UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2021

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 Stock Market LLC

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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 ☒ No ☐

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 the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 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. ☐

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

The number of shares outstanding of the registrant’s common stock as of November 2, 2021: 12,913,879 shares.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or this Quarterly Report, contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical fact contained in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "could," "will," "would," "should," "expect," "plan," "anticipate," "believe," "estimate," "intend," "predict," "seek," "contemplate," "project," "continue," "potential," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these identifying words. These forward-looking statements include, but are not limited to, statements about:

- the impact of the ongoing coronavirus 2019, or COVID-19, pandemic on our business and operations, results of operations and financial performance including: disruption in the sales of our marketed products; delays, interruptions or other adverse effects to clinical trials and patient enrollment; delays in regulatory review; manufacturing and supply chain interruptions; and the adverse effects on healthcare systems and disruption of the global economy overall;
- the potential benefits and commercial potential of rapidly infused bendamustine RTD, or Bendeka, Ryanodex® (dantrolene sodium), and bendamustine ready-to-dilute, or RTD, 500ml solution, or Belrapzo for approved indications and any expanded uses;
- sales of our products in various markets worldwide, pricing for our products, level of insurance coverage and reimbursement for our products, timing regarding development and regulatory approvals for our products or for additional indications or in additional territories;
- future expansion of our commercial organization and transition to third-parties in certain jurisdictions to perform sales, marketing and distribution functions;
- the number and timing of potential product launches, development initiatives or new indications for the Company's product candidates, and the commercial potential of additional indications for our products;
- the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development program;
- 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 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 diversion of healthcare resources away from the conduct of clinical trials as a result of the ongoing COVID-19 pandemic, including the diversion of hospitals and doctor offices serving as locations for administration of our products, including Bendeka and hospital staff supporting the conduct of such administration;
- the interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel, quarantines or social distancing protocols imposed or recommended by federal or state governments, employers and others in connection with the ongoing COVID-19 pandemic;
- the rate and degree of market acceptance of our products;
- our ability to significantly grow our commercial sales and marketing organization, whether alone or with potential future collaborators;
- the performance of our strategic partners and success of our current strategic partnerships and the timing and results of these partners' preclinical studies and clinical trials, including the Company's collaborations with its licensing partners SymBio, Combioxin SA and AOP Orphan Pharmaceuticals GmbH;
- 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 ability to obtain additional funding for our operations;
- our ability to obtain, maintain, protect and enhance intellectual property rights and proprietary technologies and operate our business without infringing the intellectual property rights and proprietary technology of third parties;
- our ability to prevent or minimize the effects of Paragraph IV patent litigation;
- our expectations regarding anticipated future costs, operating expenses and capital requirements;
- our expectations regarding our clinical trial, development plan and litigation matters for vasopressin; and
- our expectations regarding our submission of formal protocols for clinical study on fulvestrant (EA-114).

Any forward-looking statements in this Quarterly Report reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties, assumptions and other factors described under the "Risk Factors" section and elsewhere in this Quarterly Report, that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

In addition, statements such as "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, 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 as predictions of future events. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Quarterly Report also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

NOTE REGARDING COMPANY REFERENCES

References to the "Company," "Eagle Pharmaceuticals," "Eagle," "we," "us" or "our" mean Eagle Pharmaceuticals, Inc., a Delaware corporation, together with its subsidiaries, references to "Eagle Biologics" mean Eagle Biologics, Inc. and references to "Eagle Research Lab" means Eagle Research Lab Limited.

NOTE REGARDING TRADEMARKS

All trademarks, trade names and service marks appearing in this Quarterly Report are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this Quarterly Report may appear without the ® or TM symbols.

TABLE OF CONTENTS

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 99,741	$ 103,155
Accounts receivable, net	45,335	50,678
Inventories	9,315	8,075
Prepaid expenses and other current assets	17,303	4,157
Total current assets	171,694	166,065
Property and equipment, net	1,775	2,077
Intangible assets, net	10,799	12,917
Goodwill	39,743	39,743
Deferred tax asset, net	17,713	15,180
Other assets	14,537	17,208
Total assets	$ 256,261	$ 253,190
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 12,717	$ 6,268
Accrued expenses and other liabilities	27,714	23,817
Current portion of long-term debt	8,000	8,000
Total current liabilities	48,431	38,085
Other long-term liabilities	3,048	3,959
Long-term debt, less current portion	19,489	25,135
Total liabilities	70,968	67,179
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of September 30, 2021 and December 31, 2020	—	—
Common stock, $0.001 par value; 50,000,000 shares authorized; 16,886,123 and 16,739,203 shares issued as of September 30, 2021 and December 31, 2020, respectively	17	17
Additional paid in capital	320,566	305,403
Accumulated other comprehensive loss	(882)	—
Retained earnings	82,058	84,489
Treasury stock, at cost, 3,941,541 and 3,682,176 shares as of September 30, 2021 and December 31, 2020, respectively	(216,466)	(203,898)
Total stockholders' equity	185,293	186,011
Total liabilities and stockholders' equity	$ 256,261	$ 253,190

See accompanying notes to condensed consolidated financial statements (unaudited).

EAGLE PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)
(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Revenue:				
Product sales, net	$ 12,124	$ 17,317	$ 48,865	$ 49,387
Royalty revenue	27,729	27,611	80,361	83,499
License and other revenue	—	5,000	—	5,000
Total revenue	39,853	49,928	129,226	137,886
Operating expenses:				
Cost of product sales	5,486	8,726	21,835	23,804
Cost of royalty revenue	2,773	3,260	8,036	9,120
Research and development	23,289	4,828	47,488	21,390
Selling, general and administrative	18,482	17,697	54,997	60,411
Total operating expenses	50,030	34,511	132,356	114,725
(Loss) income from operations	(10,177)	15,417	(3,130)	23,161
Interest income	197	46	395	542
Interest expense	(396)	(489)	(1,240)	(2,164)
Other expense	(2,284)	(6,049)	(1,797)	(10,249)
Total other expense, net	(2,483)	(6,492)	(2,642)	(11,871)
(Loss) income before income tax benefit (provision)	(12,660)	8,925	(5,772)	11,290
Income tax benefit (provision)	7,038	(1,866)	3,341	(7,358)
Net (loss) income	$ (5,622)	$ 7,059	$ (2,431)	$ 3,932
(Loss) earnings per share attributable to common stockholders:				
Basic	$ (0.43)	$ 0.52	$ (0.19)	$ 0.29
Diluted	$ (0.43)	$ 0.51	$ (0.19)	$ 0.28
Weighted average number of common shares outstanding:				
Basic	13,077,298	13,531,372	13,103,203	13,620,981
Diluted	13,077,298	13,786,803	13,103,203	13,917,800

See accompanying notes to condensed consolidated financial statements (unaudited).

EAGLE PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS) (UNAUDITED)
(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net (loss) income	$ (5,622)	$ 7,059	$ (2,431)	$ 3,932
Other comprehensive income (loss), net of tax:				
Unrealized gain (loss) for convertible promissory note	22	—	(882)	—
Total other comprehensive income (loss)	22	—	(882)	—
Comprehensive (loss) income	$ (5,600)	$ 7,059	$ (3,313)	$ 3,932

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

	Common Stock						
	Number of Shares	Amount	Additional Paid-In Capital	Treasury Stock	Accumulated Other Comprehensive (Loss) Income	Retained Earnings	Total Stockholders' Equity
Balance at June 30, 2021	16,880	$ 17	$ 316,249	$ (208,195)	$ (904)	$ 87,680	$ 194,847
Stock-based compensation expense	—	—	4,084	—	—	—	4,084
Issuance of common stock upon exercise of stock option grants	6	—	233	—	—	—	233
Common stock repurchases	—	—	—	(8,271)	—	—	(8,271)
Other comprehensive income	—	—	—	—	22	—	22
Net (loss)	—	—	—	—	—	(5,622)	(5,622)
Balance at September 30, 2021	16,886	$ 17	$ 320,566	$ (216,466)	$ (882)	$ 82,058	$ 185,293

	Common Stock						
	Number of Shares	Amount	Additional Paid-In Capital	Treasury Stock	Accumulated Other Comprehensive Loss	Retained Earnings	Total Stockholders' Equity
Balance as of December 31, 2020	16,739	$ 17	$ 305,403	$ (203,898)	$ —	$ 84,489	$ 186,011
Stock-based compensation expense	—	—	14,873	—	—	—	14,873
Issuance of common stock upon exercise of stock option grants	84	—	1,841	—	—	—	1,841
Issuance of common stock related to vesting of restricted stock units	63	—	(1,551)	—	—	—	(1,551)
Common stock repurchases	—	—	—	(12,568)	—	—	(12,568)
Other comprehensive loss	—	—	—	—	(882)	—	(882)
Net (loss)	—	—	—	—	—	(2,431)	(2,431)
Balance as of September 30, 2021	16,886	$ 17	$ 320,566	$ (216,466)	$ (882)	$ 82,058	$ 185,293

	Common Stock					
	Number of Shares	Amount	Additional Paid-In Capital	Treasury Stock	Retained Earnings	Total Stockholders' Equity
Balance at June 30, 2020	16,622	$ 17	$ 291,434	$ (176,860)	$ 69,373	$ 183,964
Stock-based compensation expense	—	—	4,722	—	—	4,722
Issuance of common stock upon exercise of stock option grants	3	—	42	—	—	42
Payment of employee withholding tax upon vesting of stock-based awards	—	—	—	—	—	—
Issuance of common stock related to vesting of restricted stock units	—	—	—	—	—	—
Common stock repurchases	—	—	—	(23,000)	—	(23,000)
Net income	—	—	—	—	7,059	7,059
Balance at September 30, 2020	16,625	$ 17	$ 296,198	$ (199,860)	$ 76,432	$ 172,787

	Common Stock					
	Number of Shares	Amount	Additional Paid-In Capital	Treasury Stock	Retained Earnings	Total Stockholders' Equity
Balance at December 31, 2019	16,538	$ 17	$ 278,518	$ (171,861)	$ 72,500	$ 179,174
Stock-based compensation expense	—	—	18,435	—	—	18,435
Issuance of common stock upon exercise of stock option grants	42	—	555	—	—	555
Payment of employee withholding tax upon vesting of stock-based awards	—	—	(1,310)	—	—	(1,310)
Issuance of common stock related to vesting of restricted stock units	45	—	—	—	—	—
Common stock repurchases	—	—	—	(27,999)	—	(27,999)
Net income	—	—	—	—	3,932	3,932
Balance at September 30, 2020	16,625	$ 17	$ 296,198	$ (199,860)	$ 76,432	$ 172,787

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2021	**2020**
Cash flows from operating activities:		
Net (loss) income	$ (2,431)	$ 3,932
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Deferred income taxes	(2,533)	(1,671)
Depreciation expense	575	656
Noncash operating lease expense related to right-of-use assets	768	980
Amortization expense of intangible assets	2,118	1,999
Fair value adjustments on equity investment	1,900	7,700
Stock-based compensation expense	14,873	18,435
Convertible promissory note related credit losses	150	—
Amortization of debt issuance costs	354	301
Fair value adjustments related to derivative instrument	(254)	2,549
Accretion of discount on convertible promissory note	(102)	—
Changes in operating assets and liabilities which provided (used) cash:		
Accounts receivable	5,343	(4,195)
Inventories	(1,240)	(20)
Prepaid expenses and other current assets	(8,821)	(2,774)
Accounts payable	6,449	7,606
Accrued expenses and other liabilities	3,897	(3,916)
Other assets and other long-term liabilities, net	(908)	(1,845)
Net cash provided by operating activities	20,138	29,737
Cash flows from investing activities:		
Purchase of equity investment security	—	(17,500)
Purchase of property and equipment	(274)	(577)
Purchase of convertible promissory note	(5,000)	—
Net cash used in investing activities	(5,274)	(18,077)
Cash flows from financing activities:		
Proceeds from common stock option exercises	1,841	555
Employee withholding taxes related to stock-based awards	(1,551)	(1,310)
Proceeds from existing revolving credit facility	—	110,000
Repayment of existing revolving credit facility	—	(110,000)
Payment of debt	(6,000)	(3,000)
Repurchases of common stock	(12,568)	(27,999)
Net cash used in financing activities	(18,278)	(31,754)
Net decrease in cash and cash equivalents	(3,414)	(20,094)
Cash and cash equivalents at beginning of period	103,155	109,775
Cash and cash equivalents at end of period	$ 99,741	$ 89,681
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Income taxes, net	$ 6,303	$ 3,036
Interest	917	1,878
Right-of-use asset obtained in exchange for lease obligation - lease amendment	—	842

See accompanying notes to condensed consolidated financial statements (unaudited).

1. Basis of Presentation and Other Company Information

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”) for interim information and pursuant to the rules and regulations of the Securities and Exchange Commission (“SEC”) for reporting quarterly information. Accordingly, certain information and footnote disclosures required for complete financial statements are not included herein. The condensed consolidated balance sheet at December 31, 2020 was derived from audited financial statements, but certain information and footnote disclosures normally included in our annual consolidated financial statements have been condensed or omitted. In the opinion of management, all adjustments (consisting only of normal recurring adjustments) necessary for the fair presentation of the financial information for the interim periods reported have been made. Results of operations for the three and nine months ended September 30, 2021 are not necessarily indicative of the results for the year ending December 31, 2021 or any period thereafter. These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited financial statements and related notes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, filed with the SEC on March 5, 2021.

We are an integrated pharmaceutical company focused on finding ways to help medicines do more for patients. We and our collaborators have the capabilities to take a molecule from preclinical research through regulatory approval and into the marketplace, including development, manufacturing and commercialization. Our business model applies our scientific expertise, proprietary research-based insights and marketplace proficiency to identify challenging-to-treat diseases of the central nervous system or metabolic critical care therapeutic areas as well as in oncology. By focusing on patients' unmet needs, we strive to provide healthcare professionals with urgently needed treatment solutions that are designed to improve patient care and outcomes and create near- and long-term value for our stakeholders, including patients and healthcare providers and our employees, marketing partners, collaborators and investors. Our science-based business model has a proven track record with U.S. Food and Drug Administration ("FDA") approval and commercial launches of three products: Ryanodex® (dantrolene sodium) ("Ryanodex"), bendamustine ready-to-dilute ("RTD") 500ml solution ("Belrapzo"), and rapidly infused bendamustine RTD ("Bendeka"). We market our products through marketing partners and/or our internal direct sales force. We market Ryanodex and Belrapzo, and Teva Pharmaceutical Industries Ltd. ("Teva") markets Bendeka through its subsidiary Cephalon, Inc. SymBio Pharmaceuticals Limited, or SymBio, markets Treakisym, a RTD product, in Japan. Reflecting further expansion of our oncology portfolio, in February 2020, we received final FDA approval for Pemfexy, a branded alternative to Alimta for metastatic non-squamous non-small cell lung cancer and malignant pleural mesothelioma.

With several pipeline projects underway and the potential for up to five product launches over the next several years, we believe we have many growth opportunities ahead. We believe that each of our pipeline projects currently has the potential to enter the market as a first-in-class, first-to-file, first-to-market or best-in-class product. In particular, we are applying our expertise to conduct novel research regarding the potential for Ryanodex to address conditions including Alzheimer’s disease, traumatic brain injury/concussion, nerve agent exposure and acute radiation syndrome. In addition, our clinical development program includes a strategic partnership with Tyme Technologies, Inc., or Tyme, for Tyme’s product candidate for the treatment of patients with pancreatic or other advanced cancers, SM-88, as well as investigations of compounds such as EA-114 (our fulvestrant product candidate) for patients with HR-positive advanced breast cancer. Other products in development include Vasopressin, our first-to-file Abbreviated New Drug Application, or ANDA, that references Endo International plc’s Vasostrict indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines; and EA-111, a new chemical entity and next-generation ryanodine receptor antagonist, in an intramuscular formulation that that would allow for easier and more rapid administration in emergency situations (military and civilian).

2. Summary of Significant Accounting Policies

Significant Accounting Policies

Our significant accounting policies are described in the audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2020 and the notes thereto filed with the SEC on March 5, 2021. Since the date

of those consolidated financial statements, there have been no material changes to our significant accounting policies other than as listed below.

Significant Risks and Uncertainties

In response to the ongoing COVID-19 pandemic, we have taken and continue to take active measures designed to address and mitigate the impact of the COVID-19 pandemic on our business, such as remote working policies, facilitating management's periodic communication to address employee and business concerns and providing frequent updates to our Board of Directors ("Board"). During the second quarter of 2021, we implemented a plan to reopen our office to allow employees to return to the office, with a focus on employee safety and optimal work environment. Our management continues to monitor and evaluate such plans as the pandemic continues to evolve. We anticipate that the COVID-19 pandemic may also have an impact on the clinical development timelines for certain of our clinical programs. We also anticipate that the COVID-19 pandemic may have an impact on our supply chain. The COVID-19 pandemic and associated lockdowns have resulted in a decrease in healthcare utilization broadly and specifically lead to a continuing reduction in the utilization of physician-administered oncology products including Belrapzo and Bendeka. In addition, the COVID-19 pandemic has delayed the timing of certain litigation, including the litigation with Par (as defined below) with respect to Vasopressin, and we anticipate that such delays will continue for the duration of the pandemic. The extent to which the COVID-19 pandemic will continue to impact our business, clinical development and regulatory efforts, supply chain and sales efforts, corporate development objectives and the value of, and market for, our common stock will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States, and other countries, and the effectiveness of actions taken globally to contain and treat the disease. The global economic slowdown, the overall disruption of global healthcare systems and other risks and uncertainties associated with the pandemic have impacted our operations and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition, we are subject to other challenges and risks specific to our business and our ability to execute on our business plan and strategy, as well as risks and uncertainties common to companies in the pharmaceutical industry with research and development operations, including, without limitation, risks and uncertainties associated with: delays or problems in obtaining clinical supply; obtaining regulatory approval of product candidates; loss of single source suppliers or failure to comply with manufacturing regulations; identifying, acquiring or in-licensing additional products or product candidates; product development and the inherent uncertainty of clinical success; the challenges of protecting and enhancing intellectual property rights; and the challenges of complying with applicable regulatory requirements. In addition, as the ongoing COVID-19 pandemic affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties discussed above.

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 condensed 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. Our critical accounting policies are those that are both most important to our 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. We anticipate that the COVID-19 pandemic will continue to disrupt our supply chain and marketing and sales efforts for certain of our products, including Bendeka, although it is not currently expected that any disruption would be significant. As of the date of issuance of these financial statements, we are not aware of any specific event or circumstance that would require us to update our estimates, assumptions and judgments or revise the carrying value of our assets or liabilities. 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, and any such differences may be material to our financial statements.

Reclassifications

Certain reclassifications have been made to prior year amounts to conform with the current year presentation, including for amounts related to accounts receivable, net and prepaid expenses and other current assets. None of the amounts pertaining to the reclassifications were significant.

Cash and Cash Equivalents

We consider 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.

We, at times, maintain balances with financial institutions in excess of the Federal Deposit Insurance Corporation ("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.

Financial assets and liabilities measured and recognized at fair value are as follows:

	September 30, 2021			
	Total	**Level 1**	**Level 2**	**Level 3**
Assets:				
Money market funds	$ 95,255	$ 95,255	$ —	$ —
Convertible promissory note	3,795	—	—	3,795
Embedded derivative asset in convertible promissory note	530	—	—	530
Investment in Tyme	10,300	10,300	—	—
Total financial assets	$ 109,880	$ 105,555	$ —	$ 4,325

	December 31, 2020			
	Total	**Level 1**	**Level 2**	**Level 3**
Assets:				
Money market funds	$ 79,682	$ 79,682	$ —	$ —
Investment in Tyme	12,200	12,200	—	—
Total financial assets	$ 91,882	$ 91,882	$ —	$ —

We recognize transfers between levels within the fair value hierarchy, if any, at the end of each quarter. There were no transfers in or out of Level 1, Level 2 or Level 3 during the three months or nine months ended September 30, 2021 and 2020, respectively.

Our investment in the convertible promissory note and the embedded derivative are classified as Level 3. We analyzed and accessed the embedded derivative feature contained in the convertible promissory note agreement. We used a probability factor to value the embedded derivative asset based on management's best estimate, including the principal and estimated accrued interest among other contractual terms. The convertible promissory note is accounted for as available for sale. The convertible promissory note is reported at fair value with unrealized gains and losses included in Accumulated other comprehensive income (loss). Refer to Note 13, Convertible Promissory Note for further details.

Our investment in restricted shares of common stock of Tyme Technologies, Inc.are classified as Level 1. Refer to Note 12, License and Collaboration Agreements for further details.

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

Intangible Assets

We review the recoverability of our finite-lived intangible assets and long-lived assets for indicators of impairments. Events or circumstances that may require an impairment assessment include negative clinical trial results, a significant decrease in the market price of the asset, or a significant adverse change in legal factors or the manner in which the asset is used. If such indicators are present, we assess the recoverability of affected assets by determining if the carrying value of such assets is less than the sum of the undiscounted future cash flows of the assets. If such assets are found to not be recoverable, we measure the amount of the impairment by comparing to the carrying value of the assets to the fair value of the assets. The Company determined that no indicators of impairment of finite-lived intangible assets or long-lived assets existed as of September 30, 2021.

Goodwill

Goodwill represents the excess of purchase price over the fair value of net assets acquired in the Eagle Biologics 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 its carrying amount. We did not identify any impairment to goodwill during the periods presented.

Concentration of Major Customers and Vendors

We are dependent on our commercial partner, Teva, who markets and sells Bendeka. Our customer for Bendeka is our commercial and licensing partner; therefore, our future revenues are highly dependent on the related exclusive license and distribution arrangement.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Total revenues				
Teva - See *Revenue Recognition*	69 %	74 %	66 %	72 %
Other	31 %	26 %	34 %	28 %
	100 %	100 %	100 %	100 %

	September 30, 2021	December 31, 2020
Accounts receivable		
Teva - See *Revenue Recognition*	63 %	58 %
Other	37 %	42 %
	100 %	100 %

Inventories

Inventories are recorded at the lower of cost and net realizable value, with cost determined on a first-in first-out basis. We periodically review the composition of inventory in order to identify obsolete, slow-moving or otherwise non-saleable items. If non-saleable items are observed and there are no alternate uses for the inventory, we will record a write-down to lower of cost and net realizable value in the period that the decline in value is first recognized.

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 in licensing intellectual property related to new projects, 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 us by our 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 condensed 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 $0.5 million and $0.3 million for the three months ended September 30, 2021 and 2020, respectively, and $1.3 million and $2.2 million for the nine months ended September 30, 2021 and 2020, respectively.

Income Taxes

We account for income taxes using the liability method in accordance with Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”), 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 (loss) 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 a 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 - Revenue from Contracts with Customers ("ASC 606"), we perform 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. We only apply 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, we assess the goods or services promised within each contract and determines those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize 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. 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.

Product revenue - We recognize net revenue on sales to our commercial partners and to end users. In each instance, revenue is generally recognized when the customer obtains control of our 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 Bendeka and Treakisym. Sales to our commercial partners are presented gross because we are primarily responsible for fulfilling the promise to provide the product, and are responsible to ensure that the product is produced in accordance with the related supply agreement and we bear risk of loss while the inventory is in-transit to the commercial partner.

Revenue is measured as the amount of consideration we expect to receive in exchange for transferring products or services to a customer. To the extent the transaction price includes variable consideration, we estimate the amount of variable consideration that should be included in the transaction price utilizing the expected value method to which we expect to be entitled. As such, revenue on sales to customers 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. We have a product return policy on some of our 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. Our 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. We have terms on sales of Ryanodex by which we do not accept returns. Variable consideration is included in the transaction price if, in our 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 our anticipated performance and all information (historical, current and forecasted) that is reasonably available. We believe that the estimates we have 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.

Components of Gross-to-Net (GTN) Estimates

Chargebacks: Chargebacks are discounts that occur when certain contracted customers, including group purchasing organizations ("GPOs"), public health service institutions and federal government entities purchasing via the Federal Supply Schedule, purchase from our distributors. Our distributors purchase product from us at invoice price, then resell the product to certain contracted customers on the basis of prices negotiated between us and the providers. The difference between the distributors' purchase price and the typically lower certain contracted customers' purchase price is refunded to the distributors through a chargeback credit. We record estimates for these chargebacks at the time of sale as deductions from gross revenues, with corresponding adjustments to our accounts receivable reserves and allowances.

The provision for chargebacks is the most significant provision in the context of our gross-to-net adjustments in the determination of net revenue. Chargebacks are estimated based on payer mix and contracted price, adjusted for current period assumptions.

Commercial and Medicaid Rebates: We contract with government agencies or collectively, third-party payors, so that Belrapzo and Ryanodex will be eligible for purchase by, or partial or full reimbursement from, such third-party payors. We estimate the rebates we will provide to third-party payors and deducts these estimated amounts from total gross product revenues at the time the revenues are recognized. These reserves are recorded in the same period in which the revenue is recognized, resulting in a

reduction of product revenue and the establishment of a current liability. The current liability is included in accrued expenses and other current liabilities on the consolidated balance sheets. We estimate the rebates that we will provide to third-party payors based upon (i) our contracts with these third-party payors, (ii) the government mandated discounts applicable to government-funded programs, (iii) a range of possible outcomes that are probability-weighted for the estimated payer mix, and (iv) information obtained from our distributors.

The information that we also consider when establishing our rebate reserves are purchases by customers, projected annual sales for customers, actual rebates payments made, processing time lags, and for indirect rebates, the level of inventory in the distribution channel that will be subject to indirect rebates. We do not provide incentives designed to increase shipments to our customers that we believe would result in out-of-the-ordinary course of business inventory for them. We regularly review and monitor estimated or actual customer inventory information at our largest distributors for our key products to ascertain whether customer inventories are in excess of ordinary course of business levels.

Product Returns: Our distributors have the right to return unopened unprescribed Belrapzo during certain time periods around the period beginning prior to the labeled expiration date and ending after the labeled expiration date. We estimate future product returns on sales of Belrapzo based on: (i) data provided to us by our distributors (including weekly reporting of distributors' sales and inventory held by distributors that provided us with visibility into the distribution channel in order to determine what quantities were sold to retail pharmacies and other providers), (ii) information provided to us from retail pharmacies, (iii) data provided to us by a third-party data provider which collects and publishes prescription data, and other third parties, (iv) historical industry information regarding return rates for similar pharmaceutical products, (v) the estimated remaining shelf life of Belrapzo previously shipped and currently being shipped to distributors and (vi) contractual agreements intended to limit the amount of inventory maintained by our distributors. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets.

Our provision for product returns based on the factors noted above generally encompass a time range from 12 to 48 months after revenue is recognized. Additionally, we consider other factors when estimating our current period return provision, including levels of inventory in the distribution channel, significant market changes that may impact future expected returns, and actual product returns, and may record additional provisions for specific returns that it believes are not covered by the historical rates. Our commercial returns policy and terms with certain customers also states that certain products are sold as non-returnable.

Wholesaler fees and other incentives: We generally provide invoice discounts on Belrapzo and Ryanodex sales to our distributors for prompt payment and fees for distribution services, such as fees for certain data that distributors provide to us. The payment terms for sales to distributors generally include a 2% discount for prompt payment which is generally defined in invoice terms as a range from 30 to 70 days, while the fees for distribution services are based on contractual rates agreed with the respective distributors. Based on historical data, we expect our distributors to earn these discounts and fees, and deducts the full amount of these discounts and fees from our gross product revenues and accounts receivable at the time such revenues are recognized.

Other GTN considerations

We may at our discretion provide price adjustments due to various competitive factors. There are circumstances under which we may not provide price adjustments to certain customers as a matter of business strategy, and consequently may lose future sales volume to competitors and risk a greater level of product returns.

As detailed above, we have the experience and access to relevant information that we believe are necessary to reasonably estimate the amounts of such deductions from gross revenues. Some of the assumptions we use for certain of these estimates are based on information received from third parties, such as wholesale customer inventories and market data, or other market factors beyond our control. The estimates that are most critical to the establishment of these reserves, and therefore, would have the largest impact if these estimates were not accurate, are estimates related to contract sales volumes, average contract pricing, customer inventories and return volumes. We regularly review the information related to these estimates and adjust our reserves accordingly, if and when actual experience differs from previous estimates. With the exception of the product returns allowance, the ending balances of accounts receivable reserves and allowances generally are processed during a two-month to four-month period.

Royalty Revenue — We recognize revenue from license arrangements with our 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. Our commercial partners are obligated to report their net product sales and the resulting royalty due to us within 25 days for Bendeka. Based on historical product sales, royalty receipts and other relevant information, we accrue royalty revenue each quarter and subsequently determine a true-up when we receive royalty reports from our commercial partners. Historically, these true-up adjustments have been immaterial.

License and other revenue — We analyze each element of our 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. We recognize 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. We determine 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, we estimate the standalone selling price taking into account available information such as market conditions and internally approved pricing guidelines related to the performance obligations.

We recognize 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, we 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, we assess each milestone to determine the probability and substance behind achieving each milestone. Given the inherent uncertainty of the occurrence of these future events, we 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, we do not assess whether a significant financing component exists if the period between when we perform our obligations under the contract and when the customer pays is one year or less. None of our contracts contained a significant financing component as of September 30, 2021.

Stock-Based Compensation

We account 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.

We account for stock-based compensation by measuring and recognizing compensation expense for all stock-based payments made to employees and directors based on estimated grant date fair values. 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 our stock option awards to employees and directors is estimated using the Black-Scholes valuation model and a Monte Carlo simulation model is used to estimate the fair value for market condition share units. These models require the input of subjective assumptions, including the expected stock price volatility, the calculation of expected term, historical 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. The fair value of restricted stock units ("RSUs") granted are estimated based on the trading price of our common stock on the date of grant. The fair value of performance condition performance-based stock units ("PSUs") granted are also estimated based on the trading price of our common stock on the date of grant and adjusted for the probability of achievement of the performance conditions. Forfeitures are estimated for all stock-based awards.

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 share equivalents outstanding for the three and nine months ended September 30, 2021 and 2020 were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Stock options	2,446,657	3,156,166	2,777,995	2,905,021
Restricted stock units	—	205,891	123,600	225,177
Total	2,446,657	3,362,057	2,901,595	3,130,198

The following table sets forth the computation for basic and diluted net (loss) earnings per share for the three and nine months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Numerator				
Numerator for basic and diluted (loss) earnings per share-net (loss) earnings	$ (5,622)	$ 7,059	$ (2,431)	$ 3,932
Denominator				
Basic weighted average common shares outstanding	13,077,298	13,531,372	13,103,203	13,620,981
Dilutive effect of stock awards	—	255,431	—	296,819
Diluted weighted average common shares outstanding	13,077,298	13,786,803	13,103,203	13,917,800
Basic net (loss) earnings per share				
Basic net (loss) earnings per share	$ (0.43)	$ 0.52	$ (0.19)	$ 0.29
Diluted net (loss) earnings per share				
Diluted net (loss) earnings per share	$ (0.43)	$ 0.51	$ (0.19)	$ 0.28

All potentially dilutive items were excluded from the diluted share calculation for the three months and nine months ended September 30, 2021 because their effect would have been anti-dilutive, as the Company was in a loss position.

