net Sales for each of such calendar month and the Fiscal Quarter-to-date period, together with its good faith estimates of each of the items described in Section 6.2.1 above. The Parties acknowledge and agree that the monthly reports shall only set forth TYME’s good faith estimates of the items contained therein and are being provided to Eagle for information purposes only and shall not be determinative of the any amounts due hereunder.

6.2.3 **Payment Adjustments**. If new information becomes available after the close of a Fiscal Quarter under the process described in Section 6.2.1 that would adjust the amount of recognized Net Sales or payments under this Agreement, such adjustments shall be made in the Fiscal Quarter they become available. Additions or deductions in payments resulting from any adjustments shall be applied to the next regularly scheduled quarterly payment.

6.2.4 **Disputes**. Promptly upon receipt of the quarterly or monthly reports described in this Section 6.2, Eagle shall review such reports and, in the event that Eagle disputes any of the items described in such report, Eagle shall promptly notify TYME of any such disputes. The Parties shall meet promptly thereafter to attempt to resolve such disputes.

6.2.5 **Manner of Payment**. All payments under this Agreement shall be made in US Dollars by wire transfer or Automated Clearing House to a bank account designated in writing by Eagle or TYME, as applicable, which shall be designated at least five (5) Business Days before such payment is due.

6.2.6 **Late Payments**. If Eagle does not receive payment of any sum due to it on or before the due date, simple interest shall thereafter accrue on the sum due to Eagle from the due date until the date of payment at the prime rate published in the Wall Street Journal on the due date plus two percent (2.0%) per annum or the maximum rate allowable by Applicable Law, whichever is less. Notwithstanding the foregoing, if the reason for any late payment is resulting from or arising out of any act or omission on the part of Eagle, including, but not limited to, any delay providing the payment instructions pursuant to Section 6.2.5, such interest shall not accrue. For clarity, any payments due from adjustments under Section 6.2.3 shall not be considered late payments.

6.3 **Taxes**. To the extent TYME is required to deduct and withhold taxes from any payment to Eagle, TYME shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Eagle an official tax receipt or other evidence of timely payment sufficient to enable Eagle to claim the payment of such taxes as a deduction or tax credit. Eagle may provide to TYME any tax forms that may be reasonably necessary in order for TYME to not withhold tax and TYME shall dispense with withholding, as applicable. TYME shall provide Eagle with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding taxes.

6.4 **Recordkeeping**. Each Party shall maintain complete and accurate books and records in sufficient detail, in accordance with GAAP (to the extent applicable and in accordance with the Agreement) and all Applicable Law, to enable verification of the performance of such Party's obligations under this Agreement and any payments due to a Party under this Agreement. Unless otherwise specified herein, the books and records for a given Fiscal Year of the Term shall be maintained for a period of three (3) years after the end of such Fiscal Year or longer if required by Applicable Law.

6.5 **Eagle Rights**. Eagle shall have the right, at its own expense, during normal business hours and upon reasonable prior notice, through an independent certified public accountant reasonably acceptable to Tyme, and upon execution of a confidentiality agreement reasonably satisfactory to TYME in form and substance, to inspect the applicable records and books maintained by TYME solely for purposes of verifying the accuracy of Net Sales amounts reported by TYME pursuant to Section 6.2.1 hereof and the fees payable by TYME to Eagle under this Agreement in respect of such amounts. For clarity, such inspection right described in this Section 6.5 shall be limited to only those books and records of payment reports and amounts owed to Eagle as a result of Tyme's achievement of Net Sales of the Product in the Territory under this Agreement and (i) may be conducted no more than once per calendar year, (ii) may only cover the most recently completed Fiscal Year and the two (2) years prior to such Fiscal Year, and (iii) may not be conducted in March through June of any given Fiscal Year. Disputes, if any, must be submitted to TYME within sixty (60) days after the completion of such inspection. TYME shall reasonably cooperate in any such inspection or audit conducted by Eagle. Eagle shall treat all information subject to review under this Section 6.5 in accordance with the confidentiality provisions of this Agreement.

ARTICLE 1 INTELLECTUAL PROPERTY

1.1 **Ownership of Intellectual Property**.

1.1.1 **Eagle Property**. TYME acknowledges that Eagle owns or is licensed to use certain Know-How relating to proprietary sales and marketing information, methods and plans that has been independently developed or licensed by Eagle (such Know-How, the "**Eagle Property**"). The Parties agree that any improvement, enhancement or modification made, discovered, conceived, or reduced to practice by Eagle to any Eagle Property in performing its activities pursuant to this Agreement which is not primarily related to the Product, or which is not otherwise derived from the Confidential Information of TYME, shall be deemed Eagle Property. Eagle hereby grants to TYME a fully paid-up, royalty free, non-transferable, non-exclusive perpetual license (with a limited right to sub-license to its Affiliates) to any Eagle Property that appears on, embodied on or contained in Product Materials or Product Labeling solely for use in connection with TYME's promotion or other Commercialization of the Product in the Territory.

1.1.2 **TYME Property**. Subject to the terms of Section 7.1.1, TYME shall have and retain sole and exclusive right, title and interest in and to all inventions, developments, discoveries, writings, trade secrets, Know-How, methods, practices, procedures, designs, improvements and other technology, whether or not patentable or copyrightable, and any patent applications, patents, or copyrights based thereon (collectively, "**Intellectual Property**") relating to the Product that are (i) owned or controlled by TYME as of the Effective Date, (ii) made, discovered, conceived, reduced to practice or generated by TYME (or its employees or representatives) during the Term, or (iii) made, discovered, conceived, reduced to practice or generated by Eagle (or its employees or representatives) in performing its activities pursuant to this Agreement to the extent primarily related to the Product or which is otherwise derived from the Confidential Information of TYME ("**Inventions**"). Eagle agrees to assign, and hereby does assign, to TYME (and shall cause its Affiliates and its and their respective employees and other representatives to assign to TYME) any and all right, title and interest that Eagle (or any such Affiliates, employees or other representatives) may have in or to any Invention. For clarity, any and all Inventions and any information contained therein or related thereto shall constitute Confidential Information of TYME.

1.2 **Title to Trademarks and Copyrights**. The ownership, and all goodwill from the use, of any TYME Trademarks and Copyrights shall at all times vest in and inure to the benefit of TYME, and Eagle shall assign, and hereby does assign, any rights it may have in the foregoing to TYME. Eagle shall not, directly or indirectly, adopt, apply for or acquire any trademarks, trade names, or domain names that include or are confusingly similar to any of the TYME Trademarks and Copyrights.

1.3 **Protection of Trademarks and Copyrights**. As between the Parties, TYME shall have the sole right (but not the obligation), as determined by TYME in its sole discretion, to (i) maintain the TYME Trademarks and Copyrights and/or (ii) protect, enforce and defend the TYME Trademarks and Copyrights. Eagle shall give notice to TYME of any infringement of, or challenge to, the validity or enforceability of the TYME Trademarks and Copyrights promptly after learning of such infringement or challenge. If TYME institutes an action against Third Party infringers or takes action to defend the TYME Trademarks and Copyrights, Eagle shall reasonably cooperate with TYME, at TYME's cost and expense. Any recovery obtained by TYME as a result of such proceeding or other actions, whether obtained by settlement or otherwise, shall be retained by TYME. Eagle shall not have any right to institute any action to defend or enforce the TYME Trademarks and Copyrights.

1.4 **Protection of Patent Rights**. As between the Parties, TYME shall have the sole right (but not the obligation), as determined by TYME in its sole discretion, to (i) prosecute and maintain the TYME Patent Rights and/or (ii) protect, enforce and defend the TYME Patent Rights. Eagle shall give notice to TYME of any misappropriation or infringement of, or challenge to, the validity or enforceability of the TYME Patent Rights promptly after learning of such misappropriation or infringement or challenge. If TYME institutes an action against Third Party infringers or takes action to stop the misappropriation or infringement of the TYME Patent Rights, Eagle shall reasonably cooperate with TYME, at TYME's cost and expense. Any recovery obtained by TYME as a result of such proceeding or other actions, whether obtained by settlement or otherwise, shall be retained by TYME. Eagle shall not have any right to institute any action to defend or enforce the TYME Patent Rights.

1.5 **Disclosure of Know-How**. For clarity, the Parties hereby agree and acknowledge that to the extent that either Party hereto has disclosed, or in the future discloses, to the other Party any Know-How or other Intellectual Property of such Party or its Affiliates pursuant to this Agreement, the other Party shall not acquire any ownership rights in such Know-How or other Intellectual Property by virtue of this Agreement or otherwise, and as between the Parties, all ownership rights therein shall remain with the disclosing Party (or its Affiliate).

ARTICLE 2 CONFIDENTIALITY

2.1 **Confidential Information**.

2.1.1 **Confidentiality and Non-Use**. Each Party agrees that, during the Term and for a period of five (5) years thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of its rights or performance of any obligations hereunder) any Confidential Information furnished to it by or on behalf of the other Party pursuant to this Agreement, except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties. Without limiting the foregoing, each Party shall use at least the same standard of care as it uses to protect its own Confidential Information to ensure that its employees, agents, consultants and contractors do not disclose or make any unauthorized use of such Confidential Information. Each Party shall promptly notify the other upon discovery of any unauthorized use or disclosure of the other's Confidential Information. Any and all information and materials disclosed by a Party pursuant to the Confidentiality Agreement between the Parties dated June 25, 2019 (the "**Confidentiality Agreement**") shall be deemed Confidential Information disclosed pursuant to this Agreement. The foregoing confidentiality and non-use obligations shall not apply to any portion of the other Party's Confidential Information that the receiving Party can demonstrate by competent tangible evidence:

(a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure to the receiving Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party or its Affiliates in breach of this Agreement;

(d) was disclosed to the receiving Party or its Affiliate by a Third Party who has a legal right to make such disclosure and who did not obtain such information directly or indirectly from the other Party (or its Affiliate); or

(e) was independently discovered or developed by the receiving Party or its Affiliate without access to or aid, application, use of the other Party's Confidential Information, as evidenced by a contemporaneous writing.