Recent Accounting Pronouncements

Recent Accounting Pronouncements - Not Yet Adopted

In March 2020, the FASB issued Update 2020-04 Reference Rate Reform (Topic 848), Facilitation of the Effects of Reference Rate Reform on Financial Reporting to provide temporary optional guidance to ease the potential burden in accounting for

reference rate reform. The amendments in Update 2020-04 are elective and apply to all entities that have contracts, hedging relationships, and other transactions that reference LIBOR, formerly known as the London Interbank Offered Rate,
or another reference rate expected to be discontinued due to reference rate reform. The new guidance provides optional expedients, including; (1) Simplify accounting analyses under current GAAP for contract modifications, such as modifications of contracts within the scope of Topic 470, Debt, that will be accounted for by prospectively adjusting the effective interest rate, as if any modification was not substantial. That is, the original contract and the new contract shall be accounted for as if they were not substantially different from one another; (2) Simplify the assessment of hedge effectiveness and allow hedging relationships affected by reference rate reform to continue; (3) Allow a one-time election to sell or transfer debt securities classified as held to maturity before January 1, 2020 that reference a rate affected by reference rate reform. The amendments are effective for all entities from the beginning of an interim period that includes the issuance date of the ASU. An entity may elect to apply the amendments prospectively through December 31, 2022. The adoption of ASU 2020-4 is not expected to have a material impact on our financial position or results of operations.

3. Property and Equipment, net

Property and equipment consisted of the following:

	September 30, 2021	December 31, 2020	Estimated Useful Life (years)
Furniture and fixtures	$ 1,476	$ 1,476	7
Office equipment	1,077	1,152	3
Equipment	3,834	3,485	7
Leasehold improvements	1,155	1,155	2
	7,542	7,268	
Less accumulated depreciation	(5,767)	(5,191)	
Property and equipment, net	$ 1,775	$ 2,077	

Depreciation expense related to property and equipment amounted to $197 and $196 for the three months ended September 30, 2021 and 2020, respectively, and $575 and $656 for the nine months ended September 30, 2021 and 2020, respectively.

4. Inventories

Inventories consist of the following:

	September 30, 2021	December 31, 2020
Raw materials	$ 6,006	$ 3,515
Work in process	1,309	2,589
Finished products	2,000	1,971
Total inventories	$ 9,315	$ 8,075

5. Balance Sheet Accounts

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	September 30, 2021	December 31, 2020
Prepaid income taxes	$ 5,898	$ —
Prepaid FDA user fee and advances to clinical research organization	1,478	1,262
Prepaid insurance	468	191
Advances to commercial manufacturers	734	660
Receivable from commercial partner	1,746	439
Convertible promissory note, net	4,551	—
All other	2,428	1,605
Total prepaid expenses and other current assets	$ 17,303	$ 4,157

Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2021	December 31, 2020
Accrued sales reserves	$ 3,046	$ 4,966
Royalties payable to commercial partners	4,879	5,996
Accrued salary and other compensation	5,255	4,686
Accrued professional fees	2,552	2,370
Accrued research & development	8,528	2,724
Current portion of lease liability	1,199	1,123
Accrued other	2,255	1,952
Total accrued expenses	$ 27,714	$ 23,817

Leases

We lease office space in Woodcliff Lake, New Jersey for our principal office under an amended lease agreement through June 2025. We also lease a lab space in Cambridge, Massachusetts under a lease agreement through April 2024. Both of our leases are classified as operating leases and have remaining lease terms of approximately 3.3 years. The principal office and the lab space leases include renewal options to extend the lease for up to 5 years. Furthermore, we have not elected the practical expedient to separate lease and non-lease components for all classes of underlying assets.

The table below summarizes our total lease costs included in the condensed consolidated financial statements, as well as other required quantitative disclosures (in thousands):

	September 30, 2021	December 31, 2020
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows for operating leases	$ 1,040	$ 1,323
Right-of-use assets obtained in exchange for new operating lease liabilities	$ —	$ 855
Weighted-average remaining lease term - operating leases	3.3 years	4.1 years
Weighted-average discount rate - operating leases	6.0 %	6.0 %

Balance Sheet Classification as of September 30:	
Current lease liabilities (included with Accrued Expenses and other liabilities)	$ 1,199
Long-term lease liabilities (included with Other long-term liabilities)	3,048
Total lease liabilities	$ 4,247

6. Intangible Assets, Net

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

		September 30, 2021		
	Useful Life (In Years)	**Gross Carrying Amount**	**Accumulated Amortization**	**Net Book Value**
Ryanodex intangible *(i)*	20	$ 15,000	$ (4,404)	$ 10,596
Developed technology	5	8,100	(7,897)	203
Total		$ 23,100	$ (12,301)	$ 10,799

		December 31, 2020		
	Useful Life (In Years)	**Gross Carrying Amount**	**Accumulated Amortization**	**Net Book Value**
Ryanodex intangible *(i)*	20	15,000	(3,500)	11,500
Developed technology	5	8,100	(6,683)	1,417
Total		$ 23,100	$ (10,183)	$ 12,917

(i) Represents a one-time payment made to reduce the royalties payable to a third party on Ryanodex net sales.

Amortization expense was $706 and $667 for the three months ended September 30, 2021 and 2020, respectively and $2,118 and $1,999 for the nine months ended September 30, 2021 and 2020, respectively.

Estimated Amortization Expense for Intangible Assets

Based on definite-lived intangible assets recorded as of September 30, 2021, and assuming that the underlying assets will not be impaired and that we will not change the expected lives of the assets, future amortization expenses are estimated as follows:

	Estimated Amortization Expense
Year Ending December 31,	
2021 (remainder)	504
2022	1,369
2023	1,570
2024	1,898
2025	1,520
Thereafter	3,938
Total estimated amortization expense	$ 10,799

7. Common Stock and Stock-Based Compensation

Common Stock

Share Repurchase Program

On March 17, 2020, we announced that our Board approved a new share repurchase program, or the Share Repurchase Program, providing for the repurchase of up to an aggregate of $160 million of our outstanding common stock. The Share Repurchase Program replaced our then existing share repurchase program, or the Previous Share Repurchase Program, which was announced on October 30, 2018 and was terminated in connection with the Board's approval of the Share Repurchase Program. At termination, we had repurchased approximately $68 million of our outstanding common stock under the Previous Share Repurchase Program.

Under the Share Repurchase Program, we are 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. The 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 our cash resources.

On September 23, 2020, our Board of Directors approved a $25 million accelerated share repurchase ("ASR") transaction with JPMorgan Chase Bank, National Association ("JP Morgan") as part of our existing $160 million share repurchase program. The specific number of shares to be repurchased pursuant to the ASR is based on the average of the daily volume weighted average share prices of our common stock, less a discount, during the term of the ASR program. Under the terms of our agreement with JP Morgan, we paid $25 million to JP Morgan on September 24, 2020, and received 550,623 shares, representing the notional amount of the ASR, based on the average of the daily volume weighted average share prices of our common stock, less a discount, during the term of the ASR, which was $45.40. The ASR was completed in the fourth quarter of 2020. We determined the ASR contained a forward contract and therefore we recorded fair value adjustments on the accelerated share repurchase agreement in the amount of $3 million which was a loss recorded in Other expense on our consolidated statements of operations in the year ended December 31, 2020.

As of September 30, 2021, we had repurchased an aggregate of 3,941,541 shares of common stock for an aggregate of $219.5 million pursuant to our share repurchase programs in effect since August 2016.

Stock-Based Compensation

In November 2013, our Board of Directors approved the 2014 Equity Incentive Plan (the "2014 Plan") which became effective on February 11, 2014. 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 may be 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.

During the first quarter of 2018, we introduced a new long-term incentive program with the objective to better align the stock-based awards granted to management with our focus on improving total shareholder return over the long-term. The stock-based awards granted under this long-term incentive program consist of time-based stock options, time-based RSUs and PSUs. PSUs are comprised of awards: i) that would have vested upon achievement of certain share price appreciation conditions or ii) that would have vested upon achievement of certain milestone events. These PSUs expired in the first quarter of 2021.

During the first quarter of 2021, 97,750 market condition PSUs expired. We also granted 99,500 market condition PSUs based on our total shareholder return ("TSR") relative to the TSR of each member of the S&P Biotechnology Select Industry Index (the defined peer group) with a weighted-average grant date fair value of $71.09 per respective PSU. 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 0.18%, an expected volatility of 44%, contractual term of 3 years, and no expected dividend yield.

During the first quarter of 2021, we also granted 59,500 performance based (milestones) PSUs with grant date fair value of $49.32 using our closing stock price on the date of the grant. These PSUs will vest (if earned) from 0% to 200% of target number granted based on the achievement of one or more of three milestones related to i) regulatory approval of Fulvestrant ("EA-114"), ii) sales of Pemfexy and; iii) sales of Vasopressin, respectively. The contractual term of these awards is 3 years. We estimated 0% probability of achievement for the year-to-date period of 2021.

A summary of stock option, RSU and PSU activity under the 2014 Plan during the nine months ended September 30, 2021 and 2020 is presented below:

	Stock Options	RSUs	PSUs
Outstanding at December 31, 2019	3,096,161	251,215	116,181
Granted	662,700	231,450	—
Options exercised/RSUs vested/PSUs vested	(41,951)	(67,970)	—
Forfeited or expired	(185,615)	(53,824)	(11,431)
Outstanding at September 30, 2020	3,531,295	360,871	104,750
Outstanding at December 31, 2020	3,331,890	328,396	97,750
Granted	109,000	106,600	159,000
Options exercised/RSUs vested/PSUs vested	(100,477)	(94,273)	—
Forfeited or expired	(308,815)	(46,941)	(97,750)
Outstanding at September 30, 2021	3,031,598	293,782	159,000

Stock Options

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Risk-free interest rate	0.82% - 0.93%	0.37% - 0.41%	0.51% - 1.12%	0.37% - 1.65%
Volatility	54.92%	55.42%	56.07%	54.98%
Expected term (in years)	6.08 years	6.07 years	5.68 years	6.03 years
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

RSUs

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

PSUs

The fair value of market condition PSUs granted to employees was estimated using a Monte Carlo simulation model. Inputs used in the calculation are described above.

The fair value of performance condition PSUs granted to employees was estimated based on the trading price of our common stock on the date of grant adjusted for probability of achievement of the performance conditions as described above.

We did not recognize any expense for performance based PSUs granted to employees based on our estimated probability of achievement as described above.

We recognized stock-based compensation in our condensed consolidated statements of operations for the three and nine months ended September 30, 2021 and 2020 as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Stock options	$ 2,515	$ 3,685	$ 8,393	$ 12,831
RSUs	1,046	928	4,051	4,115
PSUs	523	109	2,429	1,489
Stock-based compensation expense	$ 4,084	$ 4,722	$ 14,873	$ 18,435
Selling, general and administrative	$ 3,443	$ 5,236	$ 12,696	$ 16,365
Research and development	641	(514)	2,177	2,070
Stock-based compensation expense	$ 4,084	$ 4,722	$ 14,873	$ 18,435

8. Commitments

Our future material contractual obligations as of September 30, 2021, included the following:

Obligations	Total	2021	2022	2023	2024	2025	2026	Beyond
Operating leases (1)	$ 4,680	$ 351	$ 1,423	$ 1,455	$ 1,038	$ 413	$ —	$ —
Credit facility (2)	28,000	2,000	26,000	—	—	—	—	—
Purchase obligations (3)	53,176	53,176	—	—	—	—	—	—
Total obligations	$ 85,856	$ 55,527	$ 27,423	$ 1,455	$ 1,038	$ 413	$ —	$ —

(1) We lease our corporate office location. The term of our existing lease expires on June 30, 2025. We also lease our lab space under a lease agreement that expires on October 31, 2023. Rental expense for the operating leases was $325 and $276, for the three months ended September 30, 2021 and 2020, respectively. Rental expense for the operating leases was $976 and $910 for the nine months ended September 30, 2021 and 2020. The remaining future lease payments under the operating leases are $4.7 million as of September 30, 2021.

(2) Refer to Note 9, “Debt” for further information regarding our Credit Agreement.

(3) As of September 30, 2021, we had purchase obligations in the amount of $53.2 million which represents the contractual commitments under contract manufacturing and supply agreements with suppliers. The obligations under the supply agreements are primarily for finished product, inventory, and research and development.

9. Debt

On November 8, 2019, we entered into the Second Amended and Restated Credit Agreement (the “Credit Agreement”), with JPMorgan Chase Bank, N.A., as administrative agent (the “Agent”) and the lenders party thereto. The terms and amounts borrowed under the Credit Agreement includes a drawn term loan of $40 million and an undrawn revolving credit facility of $110 million. The schedule of principal payments for the new term loan facility was extended to November 8, 2022.

We classified the current portion of long-term debt of $8 million on the condensed consolidated balance sheet as of September 30, 2021. Per the terms of the Credit Agreement, the Company is limited in its ability to pay dividends. As of September 30 2021, we were in compliance with each of the senior secured net leverage ratio; total net leverage ratio; and fixed charge coverage ratio covenants.

The term loan facility bears 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 us may amend the Credit Agreement to replace the LIBOR with a Benchmark Replacement, described below.

Loans under the 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 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.

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

As of September 30, 2021, we had $0.5 million of unamortized deferred debt issuance costs as part of long-term debt in its condensed consolidated balance sheets.

Debt Maturities	As of September 30, 2021
2021 (remainder)	$ 2,000
2022	26,000
Total	$ 28,000

10. Income Taxes

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Income tax benefit (provision)	$ 7,038	$ (1,866)	$ 3,341	$ (7,358)
Effective tax rate	56 %	21 %	58 %	65 %

For interim periods, we recognize an income tax provision based on our estimated annual effective tax rate expected for the entire year plus the effects of certain discrete items occurring in the quarter. The interim annual estimated effective tax rate is based on the statutory tax rates then in effect, as adjusted for changes in estimated permanent differences, and certain discrete items whose tax effect, when material, is recognized in the interim period in which they occur.

The effective tax rate for the three and nine months ended September 30, 2021, reflects an interim tax benefit resulting from our research and development expense of acquired licenses and credits for research and development activity, partially offset by impact of certain non-deductible executive compensation and expired stock compensation. We review the realizability of our deferred tax assets on a quarterly basis, or whenever events or changes in circumstances indicate that a review is required. In determining the requirement for a valuation allowance, the historical and projected financial results of the legal entity or consolidated group recording the net deferred tax asset are considered, along with any other positive or negative evidence. Since future financial results, including the fair value adjustment on our investment in Tyme may differ from previous estimates, periodic adjustments to our valuation allowances may be necessary.

Deferred income tax assets as of September 30, 2021 consisted of temporary differences primarily related to stock-based compensation and research and development tax credit carryforwards, partially offset by temporary differences related to intangible assets.

We file income tax returns in the U.S. federal jurisdiction and several states. Given that we have incurred tax losses in most years since our inception, all of our tax years are effectively open to examination. We are currently under audit by three State tax jurisdictions. We had no amount recorded for any unrecognized tax benefits as of September 30, 2021. We regularly evaluate our 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. We reflect interest and penalties attributable to income taxes, to the extent they arise, as a component of income tax provision or benefit.

11. Legal Proceedings

In addition to the below legal proceedings, from time to time, we 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, we currently believe that the final outcome of these ordinary course matters, or matters discussed below, will not have a material adverse effect on our business nor have we recorded any loss in connection with these matters because we believe that loss is neither probable nor estimable. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Commercial Litigation

Cipla v. Eagle

On April 16, 2020, Cipla Limited (“Cipla”) filed a request for arbitration against Eagle with the London Court of International Arbitration. The request alleges that Eagle’s refusal to take delivery of several batches of Argatroban finished drug product

constitutes a breach of the parties' December 14, 2012 supply agreement. Eagle believes that the allegations against it are without merit and is vigorously defending itself in the Arbitration, which was scheduled for June 2021, has been rescheduled for April 2022.

Patent Litigation

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.; Teva Pharmaceuticals Int'l GmbH et al v. Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., and Eugia Pharma Specialities Ltd.; Teva Pharmaceuticals Int'l GmbH et al v. Accord Healthcare Inc., Accord Healthcare Ltd., and Intas Pharmaceuticals Ltd.; Teva Pharmaceuticals Int'l GmbH et al v. Dr. Reddy's Laboratories, Ltd., and Dr. Reddy's Laboratories, 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. Slayback Pharma Limited Liability Company ("Slayback"), Apotex Inc. and Apotex Corp. ("Apotex"), Fresenius Kabi USA, LLC ("Fresenius"), Mylan Laboratories Limited ("Mylan"), Lupin, Ltd. and Lupin Pharmaceuticals, Inc. ("Lupin"), and Aurobindo Pharma, Ltd, Aurobindo Pharma USA, Inc., and Eugia Pharma Specialities Ltd ("Aurobindo") 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.

We, Cephalon, Inc. and/or Teva Pharmaceuticals International GMBH (together the "Patentees"), filed separate suits against Slayback, Apotex, Fresenius, Mylan, Hospira, Lupin, and Aurobindo 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) and May 11, 2020 (Aurobindo). 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 and of U.S. Patent Nos. 8,609,707, 9,265,831, 9,572,796, 9,572,797, 9,034,908, 9,144,568, 9,572,887, 9,597,397, 9,597,398, 9,597,399, 9,000,021, 9,579,384, 10,010,533, and 10,052,385 against Aurobindo. 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 (the "Consolidated Bendeka Litigation"), and a bench trial in these cases was held September 9-19, 2019. On April 27, 2020, the district court held that the asserted patents are valid and infringed by Slayback, Apotex, Fresenius and Mylan. On July 6, 2020, the district court entered a final judgment reflecting this decision, stating that pursuant to 35 U.S.C. § 271(e)(4)(A), the FDA shall not approve Apotex's, Fresenius's, Mylan's, or Slayback's ANDA products on a date which is earlier than January 28, 2031, and enjoining Apotex, Fresenius, Mylan, and Slayback from commercially manufacturing, using, offering to sell, or selling within the US or importing into the US, their ANDA products before that date. On August 4, 2020, Apotex, Fresenius, and Mylan appealed this final judgment, and filed their opening briefs on November 4, 2020. Plaintiffs' responsive appeal brief was filed on February 12, 2021. Defendants' reply briefs were filed April 5, 2021. On August 2, 2021, Fresenius's appeal was dismissed pursuant to a settlement agreement reached with Patentees. Oral argument for the remaining defendants occurred on August 3, 2021. On August 13, 2021, the appeals court affirmed the trial court's decision. The mandate was issued on October 22, 2021.

Hospira filed a motion to dismiss, 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. On December 15, 2020, the Court held a claim construction hearing, ruling in our favor on all claim terms. Fact discovery closed on April 1, 2021. Expert discovery is ongoing. Trial has been rescheduled for April 25, 2022. The case remains pending.

On March 10, 2020, the parties filed a stipulation and order of dismissal without prejudice as to Lupin, which the Court entered March 11, 2020.

Aurobindo answered the Complaint on July 20, 2020. The parties exchanged initial disclosures on December 11, 2020. Plaintiffs provided their infringement contentions on March 12, 2021. On October 20, 2021 the Court entered a stipulation of dismissal based on a settlement between the parties.

Patentees filed suit against Dr. Reddy's Laboratories on May 13, 2021. Patentees have asserted U.S. Patent Nos. 8,609,707, 9,265,831, 9,572,796, 9,572,797, 9,034,908, 9,144,568, 9,572,887, 9,597,397, 9,597,398, 9,597,399, 9,000,021, 9,579,384, 10,010,533, and 10,052,385. Dr. Reddy's answer was filed August 16, 2021. Scheduling for the case is ongoing.

Patentees filed suit against Accord Healthcare on June 29, 2021. Patentees have asserted U.S. Patent Nos. 8,609,707, 9,265,831, 9,572,796, 9,572,797, 9,034,908, 9,144,568, 9,572,887, 9,597,397, 9,597,398, 9,597,399, 9,000,021, 9,579,384, 10,010,533, and 10,052,385. Accord has answered the complaint.

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. Pursuant to a stipulation between the parties, Slayback is bound by any final judgment entered in the Consolidated Bendeka Litigation. This case is currently stayed.

Eagle Pharmaceuticals, Inc. v. Slayback Pharma Limited Liability Company, Apotex, Inc. and Apotex Corp.

Both Slayback and Apotex filed NDAs referencing Eagle's Belrapzo NDA. On August 31, 2021, the Company filed suit against Slayback and Apotex in the United States District Court for the District of Delaware, alleging infringement of U.S. Patent No. 11,103,483. On September 22, 2021, both Slayback and Apotex filed their Answers. Scheduling for the case is ongoing.

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 took place on March 3, 2020. On April 17, 2020, we submitted a letter requesting leave to file a motion for summary judgment of non-infringement. Par's responsive letter was submitted on May 8, 2020. On May 18, 2020, the court said it would hear non-infringement arguments at trial and not through summary judgment. Fact discovery ended in October 2019, and expert discovery ended in February 2020. Due to the COVID-19 pandemic, the trial, which was scheduled to begin May 18, 2020, was rescheduled to and occurred on July 7-9, 2021. Post-trial briefing was submitted on July 28, 2021. The Court issued an opinion on August 31, 2021 and entered a final judgment of non-infringement in favor of Eagle on September 16, 2021. Par filed a Notice of Appeal of the final judgment on September 22, 2021, and the appeal was docketed with the United States Court of Appeals for the Federal Circuit on September 23, 2021. The 30-month stay of FDA approval expired on October 17, 2020. This suit is pending.

On December 7, 2020, Par filed a separate suit against us in the United States District Court for the District of New Jersey, asserting patent infringement of U.S. Patent No. 10,844,435, based on the filing of our ANDA seeking approval to manufacture and sell our vasopressin product. Eagle moved to dismiss Par's complaint on March 2, 2021. On March 22, 2021, Par amended its complaint to additionally assert U.S. Patent No. 10,920,278, and on April 5, 2021, Eagle moved to dismiss Par's amended complaint. This suit is pending.

12. License and Collaboration Agreements

License agreement with Combioxin

In August 2021, we entered into a license agreement with Combioxin, SA under which the Company was granted exclusive, worldwide development and commercialization rights to CAL02, a novel first-in-class antitoxin agent ready for Phase 2b/3 development for the treatment of severe pneumonia in combination with traditional antibacterial drugs. The Company will be solely responsible for the development, regulatory, manufacturing and commercialization activities of CAL02. Combioxin will assist the Company in transitioning the manufacturing and supply of CAL02 to the Company.

Under the terms of the agreement, we paid $10 million as upfront license consideration that was expensed immediately as research and development and is reflected within the operating activities of the condensed consolidated statements of cash flows. The Company may pay to Combioxin up to $105 million upon achievement of certain development, regulatory and sales based milestone payments plus royalty payments at royalty rates ranging in low double digit percentages on the net sales of all products sold, subject to certain adjustments as provided in the agreement. The Company is also obligated to make certain payments based upon amounts received by sublicensees under the agreement.

License agreement with AOP Orphan

In August 2021, we entered into a licensing agreement with AOP Orphan Pharmaceuticals GmbH ("AOP Orphan"), a privately owned Austrian company devoted to the treatment of rare and special diseases, for the commercial rights to its product, landiolol in the United States. Landiolol, a leading hospital emergency use product, is currently approved in Europe for the treatment of non-compensatory sinus tachycardia and tachycardic supraventricular arrhythmias. We will support the submission of a new drug application ("NDA") by AOP Orphan to the FDA seeking approval for landiolol for the short term reduction of ventricular rate in patients with supraventricular tachycardia ("SVT"), including atrial fibrillation and atrial flutter.

Under the terms of the agreement, we accrued a $5 million upfront license consideration that was expensed immediately as research and development and is reflected within the operating activities of the condensed consolidated statements of cash flows. The Company may pay to AOP Orphan up to $25 million upon achievement of certain regulatory milestone payments plus profit share payments, subject to certain adjustments as provided in the agreement. We also entered into a supply agreement at the same time as the licensing agreement.

Collaboration with Tyme

On January 7, 2020, Tyme and we announced a strategic collaboration to advance SM-88, an oral product candidate for the treatment of patients with cancer. SM-88 is an investigational agent in two Phase II studies, one for pancreatic cancer and another for prostate cancer.

Under the terms of a related co-promotion agreement, we would be responsible for 25% of the promotional sales effort of SM-88 and would receive 15% royalty on the net revenues of SM-88 in the United States. Tyme is responsible for clinical development, regulatory approval, commercial strategy, marketing, reimbursement and manufacturing of SM-88. Tyme retains the remaining 85% of net U.S. revenues and reserves the right to repurchase our U.S. co-promotion right for $200.0 million.

Our equity investment in Tyme is included in Other assets on our condensed consolidated balance sheet. For the three months ended September 30, 2021 and 2020, the fair value adjustments for the equity investment was a loss of $2.3 million and $3.5 million, respectively. For the nine months ended September 30, 2021 and 2020, the fair value adjustments for the equity investment was a loss of $1.9 million and a loss of $7.7 million, respectively. These adjustments were recorded in Other (expense) income on our condensed consolidated statements of operations.

13. Convertible Promissory Note

During the first quarter of 2021, we invested $5 million in a convertible promissory note ("the note") of a privately held clinical-stage biotechnology company (the "issuer"). The note bears an 8% annual interest rate and has an 18-month term. The issuer is not required to make any principal or interest payments until the end of the term. The note, along with any accrued interest, may automatically convert into equity securities of the issuer under either a financing event or a change in control event as defined in the convertible promissory note agreement. The issuer's product development efforts could encounter technical or other difficulties that could increase their development costs more than expected. The issuer will likely require additional capital prior to obtaining certain regulatory approval or to be able to repay the convertible promissory note with accrued interest at the end of the term.

The following table summarizes the amounts recorded and activity during the nine months ended September 30, 2021;

	Initial	Fair Value Adjustments to the note	Accretion of Discount	Estimated Credit Loss	Interest Income	Fair Value Adjustment to Embedded Derivative	September 30, 2021
Fair value of the note	$ 5,000	$ (882)	$ —	$ —	$ —	$ —	$ 4,118
Discount on the note	(276)	—	102	—	—	—	(174)
Estimated Credit Loss	—	—	—	(150)	—	—	(150)
Convertible Promissory Note, net	$ 4,724	$ (882)	$ 102	$ (150)	$ —	$ —	$ 3,794
Embedded Derivative	$ 276	$ —	$ —	$ —	$ —	$ 254	$ 530
Interest Receivable	$ —	$ —	$ —	$ —	$ 227	$ —	$ 227
Total in Other Current Assets	$ 5,000	$ (882)	$ 102	$ (150)	$ 227	$ 254	$ 4,551

The following table summarizes the activity during the three months ended September 30, 2021;

	June 30, 2021	Fair Value Adjustments to the note	Accretion of Discount	Estimated Credit Loss	Interest Income	Fair Value Adjustment to Embedded Derivative	September 30, 2021
Fair value of the note	$ 4,096	$ 22	$ —	$ —	$ —	$ —	$ 4,118
Discount on the note	(220)	—	46	—	—	—	(174)
Estimated Credit Loss	(100)	—	—	(50)	—	—	(150)
Convertible Promissory Note, net	$ 3,776	$ 22	$ 46	$ (50)	$ —	$ —	$ 3,794
Embedded Derivative	$ 464	$ —	$ —	$ —	$ —	$ 66	$ 530
Interest Receivable	$ 125	$ —	$ —	$ —	$ 102	$ —	$ 227
Total in Other Current Assets	$ 4,365	$ 22	$ 46	$ (50)	$ 102	$ 66	$ 4,551

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following information should be read in conjunction with our unaudited consolidated financial statements and the notes thereto included in this Quarterly Report on Form 10-Q, or the Quarterly Report, and the audited financial information and the notes thereto included in our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission, or the SEC, on March 5, 2021, or our Annual Report. This discussion and analysis contains forward-looking statements that involve significant risks and uncertainties. Our actual results, performance or experience could differ materially from what is indicated by any forward-looking statement due to various important factors, risks and uncertainties, including, but not limited to, those set forth under "Risk Factors" included elsewhere in this Quarterly Report. Such factors may be amplified by the COVID-19 pandemic and its current or its potential impact on our business and the global economy. Unless otherwise indicated or required by context, references throughout to "Eagle," the "Company," "we," "our," or "us" refer to financial information and transactions of Eagle Pharmaceuticals, Inc.

Overview

We are an integrated pharmaceutical company focused on finding ways to help medicines do more for patients. Along with our collaborators, we have the capabilities to take a molecule from preclinical research through regulatory approval and into the marketplace, including development, manufacturing and commercialization of our products and product candidates. Our business model applies our scientific expertise, proprietary research-based insights and marketplace proficiency to identify challenging-to-treat diseases of the central nervous system or metabolic critical care therapeutic areas as well as in oncology. By focusing on patients' unmet needs, we strive to provide healthcare professionals with urgently needed treatment solutions that are designed to improve patient care and outcomes and create near- and long-term value for our stakeholders, including patients and healthcare providers and our employees, marketing partners, collaborators and stockholders.

Our science-based business model has a proven track record with the U.S. Food and Drug Administration, or FDA, approval and commercial launches of three products: Ryanodex, Belrapzo and Bendeka. We market our products through marketing partners and/or our internal direct sales force. We market Ryanodex and Belrapzo, and Teva markets Bendeka through its subsidiary, Cephalon, Inc. SymBio Pharmaceuticals Limited, or SymBio, markets Treakisym, a RTD product, in Japan. Reflecting further expansion of our oncology portfolio, in February 2020, we received final FDA approval for Pemfexy, a branded alternative to Alimta for metastatic non-squamous non-small cell lung cancer and malignant pleural mesothelioma. We expect to launch Pemfexy in early 2022.

With several pipeline projects underway and the potential for up to five product launches over the next several years, we believe we have many growth opportunities ahead. We believe that each of our pipeline projects currently has the potential to enter the market as a first-in-class, first-to-file, first-to-market or best-in-class product. In particular, we are applying our expertise to conduct novel research regarding the potential for Ryanodex to address conditions including Alzheimer's disease, traumatic brain injury/concussion, nerve agent exposure and acute radiation syndrome. In addition, our clinical development program includes a strategic partnership with Tyme Technologies, Inc., or Tyme, for Tyme's product candidate for the treatment of patients with pancreatic or other advanced cancers, SM-88, as well as investigations of compounds such as EA-114 (our fulvestrant product candidate) for patients with HR-positive advanced breast cancer. Other products in development include Vasopressin, our first-to-file Abbreviated New Drug Application, or ANDA, that references Endo International plc's Vasostrict indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines; and EA-111, a new chemical entity and next-generation ryanodine receptor antagonist, in an intramuscular formulation that that would allow for easier and more rapid administration in emergency situations (military and civilian).

Recent Developments

Vasopressin - Patent litigation

On February 2, 2021, we also announced that our ongoing patent suit with Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC, or together, Par, was rescheduled to July 7, 2021. The trial took place on July 7-9, 2021, and post-trial briefing was submitted on July 28, 2021. On August 31, 2021, we announced the U.S. District Court for the District of Delaware held that Eagle's proposed vasopressin product does not infringe any of the patents Par asserted against the Company. We are confident that our ANDA will be approved in a reasonable timeframe.

Combioxin License Agreement

In August 2021, we entered into a license agreement with Combioxin, SA under which the Company was granted exclusive, worldwide development and commercialization rights to CAL02, a novel first-in-class antitoxin agent ready for Phase 2b/3 development for the treatment of severe pneumonia in combination with traditional antibacterial drugs. The Company will be solely responsible for the development, regulatory, manufacturing and commercialization activities of CAL02. Combioxin will assist the Company in transitioning the manufacturing and supply of CAL02 to the Company.

Under the terms of the agreement, we paid $10 million as upfront license consideration that was expensed immediately as research and development. The Company may pay to Combioxin up to $105 million upon achievement of certain development, regulatory and sales based milestone payments plus royalty payments at royalty rates ranging in low double digit percentages on the net sales of all products sold, subject to certain adjustments as provided in the agreement. The Company is also obligated to make certain payments based upon amounts received by sublicensees under the agreement.

We and Combioxin will establish a joint development committee to review and discuss the overall strategy for the development and regulatory activities of CAL02, oversee the activities under the license agreement, including with respect to clinical trials and manufacturing activities, and perform such other functions as expressly set forth in the license agreement or allocated to it by the parties.

AOP License Agreement

In August 2021, we entered into a licensing agreement with AOP Orphan Pharmaceuticals GmbH ("AOP Orphan"), a privately owned Austrian company devoted to the treatment of rare and special diseases, for the commercial rights to its product, landiolol in the United States. Landiolol, a leading hospital emergency use product, is currently approved in Europe for the treatment of non-compensatory sinus tachycardia and tachycardic supraventricular arrhythmias. We will support the submission of a NDA by AOP Orphan to the FDA seeking approval for landiolol for the short term reduction of ventricular rate in patients with SVT, including atrial fibrillation and atrial flutter. We anticipate the filing of such NDA in the first half of 2022, with an expected ten-month review, based on feedback from the FDA provided during AOP Orphan's Type C meeting with the FDA. We will be responsible for the U.S. commercialization of the product upon approval. Landiolol, which has not previously been marketed in the U.S., is covered by several patents, and we anticipate five years of new chemical entity exclusivity. Landiolol is already commercially available in Japan and several European markets. The licensing agreement is subject to regulatory clearance. We also entered into a supply agreement at the same time as the licensing agreement.

We accrued $5 million as upfront license consideration, and we may pay up to $25 million upon achievement of certain regulatory milestone payments plus profit share payments, subject to certain adjustments as provided in the license agreement.

Vasopressin - FDA

On February 2, 2021, we announced that the U.S. Food and Drug Administration, or FDA, issued a complete response letter, or CRL, for our ANDA for vasopressin. We completed the last study required by the FDA for vasopressin during the first quarter of 2021, and we submitted our response to the CRL on June 15, 2021. The FDA has assigned a Generic Drug User Fee Amendments / Act, or GDUFA, date of December 15, 2021, and we expect a commercial launch prior to year-end. Importantly, we have completed an extensive amount of developmental work and continue to do so for our first-to-file polypeptide, where brand sales of the product are over $700 million annually. In its communication with us, the FDA restated that it has prioritized our ANDA, and that the ANDA has also been flagged as a COVID-19 priority by FDA. We believe we have fully responded to the questions raised. Based on similar studies previously run on our vasopressin product, we expect the results will be satisfactory. In addition, we expect we will have a 180 day period of exclusivity for vasopressin.

Treakisym (bendamustine) Ready-to-Dilute and Rapid Infusion Formulation

On April 30, 2021, we announced that Treakisym ready-to-dilute, or RTD, (bendamustine hydrochloride 120 mg/m2) liquid formulation was approved for a new indication in combination with rituximab, or BR therapy, as treatment for relapsed or refractory diffuse large B-cell lymphoma, or r/r DLBCL, by the Pharmaceuticals and Medical Devices Agency in Japan.

On May 10, 2021, we announced that an application for Treakisym rapid infusion, or RI, (50ml) liquid formulation was filed with the PMDA in Japan. The application is based on the results of clinical studies investigating the safety and pharmacokinetics of Treakisym RTD administered by 10-minute intravenous infusion.

Pursuant to our license agreement with SymBio, SymBio may develop and commercialize our bendamustine hydrochloride ready-to-dilute injection product and rapid infusion injection product in Japan. SymBio currently markets in Japan Treakisym, a RTD bendamustine hydrochloride indicated for CLL, relapsed or refractory low-grade NHL, mantle cell lymphoma, or MCL, and as a first line treatment of low-grade NHL and MCL. Under the license agreement, SymBio may develop and market certain other bendamustine hydrochloride products in Japan for limited indications. As part of the agreement, SymBio assumed responsibility for securing regulatory approval of the Treakisym RTD and RI products using the licensed technology in Japan.

COVID-19 Business Update

In response to the ongoing COVID-19 pandemic, we have taken and continue to take active measures designed to address and mitigate the impact of the COVID-19 pandemic on our business, such as remote working policies, facilitating management's daily communication to address employee and business concerns and providing frequent updates to the Board. During the second quarter of 2021, we implemented a plan to reopen our office to allow employees to return to the office, with a focus on employee safety and optimal work environment. Our management continues to monitor and evaluate such plans as the pandemic continues to evolve. We anticipate that the COVID-19 pandemic may have an impact on the clinical development timeline for EA-114. We anticipate that the COVID-19 pandemic will continue to delay our supply chain and marketing and sales efforts for certain of its products, including Bendeka, although it is not currently expected that any disruption would be material. The COVID-19 pandemic and associated lockdowns have resulted in a decrease in healthcare utilization broadly and specifically lead to a continuing reduction in the utilization of physician-administered oncology products including Belrapzo and Bendeka. In addition, the COVID-19 pandemic has delayed the timing of ongoing litigation, including the litigation with Par Pharmaceutical, Inc. and its affiliated entities with respect to Vasopressin, and we anticipate that such delays will continue for the duration of the pandemic. While we have experienced variable financial impacts to date, the ongoing COVID-19

pandemic, including the global economic slowdown, government measures taken in response thereto, the overall disruption of global healthcare systems and other risks and uncertainties associated with the pandemic, could materially adversely affect our business, financial condition, results of operations and growth prospects. We continue to closely monitor the COVID-19 pandemic as we evaluate and evolve our business plans and response strategy. The impact of the COVID-19 pandemic on our business and financial condition is more fully described below in *Trends and Uncertainties*.

Financial Operations Overview

Revenue

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

Product Sales. Through September 30, 2021, we have recognized revenues from product sales including Bendeka, Treakisym, Ryanodex and Belrapzo. Sales of Bendeka were made to our commercial partner, Teva, and are typically made at little or no profit for resale. Sales of Treakisym were made to Symbio pursuant to a supply agreement with Symbio. Ryanodex and Belrapzo were sold directly to wholesalers, hospitals and surgery centers through a third-party logistics partner.

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 provide 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 Symbio's net sales of Treakisym, 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 Teva, 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 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 expenses 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 condensed 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.

Selling, General and Administrative

Selling, general and administrative costs consist of employee-related costs including salaries, benefits and other related costs, 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 Accounting Standards Codification Topic 740, "Income Taxes," or 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 (loss) 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 it 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.

The provision for income taxes was based on the applicable federal and state tax rates for those periods. The effective tax rate for the nine months ended September 30, 2021 reflects certain non-deductible executive compensation and expired stock compensation, partially offset by credits for research and development activity and excess tax deduction we can realize for our stock based awards. The effective tax rate for the nine months ended September 30, 2020 reflects the impact of a valuation allowance established and adjusted for the fair value adjustments on our investment in Tyme, certain non-deductible executive compensation and changes in state filing positions, partially offset by credits for research and development activity.

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Results of Operations

Comparison of Three Months Ended September 30, 2021 and 2020

Revenues

	Three Months Ended September 30,		(Decrease) Increase
	2021	2020	
	(in thousands)		
Product sales, net	$ 12,124	$ 17,317	$ (5,193)
Royalty revenue	27,729	27,611	118
License and other revenue	—	5,000	(5,000)
Total revenue	$ 39,853	$ 49,928	$ (10,075)

Our product sales decreased $5.2 million during the three months ended September 30, 2021 as compared to the three months ended September 30, 2020. The decrease was attributable to lower product sales for Belrapzo and Bendeka of $3.8 million and $3.3 million, respectively, which were primarily due to volume decreases, partially offset by $1.6 million in product sales of Treakisym, following the launch of Treakisym in Japan by Symbio in the first quarter of 2021.

Our royalty revenue increased $0.1 million during the three months ended September 30, 2021 as compared to the three months ended September 30, 2020. The increase was primarily as a result of $1.2 million royalty revenue from Treakisym, offset by $1.1 million decrease in royalty revenue from Bendeka.

We earned a $5.0 million milestone payment during the three months ended September 30, 2020 when SymBio received regulatory approval for Treakisym RTD bendamustine formulation from the Pharmaceuticals and Medical Devices Agency in Japan.

Cost of revenue

	Three Months Ended September 30,		
	2021	2020	Decrease
	(in thousands)		
Cost of product sales	$ 5,486	$ 8,726	$ (3,240)
Cost of royalty revenue	2,773	3,260	(487)
Total cost of revenue	$ 8,259	$ 11,986	$ (3,727)

Our cost of product sales decreased $3.2 million during the three months ended September 30, 2021 as compared to the three months ended September 30, 2020. This was primarily attributable to a decrease of $3.6 million in Bendeka cost of revenue resulting from lower product unit sales, coupled with a decrease of $1.2 million in Belrapzo cost of revenue resulting from lower product unit sales. These decreases were partially offset by an increase of $1.5 million in Treakisym cost of revenue resulting from product unit sales, following the launch of Treakisym RTD in Japan by Symbio in the first quarter of 2021.

Our cost of royalty revenue decreased by $487 thousand during the three months ended September 30, 2021 as compared to the three months ended September 30, 2020. This was primarily attributable to costs related to the royalty revenue for Belrapzo and Bendeka of $0.5 million and $0.1 million, respectively. These decreases were partially offset by an increase in costs as a result of royalties related to Treakisym of $0.1 million.

Research and development

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

	Three Months Ended September 30,		
	2021	2020	Increase /(Decrease)
	(in thousands)		
Fulvestrant "EGL-5385-C-1701"	$ 729	$ 474	$ 255
Vasopressin	2,086	1,298	788
CAL02 / Combioxin	10,000	—	10,000
Landilol / AOP	5,000	—	5,000
Pemfexy	1,386	288	1,098
All other projects	602	904	(302)
Salary and other personnel related costs	3,486	1,864	1,622
Research and development	$ 23,289	$ 4,828	$ 18,461

Our research and development expenses increased $18.5 million in the three months ended September 30, 2021 as compared to the three months ended September 30, 2020. The increase primarily resulted from a $10.0 million upfront payment related to our license agreement with Combioxin, a $5.0 million upfront payment related our licensing agreement with AOP Orphan, a $0.8 million increase in development cost for the Vasopressin project, a $1.1 million increase related to Pemfexy and a $1.2 million increase in stock compensation, included with Salary and other personnel related costs.

Selling, general and administrative

	Three Months Ended September 30,		
	2021	2020	Increase
	(in thousands)		
Selling, general and administrative	$ 18,482	$ 17,697	$ 785

Our selling, general and administrative expenses increased $0.8 million for the three months ended September 30, 2021 as compared to the three months ended September 30, 2020. This increase is primarily related to an increase in external legal costs partially offset by a decrease in stock compensation expense.

Other expense, net

	Three Months Ended September 30,		
	2021	2020	Increase / (Decrease)
	(in thousands)		
Interest income	$ 197	$ 46	$ 151
Interest expense	(396)	(489)	(93)
Other expense	(2,284)	(6,049)	3,765
Total other expense, net	$ (2,483)	$ (6,492)	$ 4,009

Our interest income slightly increased $151 thousand for the three months ended September 30, 2021 as compared to the three months ended September 30, 2020. This increase is primarily due to accrued interest recorded on the convertible promissory note agreement entered into in the first quarter of 2021.

Our interest expense decreased $0.1 million for the three months ended September 30, 2021 as compared to the three months ended September 30, 2020. This decrease is primarily due to lower borrowings from our revolving credit facility during the three months ended September 30, 2021.

Our other (expense) income was a net expense of $2.3 million for the three months ended September 30, 2021 as compared to a net expense of $6.0 million the three months ended September 30, 2020. The $2.3 million related to fair value adjustments on our equity investment in Tyme during the three months ended September 30, 2021. The $6.0 million primarily related to fair value adjustments on the Company's equity investment in Tyme in the amount of $3.5 million and the related fair value adjustments related to the final settlement of the $25.0 million accelerated share repurchase, or ASR, transaction with JPMorgan Chase Bank, National Association, or JP Morgan, as part of our existing $160 million share repurchase program. We determined the ASR contained a forward contract and therefore we recorded fair value adjustments on unsettled accelerated share repurchase agreement in the amount of $2.5 million in the three months ended September 30, 2020.

Income tax benefit (provision)

	Three Months Ended September 30,	
	2021	2020
	(in thousands)	
Benefit (provision) for income taxes	$ 7,038	$ (1,866)
Effective tax rate	56 %	21 %

The effective tax rate for the three months ended September 30, 2021, reflects an interim tax benefit resulting from our research and development expense of acquired licenses and credits for research and development activity, partially offset by impact of certain non-deductible executive compensation and expired stock compensation. The effective tax rate for the three months ended September 30, 2020 reflects the impact of a valuation allowance established and adjusted for the fair value adjustments on our investment in Tyme, certain non-deductible executive compensation partially offset by credits for research and development activity.

Comparison of Nine Months Ended September 30, 2021 and 2020
Revenues

	Nine Months Ended September 30,		
	2021	2020	(Decrease)
	(in thousands)		
Product sales, net	$ 48,865	$ 49,387	$ (522)
Royalty revenue	80,361	83,499	(3,138)
License and other revenue	—	5,000	(5,000)
Total revenue	$ 129,226	$ 137,886	$ (8,660)

Our product sales decreased $0.5 million in the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020 primarily driven by decreases in product sales of Ryanodex of $1.2 million and Bendeka of $3.9 million primarily due to a decrease in unit volume. These decreases were partially offset by $3.9 million in product sales of Treakisym, following the launch of Treakisym RTD in Japan by Symbio in the first quarter of 2021, coupled with an increase in product sales of $0.9 million of Belrapzo primarily due to unit volume.

Our royalty revenue decreased $3.1 million in the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020, primarily as a result of lower royalties on Teva's sales of Bendeka of $5.0 million, which were partially offset by new royalties on Symbio's sales of Treakisym of $2.2 million.

Cost of revenue

	Nine Months Ended September 30,		
	2021	2020	(Decrease)
	(in thousands)		
Cost of product sales	$ 21,835	$ 23,804	$ (1,969)
Cost of royalty revenue	8,036	9,120	(1,084)
Total cost of revenue	$ 29,871	$ 32,924	$ (3,053)

Our cost of product sales decreased $2.0 million in the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020, primarily as a result of decreased cost of product sales of Ryanodex of $1.7 million and of Bendeka of $4.9 million, each related to lower unit sales. These decreases were partially offset by an increase of $3.9 million in Treakisym cost of product sales resulting from product unit sales, following the launch of Treakisym RTD in Japan by Symbio in the first quarter of 2021 coupled with an increase for Argatroban of $0.4 million related end of product life costs.

Our cost of royalty revenue decreased $1.1 million in the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020, primarily as a result of a decrease in royalty revenue on Teva’s sales of Bendeka coupled with lower cost of royalty associated with Belrapzo and the ending of royalties related to Argatroban.

Research and development

	Nine Months Ended September 30,		
	2021	2020	Increase / (Decrease)
	(in thousands)		
Fulvestrant “EGL-5385-C-1701”	$ 5,207	$ 4,633	$ 574
Vasopressin	7,297	2,440	4,857
Ryanodex related projects	3,625	2,325	1,300
CAL02 / Combioxin	10,000	—	10,000
Landilol / AOP	5,000	—	5,000
Pemfexy	2,502	340	2,162
All other projects	2,475	1,810	665
Salary and other personnel related costs	11,382	9,842	1,540
Research and development	$ 47,488	$ 21,390	$ 26,098

Our research and development expenses increased $26.1 million in the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020. The increase primarily resulted from a $10.0 million upfront payment related to our license agreement with Combioxin, a $5.0 million upfront payment related our licensing agreement with AOP Orphan, a $4.9 million increase in development cost for the Vasopressin project, a $2.2 million increase related to Pemfexy, coupled with a net increase in our Ryanodex related projects of $1.3 million and a $1.5 million total increase in salaries, bonuses, and severance, included with Salary and other personnel related costs.

Selling, general and administrative

	Nine Months Ended September 30,		
	2021	2020	(Decrease)
	(in thousands)		
Selling, general and administrative	$ 54,997	$ 60,411	$ (5,414)

Our selling, general and administrative expenses decreased $5.4 million in the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020. The decrease is primarily related to lower stock compensation expense of $3.7 million, the non-recurrence of $2.5 million of costs related to the collaboration with Tyme in 2020, coupled with decreased spend on marketing consultants of $1.1 million, partially offset by increased expense related to ongoing litigation matters of $2.4 million.

Other expense, net

	Nine Months Ended September 30,		
	2021	2020	(Decrease) / Increase
	(in thousands)		
Interest income	$ 395	$ 542	$ (147)
Interest expense	(1,240)	(2,164)	(924)
Other expense	(1,797)	(10,249)	8,452
Total other expense, net	$ (2,642)	$ (11,871)	$ 9,229

Our interest income decreased $0.1 million in the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020. This decrease is primarily due to lower interest rates associated with money market funds as compared to the nine months ended September 30, 2020.

Our interest expense decreased $0.9 million in the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020. This decrease is primarily due to lower borrowings from our revolving credit facility during the 2021 year to date period.

Our other (expense) income was an expense amount of $1.8 million for the nine months ended September 30, 2021 as compared to an expense amount of $10.2 million for the nine months ended September 30, 2020. The $1.8 million expense amount for the nine months ended September 30, 2021 primarily resulted from fair value adjustments on equity investment in Tyme during the nine months ended September 30, 2021. The $10.2 million expense amount for the nine months ended September 30, 2020 related to fair value adjustments on equity investment in Tyme in the amount of $7.7 million and the related fair value adjustments related to the final settlement of the $25.0 million ASR transaction with JPMorgan. We determined the ASR contained a forward contract and therefore we recorded fair value adjustments on unsettled accelerated share repurchase agreement in the amount of $2.5 million in the nine months ended September 30, 2020.

Income tax benefit (provision)

	Nine Months Ended September 30,	
	2021	2020
	(in thousands)	
Benefit (Provision) for income taxes	$ 3,341	$ (7,358)
Effective tax rate	58 %	65 %

The effective tax rate for the nine months ended September 30, 2021, reflects an interim tax benefit resulting from our research and development expense of acquired licenses and credits for research and development activity, partially offset by impact of certain non-deductible executive compensation and expired stock compensation. The effective tax rate for the nine months ended September 30, 2020 reflects the impact of a valuation allowance established and adjusted for the fair value adjustments on our investment in Tyme, certain non-deductible executive compensation, non-deductible nature of the fair value adjustment on the unsettled ASR agreement and changes in state filing positions, partially offset by credits for research and development activity.

Liquidity and Capital Resources

Our primary uses of cash are to fund working capital requirements, product development costs and operating expenses. Cash and cash equivalents were $99.7 million and $89.7 million as of September 30, 2021 and September 30, 2020, respectively.

For the nine months ended September 30, 2021, we realized a net loss of $2.4 million. As of September 30, 2021, our working capital surplus was $123.3 million. For the nine months ended September 30, 2020, we realized net income of $3.9 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 12 months.

The COVID-19 pandemic has disrupted and continues to disrupt the U.S. healthcare system, global economies and global capital markets. There remain significant uncertainties surrounding the full extent and duration of the impact of the COVID-19 pandemic on our business and operations. We have experienced variable financial impacts to date, as a result of the COVID-19 pandemic and the ongoing pandemic could have a material adverse impact on our financial condition and results of operations in the future, including our ability to obtain financing when and if needed. The impact of COVID-19 on our business and financial condition is more fully described below in *Trends and Uncertainties.*

Operating Activities:

Net cash provided by operating activities for the nine months ended September 30, 2021 was $20.1 million. Net loss for the period was $2.4 million offset by the net of non-cash adjustments of approximately $17.8 million from deferred income taxes, depreciation expense, amortization expense of right-of-use assets, amortization expense of intangible assets, fair value adjustments on equity investment, stock-based compensation expense, amortization of debt issuance costs and other items. Net changes in working capital increased cash from operating activities by approximately $4.7 million, due to changes in working capital accounts. The total amount of accounts receivable at September 30, 2021 was approximately $45.3 million, which included $17.4 million related to product sales and $27.9 million related to royalty revenue. Receivables from our product sales have payment terms ranging from 30 to 70 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.

Investing Activities:

Net cash used by investing activities for the nine months ended September 30, 2021 was $5.3 million, as a result of $5.0 million of investment to purchase a convertible promissory note and we spent $0.3 million for purchases of property and equipment.

Financing Activities:

Net cash used by financing activities for the nine months ended September 30, 2021 was $18.3 million, as a result of $6 million of principal payments for debt required by our Second Amended and Restated Credit Agreement with JPMorgan Chase Bank, N.A., as administrative agent and the lenders party thereto, or the Credit Agreement, $12.6 million in payments related to the repurchases of our common stock, $1.6 million of payments associated with employee withholding tax upon vesting of stock-based awards, partially offset by $1.8 million of proceeds from common stock exercises of employee stock options.

Trends and Uncertainties

Impact of the COVID-19 Pandemic

The COVID-19 pandemic has resulted in authorities implementing aggressive actions. Government authorities in the United States have recommended or imposed various social distancing, quarantine, and isolation measures on large portions of the population, and similar measures have also been taken in many other countries around the world. While many of these
governmental restrictions have begun to be lifted, the timing and extent to which such orders and restrictions will be removed
remains uncertain. Both the COVID-19 pandemic and the containment and mitigation efforts related to the pandemic have had a serious adverse impact on the U.S. economy and the economies of other countries around the world, the severity and duration of which are uncertain. There is no guarantee that prior or new restrictions will not be reinstated in response to the continued spread of COVID-19.

During the nine months ended September 30, 2021, we have experienced a variable impact on our business and financial condition due to the COVID-19 pandemic, which impacts include a decrease in revenue from sales of Belrapzo resulting, in part, from a decrease in inventory stocking and utilization rates, as well as a decrease in research and development expenses partially resulting from preclinical program delays. We also incurred an insignificant amount of incremental administrative costs related to the COVID-19 pandemic. The COVID-19 pandemic, including containment and mitigation measures, has impacted, and is expected to continue to impact, our business and operations in a number of ways, including:

- *Day-to-Day Operations*: Since mid-March 2020, certain of our employees, including customer-facing employees, had been primarily working remotely. The duration and extent of these restrictions are anticipated to be eased in the short term. During the second quarter of 2021, we developed and implemented plans to resume in-person work practices while adhering to relevant health authority guidance. We expect to incur additional expenses in 2021 related to the impact of the COVID-19 pandemic on our operations, including updates to our facilities to align with safety protocols.
- *Manufacturing and Supply Chain:* We are working closely with our commercial partners and third-party manufacturers to mitigate potential disruptions as a result of the COVID-19 pandemic by continuing to monitor the supply and availability of Bendeka, Ryanodex and Belrapzo for the patients who rely on these products. We anticipate that the COVID-19 pandemic will continue to delay our supply chain and marketing and sales efforts for certain of our products, including Bendeka, although it is not currently expected that any disruption would be material. If the COVID-19 pandemic continues to persist for an extended period of time and impacts essential distribution systems such as FedEx and postal delivery, we could experience future disruptions to our supply chain and operations, and associated delays in the manufacturing and our clinical supply, which would adversely impact our development activities.
- *Marketing and Sale of Products*: In addition to the impact on our product revenues resulting in a decrease in sales from Belrapzo, driven, in part, by the COVID-19 pandemic, we have also observed a reduction in the number of Bendeka patients visiting infusion centers, hospitals and clinics for intravenous administration of Bendeka due to interruptions in healthcare services, and the patients' inability to visit administration sites as well as desire to avoid contact with infected individuals. In addition, our sales and marketing teams have been working remotely and our virtual initiatives with respect to marketing and supporting the sale and administration of our products have not been as effective as our in-person sales and marketing activities.
- *Liquidity and Capital Resources*: We believe that future cash flows from operations will be sufficient to fund our currently anticipated working capital requirements for the next 12 months. While the COVID-19 pandemic has not had, and we do not expect it to have, a material adverse effect on our liquidity, the situation continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. If the disruption persists or deepens, we could experience an inability to access additional capital when and if needed. If we are unable to obtain funding, we

could be forced to delay, reduce or eliminate distribution of our commercialized products, product portfolio expansion or some or all of our research and development programs, which would adversely affect our business prospects. We expect to be able to obtain future funding under the terms of the Credit Agreement, for general corporate purposes and any strategic acquisitions.

- *Regulatory Activities*: We may experience further delays in the timing of NDA review and/or our interactions with FDA due to, for example, absenteeism by governmental employees, inability to conduct planned physical inspections related to regulatory approval, or the diversion of FDA's efforts and attention to approval of other therapeutics or other activities related to the COVID-19 pandemic, which could further delay approval decisions with respect to regulatory submissions or obtain new product approvals.
- *Clinical Development Timelines:* The clinical trial timelines for certain of our product candidates have been delayed given difficulties with limited patient enrollment resulting from the impact of the COVID-19 pandemic, and we expect that our clinical trial timelines will continue to be impacted for the duration of the pandemic.

There are significant uncertainties surrounding the extent and duration of the impact of the COVID-19 pandemic on our business and operations. We continue to evaluate the impact of the COVID-19 pandemic on our operating results and financial condition. The COVID-19 pandemic has had a variable impact on our results of operations during the nine months ended September 30, 2021 and, it could have a material adverse impact on our financial condition and results of operations in the future.

Contractual Obligations

Other than as set forth below, there have been no material changes to our contractual and commercial obligations during the nine months ended September 30, 2021, as compared to the obligations disclosed in our Annual Report.

Our future material contractual obligations included the following as of September 30, 2021 (in thousands):

Obligations	Total	2021	2022	2023	2024	2025	2026	Beyond
Operating leases (1)	$ 4,680	$ 351	$ 1,423	$ 1,455	$ 1,038	$ 413	$ —	$ —
Credit facility (2)	28,000	2,000	26,000	—	—	—	—	—
Purchase obligations (3)	53,176	53,176	—	—	—	—	—	—
Total obligations	$ 85,856	$ 55,527	$ 27,423	$ 1,455	$ 1,038	$ 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. We also lease lab space under a lease agreement that expires on April 1, 2024.

(2) Refer to Note 9 Debt for details of our Credit Agreement.

(3) As of September 30, 2021, we had purchase obligations in the amount of $53.2 million 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.

Critical Accounting Policies

Our significant accounting policies are disclosed in "Note 2. Summary of Significant Accounting Policies" in our audited financial statements for the year ended December 31, 2020 included in our Annual Report. Since the date of such financial statements, there have been no changes to our significant accounting policies other than those described in Note 2 of the notes to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

Recent Accounting Pronouncements

Recent Accounting Pronouncements - Not Yet Adopted

In March 2020, the FASB issued Update 2020-04 Reference Rate Reform (Topic 848), Facilitation of the Effects of Reference Rate Reform on Financial Reporting to provide temporary optional guidance to ease the potential burden in accounting for reference rate reform. The amendments in Update 2020-04 are elective and apply to all entities that have contracts, hedging relationships, and other transactions that reference LIBOR, formerly known as the London Interbank Offered Rate, or another reference rate expected to be discontinued due to reference rate reform. The new guidance provides optional expedients, including; (1) Simplify accounting analyses under current GAAP for contract modifications, such as modifications of contracts within the scope of Topic 470, Debt, that will be accounted for by prospectively adjusting the effective interest rate, as if any

modification was not substantial. That is, the original contract and the new contract shall be accounted for as if they were not substantially different from one another; (2) Simplify the assessment of hedge effectiveness and allow hedging relationships affected by reference rate reform to continue; (3) Allow a one-time election to sell or transfer debt securities classified as held to maturity before January 1, 2020 that reference a rate affected by reference rate reform. The amendments are effective for all entities from the beginning of an interim period that includes the issuance date of the ASU. An entity may elect to apply the amendments prospectively through December 31, 2022. The adoption of ASU 2020-4 is not expected to have a material impact on the Company's financial position or results of operations.

Recently Adopted Accounting Pronouncements

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. This standard is effective for fiscal years beginning after December 15, 2019 and the Company adopted the standard effective January 1, 2020. The adoption of ASU 2016-13 had no material impact on the Company's financial position and results of operations.

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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

During the nine months ended September 30, 2021, there were no material changes to our market risk disclosures as set forth in Part II, Item 7A "Quantitative and Qualitative Disclosures About Market Risk" in our Annual Report, except as discussed below.

We are monitoring the ongoing impacts of the COVID-19 pandemic on our business. While the full extent of the economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact on the global financial markets may reduce our ability to access capital, which could negatively impact our long-term liquidity.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the "Exchange Act", that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on their evaluation at September 30, 2021, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended September 30, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II-OTHER INFORMATION

Item 1. Legal Proceedings

The disclosures under Note 11. Legal Proceedings in the Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report are incorporated into this Part II, Item 1 by reference.

Item 1A. Risk Factors

An investment in our securities involves a high degree of risk. Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. Except for the updated risk factor set forth immediately below, our risk factors have not changed materially from those described in “Part I, Item 1A. Risk Factors” of our Annual Report.

Current and future legislation and regulations 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 Patient Protection and Affordable Care Act, as amended by the Health Care Education and Reconciliation Act, or collectively, the ACA, was passed, which significantly changed health care financing by both governmental and private insurers. There have been executive, judicial and Congressional challenges to certain aspects of the ACA. 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”. On June 17, 2021, the United States Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Thus, the ACA will remain in effect in its current form. Moreover, prior to the United States Supreme Court ruling, on January 28, 2021, the current U.S. President issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the current Presidential administration will impact the 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, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2021. 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 former U.S. Presidential administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, in May 2019, the Centers for Medicare & Medicaid Services, or 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. In a final rule issued by CMS on December 31, 2020, CMS established a broader definition for a "line extension" drug such that the line extension of the initial brand name listed drug would not need to be an oral solid dosage form. This final rule, may impact the rebate amounts associated with our products and negatively affect the commercial success of our products. Additionally, on December 2, 2020, CMS published changes to the Medicare Physician Fee Schedule for Calendar Year 2021 that also may adversely impact the coverage and reimbursement of our products. Under the changes, CMS will assign certain 505(b)(2) drug products to existing multiple source drug codes because, according to CMS, some drug products approved under the 505(b)(2) pathway share similar labeling and uses with generic drugs that are assigned to multiple source drug codes. CMS noted that this change is consistent with efforts to "curb drug prices" and encourages competition among products that are described by one billing code and share similar labeling. On July 24, 2020 and September 13, 2020, the former U.S. Presidential administration announced several executive orders related to prescription drug pricing that attempted to implement several of the administration's proposals. As a result, the FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the current administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing the former President's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the Most Favored Nation model, on August 10, 2021, CMS published a proposed rule that seeks to rescind the Most Favored Nation Model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of the budget reconciliation process. 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. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic. 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Issuer Purchases of Equity Securities

Share Repurchase Program

On March 17, 2020, we announced that our Board approved a new share repurchase program, or the Share Repurchase Program, providing for the repurchase of up to an aggregate of $160 million of the Company's outstanding common stock. The Share Repurchase Program replaced the Previous Share Repurchase Program, which was announced on October 30, 2018 and was terminated in connection with the Board's approval of the Share Repurchase Program. At termination, we had repurchased approximately $68 million of our outstanding common stock under the Previous Share Repurchase Program.

Under the Share Repurchase Program, we are 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 Securities Exchange Act of 1934, as amended. The

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 our cash resources.

We made the following purchases of our equity securities during the period covered by this Quarterly Report on Form 10-Q.