2.1.2 **Authorized Disclosure**. Notwithstanding the obligations set forth in Section 8.1.1, a Party may disclose the other Party's Confidential Information and the terms of this Agreement to the extent:

(a) such disclosure is reasonably necessary (x) to comply with the requirements of Governmental Authorities; or (y) for the prosecuting or defending litigation as contemplated by this Agreement;

(b) such disclosure is reasonably necessary to its Affiliates, employees, agents, consultants and contractors on a need-to-know basis for the sole purpose of performing its obligations or exercising its rights under this Agreement; provided that in each case, the disclosees are bound by obligations of confidentiality and non-use consistent with those contained in this Agreement and the disclosing Party shall be liable for any failures of such disclosees to abide by such obligations of confidentiality and non-use; or

(c) such disclosure is reasonably necessary to comply with Applicable Laws, including regulations promulgated by applicable securities exchanges, court order, administrative subpoena or order.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 8.1.2(a) or 8.1.2(c), such Party shall, if permitted, promptly notify the other Party of such required disclosure and shall use reasonable efforts to assist the other Party (at the other Party's cost) in obtaining, a protective order preventing or limiting the required disclosure.

2.2 **Public Announcements**. No public announcement or statements (including presentations to investor meetings and customer updates) concerning the existence of or terms of this Agreement or incorporating the marks of the other Party or their respective Affiliates shall be made, either directly or indirectly, by either Party or a Party's Affiliates, without first obtaining the written approval of the other Party and agreement upon the nature, text and timing of such announcement or disclosure. Either Party shall have the right to make any such public announcement or other disclosure required by Applicable Law after such Party has provided to the other Party a copy of such announcement or disclosure and an opportunity to comment thereon and the disclosing Party shall reasonably consider the other Party's comments. Each Party agrees that it shall cooperate fully with the other with respect to all disclosures regarding this Agreement to the Securities Exchange Commission and any other Governmental Authorities, including requests for confidential treatment of proprietary information of either Party included in any such disclosure. Once any written statement is approved for disclosure by the Parties or information is otherwise made public in accordance with this Section 8.2, either Party may make a subsequent public disclosure of the same contents of such statement in the same context as such statement without further approval of the other Party. Notwithstanding anything to the contrary contained herein, in no event shall either Party disclose any financial information of the other without the prior written consent of such other Party, unless such financial information already has been publicly disclosed by the Party owning the financial information or otherwise has been made part of the public domain by no breach of a Party of its obligations under this ARTICLE 8.

ARTICLE 3 REPRESENTATIONS AND WARRANTIES; ADDITIONAL COVENANTS

3.1 **Representations and Warranties of TYME**. TYME represents and warrants to Eagle as of the Effective Date that:

3.1.1 it is a corporation duly organized and validly existing under the laws of the state or other jurisdiction of its incorporation;

3.1.2 the execution, delivery and performance of this Agreement by it has been duly authorized by all requisite corporate action;

3.1.3 it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;

3.1.4 this Agreement constitutes a legal, valid and binding obligation enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity);

3.1.5 the execution, delivery and performance of this Agreement by TYME does not require the consent of any Person (including under any agreement with a Third Party) or the authorization of (by notice or otherwise) any Governmental Authority including the FDA;

3.1.6 there is no action, suit or proceeding pending or, to the knowledge of TYME, threatened, against TYME or any of its Affiliates, or to the knowledge of TYME, any Third Party acting on their behalf, which would be reasonably expected to impair, restrict or prohibit the ability of TYME or

Eagle to perform its obligations and enjoy the benefits of this Agreement;

3.1.7 it has no knowledge of any information relating to the safety or efficacy of the Product or any communications with any Governmental Authority, which would reasonably be expected to materially impair, restrict, prohibit or affect TYME's ability to perform its obligations and enjoy the benefits of this Agreement;

3.1.8 it is in compliance in all material respects with all Applicable Laws applicable to the subject matter of this Agreement;

3.1.9 it is not a party to any agreement or arrangement with any Third Party or under any obligation or restriction agreement (including any outstanding order, judgment or decree of any court or administrative agency) which in any way limits or conflicts with its ability to execute and deliver this Agreement and to fulfill any of its obligations under this Agreement;

3.1.10 it is currently conducting a Pivotal Clinical Study for SM-88 (racemetyrosine) though its TYME-88-Panc trial and SM-88 (racemetyrosine) is also being studied in the Pancreatic Cancer Action Network adaptive Phase II/III trial known as Precision Promise℠, which TYME believes can serve as a Pivotal Clinical Study; however, TYME does not currently have an NDA for SM-88 (racemetyrosine) accepted by the FDA;

3.1.11 neither TYME nor any of its personnel (i) have been debarred under the 21 U.S.C. § 335a, (ii) are excluded, debarred, suspended, or otherwise ineligible to participate in the federal health care programs or in federal procurement or nonprocurement programs, (iii) are convicted of a criminal offense that falls within the ambit of the federal statute providing for mandatory exclusion from participation in federal health care programs but has not yet been excluded, debarred, suspended, or otherwise declared ineligible to participate in those programs, (iv) are listed on the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov) or (v) are listed on the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at hhtp://epls.arnet.gov). If, during the Term, TYME or any of its personnel becomes or is the subject of a proceeding that could lead to, as applicable, (i) debarment under 21 U.S.C. § 335a, (ii) exclusion, debarment, suspension or ineligibility to participate in the federal health care programs or in federal procurement or nonprocurement programs, (iii) convicted (or conviction) of a criminal offense that falls within the ambit of the federal statute providing for mandatory exclusion from participation in federal healthcare programs, (iv) listed (or listing) on the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov) or (v) listed (or listing) on the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at hhtp://epls.arnet.gov), TYME shall immediately notify Eagle, and Eagle shall have the option to prohibit such Person from performing work relating to this Agreement or the Product; and

9.1.12 the Product Materials provided by TYME to Eagle for the conduct of Eagle Activities are, and shall be, compliant with the Regulatory Approval for the Product, the Product Labeling and Applicable Law.