Period	Total Number of Shares Purchased (1)	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)
July 1, 2021 to July 31, 2021	—	N/A	—	120,691
August 1, 2021 to August 31, 2021	—	N/A	—	120,691
September 1, 2021 to September 30, 2021	158,680	$ 52.12	158,680	113,316
Total	158,680		158,680	

(1) All shares repurchased by us during the three months ended September 30, 2021 were repurchased pursuant to the Share Repurchase Program, described above.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number		Description of Exhibit
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)
10.1+	(1)	License Agreement, dated as of August 19, 2021, between the Registrant and Combioxin SA.
10.2+	(1)	License Agreement, dated as of August 6, 2021, between the Registrant and AOP Orphan Pharmaceuticals GmbH.
31.1	(1)	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	(1)	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	**	Certification of Principal 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		XBRL 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		Inline XBRL Taxonomy Extension Schema Document
101.CAL		Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF		Inline XBRL Taxonomy Definition Linkbase Document
101.LAB		Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE		Inline XBRL Taxonomy Extension Presentation Linkbase Document
104		Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101).

(1) Filed herewith.

+ Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

**The certifications attached as Exhibit 32.1 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the SEC and are 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 hereof), irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements 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

EAGLE PHARMACEUTICALS, INC.

DATED: November 9, 2021

By: /s/ Scott Tarriff

Scott Tarriff

(On behalf of the Registrant and as Chief Executive Officer as Principal Executive Officer)

DATED: November 9, 2021

By: /s/ Brian J. Cahill

Brian J. Cahill

Chief Financial Officer

(Principal Accounting Officer and Principal Financial Officer)

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

CONFIDENTIAL
Execution Copy

LICENSE AGREEMENT

BETWEEN

EAGLE PHARMACEUTICALS, INC.

AND

COMBIOXIN SA

259471316 v2

259471316 v2

LICENSE AGREEMENT

THIS LICENSE AGREEMENT ("**Agreement**") dated as of August 19, 2021 ("**Effective Date**"), is entered into between Eagle Pharmaceuticals, Inc., a Delaware corporation having offices at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey, United States ("**Eagle**") and Combioxin SA, a Swiss corporation having offices at Route de la Corniche 5, 1066 Epalinges, Switzerland ("**Combioxin**").

BACKGROUND

A. Eagle is a specialty pharmaceutical company focused on developing and commercializing drugs;

B. Combioxin is a biotechnology company dedicated to the development of drugs for severe bacterial and viral infections;

C. Combioxin has developed that certain liposome product known as CAL02 and controls certain related Patents and know-how;

D. Eagle desires to obtain from Combioxin and Combioxin desires to grant to Eagle an exclusive license with respect to the development, and manufacture and commercialization of the Licensed Products (as defined below), all on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE I
DEFINITIONS

I.1 "**Affiliate**" of a Party means any Person that, directly or indirectly, controls, is controlled by, or is under common control with such Party, as the case may be. As used in this Section 1.1, the word "**control**" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such Person, whether by the ownership of more than fifty percent (50%) of the voting share capital in such Person, or by contract or otherwise.

I.2 "**Anti-Corruption Laws**" shall mean the U.S. Foreign Corrupt Practices Act (15 U.S.C. §§78dd-1, et. seq.), as amended, the Organization for Economic Co-operation and Development (OECD) Convention on combating bribery of foreign public officials in international business transactions, and any other applicable anti-corruption laws.

I.3 "**Applicable Law**" means the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidances, ordinances, judgments, decrees, directives, injunctions, orders, permits of or from any court, arbitrator, Regulatory Authority, Governmental Authority or authority having jurisdiction

over or related to the subject item, including the FD&C Act, GCP, GLP, GMP, Anti-Corruption Laws and Export Control Laws.

I.4 "**Change of Control**" means, with respect to a Party: (a) the sale of all or substantially all of its assets or all of its assets relating to the Licensed Products; (b) a merger, reorganization or consolidation involving such Party in which the holders of the voting securities of such Party outstanding immediately prior thereto cease to beneficially own at least fifty percent (50%) of the combined voting power of the surviving entity, directly or indirectly, immediately after such merger, reorganization or consolidation; or (c) a transaction in which an entity or individual, or group of entities and/or individuals acting in concert, acquires more than fifty percent (50%) of the voting equity securities of such Party.

I.5 "**Clinical Studies**" means any human clinical study or clinical trial of a Licensed Product.

I.6 "**CMC Data**" means analytical and quality control data, stability data, batch records, and other data or information relating to chemistry, manufacturing and control of Licensed Products, including that which is filed or required to be filed to obtain authorization to conduct Clinical Studies or to obtain or maintain Regulatory Approval for a Licensed Product.

I.7 "**Combination Product**" means: (a) a pharmaceutical product that consists of a Licensed Product and at least one other pharmaceutically active ingredient that is not a Licensed Product in a fixed dose combination; or (b) any combination of a Licensed Product and another pharmaceutical product that [***]. The other pharmaceutically active ingredient(s) in clause (a) and the other pharmaceutical product(s) in clause (b) are each referred to as the "**Other Product(s)**".

I.8 "**Commercialization**" means any and all activities related to pre-marketing, launching, marketing, promotion (including advertising and detailing), labeling, bidding and listing, pricing and reimbursement, distribution, storage, handling, offering for sale, selling, having sold, importing, having imported, exporting, having exported, distributing, having distributed, providing customer service and support, conducting medical affairs, conducting post-marketing safety surveillance and reporting of or otherwise commercializing or exploiting Licensed Products. "**Commercialize**" and "**Commercializing**" have the correlative meanings.

I.9 "**Commercially Reasonable Efforts**" means, with respect to the efforts to be expended by Eagle in connection with a particular activity or objective to be conducted under this Agreement, that level of efforts that [***] would normally use, in the exercise of its prudent scientific and business judgment, for the development and/or commercialization of a comparable pharmaceutical product for a similar patient population at a similar stage of its development or commercialization, taking into account all relevant scientific, commercial, business and other factors, including issues of safety and efficacy, expected and approved product labeling, expected and actual cost and time to develop, expected and actual profitability, expected and actual return on investment, expected and actual competitiveness of Third Party alternative products (including generic products) in the marketplace, the nature and extent of expected and actual market exclusivity (including Patent coverage and regulatory exclusivity), the expected likelihood of marketing

approval, the expected and actual pricing and level of reimbursement, and the expected and actual amounts of marketing and promotional expenditures required. [***]

I.10 "**Control**" (including any variations such as "**Controlled**" and "**Controlling**"), in the context of intellectual property rights, material, data and/or other information or subject matter, means the possession by a Person or its Affiliate of the ability (whether by ownership or license, other than pursuant to a license granted to such Person by a Party to this Agreement) to grant the applicable access to, or a license or sublicense under this Agreement, without violating the terms of any agreement or other arrangement with any Third Party existing as of the Effective Date or at such later time as such Party or its Affiliate first acquired rights to such subject matter.

I.11 "**Cover**" means, with respect to a claim of a Patent and a Licensed Product, that such claim would be infringed, absent a license, by the manufacture, use, offer for sale, sale or importation of such Licensed Product (considering claims of patent applications to be issued as then pending).

I.12 "**Data**" means any and all data, information and materials relating to a Licensed Product, including manufacturing data (including without limitation, CMC Data), research data, pharmacology data, preclinical data, clinical data (including patient samples and associated annotations), master clinical trial records and databases, safety databases, and all Regulatory Filings and/or other regulatory documentation, information and submissions pertaining to, or made in association with an IND, Marketing Approval Application, or Regulatory Approval, for a Licensed Product, in each case to the extent Controlled by Combioxin as of the Effective Date or during the term of this Agreement.

I.13 "**Development**" or "**Develop**" means all activities that relate to the development of Licensed Products or to (a) obtaining, maintaining or expanding Regulatory Approval of a Licensed Product, or (b) developing the ability to manufacture clinical and commercial quantities of a Licensed Product. This includes: [***].

I.14 "**EMA**" means the European Medicines Agency or any successor entity.

I.15 "**Europe**" means the European Economic Area, Switzerland and the United Kingdom.

I.16 "**Export Control Laws**" shall mean: (a) all applicable U.S. laws and regulations relating to sanctions and embargoes imposed by U.S. Department of Treasury's Office of Foreign Assets Control (or its successor office or other body having substantially the same function); (b) all applicable U.S. export control laws, including the Arms Export Controls Act (22 U.S.C. Ch. 39), the International Emergency Economic Powers Act (50 U.S.C. §§ 1701 et seq.), the Trading With the Enemy Act (50 U.S.C. app. §§ 1 et seq.), the Export Administration Act of 1979 (50 U.S.C. app. §§ 2401 et seq.), International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986, and all rules, regulations and executive orders relating to any of the foregoing, including but not limited to the International Traffic in Arms Regulations (22 C.F.R. §§ 120 et seq.), the Export Administration Regulations (15 C.F.R. §§ 730 et. seq.), and the regulations administered by the Office of Foreign Assets Controls of the United States Department of the Treasury; and (c) all export

controls imposed on any Licensed Product by any country or organization or nation within the jurisdiction of which either party operates or does business.

I.17 "**FD&C Act**" means the U.S. Federal Food, Drug and Cosmetic Act, as amended.

I.18 "**FDA**" means the U.S. Food and Drug Administration, or any successor entity thereto performing similar functions.

I.19 "**Field**" means any and all indications and uses.

I.20 "**First Commercial Sale**" means, on a country-by-country basis, the first commercial transfer or disposition for monetary value of a Licensed Product in a country in the Territory for use or consumption by a Third Party end user, in each case, after all Regulatory Approvals [***] have been obtained for such country and where such disposition or transfer results in a recordable Net Sale in accordance with Eagle's, or its Affiliate's or Sublicensee's, applicable accounting practices (consistently applied).

I.21 "**Generic Product**" means, with respect to a particular Licensed Product and a particular country, any pharmaceutical product that: (a) [***].

I.22 "**Good Clinical Practice**" or "**GCP**" means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in the guidelines entitled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

I.23 "**Good Laboratory Practice**" or "**GLP**" means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, and comparable regulatory standards promulgated by the EMA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

I.24 "**Good Manufacturing Practices**" or "**GMP**" means the then-current Good Manufacturing Practices required by the FDA, as set forth in the FD&C Act and the regulations promulgated thereunder, for the manufacture and testing of pharmaceutical materials, and comparable laws and regulations applicable to the manufacture and testing of pharmaceutical materials promulgated by other Regulatory Authorities, as they may be updated from time to time.

I.25 "**Governmental Authority**" means any multi-national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, counsel, court or other tribunal).

I.26 "**ICH**" means International Conference on Harmonisation.

I.27 "**IND**" means an Investigational New Drug application, as defined in the U.S. Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder, or the equivalent application to the equivalent agency in any other regulatory jurisdiction, the filing of which is necessary to Initiate or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction, in each case with respect to a Licensed Product for use within the Field.

I.28 "**Information**" means any data, results, technology, business or financial information or information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, software, algorithms, marketing reports, expertise, technology, test data (including pharmacological, biological and chemical, biochemical, clinical test data and data resulting from non-clinical studies), CMC information, stability data and other study data and procedures.

I.29 "**Initiation**" means, with respect to any Clinical Study, the first dosing of the first human subject in such Clinical Study. "**Initiate**" and "**Initiated**" have correlative meanings.

I.30 "**Joint Development Committee**" or "**JDC**" means the committee formed by the Parties as described in Section 3.1.

I.31 "**Licensed Know-How**" means all Information that both (a) is owned or Controlled by Combioxin or any of its Affiliates [***] and (b) is necessary or reasonably useful in the Development, Manufacture, Commercialization and other exploitation of a Licensed Product (including the Data and all tangible embodiments thereof).

I.32 "**Licensed Patent Rights**" means any Patents owned or Controlled by Combioxin or any of its Affiliates as of the Effective Date or at any time during the Term of the Agreement that Cover the Development, Manufacture, Commercialization, and other exploitation of a Licensed Product. A list of Licensed Patent Rights as of the Effective Date is set forth on **Exhibit 1.32** (the "**Program Patent Rights**").

I.33 "**Licensed Product(s)**" means Combioxin's engineered liposome products, including its product referred to as "CAL02" as further described in **Exhibit 1.33**, [***].

I.34 "**Licensed Intellectual Property**" means Licensed Patent Rights and Licensed Know-How.

I.35 "**Manufacture**" and "**Manufacturing**" means all activities related to the synthesis, making, production, processing, purifying, formulating, filling, finishing, packaging, labeling, shipping, and holding of the any Licensed Product or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial production and analytic development, product characterization, stability testing, quality assurance, and quality control.

I.36 "**Manufacturing Process**" means all information pertaining to the Manufacture of a Licensed Product, as applicable, including without limitation the manufacturing methods, test

methods, specifications, materials, and other procedures, directions and controls associated with the Manufacture and testing of such Licensed Product, as applicable.

I.37 "**Marketing Approval Application**" (or "**MAA**") means application to the appropriate Regulatory Authority for approval to market a Licensed Product in any particular jurisdiction, including an NDA in the U.S.

I.38 "**NDA**" means a New Drug Application, as defined in the FD&C Act, as amended, and applicable regulations promulgated thereunder by the FDA.

I.39 "**Net Sales**" means, with respect to any Licensed Product, the gross amounts invoiced by Eagle and its Affiliates and Sublicensees for sales of such Licensed Product in the Field to Third Parties, less the following deductions as accrued:

(a) [***];

(b) [***];

(c) [***];

(d) [***];

(e) [***];

(f) [***];

(g) [***]; and

(h) [***].

Notwithstanding the foregoing, amounts received or invoiced by Eagle or its Affiliates or Sublicensees for the sale of Licensed Products among Eagle and its Affiliates and Sublicensees shall not be included in the computation of Net Sales hereunder. Net Sales shall be accounted for in accordance with the selling party's standard practices in the relevant country in the Territory.

[***], either Party may submit the matter to dispute resolution pursuant to Section 13.1.

I.40 "**Party**" means Combioxin or Eagle, individually; and "**Parties**" means Combioxin and Eagle, collectively.

I.41 "**Patent(s)**" means all patents and patent applications (including provisional applications), including all divisionals, continuations, substitutions, continuations-in-part, re-examinations, re-issues, additions, renewals, extensions, confirmations, registrations, any other pre- or post-grant forms of any of the foregoing, any confirmation patent or registration patent or patent of addition, utility models, patent term extensions, and supplemental protection certificates or requests for continued examinations, foreign counterparts, and the like of any of the foregoing.

I.42 "**Person**" means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, Governmental Authority or agency, or any other entity not specifically listed herein.

I.43 "**Phase 2 Clinical Study**" means a human clinical trial of a Licensed Product, the principal purpose of which is to evaluate the effectiveness and/or safety of such Licensed Product in the target patient population, as described in 21 C.F.R. § 312.21(b), as amended from time to time, or the corresponding foreign regulations, and which trial is intended to be the final clinical trial before the initiation of a Pivotal Clinical Trial and to establish the dosing for such Pivotal Clinical Trial. A "Phase 2/3 Clinical Study" shall be deemed to be a Phase 2 Clinical Study with respect to the portion of that clinical trial that is regarded as its Phase 2 component, in accordance with the applicable protocol.

I.44 "**Phase 3 Clinical Study**" means a human clinical trial of a Licensed Product, the principal purpose of which is to establish safety and efficacy in patients with the disease being studied and that would satisfy the requirements under 21 C.F.R. §312.21(c) for the U.S., as amended from time to time, or the corresponding foreign regulations for a comparable filing with a comparable Regulatory Authority. A "Phase 2/3 Clinical Study" shall be deemed to be a Phase 3 Clinical Study with respect to the portion of that clinical trial that is regarded as its Phase 3 component, in accordance with the applicable protocol.

I.45 "**Pivotal Clinical Trial**" means a pivotal human clinical trial of a Licensed Product (whether or not denominated a "Phase 3" clinical trial under applicable regulations) with a defined dose or a set of defined doses of such Licensed Product designed to ascertain efficacy and safety of such Licensed Product for the purpose of enabling the preparation and submission of an MAA to the competent Regulatory Authorities in a country of the Territory, as further defined in 21 C.F.R. § 312.21(c) for the U.S., as amended from time to time, or the corresponding foreign regulations.

I.46 "**Pricing and Reimbursement Approval**" means, with respect to any country or jurisdiction in the Territory in which Governmental Authorities determine the pricing at which a Licensed Product will be reimbursed, the approval, agreement, determination or decision by the applicable Governmental Authorities establishing the pricing and reimbursement status for such Licensed Product.

I.47 "**Regulatory Approval**" means all approvals, licenses, registrations or authorizations of any governmental entity that are necessary for the manufacturing, use, storage, import, transport and sale of Licensed Products in a regulatory jurisdiction, including in each case, Pricing and Reimbursement Approval.

I.48 "**Regulatory Authority**" means any national (e.g., the FDA) or, supra-national (e.g., the EC or the EMA), or other governmental entity in any jurisdiction of the world involved in the granting of Regulatory Approval for pharmaceutical products.

I.49 "**Regulatory Filing**" means all approvals, licenses, registrations, submissions and authorizations made to or received from a Regulatory Authority in a jurisdiction necessary for or in connection with the development, manufacture and/or commercialization of a pharmaceutical product, including any INDs, Marketing Approval Applications and Regulatory Approvals. As used

herein, "Regulatory Filing" also includes all correspondence with Regulatory Authorities (and their agents) regarding Licensed Products, including all submissions, meeting minutes, reports and other items exchanged between or under authority from Combioxin or its licensors with respect to a Licensed Product, or the Development, Manufacture, Commercialization or exploitation thereof.

I.50 "**Senior Executives**" means the [***] of Combioxin and the [***] of Eagle.

I.51 "**SOFR**" means the secured overnight financing rate published for by the Federal Reserve Bank of New York, as the administrator of the benchmark (or a successor administrator) on the Federal Reserve Bank of New York's website, as at the date on which the respective obligation to pay interest under this Agreement arises, and re-fixed for each day thereafter for as long as that obligation remains out-standing. In no event, however, shall the SOFR, for the purposes of this Agreement, be lower than 0.00%. In the absence of a SOFR at the relevant time as provided by this Agreement, the term SOFR shall mean the successor product to the secured overnight financing rate published for by the Federal Reserve Bank of New York for deposits in United States Dollars [***].

I.52 "**Sublicensee**" means a Third Party that has been granted a right to sell, market, distribute and/or promote Licensed Products in the Territory pursuant to Section 2.2 and Section 2.3; provided that as used herein, "Sublicensee" shall not be deemed to include any distributor, wholesaler or reseller of a Licensed Product who is not responsible for marketing or promotion of such Licensed Product.

I.53 "**Sublicensee Payments**" means all (i) cash upfront payments, (ii) royalty payments, and (iii) milestone payments that are paid to Eagle by any Sublicensee to the extent in consideration for the grant of a sublicense of Eagle's rights under this Agreement, but excluding the following payments:

(a) [***];

(b) [***];

(c) [***]; and

(d) [***].

I.54 "**Terminated Country**" means any country for which this Agreement has been terminated in accordance with ARTICLE IX.

I.55 "**Territory**" means worldwide.

I.56 "**Third Party**" means any Person other than other than a Party or an Affiliate of a Party.

I.57 "**Upstream Agreement**" means that certain License Agreement between the [***].

I.58 "**US**" means the United States of America, including all possessions and territories thereof.

I.59 "**U.S. Dollars**" means the legal currency of the United States of America.

I.60 "**Valid Claim**" means a claim of an issued, unexpired patent within the Licensed Patent Rights that has not been revoked, disclaimed, abandoned or held invalid or unenforceable by a court or other body of competent jurisdiction in an unappealed or unappealable decision.

I.61 **Additional Definitions**. Each of the following terms shall have the meaning described in the corresponding section of this Agreement indicated below:

Term	**Section Defined**
Existing Supplies	Section 2.4(c)
Milestone A	Section 4.3(a)(i)
Milestone B	Section 4.3(a)(ii)
Commercialization Plan	Section 4.3(a)(ii)
Development Milestone Payment	Section 5.2(a)
Development Milestone Event	Section 5.2(a)
Total Net Sales	Section 5.3(a)
Sales Milestone Payment	Section 5.3(a)
Sales Milestone Event	Section 5.3(a)
Royalty Term	Section 5.4(b)
Third Party Payments	Section 5.4(c)(i)
Royalty Report	Section 5.4(d)
Material Underpayment	Section 6.5(b)
Receiving Party	Section 7.1
Disclosing Party	Section 7.1
Confidential Information	Section 7.1
Representatives	Section 7.1
Prior CDA	Section 7.8

Enforcement Action	Section 8.3(a)(i)
Infringement Actions	Section 8.4
Term	Section 9.1
Combioxin Indemnitees	Section 12.1
Liabilities	Section 12.1
Third Party Claim	Section 12.1
Eagle Indemnitees	Section 12.2
Indemnitor	Section 12.3
Indemnitee	Section 12.3
Dispute	Section 13.1
ICC	Section 13.2
Acquisition	Section 14.9

ARTICLE II
GRANT OF LICENSE

II.1 **License to Eagle**. Subject to the terms and conditions of this Agreement, Combioxin hereby grants to Eagle an exclusive (even as to Combioxin and its Affiliates) license, with the right to grant and authorize sublicenses as provided in Section 2.2 and Section 2.3, to the Licensed Intellectual Property and to the Licensed Products, including to Develop, Manufacture, have Manufactured, register, Commercialize, market, distribute, import and otherwise exploit the Licensed Products in the Field in the Territory.

II.2 **Sublicensing**. Eagle shall have the right to grant and authorize sublicenses (through multiple tiers) under the rights granted to Eagle under Section 2.1 to one or more of its Affiliates, Sublicensees or other Third Parties.

II.3 **Disclosure and termination**. Eagle shall cause each Sublicensee to comply with the applicable terms and conditions of this Agreement. The grant of any such sublicense shall not relieve Eagle of its liabilities and obligations under this Agreement, except to the extent they are discharged or performed by such Sublicensee. Any such permitted sublicenses shall be consistent with and expressly made subject to the terms and conditions of this Agreement. A copy of any sublicense agreement [***] by Eagle shall be provided to Combioxin within [***] its execution.

In the event of termination of this Agreement, in whole or in part, Combioxin shall have the right to determine, in is sole discretion, for each sublicense, whether [***]. Combioxin shall inform Eagle and each Sublicensee of Combioxin's decision within [***] of the effective date of termination of this Agreement.

II.4 **Transfer of Licensed Know-How**.

(a) **Initial Transfer**. Promptly following the Effective Date and in any event no later than [***] thereafter, Combioxin shall, and shall use diligent efforts to cause any Affiliates or contractors to, transfer to Eagle, subject to reimbursement by Eagle of Combioxin's out-of-pocket costs, with complete and accurate copies of all Licensed Know-How in existence as of the Effective Date, in accordance with the technology transfer plan as set forth on **Exhibit 2.4**; provided that if, despite exercising diligent efforts to do so, Combioxin is unable to transfer (or have transferred) all of the Licensed Know-How to Eagle within such [***] period, Combioxin shall continue to exercise diligent efforts to complete such transfer of Licensed Know-How to Eagle as soon as thereafter reasonably practicable.

(b) Upon Eagle's written request after the Effective Date, a transfer of the global safety database available compiled by Combioxin until then from Combioxin to Eagle will be completed within [***]. Other than with respect to such transfer of the global safety database (to the extent required and available), Combioxin shall have no ongoing pharmacovigilance obligations, and Eagle shall assume all pharmacovigilance activities and obligations for the Licensed Products as of the Effective Date.

(c) **Existing Supplies**. In addition, to the extent Eagle requests, Combioxin shall, and shall use diligent efforts to cause any Affiliates and contractors to, transfer to Eagle (or Eagle's designee) all existing quantities of the CAL02, including all intermediates, works in progress, batch and stability samples, and other materials owned or controlled by Combioxin or its Affiliates for use in manufacturing or testing the Licensed Products (collectively, "**Existing Supplies**"), [***]. Prior to Eagle's request for such transfer, Combioxin shall, and shall [***] cause any contractors to, hold and maintain (under proper storage conditions necessary to maintain compliance with GMP) such Existing Supplies for the benefit and cost of Eagle until Eagle requests such transfer (up to a maximum of [***] after the Effective Date).

(d) **Ongoing Transfer**. Without limiting Section 2.4(a), if from time to time during the term of this Agreement, Eagle learns or believes that a particular item of Licensed Know-How and/or Existing Supplies has not been provided to Eagle, then upon request by Eagle, Combioxin shall, and shall use diligent efforts to cause any Affiliate or contractors, to promptly transfer to Eagle all such Licensed Know-How and/or Existing Supplies that has not previously been provided to Eagle hereunder, [***].

(e) **Cooperation**. The Parties will cooperate and reasonably agree upon formats and procedures to facilitate the orderly and efficient exchange of the Licensed Know-How and/or Existing Supplies in accordance with this Section 2.4. Without limiting the foregoing, Combioxin shall provide all such Licensed Know-How items [***]. It is understood all Licensed Know-How shall be made available to Eagle [***]. Upon request by Eagle, Combioxin shall, and shall [***]

cause any Affiliates or contractors to, reasonably cooperate with and assist Eagle as may be necessary or desirable in order to allow Eagle to understand the Licensed Know-How and/or Existing Supplies and to utilize the Licensed Know-How and/or Existing Supplies for the purposes contemplated in this Agreement.

II.5 **Upstream Agreement**.

(a) **Payments**. All amounts payable to [***] under the Upstream Agreement shall be the responsibility of Combioxin.

(b) **Combioxin Covenants**. During the Term, Combioxin hereby covenants to Eagle and agrees as follows:

(i) Combioxin shall maintain the Upstream Agreement in full force and effect and not terminate the Upstream Agreement, except with Eagle's prior written consent;

(ii) Combioxin shall not assign or otherwise transfer its rights, title or interest in the Upstream Agreement to any Third Party;

(iii)Combioxin shall not amend the Upstream Agreement or waive any obligation of [***] under the Upstream Agreement in any manner, except with Eagle's prior written consent;

(iv)Combioxin shall not take any action or omit to take any action that would result (including through the passage of time) in a default or breach of the Upstream Agreement; and

(v) Combioxin shall promptly notify Eagle in writing of the receipt or delivery of any notice of default or notice of termination under, or any termination or amendment of, the Upstream Agreement.

(c) **Breach**. Upon notification of a breach of the Upstream Agreement, Eagle shall have the right to step in to remedy the breach on Combioxin's behalf. Upon termination of the Upstream Agreement for a breach by Combioxin, Eagle shall have the right to receive, subject to [***] consent, a direct license from [***] with respect to the Licensed Intellectual Property under the terms and conditions set forth in the Upstream Agreement, as such are available and as such terms and conditions apply to Eagle.

II.6 **No Other Rights**. Except for the rights and licenses expressly granted in this Agreement, each Party retains all rights under its intellectual property, and neither Party shall be deemed by estoppel or implication to have granted the other Party any license or other right to any intellectual property of such Party.

ARTICLE III
GOVERNANCE

III.1 **Joint Development Committee**.

(a) **Formation and Role**. Promptly, and in any event within [***] after the Effective Date, the Parties shall establish a joint development committee to oversee Eagle's Development activities in connection with the Licensed Products.

(b) **Members**. Each Party shall initially appoint up to [***] to the JDC, each of whom [***]. The JDC may change its size from time to time by mutual consent of its members, and each Party may replace its representatives at any time upon written notice to the other Party. The JDC elects a chairperson among its members.

(c) **Meetings**. For the first [***] following the Effective Date, the JDC shall meet [***]. Following [***] of the Effective Date, the JDC shall meet [***] thereafter. Meetings of the JDC may be held in person, by audio or video teleconference, as determined by the Parties. Each Party shall be responsible for all of its own expenses of participating in the JDC. The JDC shall continue to exist until the First Commercial Sale of a Licensed Product in the US or Europe. The chairperson shall be responsible for calling meeting on [***] prior written notice. Each Party shall make proposals for agenda items and shall provide all appropriate information with respect to such proposed item at least [***] in advance of the meeting. The chairperson shall prepare and circulate for review and approval of the Parties minutes of each meeting within [***] from the meeting. The Parties shall agree on the minutes of each meeting promptly, but in no event later than the next meeting of the JDC.

(d) A quorum of the JDC shall exist whenever there is present at a meeting at least [***] appointed by each Party. If the quorum is met, the JDC shall take action by consensus of the representatives present at a meeting, or by a written resolution signed by at least [***] appointed by each Party.

(e) **Duties**. The JDC shall be responsible for:

(i) reviewing the strategy of Development and Regulatory Approval for Licensed Product in the Territory;

(ii) reviewing the activities [***] proposed to be conducted by or on behalf of Licensee in the Territory;

(iii)[***];

(iv)[***];

(v) [***]; and

(vi)undertaking or approving such other matters as are specifically assigned to the JDC in this Agreement.

(f) **Limitation of JDC Authority; Information Sharing**. The JDC shall be a non-voting body and is intended as an operational and informational sharing committee that discusses Eagle's Development activities and strategies to reach the Milestones A and B defined in this Agreement as well as successful Commercialization of the Licensed Product. The JDC may

suggest actions to both Parties to reach the aforementioned aims under this Agreement, and, where necessary, suggest amendments to this Agreement or any of its Exhibits. However, the JDC shall not have the power to make decisions under this Agreement and, for clarity, the JDC shall not have the authority to: (a) modify or amend the terms and conditions of this Agreement; (b) waive or determine either Party's compliance with the terms and conditions of under this Agreement; or (c) decide any such issue in a manner that would conflict with the express terms and conditions of this Agreement.

ARTICLE IV
DEVELOPMENT AND COMMERCIALIZATION ACTIVITIES

IV.1 **Development Responsibility**. From and after the Effective Date for the Term of this Agreement, Eagle will have the exclusive right to conduct, and be solely responsible for all aspects of, the Development of Licensed Products including Manufacturing the Licensed Products, setting the regulatory strategy for seeking Regulatory Approvals for Licensed Products in the Field in the Territory, and seeking and obtaining Regulatory Approvals. As between the Parties, Eagle shall bear all of its costs and expenses incurred in connection with such Development activities.

IV.2 **Regulatory Responsibility**. Eagle shall prepare and own all Regulatory Filings (including all INDs, NDAs, MAAs and Regulatory Approvals) for each Licensed Product in the Field in the Territory. Combioxin shall not submit any Regulatory Filings for Licensed Products in the Territory without the prior written consent of Eagle. Except as expressly requested by Eagle in writing, Combioxin shall not communicate with respect to the Licensed Products with any Regulatory Authority, unless so required to comply with Applicable Laws, in which case Combioxin shall promptly notify Eagle of such requirement under Applicable Laws, shall submit any proposed communication to Eagle for prior approval or, if not practicable or legally permitted, shall provide Eagle with a copy or summary thereof as soon as reasonably practicable thereafter.

IV.3 **Development Diligence**. Eagle, directly and/or through its Affiliates or Sublicensees, shall use Commercially Reasonable Efforts to Develop the Licensed Products in the Field in the Territory.

(a) **Diligence Milestones**. Eagle, directly and/or through its Affiliates or Sublicensees, shall adhere to the following Development milestones:

(i) *Milestone A*: [***].

(ii) *Milestone B*: [***].

IV.4 **Development Reports**. At least [***] prior to the regularly scheduled JDC meetings, Eagle will provide to Combioxin a written update summarizing the material Development activities conducted by Eagle during the period since the last JDC meeting, and anticipated to be conducted by Eagle in the following [***] period, with respect to the Development of Licensed Products in the Territory, including any material interactions with Regulatory Authorities. Upon reasonable request from time to time, Eagle will use good faith efforts to apprise Combioxin of material events with respect to the Development of Licensed Products, as mutually agreed at the time.

IV.5 **Transition of Development and Regulatory Activities**. Combioxin shall cooperate fully and use diligent efforts to effect a prompt, smooth and orderly transition of all Development and regulatory activities with respect to the Licensed Products to Eagle or its designee, as reasonably requested by Eagle, including the assignment of all Regulatory Filings for the Licensed Products in the Territory existing as of the Effective Date. To the extent reasonably requested by Eagle, Combioxin shall fully assist and cooperate with Eagle in connection with Eagle's preparation of filings, reports, responding to questions and other communications with Regulatory Authorities to the extent the same pertain to activities conducted by or on behalf of Combioxin or its licensors with respect to any Licensed Product prior to the Effective Date. For clarity, [***].

IV.6 **Manufacturing**. Eagle directly and/or through its Affiliates and/or one or more Third Parties, including a designated contract manufacturer, shall have the sole and exclusive right and responsibility, at its cost, for Manufacturing Licensed Products for clinical and commercial use in the Territory. Combioxin shall cooperate fully and use diligent efforts to effect a prompt, smooth and orderly transition of the Manufacture and supply of Licensed Products to Eagle or its designee, including the following:

(a) **Arrangements with Prior CMO and Contractors**: Upon Eagle's request, Combioxin shall (i) provide contact information for any manufacturer(s) or supplier(s) used by or on behalf of Combioxin with respect to the Licensed Products, and (ii) upon request by Eagle, fully cooperate and use diligent efforts [***] with respect to or in support of the Manufacture and supply of the Licensed Product(s), for use in the Development or Commercialization activities hereunder. Without limiting the foregoing Combioxin shall provide all necessary authorizations to permit the manufacturers and suppliers to use any Licensed Know-How in such entity's possession, including the Manufacturing Process, for the benefit of Eagle.

(b) **Manufacturing Process Transfer**: Promptly following the Effective Date and in any event no later than [***] thereafter, Combioxin shall, [***], promptly disclose to Eagle or its designee, such Licensed Know-How as is reasonably necessary or useful for the Manufacture of Licensed Products, including the manufacturing portions of any existing Regulatory Filings, in each case to the extent not previously provided to Eagle in accordance with the manufacturing technology transfer plan set forth on **Exhibit 2.4**.

(c) **Transition Costs**. Combioxin shall provide all such assistance without charge, provided that in the event that a Licensed Product is being Manufactured for Combioxin by a Third Party and Eagle requests the technical assistance of such Third Party manufacturer in connection with such transfer, or the assistance of such Third Party manufacturer is necessary to effectuate such transfer, Eagle agrees to reimburse Combioxin for all amounts paid to such Third Party for such technical assistance rendered to Eagle under this Section 4.6. [***].

IV.7 **Assignment of Agreements**. Promptly following the Effective Date, Combioxin shall assign to Eagle those agreements with Third Parties listed on **Exhibit 4.7**.

IV.8 **Commercialization**. As between the Parties and for the Term of this Agreement, Eagle shall have the exclusive right to conduct, and be solely responsible for all aspects of, the Commercialization of Licensed Products in the Field in the Territory, including: [***] As between

the Parties, Eagle shall bear all of its costs and expenses incurred in connection with such Commercialization activities.

IV.9 **Commercial Diligence**. Eagle shall use Commercially Reasonable Efforts to Commercialize each Licensed Product for which it has obtained Regulatory Approval in the Territory. Eagle shall, and shall cause its Affiliates and Sublicensees to, comply with all Applicable Law and GMP with respect to the Commercialization and Manufacturing of the Licensed Products.

IV.10 **Product Trademarks**. As between the Parties, Eagle shall have the sole and exclusive right to determine and own the trademarks to be used with respect to the Commercialization of the Licensed Products in the Field in the Territory, which branding may vary by country and Licensed Product. Eagle may, directly or through one or more Affiliates or Third Parties, register, maintain, enforce and defend such trademarks in the Territory, where and how it determines appropriate.

IV.11 **Subcontracting**. Eagle may subcontract with a Third Party to perform any or all of its obligations hereunder, provided that no such permitted subcontracting shall relieve Eagle of any liability or obligation hereunder.

ARTICLE V
PAYMENTS

V.1 **Upfront Payment**. Eagle shall pay to Combioxin a one-time, non-refundable, non-creditable upfront payment of ten million U.S. dollars ($10,000,000) within [***] following the Effective Date in accordance with the payment provisions of ARTICLE VI.

V.2 **Development Milestone Payments**.

(a) **Development Milestone Payments**. Eagle shall pay to Combioxin the one-time milestone payments set forth below following the first achievement by Eagle, and/or any of its Affiliates or Sublicensees, of the corresponding milestone events defined below with respect to the first Licensed Product to achieve such event (each, a "**Development Milestone Payment**" and "**Development Milestone Event**," respectively). The Development Milestone Payments shall be payable in accordance with the payment provisions in ARTICLE VI and following receipt of the relevant invoice from Combioxin as further described in Section 5.2(c).

No.	**Development Milestone Event**	**Payment**
1	[***]	[***]
2	[***]	[***]
	Total	**[***]**

(b) **One-Time Payments**. Each Development Milestone Payment is payable one time only, regardless of the number of times the corresponding event is achieved by a Licensed

Product and regardless of the number of Licensed Products to achieve such Development Milestone Event. Accordingly, in no event shall the aggregate amount to be paid to Combioxin pursuant to this Section 5.2 exceed [***] with respect to the achievement of all Development Milestone Events for all Licensed Products.

(c) **Reports and Payments**. Eagle shall notify Combioxin in writing within [***] after the achievement of each Development Milestone Event set out in Section 5.2(a) by Eagle, or any of its Affiliates, and in the case of Sublicensees, within [***] after such Development Milestone Event is achieved by such Sublicensee. Based on this notice, Combioxin shall then issue and send to Eagle the invoice for the appropriate Development Milestone Payment, which shall be paid by Eagle within [***] of receipt of such invoice.

V.3 **Sales Milestone Payments**.

(a) **Sales Milestone Payments**. Eagle shall pay to Combioxin the one-time sales milestone payments set out below when cumulative Net Sales of all Licensed Products (combined) in the Territory since the First Commercial Sale ("**Total Net Sales**") reach the respective thresholds (each, a "**Sales Milestone Payment**" and a "**Sales Milestone Event**," respectively), in accordance with this Section 5.3 and the payment provisions in ARTICLE VI and following receipt of the relevant invoice from Combioxin as further described in Section 5.3(c).

No.	**Sales Milestone Event**	**Payment**
1	Total Net Sales equals [***]	[***]
2	Total Net Sales equals [***]	[***]
3	Total Net Sales equals [***]	[***]
	Total	**[***]**

(b) **One-Time Payments**. Each of the foregoing Sales Milestone Payments shall be paid no more than once. In no event shall the aggregate amount to be paid to Combioxin pursuant to this Section 5.3 exceed [***].

(c) **Reports and Payments**. Eagle shall notify Combioxin in writing within [***] after the achievement of each Sales Milestone Event set out in Section 5.3(a). Based on this notice, Combioxin shall then issue and send to Eagle the invoice for the appropriate Sales Milestone Payment, which shall be paid by Eagle within [***] of receipt of such invoice.

V.4 **Royalty Payments**.

(a) **Base Royalties**. Subject to the terms and conditions of this Agreement, in consideration for the rights and licenses granted under this Agreement, Eagle shall pay to Combioxin the following royalties on Net Sales of Licensed Products by Eagle and its Affiliates (but not Sublicensees), in accordance with this Section 5.4 and the payment provisions in ARTICLE VI, equal to the following percentages of such Net Sales:

Total Net Sales of Licensed Product by Eagle and its Affiliates (but not Sublicensees)	**Royalty Rate**
Total Net Sales of Licensed Products equal to or less than [***]	[***]
Total Net Sales of Licensed Products greater than [***] but equal to or less than [***]	[***]
Total Net Sales of Licensed Products greater than [***] but equal to or less than [***]	[***]
Total Net Sales of Licensed Products greater than [***]	[***]

(b) **Royalty Term**. Eagle's obligation to pay royalties under this Section 5.4 shall continue with respect to sales of Licensed Products on a country-by-country and Licensed Product-by-Licensed Product basis until the date which is the later of: (a) expiration of the last to expire Valid Claim of a Program Patent Right Covering the Licensed Product in the country for which such Licensed Product is sold; or (b) [***] after the First Commercial Sale of the first Licensed Product in such country ("**Royalty Term**"). After the expiration of the applicable Royalty Term with respect to a Licensed Product in a country, no further royalties shall be due with respect to such Licensed Product in such country and the licenses and rights granted by Combioxin to Eagle under this Agreement with respect to such Licensed Product in such country will become fully paid-up, royalty-free, perpetual and irrevocable (except as otherwise expressly set forth in Section 5.5).

(c) **Royalty Adjustments**.

(i) **Third Party Payments**. If Eagle, its Affiliate or Sublicensee becomes obligated to make payment to a Third Party [***] ("**Third Party Payments**"), Eagle may [***] of the amount payable to each such Third Party from the amounts payable to Combioxin under this ARTICLE V; provided that such deduction shall not reduce the amounts so payable to Combioxin to [***] of the amount that would otherwise be due hereunder. Eagle may carry forward to subsequent calendar quarters any deductions that it was not able to deduct as a result of the foregoing proviso. For the avoidance of doubt, if Eagle elects to develop or use a Third Party intellectual property right solely for the Manufacture, use or sale of an Other Product that is part of a Combination Product, then no royalty adjustment shall be applied pursuant to this Section 5.4(c)(i).

(ii) **Valid Claim Coverage**. If the Licensed Product is not Covered by a Valid Claim of a Licensed Patent Right in the country for which such Licensed Product is sold, the royalty payable by Eagle with respect to such Licensed Product in such country shall be reduced [***] of the amount otherwise payable pursuant to this Section 5.4. Notwithstanding the foregoing, the reduction in this Section 5.4(c)(ii) shall not apply with respect to a Licensed Product in a calendar quarter in a particular country if a reduction is made under Section 5.4(c)(iii) below for such Licensed Product in such quarter in such country.

(iii)**Generic Products**. If, in any country in the Territory during the Royalty Term for a Licensed Product, Generic Products to such Licensed Product are sold by any Third Party that is not a Sublicensee, and the aggregated (all package sizes) sales turnover of the Licensed Product in such country (measured in unit sales) is [***] of the aggregated sales volume of such Licensed Product for the [***] immediately prior to the launch of the Generic Product in such country, then the then-applicable royalty rates (i.e., as set forth in Section 5.4(a) and as such royalties may have been further reduced pursuant to Section 5.4(c)) for such calendar quarter for Licensed Product sold in such country will be reduced [***] of the royalty rates then applicable. If, in any country in the Territory during the Royalty Term for a Licensed Product, Generic Products to such Licensed Product are sold by any Third Party that is not a Sublicensee, and the aggregated (all package sizes) sales turnover of the License Product in such country (measured in unit sales) is [***] of the aggregated sales volume of such Licensed Product for the [***] immediately prior to the launch of the Generic Product in such country, then the then-applicable royalty rates (i.e., as set forth in Section 5.4(a) and as such royalties may have been further reduced pursuant to Section 5.4(c)) for such calendar quarter for Licensed Product sold in such country will be reduced [***] of the royalty rates then applicable. All such determinations of unit sales shall be based upon a mutually acceptable calculation method using market share data provided by a reputable and mutually agreed upon provider, [***].

(iv)**One Royalty**. No more than one royalty payment shall be due under this Agreement with respect to a sale of a particular Licensed Product (e.g., even if such Licensed Product is Covered by multiple Valid Claims or multiple Licensed Patent Rights).

(d) **Royalty Reports**. Commencing with the calendar quarter in which the First Commercial Sale of a Licensed Product occurs in the Territory or Eagle first receives a Sublicensee Payment, Eagle shall deliver to Combioxin a report (each, a "**Royalty Report**") setting out the following details as reasonably necessary to calculate the payments due under this Section 5.4:

(i) [***];

(ii) [***];

(iii)[***];

(iv)[***]; and

(v) [***].

Royalty Reports shall be due [***] following the end of each such calendar quarter during the term of this Agreement. Promptly following the delivery of the applicable Royalty Report, Combioxin will invoice Eagle for the royalties due to Combioxin under Section 5.4 above with respect to the Net Sales in the Territory in such calendar quarter and the share of Sublicensee Payments due to Combioxin under Section 5.5 below with respect to such calendar quarter. Eagle shall pay such amounts to Combioxin within [***] following Eagle's receipt of such invoice.

V.5 **Sublicensees**.

(a) **Sales by Sublicensees.** Eagle shall pay to Combioxin [***] of all Sublicensee Payments. Notwithstanding the foregoing, regardless of the actual royalty rate set forth in the applicable sublicense agreement with a Sublicensee, Combioxin's share of any Sublicensee Payments that constitute a royalty on Net Sales of a Licensed Product shall not be less than [***] or greater than [***] of the Net Sales of such Sublicensee of such Licensed Product. For example, [***].

(b) **Termination of Royalty-Based Sublicensee Payments**. Notwithstanding the forgoing Section 5.5(a), on a country-by-country and Licensed Product-by-Licensed Product basis, in the event that Combioxin does not owe a royalty payment to the [***] pursuant to Section 3.1(b) of the Upstream Agreement with respect to a particular Licensed Product in a particular country, then the minimum royalty rate set forth in Section 5.5(a) shall no longer apply.

ARTICLE VI
PAYMENTS; BOOKS AND RECORDS

VI.1 **Payment Method; Currency Conversion**. All amounts specified in this Agreement are in U.S. Dollars, and all cash payments under this Agreement shall be paid in U.S. Dollars. As applicable, Net Sales and any royalty reductions incurred in other currencies will be translated into U.S. Dollars in the manner used by Eagle from time to time in the preparation of its audited financial statements for external reporting purposes. All payments under this Agreement will be paid in U.S. Dollars by wire transfer to an account designated by Combioxin (which account Combioxin may update from time to time in writing, subject to Eagle's reasonable confirmation). If at any time legal restrictions prevent the prompt remittance of any royalties or other amounts with respect to any country where Licensed Products are sold, Eagle shall have the right, at its option, to make such payments by depositing, or causing to be deposited, the amount of such payments in local currency to Combioxin's account in a bank or other depository designated by Combioxin in such country.

VI.2 **Withholding Taxes**. Notwithstanding any other provision of this Agreement, Eagle shall be entitled to deduct and withhold from any payments such amounts as it is required to deduct and withhold pursuant to any tax laws of any jurisdiction or any regulation of any taxing authority thereof. To the extent such amounts are deducted, withheld and paid by or on behalf of Eagle to the appropriate taxing authority, such amounts shall be treated for all purposes of this Agreement as having been paid to Combioxin. Eagle shall provide Combioxin with official receipts issued by the appropriate governmental agency to Eagle. Each Party shall provide to the other Party such assistance as may be reasonably requested in connection with any application to qualify for the benefit of a reduced rate of withholding taxation, under the terms of any income tax treaty between the United States and other jurisdictions, in particular under the terms of the existing tax treaty between the United States and Switzerland.

If Eagle assigns this Agreement as per Section 14.8 or moves its business operations out of the US, or if Eagle is acquired by a company outside the US, then any negative withholding taxes consequences shall be fully and solely be compensated by Eagle.

VI.3 **Late Payments**. In the event that any undisputed amount payable by Eagle to Combioxin hereunder is not made when due, such outstanding payment shall accrue interest, to the

extent permitted by Applicable Law, at an annual rate of [***], computed from the date such payment was due until the date Eagle makes the payment.

VI.4 **Records.** Eagle and its Affiliates shall keep complete and accurate books of account and records in reasonably sufficient detail to enable the amounts payable under this Agreement to be determined. Such books and records shall be kept at the principal place of business of Eagle, its Affiliate or Sublicensee, as the case may be, for at least [***] following the end of the calendar year to which such books and records pertain.

VI.5 **Audits.**

(a) **Audit Rights.** Upon at least [***] prior written notice from Combioxin, Eagle shall permit, and shall require its Affiliates and use reasonable efforts to require its Sublicensees, to permit, an independent certified public accounting firm of nationally recognized standing, selected by Combioxin and reasonably acceptable to Eagle, to have access during normal business hours to such books of account and records of Eagle, and its Affiliates and Sublicensees, at such Person's principal place of business, as may be reasonably necessary to verify the accuracy of the reports provided by Eagle pursuant to Section 5.4(d). Such audits may not (i) be conducted for any calendar year ending more than [***] prior to the date of such request, (ii) be conducted more than [***] in any calendar year or (iii) [***].

(b) **Audit Results.** Combioxin shall require the independent accountant to provide to Eagle an audit report containing its conclusions regarding any audit, and specifying whether the amounts paid were correct or, if incorrect, the amount of any underpayment or overpayment. The independent accountant shall provide to Eagle a preliminary copy of its audit report and shall discuss with Eagle any issues or discrepancies that Eagle identifies, prior to submission to Combioxin. If such audit establishes that additional royalties and/or Sales Milestones Payments are properly owed to Combioxin in accordance with this Agreement during the period covered by any audit pursuant to Section 6.5(a), Eagle shall remit to Combioxin within [***] of the date on which Combioxin delivers to Eagle an invoice for such amounts: (i) the amount of such additional royalties and/or Development Milestone Payments or Sales Milestone Payments; and (ii) interest on such amount which shall be calculated pursuant to Section 6.3. In the event such audit establishes that amounts were overpaid by Eagle during such period, the amount of such overpayment shall be credited to Eagles next payments and Combioxin will include such amount in the next invoice issued in accordance with this Agreement. The fees charged by the independent accountant in connection with any audit pursuant to this Section 6.5 shall be paid by Combioxin; provided, however, that if a discrepancy in favor of Combioxin of more than [***] of the payments due hereunder for the period being audited (a "**Material Underpayment**") is established, then Eagle shall pay the reasonable fees and expenses charged by such accounting firm in connection with such audit.

(c) **Confidential Financial Information; Other Matters.** Combioxin shall treat all financial information subject to review under this ARTICLE VI as the Confidential Information of Eagle in accordance with Section 7.1. Any such auditor appointed by Combioxin shall enter into a confidentiality agreement with Eagle and shall not disclose or use Eagle's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports

furnished by Eagle or the amount of payments due by Eagle to Combioxin under this Agreement. If Eagle is unable to obtain from any Sublicensee a right for Combioxin to audit the books of account and records of such Sublicensee, Eagle shall obtain the right to inspect and audit such Sublicensee's books and records for itself and shall exercise such audit rights on behalf and at the expense of Combioxin upon Combioxin's written request and disclose the results of any such audit to Combioxin in accordance with Section 6.5(b). Combioxin shall be responsible for the costs incurred by Eagle with respect to such audit and inspection, provided that if such audit establishes a Material Underpayment, Eagle shall reimburse Combioxin for the costs so paid by Combioxin to Eagle with respect to such audit.

ARTICLE VII
CONFIDENTIALITY

VII.1 **Confidential Information**. Except to the extent expressly authorized by this Agreement, each Party agrees that, during the term of this Agreement, and for [***] thereafter, such Party (the "**Receiving Party**") shall keep confidential, and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement or in the exercise of rights granted to it hereunder, any information furnished to it by or on behalf of the other Party (the "**Disclosing Party**") pursuant to this Agreement that is marked or otherwise identified as confidential or proprietary at the time of disclosure or is disclosed in such a manner or is of such a nature that a reasonable person would understand such information to be confidential or proprietary, independent of whether such information was shared in writing, orally, electronically or any other form tangible or intangible form (collectively, "**Confidential Information**"). The Receiving Party shall use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but in no event less than reasonable care) to prevent unauthorized access, use and disclosure of the Disclosing Party's Confidential Information and to ensure that its, and its Affiliates', employees, agents, consultants, other representatives ("**Representatives**") do not disclose, except as otherwise expressly permitted under this Agreement, or make any unauthorized use of, the Disclosing Party's Confidential Information. The Receiving Party shall promptly notify the Disclosing Party upon discovery of any unauthorized use or unauthorized disclosure of the Disclosing Party's Confidential Information. For purposes of this Agreement, the terms of this Agreement and the Licensed Know-How (to the extent such Licensed Know-How is related to the Licensed Products) shall be deemed the Confidential Information of both Eagle and Combioxin.

VII.2 **Exceptions.** Confidential Information of a Disclosing Party shall not include any information to the extent that such information (which the Receiving Party can prove by competent written evidence): (a) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party in breach of this Agreement, generally known or available to the public; (b) is lawfully known by the Receiving Party or any of its Affiliates (to the extent such Receiving Party or Affiliate has the right to use and disclose such information) at the time of receiving such information from the Disclosing Party; (c) is hereafter furnished to the Receiving Party or any of its Affiliates 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 Receiving Party (to the extent such Receiving Party or Affiliate has the right to use and disclose such information); or (d) is independently discovered or developed by the Receiving Party or any of its Affiliates, without the use of or reference to Confidential Information of the Disclosing Party.

VII.3 **Authorized Disclosure.** Notwithstanding the provisions of Section 7.1, the Receiving Party may disclose Confidential Information of the Disclosing Party as expressly permitted by this Agreement, or if and to the extent such disclosure is reasonably necessary in the following instances:

(a) In the case of either Party as the Receiving Party:

(i) enforcing such Party's rights or performing its obligations under this Agreement;

(ii) prosecuting or defending litigation as permitted by this Agreement;

(iii)such disclosure is reasonably necessary to its employees, agents, consultants, contractors, licensees or Sublicensees 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;

(iv)such disclosure is necessary to comply with Applicable Laws, including regulations promulgated by applicable security exchanges, court order, administrative subpoena or order; provided in the event the Receiving Party is required to make a disclosure of the Disclosing Party's Confidential Information pursuant to this subparagraph 7.3(a)(iii), it will, except where legally prohibited, (i) give reasonable advance notice to the Disclosing Party of such disclosure, (ii) use efforts to secure confidential treatment of such information at least as diligent as the Receiving Party would use to protect its own confidential information, and (iii) in the case of disclosures under this subparagraph 7.3(a), cooperate with any efforts by the Disclosing Party, at the Disclosing Party's request and expense, to prevent or limit disclosure of such Confidential Information; or

(v) disclosure to Third Parties in connection with due diligence or similar investigations, and disclosure to any bona fide potential or actual investor, acquiror or merger partner for the sole purpose of evaluating an actual or potential investment, acquisition or merger; provided that in connection with such disclosure, such Party shall inform each disclosee of the confidential nature of such Confidential Information and ensure that any such Third Party agrees to be bound by obligations of confidentiality and non-use similar to those contained in this Agreement.

(b) In the case of Eagle as the Receiving Party:

(i) [***];

(ii) [***]; and

(iii)[***].

(c) In the case of Combioxin as the Receiving Party in case of a termination of this Agreement and return of any Licensed Know-How, Licensed Product and Licensed Patent

Rights to Combioxin in accordance with Section 10.3, Section 10.4 and Section 10.5 that includes Eagle Confidential Information:

(i) [***];

(ii) [***]; and

(iii)[***].

(d) Each Party shall be responsible for any breaches of confidentiality by any of its Affiliates, subcontractors, Representatives, advisors and Third Parties to whom it discloses Confidential Information pursuant to Section 7.3.

VII.4 **Confidential Disclosure of Terms**. The Parties agree that the terms of this Agreement are the Confidential Information of both Parties that a Party shall not disclose to any Third Party without the prior written consent of the other Party hereto, except as permitted under Section 7.2 or 7.3 above, and notwithstanding the foregoing, each Party may disclose the existence and/or terms of this Agreement to [***] on a reasonable need to know basis, in each case under circumstances that reasonably protect the confidentiality thereof.

VII.5 **Publications**. As between the Parties, from and after the Effective Date until termination, Eagle shall have the sole and exclusive right to publish and present the results of any Development activities with respect to Licensed Products and may further publish and disclose the results of any Clinical Study and other Data included in the Licensed Know-How.

VII.6 **Use of Name**. Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo, or trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any public communication without the prior written consent of the other Party. The restrictions imposed by this Section 7.6 shall not prohibit either Party from making any disclosure identifying the other Party that, in the opinion of the Disclosing Party's counsel, is required by Applicable Law; provided such Party shall submit the proposed disclosure identifying the other Party in writing to the other Party as far in advance as reasonably practicable so as to provide a reasonable opportunity to comment thereon.

VII.7 **Press Releases**.

(a) The Parties have mutually approved a joint press release attached hereto as **Exhibit 7.7** with respect to this Agreement to be published on the Effective Date or immediately thereafter. Each Party agrees not to issue any other press release or other public statement, whether oral or written, disclosing the terms hereof or any of the activities conducted hereunder without the prior written consent of the other Party (such consent not to be unreasonably withheld, conditioned or delayed), except as permitted under Section 7.3(a) above. Notwithstanding the foregoing, after release of a press release in accordance with this Section 7.7(a), either Party may disclose to Third Parties the information contained in such press release without further consent.

(b) For clarity, Eagle shall have the right to issue subsequent press releases or other public statements pertaining to the activities conducted hereunder. For avoidance of doubt, Eagle shall have the right to publicly disclose without Combioxin's prior written consent: [***].

(c) Eagle shall have the right to hold an investors' day following the issue of the joint press release and to discuss matters pertaining to this Agreement during that investors' day, provided that Eagle shall comply with its confidentiality obligations hereunder in relation to that investors' day.

VII.8 **Prior Non-Disclosure Agreements**. This Agreement supersedes the Confidentiality and Nondisclosure Agreement between Eagle and Combioxin effective as of [***] ("**Prior CDA**") regarding the subject matter of this Agreement. All information exchanged between the Parties under the Prior CDA shall be deemed to have been disclosed under this Agreement on a going-forward basis and shall be subject to the terms of this ARTICLE VII as of the Effective Date.

VII.9 **Trade Secrets**. Eagle acknowledges that Combioxin may transfer trade secrets to Eagle in connection with this Agreement. Combioxin shall take all steps reasonably necessary to maintain such information as a trade secret for an indefinite period, notwithstanding Section 7.3. Such trade secrets may only be used by Eagle as expressly set forth in this Agreement.

ARTICLE VIII
PATENT PROSECUTION AND ENFORCEMENT

VIII.1 **Ownership of Inventions**. Inventorship of inventions shall be determined in accordance with the rules of inventorship under U.S. patent laws. As between the Parties, Eagle (or its Affiliate) shall solely own all inventions made solely by Eagle personnel, and Combioxin (or its Affiliate) shall solely own all inventions made solely by personnel of Combioxin. The Parties (or their respective Affiliates) shall jointly own all inventions made jointly by personnel of both Eagle and Combioxin; provided that, subject to the rights and licenses granted under and the restrictions set forth in this Agreement, [***].

VIII.2 **Patent Prosecution and Maintenance**.

(a) **Eagle Prosecution and Maintenance**. As between the Parties, Eagle shall, at its expense, have the first right, but not the obligation, to file, maintain and prosecute (particularly with respect to any Patent dispute) the Licensed Patent Rights throughout the Territory, including conducting any interferences, *inter parte* reviews, reexaminations, reissues, opposition, and other similar proceedings relating thereto. [***], Eagle shall keep Combioxin reasonably informed of progress with regard to the prosecution and maintenance of Licensed Patent Rights as set forth in this Section 8.2(a). Combioxin shall have the right to consult and review all material Patent filings in advance of any deadline, submission to or action with any patent office. Eagle shall furnish to Combioxin copies of all relevant drafts and documents of such material Licensed Patent Rights as reasonably as practicable in advance of such consultation for Combioxin's review. Eagle shall provide to Combioxin copies of all patent office submissions and patent office correspondence relevant to such Licensed Patent Rights within [***] following submission or receipt thereof by Eagle. Eagle shall consider in good faith any reasonable and timely comments provided by Combioxin in connection with the prosecution and maintenance of such Licensed Patents Rights. At

Eagle's request, Combioxin shall reasonably cooperate with Eagle in the prosecution and maintenance of such Licensed Patent Rights. If Eagle desires to abandon or cease prosecution or maintenance of any such Licensed Patent Right in any country in the Territory in its entirety, Eagle shall provide written notice to Combioxin of such intention promptly after Eagle makes such determination, but in no event later than [***] prior to any final deadline that must be met in order to avoid such abandonment, and Combioxin shall have the right, but not the obligation, to assume responsibility for prosecution and maintenance of such Licensed Patent Right at its sole cost and expense. If Combioxin assumes responsibility for the prosecution and maintenance of any such Licensed Patent Rights, Combioxin shall similarly (i) consult with Eagle as to the prosecution and maintenance of such Licensed Patents Rights in the Territory reasonably prior to any deadline, submission to or action with any patent office, (ii) furnish to Eagle copies of all relevant drafts and documents reasonably in advance of such consultation, (iii) provide to Eagle copies of all patent office submissions and correspondence relevant to such Licensed Patent Rights within a reasonable amount of time following submission or receipt thereof by Combioxin, (iv) consider in good faith any reasonable and timely comments provided by Eagle in connection with the prosecution and maintenance of such Licensed Patent Rights, and (v) Eagle shall have the right to veto claim amendments and prosecution arguments to the extent such amendments or arguments are reasonably likely to result in a negative impact on Eagle's prosecution and maintenance of other Patents that claim a License Product. Combioxin shall provide Eagle with an updated **Exhibit 1.32** on [***] basis or more frequently upon Eagle's reasonable request.

(b) **Patent Term Extensions**. Eagle shall have the sole right to obtain patent term extensions, supplementary protection certificates, and equivalents thereof with respect to any Licensed Product in the Field in the Territory, including with respect to any Licensed Patent Right in any country in the Territory, and Combioxin shall reasonably cooperate with Eagle in connection therewith.

VIII.3 **Enforcement**.

(a) **Enforcement Actions**.

(i) In the event that either Party becomes aware of any patent nullity, invalidity or unenforceability actions, any declaratory judgment actions, or any actual or threatened infringement of any Licensed Patent Right, including any claims arising under the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417), as amended, or its equivalent in a country other than the United States, that Party shall promptly notify the other Party in writing. Eagle (itself or through a designee) shall have the first right, but not the obligation, to initiate proceedings or take other action it believes appropriate, at its own expense, to enforce or defend the Licensed Patent Rights with respect to any such activities involving or applicable to a Licensed Product (each, an "**Enforcement Action**"). If Eagle does not initiate proceedings within [***] from the date of Combioxin's request that Eagle initiate such proceedings, (or in the event that written notice is received under any statute expediting litigation (e.g. Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417)) or any foreign counterparts of such law, within thirty (30) days of the date of such notice) or resolve the dispute, then Combioxin shall be entitled, but shall not be obliged, to initiate infringement proceedings or take other action it believes appropriate against such Third Party at its own expense.

(ii) The Party conducting such Enforcement Action under this Section 8.3(a) shall have full control over its conduct, including settlement thereof; provided, however, that the Party conducting such Enforcement Action may not settle any such Enforcement Action, or make any admissions or assert any position in such Enforcement Action, in a manner that would materially adversely affect the validity of a Licensed Patent Right, without the prior written consent of the other Party, which shall not be unreasonably withheld or delayed. If one Party brings any suit, action or proceeding under this Section 8.3(a), the other Party agrees to be joined as party plaintiff if reasonably necessary to prosecute the suit, action or proceeding and to give the first Party authority to file, prosecute and control the suit, action or proceeding; provided, however, that such other Party shall in any case have the right to be represented by its own counsel at its cost and expense. In any event, the Parties shall assist one another and cooperate in any such litigation at the other's reasonable request.

(iii)The Party initiating the Enforcement Action under Section 8.3(a) shall assume and pay all costs and expenses incurred by it with respect to such Enforcement Action, including fees and expenses of counsel selected by it.

(b) **Recovery**. Combioxin and Eagle shall each recover their respective actual out-of-pocket expenses (including attorneys' fees), or equitable proportions thereof, associated with any Enforcement Action against infringers undertaken pursuant to Section 8.3(a) from any resulting amount received by award of a court of competent jurisdiction. Any excess amount of such a recovery shall (i) be retained [***]; or (ii) otherwise retained by [***].