3.2 **<u>Representations and Warranties of Eagle</u>**. Eagle represents and warrants to TYME as of the Effective Date that:

3.2.1 it is a corporation duly organized and validly existing under the laws of the state or other jurisdiction of its incorporation;

3.2.2 the execution, delivery and performance of this Agreement by it has been duly authorized by all requisite corporate action;

3.2.3 it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;

3.2.4 this Agreement constitutes a legal, valid and binding obligation enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity);

3.2.5 the execution, delivery and performance of this Agreement by Eagle does not require the consent of any Person or the authorization of (by notice or otherwise) any Governmental Authority or the FDA;

3.2.6 there is no action, suit or proceeding pending or, to the knowledge of Eagle, threatened, against Eagle or any of its Affiliates, or to the knowledge of Eagle, any Third Party acting on their behalf, which would be reasonably expected to impair, restrict or prohibit the ability of TYME or Eagle to perform its obligations and enjoy the benefits of this Agreement;

3.2.7 it is in compliance in all material respects with all Applicable Laws applicable to the subject matter of this Agreement;

3.2.8 it is not a party to any agreement or arrangement with any Third Party or under any obligation or restriction agreement (including any outstanding order, judgment or decree of any court or administrative agency) which in any way limits or conflicts with its ability to execute and deliver this Agreement and to fulfill any of its obligations under this Agreement;

3.2.9 it has no knowledge of any information relating to any communications with any Governmental Authority, which would reasonably be expected to materially impair, restrict, prohibit or affect Eagle's ability to perform its obligations and enjoy the benefits of this Agreement;

3.2.10 neither Eagle nor any of its personnel (i) have been debarred under the 21 U.S.C. § 335a, (ii) are excluded, debarred, suspended, or otherwise ineligible to participate in the federal health care programs or in Federal procurement or nonprocurement programs, (iii) are convicted of a criminal offense that falls within the ambit of the federal statute providing for mandatory exclusion from participation in federal health care programs but has not yet been excluded, debarred, suspended, or otherwise declared ineligible to participate in those programs, (iv) are listed on the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov) or (v) are listed on the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at hhtp://epls.arnet.gov). If, during the Term, Eagle or any of its personnel become or are the subject of a proceeding that could lead to, as applicable, (i) debarment under 21 U.S.C. § 335a, (ii) exclusion, debarment, suspension or ineligibility to participate in the federal health care programs or in Federal procurement or nonprocurement programs, (iii) convicted (or conviction) of a criminal offense that falls within the ambit of the federal statute providing for mandatory exclusion from participation in federal healthcare programs, (iv) listed (or listing) on the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov) or (v) listed (or listing) on the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at hhtp://epls.arnet.gov), Eagle shall immediately notify TYME, and TYME shall have the option to prohibit such Person from performing work under this Agreement; and

3.2.11 all Field Force Personnel that are engaged in Detailing are, and shall be, licensed to the extent required and in accordance with all Applicable Laws.

3.3 **Disclaimer of Warranty**. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN THIS AGREEMENT, TYME (AND ITS AFFILIATES) AND EAGLE (AND ITS AFFILIATES) MAKE NO REPRESENTATIONS AND NO WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND TYME (AND ITS AFFILIATES) AND EAGLE (AND ITS AFFILIATES) EACH SPECIFICALLY DISCLAIM ANY OTHER REPRESENTATIONS AND WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS, STATUTORY OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY INTELLECTUAL PROPERTY OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

ARTICLE 4 INDEMNIFICATION; LIMITATIONS ON LIABILITY

4.1 **Indemnification by TYME**. TYME shall defend, indemnify and hold harmless Eagle and its Affiliates and its and their respective officers, directors, employees, agents, representatives, successors and assigns from and against all Claims, and all associated Losses, to the extent incurred or suffered by any of them to the extent resulting from or arising out of (a) any misrepresentation or breach of any representations, warranties, agreements or covenants of TYME under this Agreement, (b) the negligence, willful misconduct or violation of Applicable Laws by TYME (or any of its Affiliates or its or their respective officers, directors, employees, agents or representatives), (c) the misappropriation or infringement of the intellectual property rights of any Third Party in connection with the Product, including from the use of the TYME Trademarks and Copyrights on Product Labeling or Product Materials in accordance with this Agreement, or (d) the Development and Commercialization of the Product by or on behalf of TYME, its Affiliates and any of their respective licensees, including the death or personal injury to any person related to use of the Product; except in each case to the extent any such Claims, and all associated Losses, are caused by an item for which Eagle is obligated to indemnify TYME pursuant to Section 10.2.

4.2 **Indemnification by Eagle**. Eagle shall defend, indemnify and hold harmless TYME and its Affiliates and its and their respective officers, directors, employees, agents, representatives, successors and assigns from and against all Claims and all associated Losses, to the extent incurred or suffered by any of them to the extent resulting from or arising out of (a) any misrepresentation or breach of any representations, warranties, agreements or covenants of Eagle under this Agreement, (b) the negligence, willful misconduct, or violation of Applicable Laws by Eagle (or any of its Affiliates or its and their respective officers, directors, employees, agents or representatives) or (c) labor disputes, Equal Employment Opportunity Commission charges or employment-related claims arising from or related to Eagle's employees; except in each case to the extent any such Claims, and all associated Losses, are caused by an item for which TYME is obligated to indemnify Eagle pursuant to Section 10.1.