VIII.4 **Third Party Infringement Claims**. If the production, sale, importation, or use of any Licensed Product in any country of the Territory pursuant to this Agreement results in a claim, suit or proceeding alleging patent or other intellectual property infringement against Combioxin or Eagle (or their respective Affiliates, or Sublicensees) (collectively, "**Infringement Actions**"), such Party shall promptly notify the other Party hereto in writing. Eagle shall have the right to direct and control the defense thereof, at its own expense (subject to Combioxin's indemnification obligations set forth in Section 12.2) with counsel of its choice. Eagle shall keep Combioxin reasonably informed of all material developments in connection with any such Infringement Action. Eagle may treat any out-of-pocket costs incurred in connection with such Infringement Action, including reasonable attorneys' fees, damages and other liabilities that are part of any final judgment, and any amounts paid by Eagle in a settlement of the Infringement Action as Third Party Payments under Section 5.4(c)(i) above.

ARTICLE IX
TERM AND TERMINATION

IX.1 **Term**. This Agreement shall commence on the Effective Date and, unless terminated earlier pursuant to Section 9.2, Section 9.3, Section 9.4 or Section 9.5, shall continue in full force and effect until the expiration of the last to expire Royalty Term ("**Term**").

IX.2 **Termination for Material Breach**. If either Party materially breaches this Agreement at any time, the non-breaching Party shall have the right to terminate this Agreement by written notice to the breaching Party, if such material breach is not cured within [***] after written

notice is given by the non-breaching Party to the breaching Party specifying the breach, subject to Section 13.2 below. Notwithstanding the foregoing, to the extent any material breach is limited to a particular country, then the non-breach Party shall only have the right to terminate this Agreement with respect to such country.

IX.3 **Termination for Bankruptcy**. Either Party shall have the right to terminate this Agreement upon written notice to the other Party: (a) if such other Party is declared insolvent or bankrupt by a court of competent jurisdiction; (b) if a voluntary or involuntary petition in bankruptcy is filed in any court of competent jurisdiction against such other Party and such petition is not dismissed within [***] after filing; (c) if such other Party shall make or execute an assignment of substantially all of its assets for the benefit of creditors; or (d) substantially all of the assets of such other Party are seized or attached and not released within [***] thereafter.

IX.4 **Termination by Eagle**. Eagle shall have the right to terminate this Agreement, in its entirety or on a country-by-country basis or Licensed Product-by-Licensed Product basis, for convenience, without cause, and for any or no reason prior to the First Commercial Sale of the first Licensed Product on not less than ninety (90) days' prior written notice to Combioxin, and thereafter, on not less than one hundred and eighty (180) days' prior written notice to Combioxin.

IX.5 **Termination by Combioxin**. Combioxin shall have the right to terminate this Agreement in its entirety or on a country-by-country basis, for cause in case of:

(a) failure to achieve the Development Milestone A with prior written notice of [***]; and

(b) failure to achieve Development Milestone B, [***] prior written notice.

ARTICLE X
EFFECT OF TERMINATION

X.1 **Accrued Obligations**. The expiration or termination of this Agreement for any reason shall not release either Party from any liability which, at the time of such expiration or termination, has already accrued to the other Party prior to such expiration or termination, nor will any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, or at law or in equity, with respect to any breach of this Agreement that occurred prior to such expiration or termination.

X.2 **Return of Confidential Information**. Within [***] after the Effective Date of any such termination, each Party shall promptly return to the other Party, or delete or destroy, all Confidential Information of the other Party; provided that (i) each Party may retain copies of the Confidential Information of the other Party to the extent necessary to perform its obligations or exercise its rights that survive expiration or termination of this Agreement; (ii) each Party may retain one copy of the Confidential Information of the other Party [***]. Upon any termination of this Agreement by either Party under Section 9.2 or 9.3, by Eagle under Section 9.4, or by Combioxin under Section 9.5, Confidential Information comprising Licensed Know-How shall cease to be Confidential Information of Eagle, and thereafter shall be Confidential Information solely of Combioxin.

X.3 **Cease of use**. Upon termination, independent of its cause, Eagle shall immediately cease to use the Licensed Know-How, Licensed Product and Licensed Patent Rights except where such further use is necessary to ensure patient safety until such safety obligations are assumed by Combioxin.

X.4 **Reversion of Rights**. All rights and licenses granted to Eagle under this Agreement shall terminate and revert to Combioxin, provided that if this Agreement is only terminated with respect to one or more countries, only the rights and licenses with respect to such country or countries shall terminate and revert to Combioxin.

X.5 **Consequences of Termination**. In the event this Agreement is not terminated in its entirety, but rather is terminated on a country-by-country basis or Licensed Product-by-Licensed Product basis, then, notwithstanding anything to the contrary in this Section 10.5, the consequences of termination described herein shall only apply to such terminated country or terminated Licensed Product, and this Agreement shall remain in full force and effect with respect to all countries other than such terminated country or terminated Licensed Product, as applicable. In the event of a termination of this Agreement prior to the end of the Term,

(a) [***];

(b) [***];

(c) [***];

(d) [***];

(e) [***];

(f) [***];

(g) [***]; and

(h) [***].

X.6 **Survival**. Upon the expiration or termination of this Agreement, all rights and obligations of the Parties under this Agreement shall terminate except that [***] shall survive expiration or any termination of this Agreement.

ARTICLE XI
REPRESENTATIONS, WARRANTIES AND COVENANTS

XI.1 **Representations, Warranties and Covenants of Combioxin**. Combioxin represents, warrants and covenants to Eagle that, as of the Effective Date:

(a) Combioxin is a corporation duly organized, validly existing and is in good standing under the laws of Switzerland, is qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the conduct of its business or the ownership of its

properties requires such qualification and failure to have such would prevent Combioxin from performing its obligations under this Agreement;

(b) this Agreement is a legal and valid obligation binding upon Combioxin and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by Combioxin have been duly authorized by all necessary corporate action and do not and will not: (i) violate any law, rule, regulation, order, writ, judgment, decree, determination or award of any court, governmental body or administrative or other agency having jurisdiction over Combioxin; nor (ii) conflict with, or constitute a default under, any agreement, instrument or understanding, oral or written, to which Combioxin is a party or by which it is bound;

(c) Combioxin is the sole owner or otherwise has sufficient legal title and/or beneficial title or ownership or license with respect to the Licensed Patent Rights and the Licensed Know-How and has the full right and authority to grant the rights and licenses with respect to the Licensed Patent Rights and Licensed Know-How, without limitation or restriction;

(d) Combioxin hereby covenants that it shall not, during the Term, without the prior written approval of Eagle, (i) amend any provision of the Upstream Agreement that would adversely impact Eagle's rights under this Agreement, or (ii) assign (except an assignment to a party to which this Agreement has been assigned as permitted under Section 14.8 or to any Affiliate), in whole or in part, the Upstream Agreement in any manner that would adversely impact Eagle's rights under this Agreement, in each case, without the prior written consent of Eagle;

(e) Combioxin has provided Eagle with a true and correct copy (as of the Effective Date) of the Upstream Agreement in effect as of the Effective Date. Combioxin and its Affiliates are not in breach of the Upstream Agreement and the [***] has not threatened to terminate or otherwise allege any breach under the Upstream Agreement;

(f) The Licensed Know-How includes, to Combioxin's knowledge, all proprietary aspects of the Manufacturing Process and CMC Data, and is sufficient for Eagle, its designees and Sublicensees to Manufacture the Licensed Products, in the same manner has they have been Manufactured prior to the Effective Date;

(g) **Exhibit 1.32** sets forth a true and complete list of all Patents owned by Combioxin or its Affiliates as of the Effective Date that Cover the Licensed Products, and Combioxin has the full right and authority to grant to Eagle the right to make, use, sell, offer to sell, import, sublicense and otherwise exploit worldwide, all of the Patents described in **Exhibit 1.32**, and to prosecute and enforce such Patents in accordance with ARTICLE VIII above;

(h) **Exhibit 4.7** sets forth all contracts entered into by Combioxin or its Affiliate prior to the Effective Date that could, to Combioxin's knowledge, pertain to Licensed Products, Licensed Patent Rights or Licensed Know-How after the Effective Date.

(i) Combioxin has not previously granted and will not grant any right, license or interest in or to a Licensed Product, Licensed Know-How and/or Licensed Patent Rights, or any portion thereof, that is in conflict with, limits or derogates from the rights or licenses granted to Eagle under this Agreement;

(j) the Licensed Patent Rights and the Licensed Know-How are free and clear of all liens, claims, security interests or other encumbrances of any kind and during the term of this Agreement, Combioxin shall not permit the Licensed Patent Rights or the Licensed Know-How to become encumbered by any liens, claims, security interests or other encumbrances that could diminish Eagle's rights or licenses with respect to any Patent or other subject matter;

(k) to Combioxin's knowledge, there are no actual, pending, alleged or threatened actions, suits, claims, interference or governmental investigations involving a Licensed Product, the Licensed Patent Rights or the Licensed Know-How by or against Combioxin, or any of its Affiliates or other licensees;

(l) all necessary consents, approvals and authorizations of all Regulatory Authorities, other Governmental Authorities and other persons or entities required to be obtained by Combioxin in order to enter into this Agreement have been obtained for the Licensed Product at its current stage of development;

(m) to Combioxin's knowledge, the practice of the Licensed Patent Rights or the Licensed Know-How and the making, using, selling, offering for sale and importing of any Licensed Product does not infringe, violate or misappropriate the intellectual property rights of any Third Party;

(n) Combioxin has not received notice from a Third Party claiming that the practice of the Licensed Patent Rights or the Licensed Know-How or the making, using, selling, offering for sale and importing of a Licensed Product infringes, violates or misappropriates the intellectual property rights of any Third Party;

(o) Combioxin has not knowingly withheld any Licensed Know-How that is reasonably relevant for Eagle's conduct of activities under this Agreement and, to Combioxin's knowledge, all Licensed Know-How provided to Eagle is free from any material inaccuracies;

(p) Combioxin has disclosed to Eagle all information relating to the safety and efficacy of the Licensed Product known to it or its Affiliates;

(q) to Combioxin's knowledge, there is no actual, pending, alleged or threatened infringement by a Third Party of any of the Licensed Patent Rights or the Licensed Know-How;

(r) Combioxin has complied with all Applicable Laws in all material respects, including any disclosure requirements, in connection with the filing, prosecution and maintenance of the Licensed Patent Rights and, to Combioxin's knowledge, none of the issued Licensed Patent Rights are invalid or unenforceable;

(s) the Licensed Patent Rights and Licensed Know-How are not subject to any funding agreement with any government or Governmental Authority;

(t) Combioxin has [***];

(u) Combioxin has [***];

(v) [***];

(w) to Combioxin's knowledge, none of the materials and documents provided to Eagle in the course of Eagle's due diligence preceding execution of this Agreement contained any untrue statement of material fact; and

(x) all Licensed Products Manufactured and delivered by or under the authority of Combioxin to Eagle pursuant to Section 2.4 of this Agreement, and that are identified as being "GMP" in **Exhibit 2.4**, were Manufactured and are as of the Effective Date in compliance with all Applicable Laws, GMP and any other applicable manufacturing standards.

XI.2 **Representations and Warranties of Eagle**. Eagle represents and warrants to Combioxin that, as of the Effective Date:

(a) Eagle is a corporation duly organized, validly existing and is in good standing under the laws of the State of Delaware, U.S.A., is qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the conduct of its business or the ownership of its properties requires such qualification and failure to have such would prevent Eagle from performing its obligations under this Agreement;

(b) this Agreement is a legal and valid obligation binding upon Eagle and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by Eagle have been duly authorized by all necessary corporate action and do not and will not: (i) violate any law, rule, regulation, order, writ, judgment, decree, determination or award of any court, governmental body or administrative or other agency having jurisdiction over Eagle; nor (ii) conflict with, or constitute a default under, any agreement, instrument or understanding, oral or written, to which Eagle is a party or by which it is bound;

(c) all necessary consents, approvals and authorizations of all Regulatory Authorities, other Governmental Authorities and other persons or entities required to be obtained by Eagle in order to enter into this Agreement have been obtained;

(d) Eagle is not under any obligation, contractual or otherwise, to any Person that conflicts with the terms of this Agreement;

(e) Eagle and its Affiliates have never been, are not currently, and will not knowingly use in any capacity, in connection with the obligations to be performed under this Agreement, any Person who is or was, debarred under 21 U.S.C. §335a (a) or (b) or an equivalent Applicable Law.

XI.3 **Disclaimer**. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTIES OF ANY KIND EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE XII
INDEMNIFICATION; RECALLS

XII.1 **Indemnification of Combioxin**. Eagle shall indemnify and hold harmless each of Combioxin, its Affiliates, and the directors, officers, shareholders and employees of such entities and the successors and assigns of any of the foregoing (the "**Combioxin Indemnitees**"), from and against any and all liabilities, damages, penalties, fines, costs, expenses (including, reasonable attorneys' fees and other expenses of litigation) ("**Liabilities**") incurred by any Combioxin Indemnitee as a result of any claims, actions, suits or proceedings brought by a Third Party (a "**Third Party Claim**") against a Combioxin Indemnitee, arising from, or occurring as a result of: (a) the Development, Manufacture or Commercialization of any Licensed Product by Eagle, its Affiliates or Sublicensees; (b) any breach of any representations or warranties by Eagle in ARTICLE XI above; and (c) any breach by Eagle or failure by Eagle to perform an agreement assigned to Eagle pursuant to Section 4.7, to the extent such breach or failure first arose after the date of such assignment; except to the extent such Third Party Claims fall within the scope of Combioxin's indemnification obligations set forth in Section 12.2 below or result from the fault of a Combioxin Indemnitee.

XII.2 **Indemnification of Eagle**. Combioxin shall indemnify and hold harmless each of Eagle, its Affiliates and Sublicensees and the directors, officers and employees of Eagle, its Affiliates and Sublicensees and the successors and assigns of any of the foregoing (the "**Eagle Indemnitees**"), from and against any and all Liabilities incurred by any Eagle Indemnitee as a result of any Third Party Claims against an Eagle Indemnitee, arising from, or occurring as a result of (a) the Development, Manufacture or Commercialization of any Licensed Product by Combioxin, its Affiliates or (sub)licensees prior to the Effective Date; (b) any breach of any representations, warranties or covenants by Combioxin in ARTICLE XI above, (c) any breach by Combioxin of the Upstream Agreement, and (d) any breach of or failure to perform an agreement assigned to Eagle pursuant to Section 4.7 above, to the extent such breach or failure occurred prior to such assignment; except to the extent such Third Party Claims fall within the scope of Eagle's indemnification obligations set forth in Section 12.1 above or result from the fault of an Eagle Indemnitee.

XII.3 **Procedure**. A Party that intends to claim indemnification under this ARTICLE XII (the "**Indemnitee**") shall promptly notify the other Party (the "**Indemnitor**") in writing of any Third Party Claim, in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have sole control of the defense and/or settlement thereof, except as set forth in Section 8.4. The indemnity arrangement in this Section 12.3 shall not apply to amounts paid in settlement of any action with respect to a Third Party Claim, if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld or delayed unreasonably. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim, if prejudicial to its ability to defend such action, shall relieve such Indemnitor of any liability to the Indemnitee under this Section 12.3, but the omission to so deliver written notice to the Indemnitor shall not relieve the Indemnitor of any liability that it may have to any Indemnitee otherwise than under this Section 12.3. The Indemnitee under this Section 12.3 shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Third Party Claim covered by this indemnification.

XII.4 **Recalls**. For the Term of this Agreement, Eagle shall solely be responsible for the handling any recalls, claims relating to recalls of or serious adverse events in relation to any Licensed Product that arises in the process of Development and Commercialization.

XII.5 **Limitation of Liability**. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, CONSEQUENTIAL, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 12.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 12.1 OR 12.2, AND THE FOREGOING LIMITATIONS SHALL NOT APPLY WITH RESPECT TO DAMAGES RESULTING FROM A PARTY'S WILLFUL MISCONDUCT OR GROSS NEGLIGENCE OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE VII.

ARTICLE XIII
DISPUTE RESOLUTION

XIII.1 **Referral to Senior Executives**. The Parties recognize that disputes as to certain matters relating to this Agreement may from time to time arise during the term of this Agreement (each, including any dispute arising with respect to the existence, object, interpretation, performance, enforcement, termination, invalidity or arbitrability of this Agreement, a "**Dispute**"). If any such Dispute cannot be resolved by good faith negotiations, such Dispute shall be referred, by written notice from either Party to the other, to the Senior Executives for resolution. The Senior Executives or their respective designees (with similar authority to resolve such Dispute) shall negotiate in good faith to resolve such Dispute through discussions promptly following such written notice. If the Senior Executives cannot resolve the Dispute within [***] of such written notice[***] then, the provisions of Section 13.2 shall apply.

XIII.2 **Arbitration**. Any Dispute that is not resolved pursuant to Section 13.1 shall be finally settled in accordance with the [***]. The seat of arbitration shall be [***]. The language of the arbitration shall be English. The Parties agree that decision and/or award rendered by the arbitrator shall be the sole, exclusive and binding remedy between them regarding any Dispute presented to the arbitrator. Any decision and/or award of the arbitrator may be entered in any court of competent jurisdiction for judicial recognition of the decision and an order of enforcement. The arbitration proceedings and the decision of the arbitrator shall be deemed the Confidential Information of both Parties subject to ARTICLE VII above.

XIII.3 **General Terms of Arbitration**.

(a) **Interim Relief**. Notwithstanding anything in Section 13.2 to the contrary, each Party shall have the right to apply to any court of competent jurisdiction for a temporary restraining order, preliminary injunction or other similar interim or conservatory relief, as necessary to protect the rights or property of such Party, pending the selection of the arbitrator or pending the arbitrator's determination of the merits of any Dispute. Nothing in the preceding sentence shall be

interpreted as limiting the powers of the arbitrator with respect to any Dispute subject to arbitration under this Agreement.

(b) **Jury Waiver**. EACH PARTY, TO THE EXTENT PERMITTED BY LAW, KNOWINGLY, VOLUNTARILY, AND INTENTIONALLY WAIVES ITS RIGHT TO A TRIAL BY JURY IN ANY ACTION OR OTHER LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT AND THE TRANSACTIONS IT CONTEMPLATES AND AGREES TO ARBITRATE AS SET FORTH IN SECTION 13.2 (ARBITRATION). THIS WAIVER APPLIES TO ANY ACTION OR LEGAL PROCEEDING, WHETHER SOUNDING IN CONTRACT, TORT OR OTHERWISE.

ARTICLE XIV GENERAL PROVISIONS

XIV.1 **Force Majeure**. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from events beyond the reasonable control of and which were reasonably unforeseeable at the time of the execution of this Agreement by the non-performing Party, including but not limited to fire, flood, earthquake, hurricane, embargo, shortage, epidemic, pandemic, quarantine, war, act of war (whether war be declared or not), terrorist act, insurrection, riot, civil commotion, strike, lockout or other labor disturbance (whether involving the workforce of the non-performing Party or of any other Person) or act, omission or delay in acting by any Governmental Authority, including due to a clinical hold pursuant to 21 C.F.R. §312.42, as amended (and any equivalent in any jurisdiction outside the United States). The non-performing Party shall notify the other Party of such force majeure by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than necessary to resolve such force majeure event and the non-performing Party shall use diligent efforts to remedy its inability to perform.

XIV.2 **Governing Law**. This Agreement and all questions regarding its validity or interpretation, or the breach or performance of this Agreement, shall be governed by, and construed and enforced in accordance with, the laws of [***], without reference to conflict of law principles. The Parties hereby agree that the provisions of the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement and are strictly excluded.

XIV.3 **Waiver of Breach**. The failure of either Party at any time or times to require performance of any provision hereof shall in no manner affect its rights at a later time to enforce the same. No waiver by either Party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

XIV.4 **Modification**. No amendment or modification of any provision of this Agreement shall be effective unless in writing signed by both Parties hereto. No provision of this Agreement shall be varied, contradicted or explained by any oral agreement, course of dealing or performance or any other matter not set forth in an agreement in writing and signed by both Parties hereto.

XIV.5 **Severability**. In the event any provision of this Agreement should be held invalid, illegal, or unenforceable in any jurisdiction, the Parties shall negotiate in good faith a valid, legal and

enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions of this Agreement shall remain in full force and effect in such jurisdiction. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction.

XIV.6 **Entire Agreement; Amendments**. This Agreement (including the Exhibits attached hereto) constitutes the complete, final and entire agreement between the Parties relating to the subject matter hereof and supersede all prior and contemporaneous agreements, representations and/or understandings, including the Prior CDA. The foregoing shall not be interpreted as a waiver of any remedies available to either Party as a result of any breach, prior to the Effective Date, by the other Party of its obligations under the Prior CDA. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

XIV.7 **Notices**. Unless otherwise agreed by the Parties or specified in this Agreement, all communications between the Parties relating to, and all written documentation to be prepared and provided under, this Agreement shall be in the English language. Any notice between the Parties required or permitted under this Agreement shall be in writing in the English language, and (a) delivered personally, (b) sent by air mail or express courier service providing evidence of receipt, postage pre-paid where applicable, or (c) by electronic transmission (complete transmission confirmed and a copy promptly sent by another permissible method of providing notice described in paragraph (a) or (b) above), to the following addresses of the Parties (or such other address for a Party as may be specified by like notice):

To Combioxin:

Combioxin SA.
Route de la Corniche 5
1066 Epalinges
Switzerland Attention: [***]

With a copy to:

VISCHER AG
[***]
Aeschenvorstadt 4
4051 Basel
Switzerland
Attn: Christian Wyss
Electronic mail: cwyss@vischer.com

To Eagle:

Eagle Pharmaceuticals, Inc.
50 Tice Blvd, Suite 315
Woodcliff Lake, NJ 07677
Attention: General Counsel
Electronic mail: [***]

With a copy to:

Cooley LLP
One Freedom Square
Reston Town Center
11951 Freedom Drive
Reston, Virginia 20190-5656
Attn: Kenneth J. Krisko
Electronic mail: KKrisko@cooley.com

Any notice required or permitted to be given concerning this Agreement shall be effective upon receipt by the Party to whom it is addressed.

XIV.8 **Assignment**. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that each Party may assign purely financial rights arising out of this Agreement and that each Party may make such an assignment or transfer without the other Party's consent to its Affiliates or to a Third Party successor to substantially all of the business of such Party, whether in a merger, sale of stock, sale of assets or other transaction. With respect to an assignment to an Affiliate, such Party shall remain responsible for the performance by its Affiliate of the rights and obligations hereunder. Combioxin shall not assign or otherwise transfer to any Affiliate or any Third Party any ownership interest in or to any Licensed Know-How or Licensed Patent Rights, without Eagle's prior written consent. Any permitted assignee shall assume all obligations of its assignor under this Agreement. Subject to the foregoing, this Agreement shall inure to the benefit of each Party, its successors and permitted assigns. Any purported assignment of this Agreement in contravention of this Section 14.8 shall be null and void.

XIV.9 **Effect of Acquisition**. Notwithstanding any other provision of this Agreement, in the event of the Acquisition of Combioxin, no intellectual property, compounds, products or other subject matter owned or controlled by the acquiring entity or any of its affiliates prior to such Acquisition, or developed or acquired by such acquiring entity after such acquisition, shall be included as Licensed Patent Rights, Licensed Know-How or Licensed Products hereunder, so long as (a) such intellectual property, compounds, products and other subject matter were developed without use of the Licensed Know-How and without practicing Licensed Patent Rights; and (b) such acquiring entity segregates the personnel and activities of Combioxin and its Affiliates (as determined immediately prior to such Acquisition) from any other programs of such acquiring entity and its affiliates directed to the Development or Commercialization of liposome products. "**Acquisition**" means: (a) a merger involving Combioxin, in which the shareholders of Combioxin immediately prior to such merger cease to control (as defined in Section 1.1) Combioxin after such merger; (b) a sale of all or substantially all of the business or assets of a Combioxin to an acquiring entity; or (c) a sale of a controlling (as defined in Section 1.1) interest of Combioxin to an acquiring entity.

XIV.10 **No Partnership or Joint Venture**. Nothing in this Agreement is intended, or shall be deemed, to establish a joint venture or partnership between Eagle and Combioxin. Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other Party, or to bind the other Party to any contract, agreement or undertaking with any Third Party.

XIV.11 **Interpretation**. The captions to the several Articles and Sections of this Agreement are not a part of this Agreement, but are included for convenience of reference and shall not affect its meaning or interpretation. In this Agreement: (a) the word "including" shall be deemed to be followed by the phrase "without limitation" or like expression; (b) the singular shall include the plural and vice versa; and (c) masculine, feminine and neuter pronouns and expressions shall be interchangeable. Each accounting term used herein that is not specifically defined herein shall have the meaning given to it under generally accepted cost accounting principles, but only to the extent consistent with its usage and the other definitions in this Agreement. This Agreement has been prepared jointly by the Parties and shall not be strictly construed against either Party. Ambiguities,

if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

XIV.12 **Performance by Affiliates**. Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

XIV.13 **Further Actions**. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

XIV.14 **Counterparts; Other Matters**. This Agreement and any amendment thereto may be executed in any number of counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument. Signatures to this Agreement or any amendment thereto delivered by facsimile or in electronic form (such as an electronic file which contains a scan of the wet ink signature or signed by a (qualified or non-qualified) electronic signature, such as DocuSign, AdobeSign, or a similar tool will be deemed to be binding as originals. This Agreement is established in the English language. Any translation in another language shall be deemed for convenience only and shall never prevail over the original English version.

[Remainder of this page intentionally blank.]

IN WITNESS WHEREOF, the Parties have executed this License Agreement as of the Effective Date.

COMBIOXIN SA

BY: /s/ Samareh Azeredo da Silveira Lajaunias

NAME: Samareh Azeredo da Silveira Lajaunias

TITLE: Managing Director

BY: /s/ Frédéric Lajaunias

NAME: Frédéric Lajaunias

TITLE: Managing Director

EAGLE PHARMACEUTICALS, INC.

BY: /s/ Michael S. Moran

NAME: Michael S. Moran

TITLE: Executive Vice President, Head of Sales, Business Development & Gov't Sales

EXHIBIT 1.32

[***]

259471316 v2

EXHIBIT 1.33

[***]

259471316 v2

EXHIBIT 2.4

[***]

259471316 v2

EXHIBIT 4.7

[***]

259471316 v2

EXHIBIT 7.7

Press Release

[***]

[***] For Immediate Release

Eagle Pharmaceuticals Announces Worldwide Licensing Agreement with Combioxin SA for Phase 2b/3, Novel First-in-Class Antitoxin Agent CAL02 in Development for Combination Use with Antibiotics for the Treatment of Severe Pneumonia

-- CAL02 neutralizes toxic virulence effectors ("VE") produced by bacteria; VEs play a decisive role in the development of long-term, severe and fatal pneumonia complications --

-- Results of first-in-human[1] clinical trial published in *The Lancet Infectious Diseases*, where accompanying comments characterized CAL02 as "One step closer to precision medicine for infectious diseases," describing "this study a medical breakthrough" --

-- Potential to address significant unmet need in the treatment of severe pneumonia, which accounts for 2.4 million deaths per year globally --

-- Eagle anticipates ten years of regulatory exclusivity --

-- Eagle to host CAL02 Investor Event on September 9, 2021 --

WOODCLIFF LAKE, NJ—**[***]** 2021—Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced that it has entered into a worldwide licensing agreement with Combioxin SA ("Combioxin"), a clinical-stage biotechnology company based in Epalinges, Switzerland, for the commercial rights to CAL02, a novel first-in-class antitoxin agent ready for Phase 2b/3 development for the treatment of severe pneumonia in combination with traditional antibacterial drugs.

Under the Agreement, Eagle will be solely responsible for further clinical development of CAL02, and will make an upfront payment, followed by additional payments upon achievement of development milestones, regulatory approval and based upon commercial sales. Eagle expects to invest $35 million to achieve interim results. These interim results are expected the first half of 2023.

CAL02 is designed to be an add-on therapy to antibiotics to neutralize virulence effectors. CAL02 consists of liposomes that capture and neutralize bacterial toxins produced by a broad range of Gram-positive and Gram-negative bacteria. Bacterial toxins play a critical role in severe, complicated, and resistant infections. They are known to dysregulate inflammation, cause organ damage and impede immune defense. Unlike traditional antibacterial drugs, CAL02 does not target bacteria directly.

The first-in-human clinical trial results show a favorable safety profile when administered in combination with standard antibiotics to patients with severe community-acquired bacterial pneumonia ("CABP") hospitalized in the intensive care unit ("ICU"). Furthermore, as compared to patients under placebo, patients who were treated with CAL02 presented a faster clinical improvement, including a significantly faster resolution of organ dysfunctions (as per Sequential Organ Failure Assessment score).

"We are thrilled to be part of this potentially groundbreaking advancement in the treatment of severe bacterial pneumonia. Despite the widespread availability of antibiotic drugs today, pneumonia is still the leading cause of infectious mortality in the world. CAL02's ability to neutralize virulence effectors could fill a significant medical gap by offering physicians a new treatment that has the potential to dramatically improve patient outcomes. We believe that CAL02 could change the standard of care for patients and have a broad therapeutic impact, especially in critical situations. This deal, along with the recent AOP Pharmaceuticals transaction, broadens our pipeline and provides opportunities for continued leadership in the hospital acute care space," stated Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals.

"We are thrilled to partner with Eagle Pharmaceuticals, which has shown tremendous commitment to bringing innovative solutions in the hospital acute care space. This transaction represents a significant milestone in the development of CAL02 and we believe that it will bring about a true transformation in the treatment of severely infected patients around the world," said Dr. Samareh Azeredo da Silveira Lajaunias, Managing Director of Combioxin SA.

"Pneumonia remains one of the deadliest infectious diseases in the world. In addition to the associated morbidity and mortality, severe pneumonia represents a major economic burden due to how it prolongs hospitalization. Targeting virulence effectors, CAL02 addresses the fundamental damage of severe community-acquired pneumonia. In its first in-human clinical trial, a randomized, double-blind, placebo-controlled study, CAL02 was shown to be as safe as placebo and resulted in

significantly fewer ICU days. CAL02 has the potential to transform the care for severe pneumonia," said Professor of Medicine Andrew Shorr, Georgetown University.

Clinical Status and Regulatory Path Forward

Preclinical data were published in *Nature Biotechnology*, followed by numerous peer-reviewed articles. The results of the first-in-human clinical trial (randomized, double-blind, placebo-controlled, multi-center), which was carried out in ICU patients with severe CABP, were published in *The Lancet Infectious Diseases*, in May 2019, and the study was described as a "medical breakthrough".

The clinical development plan has been discussed with the U.S. Food and Drug Administration ("FDA") and the European Medicines Agency ("EMA"). FDA and EMA each indicated no requirement of further dose finding for Phase 2b, and that empiric use of CAL02 could be added to the standard of care antibacterial drug therapy prior to pathogen identification given its mechanism of action.

"CAL02 could represent a true paradigm shift in terms of the treatment cascade for bacterial pneumonia patients. With an estimated 350,000 patients requiring treatment in the ICU in the U.S. in 2020, CAL02 could provide a significant opportunity to improve patient outcomes and save lives," stated Judith Ng-Cashin, MD, Chief Medical Officer of Eagle Pharmaceuticals.

The Company plans to advance the clinical program and initiate a robust Phase 2b/3 study in the first half of 2022. CAL02 is an acute care drug, and therefore the Company expects a fast turnaround to receive individual patient results. Interim results are expected in the second quarter of 2023.

Eagle anticipates ten years of regulatory exclusivity, including five years as a New Chemical Entity and five years as a qualified infectious disease product ("QIDP") under the Generating Antibiotic Incentives Now ("GAIN") Act. Eagle believes that CAL02 could be eligible for fast track and breakthrough therapy designations. In addition, Eagle believes a CAL02 new drug application for the treatment of severe CABP may qualify for priority review. The Company expects to build a meaningful patent portfolio for to this asset.

Large Unmet Medical Need

Complications associated with CABP represent a significant unmet medical need. CAL02 has the potential to transform the standard of care for patients with CABP, which accounts for an estimated 2.4 million deaths per year globally. In the United States, about one million adults seek hospital care for pneumonia every year, and 50,000 die from this disease. Older patients with chronic illnesses are at the greatest risk for severe infection, complications and mortality. For children, pneumonia is the most common reason for hospitalization, and it is the world's leading cause of death among children under the age of five. Pneumonia is also the most common cause of sepsis and septic shock, responsible for 50% of all episodes, and can result in admission to the ICU. Hospital-acquired pneumonia has a higher mortality rate than any other hospital-acquired infection.

Pneumonia places a huge burden on the U.S. healthcare system and is among the top ten costly conditions seen during inpatient hospitalizations. Despite the availability of antibiotics, the death rate from pneumonia in the U.S. has seen little improvement in the past half century.

Conference Call

Eagle management will host a CAL02 Investor Event as follow:

Date	Thursday, September 9, 2021
Time	8:30 A.M. EDT
Toll free (U.S.)	INSERT
International	INSERT
Webcast (live and replay)	www.eagleus.com, under the "Investor + News" section

A replay of the conference call will be available for one week after the call's completion by dialing 888-562-2815 (US) or 402-220-7352 (International) and entering conference call ID INSERT. The webcast will be archived for 30 days at the aforementioned URL.

About Eagle Pharmaceuticals, Inc.

Eagle is a fully integrated pharmaceutical company with research and development, clinical, manufacturing and commercial expertise. Eagle is committed to developing innovative medicines

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that result in meaningful improvements in patients' lives. Eagle's commercialized products include RYANODEX®, BENDEKA®, BELRAPZO®, and its oncology and CNS/metabolic critical care pipeline includes product candidates with the potential to address underserved therapeutic areas across multiple disease states. Additional information is available on Eagle's website at www.eagleus.com.

About CAL02

CAL02 is an investigational innovative anti-infective drug that acts as a trap for bacterial virulence effectors (toxins) which contribute to infection-related complications, sepsis, septic shock and death. CAL02 consists of liposomes engineered to clear away the virulence effectors produced by the most relevant bacteria seen in severe pneumonia. CAL02 is poised to play a key role in the fight against anti-microbial resistance, since its action is complementary to that of antibiotics and does not appear to give rise to drug resistance. Because of its safety profile, its breadth of activity and the fact that it is not conducive to the emergence of any new resistance, CAL02 could be administered empirically, as soon as patients with a suspected or confirmed pneumonia show signs of severity. Clinical results to date underscore the potential of CAL02 to transform the standard of care and to dramatically reduce the time and the cost of care for millions of critically ill patients.

About Combioxin

Combioxin SA is a Swiss-based clinical-stage biotechnology company founded in 2015. The company is committed to the development of disruptive treatments for severe infections. Combioxin is a recipient of the Swiss FIT SEED program and is a spin-off of LASCCO SA, a company that propels academic discovery-stage inventions into life science ventures. Additional information is available on Combioxin's website at www.combioxin.com.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and other securities law. Forward-looking statements are statements that are not historical facts. Words and phrases such as "anticipated," "forward," "will," "would," "may," "remain," "potential," "prepare," "expected," "believe," "plan,"

“near future,” “belief,” “guidance,” and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements concerning the licensing agreement between the Company and Combioxin and the timing and ability to obtain regulatory approval of CAL02; statements regarding the collaboration between the Company and Combioxin, including statements about CAL02’s ability to address unmet need in patients with severe pneumonia and its other anticipated benefits and expected duration of regulatory exclusivity for CAL02, if approved; CAL02’s potential acceptance by clinicians; the timing, progress and results of additional trials of CAL02 and the ability of such trial results to support regulatory filings and approvals; anticipated actions by FDA, EMA and other regulatory agencies; the Company’s ability to support the commercial launch of CAL02, if approved; anticipated future payments, including upfront and milestone payments, from the Company to Combioxin; the anticipated market opportunity for CAL02; and the ability of the product candidates in the Company’s pipeline to deliver value to stockholders. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the Company’s control, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. Such risks and uncertainties include, but are not limited to: the impacts of the ongoing COVID-19 pandemic, including interruptions or other adverse effects on clinical trials and delays in regulatory review or further disruption or delay of any pending or future litigation; delay in or failure to obtain regulatory approval of the Company's product candidates, including CAL02, and successful compliance with FDA, EMA and other governmental regulations applicable to product approvals; whether the Company will successfully implement its development plan for its product candidates, including CAL02; the inability to recognize the anticipated benefits of the collaboration between the Company and Combioxin; whether the Company can successfully collaborate with its partners and market and commercialize its product candidates; the outcome of litigation involving any of its products or that may have an impact on any of its products; possible safety and efficacy concerns; risks that preliminary results from clinical trials are not necessarily predictive of future clinical trial results; the strength and enforceability of the Company’s intellectual property rights or the rights of third parties; the risks inherent in drug development and in conducting clinical trials; and those risks and uncertainties identified in the “Risk Factors” section of the Company’s Annual Report on Form 10-K for the year ended December 31, 2020 filed with the Securities and Exchange Commission (the “SEC”) on March 5, 2021, as updated by the Company’s Quarterly Reports on Form 10-Q for the quarters ended March 31, 2021 and June 30, 2021, filed with the SEC on May 10, 2021 and August 9, 2021, respectively, and its other subsequent filings with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except to the extent required by law, the Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

CONFIDENTIAL

LICENSE AGREEMENT

BETWEEN

AOP ORPHAN PHARMACEUTICALS GmbH

AND

EAGLE PHARMACEUTICALS, INC.

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this "**Agreement**") dated as of **August 6, 2021** (the "**Execution Date**"), is entered into between **AOP Orphan Pharmaceuticals GmbH**, an Austrian company having offices at Leopold-Ungar-Platz 2, 1190 Vienna, Austria ("**AOP**") and **Eagle Pharmaceuticals, Inc.**, a Delaware corporation having offices at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey, United States ("**Eagle**").

BACKGROUND

A. Eagle is a specialty pharmaceutical company focused on developing and commercializing drugs.

B. AOP is a pharmaceutical company dedicated to the development of therapy options for patients with rare diseases, including therapies containing landiolol, a short acting superselective beta-1 adrenergic blocker that aims at the reduction of ventricular rate;

C. Eagle desires to obtain from AOP and AOP desires to grant to Eagle an exclusive license with respect to the development and commercialization of the Licensed Product (as defined below) in the Eagle Territory (as defined below), all on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

Article I
DEFINITIONS

I.1 "**Administrative Fees**" means the portion of administrative fees, not to exceed [***], accrued during the relevant time period to group purchasing organizations, pharmaceutical benefit managers, Medicare Prescription Drug Plans, Medicaid, or the like (including similar plans and programs outside the United States) relating to such Licensed Product.

I.2 "**Affiliate**" of a Party means any Person that, directly or indirectly, controls, is controlled by, or is under common control with such Party, as the case may be. As used in this Section 1.1, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such Person, whether by the ownership of more than fifty percent (50%) of the voting share capital in such Person, or by contract or otherwise.

I.3 "**Allowable Expenses**" means, with respect to a given period, the following expenses to the extent specifically identifiable and directly allocable to Eagle's and its Affiliates' activities in relation to exploitation of the Licensed Product in the Eagle Territory pursuant to this Agreement, incurred by or on behalf of Eagle, its Affiliates, or Sublicensees, in each case in accordance with Eagle's, its Affiliates' or Sublicensee's accounting practices (consistently applied): [***].

I.4 "**ANDA**" means an Abbreviated New Drug Application, as defined in the FD&C Act, as amended, and applicable regulations promulgated thereunder by the FDA.

I.5 "**Anti-Corruption Laws**" shall mean the U.S. Foreign Corrupt Practices Act (15 U.S.C. §§78dd-1, et. seq.), as amended, the Organization for Economic Co-operation and Development (OECD)

Convention on combating bribery of foreign public officials in international business transactions, and any other applicable anti-corruption laws.

I.6 "**AOP Background Know-How**" means any and all Know-How that (a) is Controlled by AOP or any of its Affiliates (i) as of the Effective Date, or (ii) during the Term as a result of performing activities outside the scope of this Agreement, and (b) is necessary or reasonably useful for the Development, Manufacture or Commercialization of Licensed Products and other activities under this Agreement for the Territory.

I.7 "**AOP Background Patents**" means any and all Patents that (a) are Controlled by AOP or any of its Affiliates as of the Effective Date or during the Term and (b) Cover AOP Background Know-How.

I.8 "**AOP Competitor**" means any Third Party competitor of AOP [***].

I.9 "**AOP Indemnitees**" has the meaning given to this term in Section 13.1.

I.10 "**AOP Non-Product-Specific Collaboration Know-How**" means any and all Non-Product-Specific Collaboration Know-How that is made or conceived by or on behalf of AOP or its Affiliates, solely, jointly with Eagle or its Affiliates, or jointly with a Third Party.

I.11 "**AOP Non-Product-Specific Collaboration Patents**" means any and all Collaboration Patents that cover AOP Non-Product-Specific Collaboration Know-How.

I.12 "**AOP Territory**" means all countries in the world other than the Eagle Territory.

I.13 "**AOP Trademark**" means each of the trademarks [***] owned by AOP and all registrations thereof [***], as well as future trademarks and trademark registrations owned by AOP [***] and intended to be used in connection with the Commercialization of the Licensed Product [***].

I.14 "**API**" has the meaning given to the term in the Supply Agreement.

I.15 "**Applicable Laws**" means the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidances, ordinances, judgments, decrees, directives, injunctions, orders, permits of or from any court, arbitrator, Regulatory Authority, Governmental Authority or authority having jurisdiction over or related to the subject item, including the FD&C Act, GCP, GLP, GMP, and Anti-Corruption Laws, as well as all applicable data protection and privacy laws, rules and regulations, including the United States Department of Health and Human Services privacy rules under the Health Insurance Portability and Accountability Act, as amended, and the Health Information Technology for Economic and Clinical Health Act and the EU General Data Protection Regulation 2016/679 of the European Parliament and of the Counsel of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, along with other country-level data protection laws, as may be applicable.

I.16 "**Clinical Studies**" means any human clinical study or clinical trial of a Licensed Product.

I.17 "**CMC Data**" means analytical and quality control data, stability data, batch records, and other data or information relating to chemistry, manufacturing and control of Licensed Products, including that which is filed or required to be filed to obtain authorization to conduct Clinical Studies or to obtain or maintain Regulatory Approval for a Licensed Product.

I.18 "**Collaboration Know-How**" means any and all Know-How that is made or conceived by or on behalf of either Party, solely, jointly with the other Party or its Affiliates, or jointly with a Third Party, in performing activities under this Agreement.

I.19 "**Collaboration Patents**" means any and all patents that cover Collaboration Know-How.

I.20 "**Commercialization**" means any and all activities related to pre-marketing, launching, marketing, promotion (including advertising and detailing), labeling, bidding and listing, pricing and reimbursement, distribution, storage, handling, offering for sale, selling, having sold, distributing, having distributed, providing customer service and support, conducting medical affairs, conducting post-marketing safety surveillance and reporting of or otherwise commercializing or exploiting Licensed Products. "**Commercialize**" and "**Commercializing**" have the correlative meanings.

I.21 "**Commercially Reasonable Efforts**" means, with respect to the efforts to be expended by Eagle in connection with a particular activity or objective to be conducted under this Agreement, that level of efforts that [***], taking into account all relevant scientific, commercial, business and other factors, including issues of safety and efficacy, expected and approved product labeling, expected and actual cost and time to develop, expected and actual profitability, expected and actual return on investment, expected and actual competitiveness of Third Party alternative products (including generic products) in the marketplace, the nature and extent of expected and actual market exclusivity (including Patent coverage and regulatory exclusivity), the expected likelihood of marketing approval, the expected and actual pricing and level of reimbursement, and the expected and actual amounts of marketing and promotional expenditures required. [***]

I.22 "**Competitive Change of Control Over Eagle**" shall mean, with respect to Eagle, any of the following events: [***].

I.23 "**Competing Product**" means a pharmaceutical product that is (i) [***] and (ii) [***].

I.24 "**Control**" (including any variations such as "**Controlled**" and "**Controlling**") of intellectual property rights, intangible material, Data and/or other information or subject matter, means the possession by a Person or its Affiliate of the ability (whether by ownership or license, other than pursuant to this Agreement) to grant the applicable access to, or a license or sublicense under this Agreement on, said intellectual property rights, intangible material, Data and/or other information or subject matter, without violating (i) Applicable Law or (ii) the terms of any agreement or other arrangement with any Third Party existing as of the Effective Date or at such later time as such Party or its Affiliate first acquired rights to such subject matter.

I.25 [***]:

(a) [***];

(b) [***], or

(c) [***].

I.26 "**Cover**" means, with respect to a claim of a Patent and a Licensed Product, that such claim would be infringed, absent a license, by the Manufacture, use, Development, or Commercialization of such Licensed Product (considering claims of patent applications to be issued as then pending).

I.27 "**Data**" means any and all data, information and materials relating to a Licensed Product, including manufacturing data (including without limitation, CMC Data), research data, pharmacology

data, preclinical data, clinical data (including patient samples and associated annotations), master clinical trial records and databases, safety databases, and all Regulatory Filings or other regulatory documentation, information and submissions pertaining to, or made in association with an IND, Marketing Approval Application, or Regulatory Approval, for a Licensed Product, in each case to the extent Controlled by AOP or Eagle as of the Effective Date or during the Term.

I.28 "**Development**" or "**Develop**" means all activities that relate to (a) the development of Licensed Products, or (b) obtaining, maintaining or expanding Regulatory Approval of a Licensed Product, including [***]. "**Develop**" has a correlative meaning.

I.29 "**Development Milestone Event**" has the meaning set forth in Section 6.2.

I.30 "**Development Milestone Payment**" has the meaning set forth in Section 6.2.

I.31 "**Dispute**" has the meaning given to this term in Section 14.1.

I.32 [***].

I.33 "**Eagle Background Know-How**" means any and all Know-How that (a) is Controlled by Eagle or any of its Affiliates (i) as of the Effective Date, or (ii) during the Term as a result of performing activities outside the scope of this Agreement and (b) is necessary for AOP's performance under this Agreement.

I.34 "**Eagle Background Patents**" means any and all Patents that (a) are Controlled by Eagle or any of its Affiliates as of the Execution Date or during the Term and (b) Cover Eagle Background Know-How.

I.35 "**Eagle Indemnitees**" has the meaning given to this term in Section 13.2.

I.36 "**Eagle Non-Product-Specific Collaboration Know-How**" means any and all Non-Product-Specific Collaboration Know-How that is made or conceived solely by Eagle or its Affiliates, or jointly by Eagle or its Affiliates with a Third Party.

I.37 "**Eagle Non-Product-Specific Collaboration Patents**" means any and all Collaboration Patents that cover Eagle Non-Product-Specific Collaboration Know-How.

I.38 "**Eagle Territory**" means the United States of America, including all possessions and territories thereof.

I.39 "**Effective Date**" has the meaning set forth in Section 10.2.

I.40 "**EMA**" means the European Medicines Agency or any successor entity.

I.41 "**Enforcement Action**" has the meaning set forth in Section 9.8.

I.42 "**EU**" means the European Economic Area, Switzerland and the United Kingdom.

I.43 "**Existing Licensed Product**" means the pharmaceutical product containing landiolol in a [***], as further described in Exhibit 1.43.

I.44 "**FD&C Act**" means the U.S. Federal Food, Drug and Cosmetic Act, as amended.

I.45 "**FDA**" means the U.S. Food and Drug Administration, or any successor entity thereto performing similar functions.

I.46 "**Field**" means any and all indications and uses of the Licensed Product.

I.47 "**Finance Liaison**" means a Party's appointed representative who shall act as such Party's point of contact in order to coordinate and manage the reporting of Net Sales, Net Profit, Net Loss and Allowable Expenses. Each Party can change its Finance Liaison at any time during the Term, and shall notify the other Party of its new Finance Liaison as soon as reasonably practicable.

I.48 "**First Commercial Sale**" means the first [***], in each case, after all Regulatory Approvals necessary for the lawful exercise of said transfer or disposition have been obtained in the Eagle Territory and [***].

I.49 "**Good Clinical Practice**" or "**GCP**" means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in the guidelines entitled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA or other Regulatory Authority, as they may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

I.50 "**Good Laboratory Practice**" or "**GLP**" means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, and comparable regulatory standards promulgated by the EMA or other Regulatory Authority, as they may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

I.51 "**Good Manufacturing Practices**" or "**GMP**" means the then-current Good Manufacturing Practices required by the FDA, as set forth in the FD&C Act and the regulations promulgated thereunder, for the manufacture and testing of pharmaceutical materials, and comparable laws and regulations applicable to the manufacture and testing of pharmaceutical materials promulgated by other Regulatory Authorities, as they may be updated from time to time.

I.52 "**Governmental Authority**" means any multi-national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, counsel, court or other tribunal).

I.53 "**Guaranteed Minimum Profit Share Payments**" has the meaning set forth in Section 6.4.

I.54 "**HSR Act**" means Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended from time to time, and the rules and regulations promulgated thereunder, or any successor statute, rules and regulations promulgated thereunder.

I.55 "**HSR Filing**" has the meaning set forth in Section 10.1.

I.56 "**ICH**" means International Conference on Harmonisation.

I.57 "**IND**" means an Investigational New Drug application, as defined in the U.S. Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder, or the equivalent application to the equivalent agency in any other regulatory jurisdiction, the filing of which is necessary to Initiate or

conduct clinical testing of a pharmaceutical product in humans in such jurisdiction, in each case with respect to a Licensed Product for use within the Field.

I.58 "**Indemnitee**" has the meaning given to this term in Section 13.3.

I.59 "**Indemnitor**" has the meaning given to this term in Section 13.3.

I.60 "**Infringement Actions**" has the meaning set forth in Section 9.9

I.61 "**Know-How**" means any and all commercial, technical, scientific, and other know-how and information, Data, results, inventions, methods, processes, trade secrets, techniques, technology, and other proprietary information, whether patentable or not, including discoveries, formulae, materials (including chemicals), biological materials, practices, test data (including pharmacological, toxicological, pre-clinical and clinical information and test data), analytical and quality control data (including drug stability data), manufacturing technology and data (including formulation data and CMC Data), and sales forecasts, data and descriptions; provided that Know-How does not include Patents.

I.62 "**Joint Steering Committee**" or "**JSC**" means the committee formed by the Parties as described in Section 3.1.

I.63 "**Lead Indication**" means the control of ventricular rate in patients with atrial fibrillation or atrial flutter (as such indication may be amended by the Parties following interactions with the FDA regarding such lead indication).

I.64 "**Liabilities**" has the meaning given to this term in Section 13.1.

I.65 "**Licensed Intellectual Property**" means Licensed Patent Rights and Licensed Know-How.

I.66 "**Licensed Know-How**" means all AOP Background Know-How, Product-Specific Collaboration Know-How, and AOP Non-Product-Specific Collaboration Know-How.

I.67 "**Licensed Patent Right**" means any and all Patents within the AOP Background Patents, the Product-Specific Collaboration Patents, or the AOP Non-Product-Specific Collaboration Patents. A list of AOP Background Patents as of the Effective Date is set forth on Exhibit 1.67.

I.68 "**Licensed Product**" means any pharmaceutical product containing landiolol [***]. "**Licensed Products**" shall have a correlative meaning.

I.69 "**Manufacture**" and "**Manufacturing**" means all activities related to (a) developing the ability to manufacture clinical and commercial quantities of a Licensed Product, and (b) the synthesis, making, production, processing, purifying, formulating, filling, finishing, packaging, labeling, shipping, importing, having imported, and holding of any Licensed Product or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial production and analytic development, product characterization, stability testing, quality assurance, and quality control.

I.70 "**Market Exclusivity**" means [***].

I.71 "**Marketing Approval Application**" (or "**MAA**") means application to the appropriate Regulatory Authority for approval to market a Licensed Product in any particular jurisdiction, including an NDA in the U.S.

I.72 "**NDA**" means a New Drug Application, as defined in the FD&C Act, as amended, and applicable regulations promulgated thereunder by the FDA.

I.73 "**Net Profit**" and, with correlative meaning, "**Net Losses**", means Net Sales less Allowable Expenses.

I.74 "**Net Sales**" means, with respect to any Licensed Product in a given period, the gross amounts invoiced by Eagle and its Affiliates and Sublicensees for sales of such Licensed Product in the Eagle Territory to Third Parties, less the following deductions as accrued in direct connection to the sale of a Licensed Product to a Third Party:

(a) [***];

(b) [***];

(c) [***];

(d) [***]; and

(e) [***].

Notwithstanding the foregoing, amounts [***] shall not be included in the computation of Net Sales hereunder.

I.75 "**Non-Product-Specific Collaboration Know-How**" means any and all Collaboration Know-How, except Product-Specific Collaboration Know-How, that is made or conceived by or on behalf of either Party, solely, jointly with the other Party or its Affiliates, or jointly with a Third Party, in performing activities under this Agreement.

I.76 "**Non-Product-Specific Collaboration Patents**" means any and all Collaboration Patents that cover Non-Product-Specific Collaboration Know-How.

I.77 "**P&L Report**" has the meaning given to this term by Section 6.3.

I.78 "**Patent(s)**" means all patents and patent applications (including provisional applications), including all divisionals, continuations, substitutions, continuations-in-part, re-examinations, re-issues, additions, renewals, extensions, confirmations, registrations, any other pre- or post-grant forms of any of the foregoing, any confirmation patent or registration patent or patent of addition, utility models, patent term extensions, and supplemental protection certificates or requests for continued examinations, foreign counterparts, and the like of any of the foregoing.

I.79 "**Patent Challenge**" means any direct or indirect dispute or challenge, or any assistance in the dispute or challenge, of the validity, patentability, scope, priority, construction, non-infringement, inventorship, ownership or enforceability of any Patent or any claim thereof, or opposition or assistance in the opposition of the grant of any Patents, in any legal or administrative proceedings, including in a court of law, before the United States Patent and Trademark Office or other agency or tribunal in any jurisdiction, or in arbitration including, without limitation, [***].

I.80 "**Party**" means AOP or Eagle, individually; and "**Parties**" means AOP and Eagle, collectively.

I.81 "**Person**" means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, Governmental Authority or agency, or any other entity not specifically listed herein.

I.82 "**Prior CDA**" has the meaning given to this term by Section 8.8.

I.83 "**Product-Specific Collaboration Know-How**" means, with respect to a Licensed Product, (a) any Collaboration Know-How that describes or comprises solely the composition of matter, use, or method of Manufacture of such Licensed Product, but does not describe or comprise the composition of matter, use, or method of Manufacture of a different product, and (b) all clinical data generated in the Development of a Licensed Product in the Eagle Territory or in the AOP Territory.

I.84 "**Product-Specific Collaboration Patent**" means any Patent that Covers Product-Specific Collaboration Know-How.

I.85 "**Regulatory Approval**" means all approvals, licenses, registrations, designations, or authorizations of any governmental entity that are necessary for the manufacturing, use, storage, import, transport and sale of Licensed Products in a regulatory jurisdiction.

I.86 "**Regulatory Authority**" means any national (e.g., the FDA) or, supra-national (e.g., the EC or the EMA), or other governmental entity in any jurisdiction of the world involved in the granting of Regulatory Approval for pharmaceutical products.

I.87 "**Regulatory Filing**" means all approvals, licenses, registrations, submissions, designations, and authorizations made to or received from a Regulatory Authority in a jurisdiction necessary for or in connection with the development, manufacture and/or commercialization of a pharmaceutical product, including any INDs, Marketing Approval Applications and Regulatory Approvals. As used herein, "Regulatory Filing" also includes all correspondence with Regulatory Authorities (and their agents) regarding Licensed Products, including all submissions, meeting minutes, reports and other items exchanged between or under authority from AOP or its licensors with respect to a Licensed Product, or the Development, Manufacture, Commercialization or exploitation thereof.

I.88 "[***** Licensed Product**" means a Licensed Product in [***].

I.89 "**Senior Executives**" means the [***] of AOP and the [***] of Eagle.

I.90 "**Sublicensee**" means a Third Party that has been granted a right to Develop or Commercialize Licensed Products in the Eagle Territory pursuant to Section 2.3, provided that as used herein, "**Sublicensee**" shall not be deemed to include any distributor, wholesaler or reseller of a Licensed Product with regards to its distribution, wholesale or resale activity.

I.91 "**Supply Agreement**" means a separate agreement to be entered into between the Parties regarding the supply of Licensed Product from AOP or its Affiliates to Eagle or its Affiliates.

I.92 "**Supply Failure**" has the meaning given to the term in the Supply Agreement.

I.93 "**Supply Price**" has the meaning given to this term in Section 5.2.

I.94 "**Supply Source Deficiency**" has the meaning given to the term in the Supply Agreement.

I.95 "**Term**" has the meaning given to this term by Section 10.3.

I.96 "**Third Party**" means any Person other than a Party or an Affiliate of a Party.

I.97 "**Third Party Claim**" has the meaning given to this term in Section 13.1.

I.98 "**Third Party Payments**" has the meaning given to this term by Section 9.9.

I.99 "**Valid Claim**" means a claim of an issued, unexpired patent within the Licensed Patent Rights that has not been revoked, disclaimed, abandoned or held invalid or unenforceable by a court or other body of competent jurisdiction in an unappealed or unappealable decision.

Article II
GRANT OF LICENSE

II.1 **License to Eagle**. Subject to the terms and conditions of this Agreement, AOP hereby grants to Eagle:

(a) an exclusive (even as to AOP) license under the Licensed Intellectual Property to Commercialize the Licensed Products in the Field in the Eagle Territory;

(b) an exclusive (except as to AOP and its Affiliates to the extent reasonably required or useful for AOP's performance of its obligations and exercise of its rights pursuant to this Agreement) license under the Licensed Intellectual Property to Develop the Licensed Products in the Field in the Eagle Territory;

(c) only if and when a Supply Failure occurs, a non-exclusive, worldwide license under the Licensed Intellectual Property to Manufacture finished Licensed Products for use in the Field in the Eagle Territory; and

(d) a non-exclusive, perpetual, irrevocable, fully paid-up, royalty-free, sublicensable (through multiple tiers) worldwide license for any and all purposes under the AOP Non-Product-Specific Collaboration Know-How and the AOP Non-Product-Specific Collaboration Patents, to the extent that such AOP Non-Product-Specific Collaboration Know-How and AOP Non-Product-Specific Collaboration Patents were conceived, made or generated by Eagle or any of its Affiliates jointly with AOP or its Affiliates.

II.2 **AOP Trademark License to Eagle**. Subject to the terms and conditions of this Agreement, AOP hereby grants to Eagle, an exclusive (even as to AOP) license to Commercialize the Licensed Products under an AOP Trademark in the Field in the Eagle Territory.

II.3 **Sublicensing**. Eagle shall have the right to grant and authorize sublicenses (through multiple tiers) under the rights granted to Eagle under Sections 2.1 and 2.2 to one or more of its Affiliates and to Sublicensees. Such sublicenses may only be granted provided that: (1) each Sublicensee shall agree to be subject to the terms of this Agreement and the Supply Agreement, including [***], (2) no such sublicense shall prevent Eagle (directly or with and through its Sublicensees) to perform its obligations hereunder, (3) no such sublicense shall limit or impair AOP's rights hereunder, and (4) Eagle shall remain responsible for its and its Affiliates and Sublicensees' compliance with the terms and conditions set forth herein, including without limitation the obligation to make payments as and when due hereunder, and the obligation to keep records and make reports hereunder. Eagle shall provide AOP with a true, accurate and complete copy of each sublicense agreement with its Sublicensees [***], subject to Eagle's right to redact any confidential or proprietary information of Eagle or the Sublicensee. Each sublicense granted to a Sublicensee by Eagle to any rights licensed to it hereunder shall terminate immediately upon the termination of the license from AOP to Eagle with respect to such rights as of the effective date of such

termination. Any Sublicensee engaging in Development is subject to AOP's prior written approval, not to be unreasonably withheld, conditioned, or delayed.

II.4 Transfer of Licensed Know-How

(a) Initial Transfer. [***] and in any event no later than [***] thereafter, AOP shall, and shall use diligent efforts to cause any Affiliates or Third Party contractors to, transfer to Eagle complete and accurate copies of all Licensed Know-How regarding the Licensed Product (other than Manufacturing Know-How) in existence as of the Effective Date; provided that if, despite exercising diligent efforts to do so, AOP is unable to transfer (or have transferred) all of the Licensed Know-How to Eagle within such [***] period, AOP shall [***].

(b) Ongoing Transfer and Access. Without limiting Section 2.4(a), if from time to time during the Term it becomes apparent that a particular item of Licensed Know-How should be provided to Eagle, then upon reasonable request by Eagle, AOP shall, [***].

(c) Cooperation. The Parties will cooperate in good faith and reasonably agree upon formats and procedures to facilitate the orderly and efficient exchange of the Licensed Know-How in accordance with this Section 2.4. Without limiting the foregoing, AOP shall provide all such items in electronic form to the extent the same exist in electronic form and shall provide copies and an opportunity to inspect (and copy) original versions for all other materials comprising such Licensed Know-How (including for example, original patient report forms). It is understood all Licensed Know-How shall be made available to Eagle [***]. Upon request by Eagle, AOP shall reasonably cooperate with and assist Eagle as may be necessary or desirable in order to allow Eagle to understand the Licensed Know-How and to utilize the Licensed Know-How for the purposes contemplated in this Agreement.

II.5 No Other Rights. Except for the rights and licenses expressly granted in this Agreement, each Party retains all rights under its intellectual property, and neither Party shall be deemed by estoppel or implication to have granted the other Party any license or other right to any intellectual property of such Party.

Article III
GOVERNANCE

III.1 Joint Steering Committee. [***] after the Effective Date, the Parties shall establish a joint steering committee (the "**Joint Steering Committee**" or the "**JSC**") to oversee the Development activities [***] and serve as a forum for the coordination of the Development [***].

III.2 JSC Members. Each Party shall initially appoint up to [***] to the JSC, each of whom [***]. The JSC may change its size from time to time by mutual consent of its members, and each Party may replace its representatives at any time upon written notice to the other Party. [***] not to be unreasonably withheld, conditioned or delayed.

III.3 Meetings. For the first [***] following the Effective Date, the JSC shall meet [***]. Following the [***] of the Effective Date, the JSC shall meet [***] thereafter. Meetings of the JSC may be held in person, by audio or video teleconference, as determined by the Parties. Each Party shall be responsible for all of its own expenses of participating in the JSC.

III.4 Specific Responsibilities of the JSC. The JSC shall oversee the performance of Development activities of the Licensed Product and shall, in particular:

(a) [***]; and

(b) [***]; and

(c) [***].

(d) [***].

III.5 Decision-making. All JSC decisions shall be made [***]. If, after reasonable discussion and good faith consideration of each Party's view, the JSC does not reach consensus on a matter within the responsibilities of the JSC, [***] provided that:

(a) [***];

(b) [***]; and

(c) [***].

III.6 Limitation of JSC Authority. The JSC shall not have the authority to (a) modify or amend the terms and conditions of this Agreement, (b) waive or determine [***], or (c) decide [***]. For the sake of clarity, [***].