4.3 **Indemnification Procedures**. The Party seeking indemnification under Section 10.1 or 10.2, as applicable (the "**Indemnified Party**") shall give prompt notice to the Party against whom indemnity is sought (the "**Indemnifying Party**") of the assertion or commencement of any Claim in respect of which indemnity may be sought under Section 10.1 or 10.2, as applicable, and shall provide the Indemnifying Party such information with respect thereto that the Indemnifying Party may reasonably request. The failure to give such notice shall relieve the Indemnifying Party of any liability hereunder only to the extent that the Indemnifying Party has suffered actual prejudice thereby. The Indemnifying Party shall assume and control the defense and settlement of any such action, suit or proceeding at its own expense; provided, however, if the Indemnified Party is TYME, it shall assume and control the defense and settlement of any such action, suit or proceeding. The Indemnified Party shall, if requested by the Indemnifying Party, cooperate in all reasonable respects in such defense, at the Indemnifying Party's expense. The Indemnified Party shall be entitled at its own expense to participate in such defense and to employ separate counsel for such purpose. For so long as the Indemnifying Party is diligently defending any proceeding pursuant to this Section 10.3, the Indemnifying Party shall not be liable under Section 10.1 or 10.2, as applicable, for any settlement effected without its consent. No Party shall enter into any compromise or settlement which commits the other Party to take, or to forbear to take, any action without the other Party's prior written consent (unless such compromise or settlement includes no payments by the Indemnified Party, an unconditional release of, and no admission of liability by, the Indemnified Party from all liability in respect of such Claim).

4.4 **Limitation of Liability**. NOTWITHSTANDING ANY OTHER PROVISION CONTAINED HEREIN (OTHER THAN AS SET FORTH IN THE SECOND SENTENCE OF THIS SECTION 10.4), IN NO EVENT SHALL TYME (OR ITS AFFILIATES) OR EAGLE (OR ITS AFFILIATES) BE LIABLE TO THE OTHER OR ANY OF THE OTHER PARTY'S AFFILIATES FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING LOST PROFITS) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES THAT ARISE OUT OF OR RELATE TO THIS AGREEMENT OR IN CONNECTION WITH A BREACH OR ALLEGED BREACH OF THIS AGREEMENT, WHETHER IN CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, AND REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. THE FOREGOING SENTENCE SHALL NOT LIMIT (1) THE OBLIGATIONS OF EITHER PARTY TO INDEMNIFY THE OTHER PARTY FROM AND AGAINST THIRD PARTY CLAIMS UNDER SECTION 10.1 OR 10.2, AS APPLICABLE, OR (2) DAMAGES AVAILABLE FOR A PARTY'S BREACH OF THE NON-COMPETE AND NON-SOLICIT OBLIGATIONS IN SECTION 2.3 AND THE CONFIDENTIALITY AND NON-USE OBLIGATIONS IN ARTICLE 8.

4.5 **Insurance**. Each Party acknowledges and agrees that during the Term, it shall maintain, through purchase or self-insurance, adequate insurance, including products liability coverage and comprehensive general liability insurance, adequate to cover its obligations under this Agreement and which are consistent with normal business practices of prudent companies similarly situated. Each Party shall provide reasonable written proof of the existence of such insurance to the other Party upon request. TYME does not and will not maintain or procure any worker's compensation, healthcare, or other insurance for or on behalf of any Field Force Personnel, all of which shall be Eagle's sole responsibility. For clarity, the insurance requirements of this Section 10.5 shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this ARTICLE 10.

ARTICLE 5 TERM AND TERMINATION

5.1 **Term**. This Agreement shall become effective as of the Effective Date and, unless earlier terminated as provided in this ARTICLE 11, will continue for ten (10) years (the "**Term**").

5.2 **Early Termination** . A Party shall have the right to terminate this Agreement before the end of the Term as follows:

5.2.1 by Eagle at its sole discretion and for any reason or no reason, upon twelve (12) months written notice to TYME given any time after the second (2nd) anniversary of the First Commercial Sale of the Product in the Territory;

5.2.2 by a Party upon written notice to the other Party in the event of a material breach of this Agreement by such other Party where such breach is not cured (if able to be cured) within 60 days following such other Party's receipt of written notice of such breach (and any such termination shall become effective at the end of such 60-day period unless the breaching Party has cured such breach prior to the expiration of such 60-day period), provided, however, for the avoidance of doubt such 60-day period shall not apply for termination relating to a material breach arising under Section 6.1.2 of this Agreement;

5.2.3 by either Party upon 90 days' written notice to the other Party following the withdrawal of the Product from the market by TYME (or the decision by TYME to withdraw the Product from the market) due to (i) any decision, judgment, ruling or other requirement of the FDA, or (ii) material safety concern;

5.2.4 by TYME pursuant to Section 6.1.1(b); and

5.2.5 by a Party immediately upon written notice to the other Party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings with respect to such other Party, or upon an assignment of a substantial portion of the assets for the benefit of creditors by such other Party, or in the event a receiver or custodian is appointed for such other Party's business or a substantial portion of such other Party's business is subject to attachment or similar process; provided, however, in the case of any involuntary bankruptcy proceeding such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within ninety (90) days after the filing thereof.

5.3 **Effects of Termination**. Upon the expiration or effective date of termination of this Agreement, (i) all rights and obligations of both Parties hereunder shall immediately terminate, subject to any survival as set forth in Section 11.4, (ii) Eagle, at TYME's direction, shall immediately return to TYME or destroy in accordance with all Applicable Laws all Product Materials, reports and other tangible items provided by or on behalf of TYME to Eagle or otherwise developed or obtained by Eagle pursuant to the terms of this Agreement (other than Eagle Property) (and at the request of TYME, Eagle shall certify destruction of such materials if Eagle does not to return such materials to TYME), (iii) Eagle shall immediately cease all Eagle Activities with respect to the Product, and (iv) each of TYME and Eagle shall, at the other Party's direction, either return to such other Party or destroy all Confidential Information of such other Party. Notwithstanding the foregoing, each Party may retain archival copies of any Confidential Information to the extent required by law, regulation or professional standards or copies of Confidential Information created pursuant to the automatic backing-up of electronic files where the delivery or destruction of such files would cause undue hardship to the receiving Party, so long as any such archival or electronic file back-up copies are accessible only to its legal or IT personnel, provided that such Confidential Information shall continue to be subject to the terms of this Agreement.

5.4 **Survival**. Termination or expiration of this Agreement shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such termination or expiration. Notwithstanding any expiration or termination of this Agreement, such expiration or termination shall not relieve any Party from obligations which are expressly or by implication intended to survive expiration or termination, including Sections 2.3, 4.4.2, 5.7, 5.9, 6.2.4, 6.2.5, 10.1, 10.2, 10.3, 10.4, 11.3 and 11.4, Articles 7, 8 and 12 (to the extent applicable to implementation of the survival of the preceding Sections and Articles) and, solely as it relates to the last Fiscal Quarter, Sections 6.1, 6.2 and 6.3, which shall survive and be in full force and effect.

ARTICLE 6 MISCELLANEOUS

6.1 **Force Majeure**. Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement (other than any failure to make payments owed under this Agreement) to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, potentially including, embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any Governmental Authority. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practicable, and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances and re-commence its performance hereunder as soon as practicable.

6.2 **Assignment**. Except as provided in this Section 12.2, this Agreement may not be assigned or otherwise transferred, nor may any rights or obligations hereunder be assigned or transferred, by either Party, without the written consent of the other Party (such consent not to be unreasonably withheld); provided that a merger, sale of stock or comparable transaction shall not constitute an assignment. In the event either Party desires to make such an assignment or other transfer of this Agreement or any rights or obligations hereunder, such Party shall deliver a written notice to the other Party requesting the other Party's written consent in accordance with this Section 12.2, and the other Party shall provide such Party written notice of its determination whether to provide such written consent within 30 days following its receipt of such written notice from such Party. Notwithstanding the foregoing, (a) either Party may, without the other Party's consent, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate; and (b) either Party may assign this Agreement to a successor in interest in connection with the sale or other transfer of all or substantially all of such Party's assets or rights relating to the Product; provided that such assignee shall remain subject to all of the terms and conditions hereof in all respects and shall assume all obligations of such Party hereunder whether accruing before or after such assignment. Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement. Any attempted assignment not in accordance with this Section 12.2 shall be void. This Agreement shall be binding on, and inure to the benefit of, each Party, and its permitted successors and assigns.

6.3 **Severability**. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use reasonable efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

6.4 **Notices**. All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by e-mail (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier, or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to TYME, to:	Tyme Technologies, Inc. 17 State Street – 7th Floor New York, NY 10004 Attention: Chief Executive Officer E-Mail: [***]
	With a copy to: Tyme Technologies, Inc. 17 State Street – 7th Floor New York, NY 10004 Attention: Chief Legal Officer E-Mail: [***]

if to Eagle, to:

Eagle Pharmaceuticals, Inc.
50 Tice Boulevard
Woodcliff Lake, NJ 07677
Attention: Executive Vice President & General Counsel
E-Mail: [***]

With a copy to:
Eagle Pharmaceuticals, Inc.
50 Tice Boulevard
Woodcliff Lake, NJ 07677
Attention: Chief Operating Officer & President
E-Mail: [***]

or to such other address(es) as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered if personally delivered; (b) on the Business Day after dispatch if sent by nationally-recognized overnight courier; or (c) on the fifth (5th) Business Day following the date of mailing, if sent by mail.

6.5 **Governing Law**. This Agreement and any and all matters arising directly or indirectly herefrom shall be governed by and construed and enforced in accordance with the internal laws of the State of Delaware applicable to agreements made and to be performed entirely in such state, including its statutes of limitation but without giving effect to the conflict of law principles thereof.

6.6 **Dispute Resolution**. If a dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith that (a) is expressly reserved for resolution pursuant to this Section 12.6 or (b) is outside of the decision-making authority of the SOC pursuant to Section 3.4 (a "**Dispute**"), then the Dispute shall be submitted to and finally settled by binding arbitration by JAMS under its Comprehensive Arbitration Rules and Procedures. A Dispute settled by an arbitrator shall be conducted by three arbitrators, each having ten years of experience in the pharmaceutical industry and also shall have served as an arbitrator at least three times prior to their service as an arbitrator in this arbitration. Within ten (10) days of commencement of an arbitration each Party shall select one (1) arbitrator and together select a third arbitrator who shall serve as a neutral arbitrator. The two designated arbitrators shall select a third neutral arbitrator within ten (10) days of their selection if the Parties cannot agree on the third arbitrator. If the two arbitrators cannot agree on selection of a third arbitrator within ten (10) days of their appointment, JAMS shall do so in accordance with its rules. The fees of the arbitrator(s) and JAMS shall be paid by the losing Party, which shall be designated by the arbitrator(s). If the arbitrator(s) is unable to designate a losing Party, it shall so state and the fees shall be split equally by the Parties. The arbitrator(s) is hereby empowered to award any remedy allowed by Law, including money damages, prejudgment interest and attorneys' fees, and to grant final, complete, interim or interlocutor relief, including injunctive relief. The Parties hereby submit to the exclusive jurisdiction of the federal and state courts located in Wilmington, Delaware for the purposes of an order to compel arbitration, for preliminary relief in aid of arbitration and for a preliminary injunction to maintain the status quo or prevent irreparable harm prior to the appointment of the arbitrators and to the non-exclusive jurisdiction of such courts for the enforcement of any ward issued hereunder.

6.7 **Waiver of Jury Trial**. EACH OF THE PARTIES HERETO IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.

6.8 **Entire Agreement; Amendments**. This Agreement, together with the Schedules and Exhibits hereto, contains the entire understanding of the Parties with respect to the subject matter hereof. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the subject matter hereof (including the Confidentiality Agreement, but solely with respect to information which is deemed Confidential Information hereunder) are superseded by the terms of this Agreement. The Exhibits and Schedules to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representative(s) of both Parties hereto.

6.9 **Headings**. The captions to the several Articles, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.

6.10 **Independent Contractors**. It is expressly agreed that Eagle and TYME shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Eagle nor TYME shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

6.11 **Third Party Beneficiaries**. Except as set forth in ARTICLE 10, no Person other than TYME or Eagle (and their respective Affiliates and permitted successors and assignees hereunder) shall be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.

6.12 **Waiver**. The waiver by either Party hereto of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise.

6.13 **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.

6.14 **Waiver of Rule of Construction**. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

6.15 **Use of Names**. Except as otherwise provided herein, neither Party shall have any right, express or implied, to use in any manner the name or other designation of the other Party or any other trade name, trademark or logo of the other Party for any purpose in connection with the performance of this

Agreement.

6.16 **Further Actions and Documents**. Each Party agrees to execute, acknowledge and deliver all such further instruments, and to do all such further acts, as may be reasonably necessary or appropriate to carry out the intent and purposes of this Agreement.

6.17 **Certain Conventions**. Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, or Exhibit shall be deemed to be a reference to an Article, Section, subsection, paragraph, clause, or Exhibit, of or to, as the case may be, this Agreement, unless otherwise indicated. Unless the context of this Agreement otherwise requires, (a) words of any gender include each other gender, (b) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (c) words using the singular shall include the plural, and vice versa, (d) whenever any provision of this Agreement uses the term "including" (or "includes"), such term shall be deemed to mean "including without limitation" (or "includes without limitations"), and (e) references to any Articles or Sections include Sections and subsections that are part of the references' Article or Section (e.g., a section numbered "Section 2.2.1" would be part of "Section 2.2", and references to "ARTICLE 2" or "Section 2.2" would refer to material contained in the subsection described as "Section 2.2.1").

6.18 **Counterparts**. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile or electronic mail (including pdf) and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes and shall have the same force and effect as original signatures.

[signature page follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

TYME TECHNOLOGIES, INC.

By: /s/ Steve Hoffman
Name: Steve Hoffman
Title: Chief Executive Officer

EAGLE PHARMACEUTICALS, INC.

By: /s/ Pete A. Meyers
Name: Pete A. Meyers
Title: Chief Financial Officer

Schedule 1.77
Exclusions from "Target Professionals"

Key Thought Leaders:

[***]

Schedule 4.1
Operating Parameters Schedule

(As in effect January 7, 2020)

Sales Force:

- Eagle shall provide an adequate sales force, as defined below under Sales Force Requirements, to call on community and hospital based health care providers. TYME will continue to be the exclusive contact with key opinion leaders and key academic researchers, who will be defined prior to the SM-88 launch.
- Sales Force Requirements:
  - o Eagle will be responsible for having sufficient SM-88 representatives to cover 25% of the Sales Force Requirements
    - § Eagle will have the sales representatives in place in time for appropriate training at least 90 days prior to the Target Launch Date
    - § The Eagle SM-88 sales representatives will have separate accounts from the TYME representatives as identified in the Sales Plan (as such term is defined in the Agreement)
    - § The Eagle SM-88 accounts will be identified prior to the acceptance of the NDA by the FDA
    - § The percentage of the Sales Force Requirement covered by the Eagle SM-88 representatives will be reviewed with the Sale Operations Committee, as defined below, after the initial 6 months following launch and may be increased upon committee agreement, however coverage over 25% of the Sales Force Requirements shall require the consent of Eagle
  - o The total sales force for SM-88 will be sized based on the following Sales Force Requirements:
    - § Reach: The key assumption is that the sales representatives will be detailing SM-88 to [***] Target Professionals (as defined in the Agreement) per week per representative, with the accounts to be identified prior to acceptance of the NDA by the FDA
      - Frequency: The accounts will be tiered based on Pancreatic Cancer patient volume. Accounts and the tiering will be defined prior to the acceptance of the NDA by the FDA. [***]
    - § The Sales Force Size requirement may be modified if there is a shift in reach and/or account tiering, which will be reviewed by the Sales Operations Committee, as defined in the Agreement
  - o TYME maintains the right to, on a reasonable basis, have its personnel accompany an Eagle sales representative during a detail, following appropriate advance notice
  - o Position of SM-88 in the Eagle detail: SM-88 must be considered the first call position for at least [***] of the calls for a multi-disciplinary oncologist account. SM-88 will be the sole detail for all calls that are focused on a gastrointestinal oncologist
  - o Minimum Sales Representatives Requirement: initial requirement and time period to which it will be applicable will be determined by TYME by reference to the Sales Force Requirements no later than three months prior to NDA filing
  - o Eagle Quarterly Minimum Details: initial requirement and time period to which it will be applicable will be determined by TYME by reference to the Sales Force Requirements no later than three months prior to NDA filing

Training:

- TYME will be responsible for training the Eagle sales force and for the creation of all sales training materials used by the Eagle team. As this material will be regulatory compliant, no changes can be made by Eagle without the written consent of TYME.
- Eagle sales representatives and their sales management will be required to complete mandatory training before detailing SM-88 to an account. This training will need to be completed prior to launch date of SM-88 with follow up quarterly training. Prior to the launch of SM-88, the training will be a live training. Subsequently, there will be at least 3 live trainings per year and the other training can be fulfilled via webcast. The training will include but is not limited to:
  - o Disease state education
  - o Current treatment education
  - o SM-88 clinical data education
  - o SM-88 prescribing information training
  - o SM-88 approved promotional materials
  - o Adverse Event Reporting
  - o Sales skills training
  - o Compliance training

Promotional Programs:

- In compliance with the PhRMA code and other guidelines (i.e. State guidelines), Eagle sales representatives will execute on promotional programs, utilizing the TYME approved presentation
- Eagle will be responsible for the delivery of the promotional programs to its SM-88 accounts and the cost associated with delivering the

programs

- The target number of promotional programs will be defined prior to launch and will be discussed at the Sales Operations Committee; Promotional Programs will be addressed in the Sales Plan (as updated from time to time)

Operating Principles:

- TYME also retains the right to have sales representatives promoting SM-88 and/or engaging in other co-promotion agreements, the co-promotion arrangement with Eagle shall not be exclusive
- Eagle is responsible for all costs associated with its sales force. This includes, but is not limited to:
  - Cash compensation (salary and incentives)
  - Benefits
  - Travel and related expenses
  - Training expenses, including but not limited to meeting facility, travel and lodging, meals, print materials, contests, awards
  - Sales detail print materials
  - Delivery of promotional programs

Schedule 4.1.2

<u>Qualifications and Criteria for Sales Representatives and their managers</u>

[TO BE JOINTLY DEVELOPED AND MUTUALLY AGREED BY TYME AND EAGLE]

Subsidiaries of Eagle Pharmaceuticals, Inc.

Name of Subsidiary	Jurisdiction of Incorporation
Eagle Biologics, Inc. (formerly Arsia Therapeutics, Inc.)	Delaware
Eagle Research Lab Limited	Malta

Consent of Independent Registered Public Accounting Firm

Eagle Pharmaceuticals, Inc.
Woodcliff Lake, New Jersey

We hereby consent to the incorporation by reference in the Registration Statement on Form S--3 (Nos. 333-234742 and 333-202592) and Form S-8 (Nos. 333-228876, 333-216839, 333-213683, 333-206729 and 333-194056) of Eagle Pharmaceuticals, Inc. (the “Company”) of our reports dated March 2, 2020, relating to the consolidated financial statements, and the effectiveness of the Company’s internal control over financial reporting, which appear in this Form 10-K.

/s/ BDO USA, LLP
Woodbridge, New Jersey
March 2, 2020

Exhibit 31.1

Certification of Principal Executive Officer

I, Scott Tarriff, certify that:

1. I have reviewed this annual report on Form 10-K of Eagle Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2020

/s/ Scott Tarriff

Scott Tarriff
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Principal Financial and Accounting Officer

I, Pete A. Meyers, certify that:

1. I have reviewed this annual report on Form 10-K of Eagle Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2020

/s/ Pete A. Meyers

Pete A. Meyers
Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 32.1

Certification Pursuant to

18 U.S.C. Section 1350,

As Adopted Pursuant to

Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), **Scott Tarriff**, President and Chief Executive Officer of Eagle Pharmaceuticals, Inc. (the “Company”), and **Pete A. Meyers**, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company’s Annual Report on Form 10-K for the period ended December 31, 2019 (the “Annual Report”), to which this Certification is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 2, 2020

/s/ Scott Tarriff	/s/ Pete A. Meyers
Scott Tarriff	Pete A. Meyers
Chief Executive Officer	Chief Financial Officer
(Principal Executive Officer)	(Principal Financial and Accounting Officer)

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Eagle Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.