Article IV
DEVELOPMENT AND COMMERCIALIZATION ACTIVITIES

IV.1 Development Responsibility.

(a) From and after the Effective Date, and except as otherwise set forth in this Agreement, Eagle will have the exclusive (except as to AOP and its Affiliates to the extent required for AOP's performance of its obligations and exercise of its rights pursuant to this Agreement) right to conduct the Development of Licensed Products in the Eagle Territory. From and after the Effective Date, and except as otherwise set forth in this Agreement, Eagle will have the right to set, in agreement with AOP, the regulatory strategy for Indications for the Licensed Products in the Eagle Territory and to seek and obtain Regulatory Approvals for Licensed Products in the Field in the Eagle Territory. Eagle shall, however, not initiate any Development activities in the Eagle Territory without AOP's prior written consent, such consent not to be unreasonably withheld. Neither Eagle nor AOP shall conduct, or cause or support any of their respective Affiliates or sublicensees or any other Third Party to conduct, any [***] without notifying one another in writing about [***], provided, for clarity, that nothing in this Agreement shall [***]. Eagle shall not conduct, or cause or support any of its respective Affiliates or Sublicensees or any other Third Party to conduct, [***] in the AOP Territory.

(b) Neither Party anticipates that any Clinical Studies will be required to be conducted after the Effective Date in order to obtain Regulatory Approval of the Existing Licensed Product in the Lead Indication in the Eagle Territory, whereas the Parties acknowledge that the exact wording of the Regulatory Approval for the Licensed Product in the European Union may differ from the Regulatory Approval approved by the FDA in the Eagle Territory. However, [***]. AOP shall submit any such proposed Regulatory Filing and any proposed communication in relation to such Regulatory Filings and approvals to Eagle, and shall afford Eagle the opportunity to, at Eagle's expense, participate in any meetings with Regulatory Authorities in the Eagle Territory relating to the Existing Licensed Product. For the avoidance of doubt, AOP shall be responsible for obtaining Regulatory Approval for the Existing Licensed Product in the Lead Indication.

(c) Except to the extent otherwise set forth in Section 4.1(b), Eagle shall prepare and own all Regulatory Filings (including all INDs, NDAs, and Regulatory Approvals) for each Licensed

Product in the Field in the Eagle Territory during the Term. For the avoidance of doubt, during the Term, Eagle shall be the holder of all Regulatory Approvals of the Licensed Products in the Territory.

(d) Except as set forth in Section 4.1(b), AOP shall not, without the prior written consent of Eagle, submit any Regulatory Filings for Licensed Products in the Eagle Territory or communicate with respect to the Licensed Products with any Regulatory Authority in the Eagle Territory, unless (i) so required to comply with Applicable Laws upon written advice of AOP counsel, in which case AOP shall promptly notify Eagle of such requirement under Applicable Laws, shall submit any proposed communication to Eagle for Eagle's review and comment and discussion between the Parties or, if not practicable or legally permitted, shall provide Eagle with a copy or summary thereof as soon as reasonably practicable thereafter, or (ii) the Regulatory Filings or communication relate to AOP's activities in the Eagle Territory, but such activities are exclusively aimed at obtaining Regulatory Approval or at Commercialization outside of the Eagle Territory.

(e) AOP shall be free to perform Development activities in the AOP Territory if [***]. For the sake of clarity, [***]. AOP shall be free to perform Development activities in the Eagle Territory if [***].

(f) Any benefits or proceeds gained [***].

IV.2 Development Diligence. Following assignment to Eagle of the Regulatory Approval for the Existing Licensed Product in the Lead Indication in the Eagle Territory, Eagle shall use, and shall require its Affiliates or Sublicensees to use, Commercially Reasonable Efforts to Develop Licensed Products (including the Existing Licensed Product) in the Field in the Eagle Territory.

IV.3 Development Reports. At the regularly scheduled JSC meetings, [***].

IV.4 Transition of Development and Regulatory Activities. AOP shall reasonably cooperate with Eagle and use diligent efforts to effect a prompt, smooth and orderly transition to Eagle of Development and regulatory activities with respect to the Licensed Products that are, according to this Agreement, to be carried out by Eagle, as reasonably requested by Eagle. Upon receipt of the Regulatory Approval for the Existing Licensed Product in the Lead Indication in the Eagle Territory by the FDA, AOP shall assign said Regulatory Approval to Eagle together with all Regulatory Filings associated therewith. To the extent reasonably requested by Eagle, AOP shall [***].

IV.5 Access to Data.

(a) As permitted by and in compliance with Applicable Laws (including applicable privacy laws) and other applicable contractual obligations, and solely to the extent such Data is reasonably necessary or useful for purposes of the Development and Commercialization of the Licensed Products in the Eagle Territory, Eagle will have access to, and the right to use, and AOP will provide to Eagle upon request, Data Controlled by AOP or its Affiliates and generated in connection with the Development of the Licensed Products outside the Eagle Territory and will have access to, and right to reference, all EU Regulatory Filings Controlled by AOP or its Affiliates and all relevant safety information for the Licensed Products. Following the Effective Date, AOP shall supply such Data that exists as of the Effective Date in a specific data-room for a period of [***] but shall not be obligated to maintain or regularly update the Data in the data-room.

(b) As permitted by and in compliance with Applicable Laws (including applicable privacy laws) and other applicable contractual obligations, AOP will have access to, and the right to use, Data Controlled by Eagle, its Affiliates, Sublicensees or Third Parties cooperating with Eagle, and

generated in connection with the Development of the Licensed Products in the Eagle Territory. Furthermore, AOP will have access to, and the right to reference, all Regulatory Filings Controlled by Eagle or its Affiliates in the Eagle Territory for the Licensed Products.

IV.6 Commercialization. As between the Parties, Eagle shall have the exclusive right to conduct, and be solely responsible for all aspects of, the Commercialization of Licensed Products in the Field in the Eagle Territory, including (a) [***]. Eagle shall bear all costs and expenses incurred in connection with such Commercialization activities. Subject to Applicable Laws, [***] shall conduct and will require that its respective Affiliates or Sublicensees will not conduct and will not cause or support any other Third Party to conduct, [***].

IV.7 Commercialization Diligence. Following assignment to Eagle of the Regulatory Approval for the Existing Licensed Product in the Lead Indication in the Eagle Territory, Eagle shall use Commercially Reasonable Efforts to Commercialize each Licensed Product for which Regulatory Approval has been obtained in the Eagle Territory. For each Licensed Product, Eagle shall provide to AOP [***], starting from [***], a report specifying Eagle's Commercialization efforts for such Licensed Product in the [***]. If Eagle were to fail for [***] to perform reasonable Commercialization efforts (including but not limited to promoting and marketing the Licensed Product) in the Eagle Territory, other than for reasons outside of Eagle's control, including any Force Majeure, [***], AOP shall have the right to terminate this Agreement pursuant to Section 10.4, after a discussion between the Parties on a remediation plan, such discussion not to exceed [***], if, Eagle failed to resume the applicable Commercialization efforts within [***].

IV.8 Pharmacovigilance. Following the Effective Date, the Parties shall negotiate and agree in good faith on a pharmacovigilance agreement that sets forth mutually agreed terms and conditions for the receipt, investigation, recordation, communication, and exchange (as between the Parties) of adverse event reports, pregnancy reports, medical inquiries, and any other information concerning the safety of Licensed Products. The Parties shall use reasonable and good faith efforts to execute a definitive pharmacovigilance agreement not later than [***] after the Effective Date.

IV.9 Restrictions. Each Party agrees that it will not, and will require that its Affiliates and (sub)licensees (including Sublicensees) will not, to the extent admissible under Applicable Laws, [***].

Article V
MANUFACTURING

V.1 Manufacturing Responsibility. Except in case of a Supply Failure, AOP, directly or through its Affiliates or one or more Third Parties, including a designated contract manufacturer, shall have the sole and exclusive right and responsibility for having Licensed Products Manufactured for Development and Commercialization use in the Eagle Territory.

V.2 Supply of Licensed Product

(a) During the Term, Eagle shall purchase from AOP, and AOP shall Manufacture and supply to Eagle, all of Eagle's and its Affiliates' and Sublicensees' (and any of their successor entities') requirements of Licensed Product for Development and Commercialization use in the Field in the Eagle Territory, subject to and in accordance with the terms and conditions of a Supply Agreement that will set forth the specific terms and conditions of the supply of Licensed Products for Development and Commercialization in the Eagle Territory and such other quality agreements as required to comply with Applicable Laws.

(b) The supply price for each unit of Licensed Product supplied by AOP to Eagle pursuant to the Supply Agreement for Development and Commercialization use in the Field in the Eagle Territory shall be [***] ("**Supply Price**").

(c) For the sake of clarity, [***].

(d) The term of the Supply Agreement shall be the same as the Term and termination of this Agreement shall cause the termination of the Supply Agreement.

V.3 Supply Source Deficiency. In the event of a Supply Source Deficiency, AOP shall use Commercially reasonable efforts to transfer the Licensed Know-How necessary or useful for the Manufacture of finished Products to the relevant Third Party contract manufacturers and provide to Eagle:

(a) [***], and

(b) [***];

(c) [***]; and

(d) [***].

V.4 Supply Failure. In the event that a Supply Failure occurs regarding a Licensed Product, and for the duration of such Supply Failure, Eagle shall, at Eagle's expense, have the right to enter into a direct supply agreement and quality agreement to have, under the supervision of the JSC, Manufactured the affected Licensed Product in finished form for use in the Eagle Territory through one or more Third Party contract manufacturers acceptable to both Parties (such acceptance not to be unreasonably withheld, conditioned or delayed), provided that AOP will supply API to Eagle or the relevant Third Party contract manufacturer for use in such manufacturing (*mutatis mutandis* according to Section 5.2) for as long as AOP is able to supply API to Eagle or to Eagle's Third Party contract manufacturers. The Parties will cooperate in a transition of the Manufacturing sufficient to enable Eagle or another supplier to manufacture the Licensed Products for Development and Commercialization purposes in the Eagle Territory.

Article VI
PAYMENTS

VI.1 Upfront Payment. Eagle shall pay to AOP an [***] upfront payment of five million U.S. Dollars ($5,000,000) within [***] following the Effective Date in accordance with the payment provisions of ARTICLE VII.

VI.2 Development Milestone Payments

(a) Development Milestone Payments. Eagle shall pay to AOP the [***] milestone payments set forth below following the achievement by Eagle or any of its Affiliates or Sublicensees, of the corresponding milestone events defined below (each, a "**Development Milestone Payment**" and "**Development Milestone Event,**" respectively). The Development Milestone Payments shall be payable in accordance with the payment provisions in ARTICLE VII and following receipt of the relevant invoice from AOP as further described in Section 6.2(b).

No.	Development Milestone Event	Payment
1	[***]	[***]
2	[***]	[***]
3	[***]	[***]

(b) Reports and Payments. Eagle shall notify AOP in writing within [***] after the achievement of each Development Milestone Event set out in Section 6.2(a) by Eagle, or any of its Affiliates, and in the case of Sublicensees, within [***] after such Development Milestone Event is achieved by such Sublicensee. Based on this notice, AOP shall then issue and send to Eagle the invoice for the appropriate Development Milestone Payment, which shall be paid by Eagle within [***] of receipt of such invoice.

VI.3 Profit Share Payments

(a) Profit Share Percentage. During the Term of this Agreement, AOP will receive [***] of Net Profits from each calendar quarter resulting from the Commercialization of the Licensed Product in the Eagle Territory and Eagle will receive [***] of Net Profits from each calendar quarter resulting from the Commercialization of the Licensed Product in the Eagle Territory. [***].

(b) Calculation and Payment of Net Profit Share

(i) [***].

(ii) [***].

(iii) [***].

(iv) Reports and Payments. Starting from the First Commercial Sale of a Licensed Product in the Eagle Territory, within [***], Eagle will report to AOP in a written report in the form agreed by the Parties ([***]), in relation to the Commercialization of Licensed Product in the Eagle Territory in such calendar quarter, the Net Sales, Free Goods, the Allowable Expenses ([***]), as well as [***] (such report, the "**P&L Report**"). Without limiting the generality of the foregoing, Eagle shall require its Affiliates and Sublicensees to report their Net Sales and to provide such reports with respect thereto to Eagle. [***] in accordance with Section 6.3(a).

(v) Invoices will be issued and paid as follows: [***].

VI.4 Guaranteed Minimum Profit Share Payments. From the [***] date of the First Commercial Sale of the Licensed Product, Eagle shall be required to make the annual Minimum Profit Share Payments for the Licensed Product as set forth in Exhibit 6.4 (the "**Guaranteed Minimum Profit Share Payments**"). Should Eagle fail to make the Minimum Profit Share Payments for [***], AOP shall have the right to convert the licenses granted to Eagle hereunder into non-exclusive licenses. Notwithstanding the foregoing, [***] AOP shall not be entitled to convert the exclusive licenses granted to Eagle into non-exclusive licenses.

VI.5 Sample Calculation. A sample calculation for Net Sales, Net Profit and profit share payments (cf. Section 6.3) is attached hereto as Exhibit 6.5, provided, however, that such sample

calculation is for illustration purposes only and shall not be admissible in any dispute or otherwise influence the interpretation of this Agreement.

VI.6 Royalties to Eagle

(a) With respect to Licensed Product that AOP, its Affiliates or (sub)licensees Commercialize in the AOP Territory, AOP shall pay [***], if and for as long as the following cumulative conditions are met: (i) [***] Valid Claim of a [***] covers such [***], (ii) the [***] was made or conceived [***], and (iii) such [***] provides [***].

(b) Royalties, if any, according to this Section 6.4 shall be payable on a calendar quarter basis and [***] in the appropriate form.

Article VII
PAYMENTS; BOOKS AND RECORDS

VII.1 Payment Method; Currency Conversion. All amounts specified in this Agreement are in U.S. Dollars, and all cash payments under this Agreement shall be paid in U.S. Dollars. All payments under this Agreement will be paid in U.S. Dollars by wire transfer to an account designated, as applicable, by AOP (which account AOP may update from time to time in writing, subject to Eagle's confirmation, such confirmation not be unreasonably withheld) or by Eagle (which account Eagle may update from time to time in writing, subject to AOP's reasonable confirmation).

VII.2 Withholding Taxes. The upfront, milestone, profit sharing, and royalty payments to be made under this Agreement shall be paid free and clear of any taxes, except for any withholding taxes required by Applicable Law. To the extent any withholding taxes are deducted, withheld and paid by or on behalf of a Party to the appropriate taxing authority, such amounts shall be treated for all purposes of this Agreement as having been paid to the other Party. The Parties shall provide each other with official receipts issued by the appropriate governmental agency to them. Each Party shall provide to the other Party such assistance as may be reasonably requested in connection with any application to qualify for the benefit of a reduced rate of withholding taxation, under the terms of any income tax treaty between the United States and other jurisdictions.

VII.3 Late Payments. In the event that any amount payable by Eagle to AOP or by AOP to Eagle hereunder is not made when due, such outstanding payment shall accrue interest, to the extent permitted by Applicable Laws, at the [***], computed from the date such payment was due until the date the payment is made.

VII.4 Records. Eagle and its Affiliates shall keep complete and accurate books of account and records in reasonably sufficient detail to enable the amounts payable under this Agreement to be determined. Such books and records shall be kept at the principal place of business of Eagle, its Affiliates or Sublicensees, as the case may be, for at least [***].

VII.5 Audits

(a) Audit Rights

(i) Upon at least [***] prior written notice from AOP, Eagle shall permit, and shall require its Affiliates and, under the applicable sublicense agreement, its Sublicensees, to permit, an independent certified public accounting firm of nationally recognized standing, selected by AOP and reasonably acceptable to Eagle, to have access during normal business hours to such books of account and records of Eagle, and its Affiliates and Sublicensees, at their principal place of business, as may be

reasonably necessary to verify the accuracy of the reports to be provided by Eagle pursuant to this Agreement and the Supply Agreement. Such audits may not [***].

(ii) Upon at least [***] prior written notice from Eagle, AOP shall permit, and shall require its Affiliates, to permit, an independent certified public accounting firm of nationally recognized standing, selected by Eagle and reasonably acceptable to AOP, to have access during normal business hours to such books of account and records of AOP and its Affiliates, at their principal place of business, as may be reasonably necessary to verify the accuracy of the Supply Price's calculation and reports to be provided to Eagle pursuant to Section 6.3. Such audits may not [***].

(b) Audit Results. The Parties shall require the independent accountant to provide to the auditing Party an audit report containing its conclusions regarding any audit, and specifying whether the amounts paid were correct or, if incorrect, the amount of any underpayment or overpayment. [***] If such audit establishes any underpayment, the applicable Party shall remit or reimburse to the other Party, within [***] of the date on which the applicable party delivers to the other Party an invoice for the amount of the applicable underpayment, (i) the amount of such underpayment and (ii) interest on the amount of such underpayment, with such interest being calculated pursuant to Section 7.3. In the event such audit establishes that amounts were overpaid, the amount of such overpayment shall be refunded to the applicable Party within [***] of the date on which the applicable party delivers to the other Party an invoice for the amount of the applicable overpayment. The fees charged by the independent accountant in connection with any audit pursuant to this Section 7.5 shall be paid by the auditing Party; provided, however, that if a discrepancy in favor of the auditing Party of more than [***] of the payments due under this Agreement for the period being audited is established, then the audited Party shall pay [***].

(c) Confidential Financial Information; Other Matters. Each Party shall treat all financial information subject to review under this ARTICLE VII as the Confidential Information of the other Party in accordance with Section 8.1. Any auditor shall enter into a confidentiality agreement with the audited Party and shall not disclose or use the audited Party's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by Eagle or the amount of payments due by a Party to the other Party under this Agreement. If Eagle – in breach of its obligation pursuant to Section 7.5(a)(i) – is unable to obtain from any Sublicensee a right for AOP to audit the books of account and records of such Sublicensee, Eagle shall obtain the right to inspect and audit such Sublicensee's books and records for itself and shall exercise such audit rights on behalf of AOP – with the fees and expenses associated with such audit to be borne by the applicable Party according to Section 7.5(b), with AOP being considered the auditing Party – upon AOP's written request and disclose the results of any such audit to AOP in accordance with Section 7.5(b).

Article VIII
CONFIDENTIALITY

VIII.1 Confidential Information. Except to the extent expressly authorized by this Agreement, each Party agrees that, during the term of this Agreement[***] such Party (the "**Receiving Party**") shall keep confidential, and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement, or the Supply Agreement or further agreements accompanying this Agreement, or in the exercise of rights granted to it thereunder, any information furnished to it by or on behalf of the other Party (the "**Disclosing Party**") pursuant to this Agreement that [***] (collectively, "**Confidential Information**"). The Receiving Party shall use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but in no event less than reasonable care) to prevent unauthorized access, use and disclosure of the Disclosing Party's Confidential Information and to ensure that its, and its Affiliates', employees, agents, consultants, other representatives ("**Representatives**") do not disclose, except as otherwise expressly permitted under this

Agreement, or make any unauthorized use of, the Disclosing Party's Confidential Information. The Receiving Party shall promptly notify the Disclosing Party upon discovery of any unauthorized use or unauthorized disclosure of the Disclosing Party's Confidential Information. For purposes of this Agreement, the terms of this Agreement shall be deemed the Confidential Information of both Eagle and AOP. [***].

VIII.2 Exceptions. Confidential Information of a Disclosing Party shall not include any information to the extent that such information (which the Receiving Party can prove by competent written evidence): (a) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party in breach of this Agreement, generally known or available to the public; (b) is lawfully known by the Receiving Party or any of its Affiliates (to the extent such Receiving Party or Affiliate has the right to use and disclose such information) at the time of receiving such information from the Disclosing Party; (c) is hereafter furnished to the Receiving Party or any of its Affiliates 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 Receiving Party (to the extent such Receiving Party or Affiliate has the right to use and disclose such information); or (d) is independently discovered or developed by the Receiving Party or any of its Affiliates, without the use of or reference to Confidential Information of the Disclosing Party.

VIII.3 Trade Secrets. Notwithstanding the above, any trade secrets according to Directive (EU) 2016/943 disclosed under this Agreement shall be treated confidential [***].

VIII.4 Authorized Disclosure. Notwithstanding the provisions of Section 8.1, the Receiving Party may disclose Confidential Information of the Disclosing Party as expressly permitted by this Agreement, or if and to the extent such disclosure is reasonably necessary in the following instances:

(a) In the case of either Party as the Receiving Party:

(i) enforcing such Party's rights or performing its obligations under this Agreement;

(ii) prosecuting or defending litigation as permitted by this Agreement;

(iii) such disclosure is reasonably necessary to its employees, agents, consultants, advisors (including financial advisors, attorneys and accountants), contractors, licensees or Sublicensees 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;

(iv) such disclosure is necessary to comply with Applicable Laws, including regulations promulgated by applicable security exchanges, court order, administrative subpoena or order; provided in the event the Receiving Party is required to make a disclosure of the Disclosing Party's Confidential Information pursuant to this subparagraph 8.4(a)(iv), it will, except where legally prohibited, (i) give reasonable advance notice to the Disclosing Party of such disclosure, (ii) use efforts to secure confidential treatment of such information at least as diligent as the Receiving Party would use to protect its own confidential information, and (iii) cooperate with any efforts by the Disclosing Party, at the Disclosing Party's request and expense, to prevent or limit disclosure of such Confidential Information; or

(v) disclosure to Third Parties in connection with due diligence or similar investigations, and disclosure to any bona fide potential or actual investor, acquiror or merger partner for the sole purpose of evaluating an actual or potential investment, acquisition or merger; provided that in connection with such disclosure, such Party shall inform each disclosee of the confidential nature of such

Confidential Information and ensure that any such Third Party agrees to be bound by obligations of confidentiality and non-use similar to those contained in this Agreement.

(b) In the case of either Party as the Receiving Party:

(i) filing for, prosecuting or enforcing Licensed Patent Rights in accordance with this Agreement;

(ii) in Regulatory Filings or otherwise in seeking, obtaining and maintaining Regulatory Approvals (including complying with the requirements of Regulatory Authorities with respect to filing for, obtaining and maintaining such Regulatory Approvals); and

(iii) disclosure to actual or potential Sublicensees or subcontractors, or other Third Parties in connection with the exercise of its rights under this Agreement, provided that Eagle uses Commercially Reasonable Efforts to secure confidential treatment of such information at least as diligent as it would use to protect its own confidential information of a similar nature.

(c) Each Party shall be responsible for any breaches of confidentiality by any of its Affiliates, Sublicensees, subcontractors, Representatives, advisors and Third Parties to whom it discloses Confidential Information.

VIII.5 Confidential Disclosure of Terms. The Parties agree that the terms of this Agreement are the Confidential Information of both Parties that a Party may not disclose to any Third Party without the prior written consent of the other Party hereto, except as permitted under Section 8.2 or 8.4.

VIII.6 Publications. Except for the joint press release pursuant to Section 8.7, either Party, its Affiliates, its or their Sublicensees, or its or their respective employees or consultants, wishing to make a publication or presentation relating to the terms hereof or activities hereunder, shall deliver to the other Party a (i) copy of any proposed written publication at least [***] prior to submission of such publication or, as the case may be, (ii) an outline or copy of a proposed oral disclosure or presentation at least [***] prior to such oral disclosure or presentation. The reviewing Party shall have the right (a) to propose reasonable modifications to the publication or presentation, or (b) to request a reasonable delay in publication or presentation. If the reviewing Party requests a delay, the publishing Party shall delay submission or presentation for a period of at least [***] or such period of time as agreed upon between the Parties. Upon expiration of such [***] period or such longer period as agreed upon between the Parties, the publishing Party shall be free to proceed with the publication or presentation. If the reviewing Party requests reasonable modifications to the publication or presentation, the publishing Party shall edit such publication prior to submission of the publication or presentation. Notwithstanding the foregoing, [***].

VIII.7 Joint Press Release. The Parties have mutually approved a joint press release attached hereto as Exhibit 8.7 with respect to this Agreement to be published on the Execution Date or immediately thereafter. After release of this press release in accordance with this Section 8.7, AOP may disclose to Third Parties the information contained in such press release without further consent.

For clarity, subject to AOP's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed, Eagle shall have the right to issue subsequent press releases or other written public statements pertaining to the activities conducted hereunder. For avoidance of doubt, Eagle shall have the right to disclose to its investment community without AOP's prior written consent: [***].

VIII.8 Prior Non-Disclosure Agreements. This Agreement supersedes [***].

Article IX
PATENT PROSECUTION AND ENFORCEMENT

IX.1 United States Law. For the Eagle Territory, Collaboration Know-How, inventorship of Know-How, including inventions, conceived, discovered, developed, or otherwise made under this Agreement shall be determined in accordance with Applicable Laws of the United States as such law exists as of the Execution Date irrespective of where such conception, discovery, development, or making occurs.

IX.2 AOP Ownership. AOP or an Affiliate of AOP shall own and retain all right, title, and interest in and to all Licensed Intellectual Property, including all Data, AOP Trademarks, and any other trademark (except Eagle trademarks) used exclusively for the Commercialization of the Licensed Product in the Eagle Territory.

IX.3 Eagle Ownership and License to AOP. Eagle or an Affiliate of Eagle shall own and retain all right, title and interest in and to Eagle Background Know-How, Eagle Background Patents, Eagle Non-Product-Specific Collaboration Know-How, and Eagle Non-Product-Specific Collaboration Patents. Eagle hereby grants to AOP a non-exclusive, fully paid-up, royalty-free, sublicensable (through multiple tiers) worldwide license under the Know-How and Patents referred to in this Section 9.3 for all acts necessary or useful to perform the rights or fulfill the obligations under this Agreement or the Supply Agreement, as well as a related quality agreement or pharmacovigilance agreement between the Parties.

IX.4 Disclosure. During the Term, each Party will disclose to the other Party all Collaboration Know-How that is invented, discovered, developed, or otherwise generated by or on behalf of such Party or any of its Affiliates, whether solely or jointly with the other Party or any of the other Party's Affiliates or with any Third Party, in the conduct of activities under this Agreement and of which such Party becomes aware. Such disclosure shall (a) be made [***] prior to the filing of any patent application with respect to such Collaboration Know-How, but in the case of AOP in no event more than [***] thereafter, and (b) shall include all invention disclosures or other similar documents submitted to such Party by its or its Affiliates' employees, agents, or independent contractors relating thereto.

IX.5 Cooperation. Each Party agrees and shall cause its Affiliates and Sublicensees to execute all papers and otherwise agrees to assist the other Party as reasonably required, to perfect in the other Party the rights, title and other interests owned by such Party under this ARTICLE IX. Each Party hereby assigns and automatically and in full transfers to the respective other Party all (ownership) rights, title and other interests it holds or acquires during the Term, and which the respective other Party is entitled to own under this ARTICLE IX, and the respective other Party herewith accepts such transfer of rights.

IX.6 Patent Prosecution and Maintenance.

(a) Patent Prosecution and Maintenance. As between the Parties, AOP shall, at its expense, have the first right, but not the obligation, to file, maintain and prosecute the Licensed Patent Rights throughout the Eagle Territory, including conducting any interferences, *inter parte* reviews, reexaminations, reissues, opposition, and other similar proceedings relating thereto. AOP shall keep Eagle reasonably informed of progress with regard to the prosecution and maintenance of Licensed Patent Rights as set forth in this Section 9.6(a). Eagle shall have the right to review all material Patent filings in advance of any deadline, submission to or action with any patent office. AOP shall furnish to Eagle copies of all relevant drafts and documents of such Licensed Patent Rights reasonably in advance of such consultation for Eagle's review. AOP shall provide to Eagle copies of all patent office submissions and correspondence relevant to such Licensed Patent Rights within a reasonable amount of time following submission or receipt thereof by AOP. AOP shall consider in good faith any reasonable and timely

comments provided by Eagle in connection with the prosecution and maintenance of such Licensed Patent Rights. At AOP's request, Eagle shall reasonably cooperate with AOP in the prosecution and maintenance of such Licensed Patent Rights. If AOP desires to abandon or cease prosecution or maintenance of any such Licensed Patent Right in the Eagle Territory, AOP shall provide written notice to Eagle of such intention promptly after AOP makes such determination, but in no event later than [***] prior to any deadline that must be met in order to avoid such abandonment, and Eagle shall have the right, but not the obligation, to assume responsibility for prosecution and maintenance of such Licensed Patent Right at its sole cost and expense. AOP shall provide Eagle with an updated **Exhibit 1.67** [***].

(b) Patent Term Extensions. AOP shall have the sole right to obtain patent term extensions, and supplementary protection certificates, with respect to any Licensed Product in the Field in the Eagle Territory, and Eagle shall reasonably cooperate with AOP in connection therewith, provided that Eagle shall have the right to request that AOP seek to obtain any such patent term extensions and AOP shall consider any such request by Eagle in good faith.

IX.7 Trademark Prosecution and Maintenance. As between the Parties, AOP shall[***] have the first right, but not the obligation, to file, maintain and prosecute the AOP Trademarks throughout the Eagle Territory, including conducting any proceedings relating thereto. AOP shall keep Eagle reasonably informed of progress with regard to the prosecution and maintenance of AOP Trademarks. Eagle shall have the right to consult and review all material AOP Trademark filings in advance of any deadline, submission to or action with any trademark office. AOP shall consider in good faith any reasonable and timely comments provided by Eagle in connection with the prosecution and maintenance of such AOP Trademarks. At AOP's request, Eagle shall reasonably cooperate with AOP in the prosecution and maintenance of such AOP Trademarks. If AOP desires to abandon or cease prosecution or maintenance of any such AOP Trademarks, AOP shall provide written notice to Eagle of such intention promptly after AOP makes such determination, but in no event later than [***] prior to any deadline that must be met in order to avoid such abandonment, and Eagle shall have the right, but not the obligation, to assume responsibility for prosecution and maintenance of such AOP Trademarks [***].

IX.8 Enforcement

(a) Enforcement Actions

(i) In the event that either Party becomes aware of any patent or AOP Trademark nullity, invalidity or unenforceability actions, any declaratory judgment actions, or any actual or threatened infringement of any Licensed Patent Right or AOP Trademark in the Eagle Territory, including any claims arising under the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417), as amended, that Party shall promptly notify the other Party in writing. [***].

(ii) The Party conducting such Enforcement Action under this Section 9.8(a) shall have full control over its conduct, including settlement of an Enforcement Action; provided, however, that the Party conducting such Enforcement Action may not settle any such Enforcement Action, or make any admissions or assert any position in such Enforcement Action, in a manner that would materially adversely affect the validity of a Licensed Patent Right or AOP Trademark, without the prior written consent of the other Party, which shall not be unreasonably withheld, conditioned or delayed. If one Party initiates any suit, action or proceeding under this Section 9.8(a), the other Party agrees to be joined as party plaintiff if reasonably necessary to prosecute the suit, action or proceeding, and to give the initiating Party authority to file, prosecute and control the suit, action or proceeding; provided, however, that such other Party shall in any case have the right to be represented by its own counsel at its cost and expense. In any event, the Parties shall assist and cooperate with one another in any Enforcement Action, including at their mutual reasonable requests.

(iii) Each Party shall assume and pay all costs and expenses incurred by it with respect to such Enforcement Action, including fees and expenses of counsel selected by it.

(b) Recovery. AOP and Eagle shall each recover their respective actual out-of-pocket expenses (including attorneys' fees), or equitable proportions thereof in case they cannot fully be recovered, associated with any Enforcement Action against infringers undertaken pursuant to Section 9.8(a) from any resulting monetary amount received by award of a court of competent jurisdiction. Any excess amount of such a recovery shall (i) be [***]. If Eagle is the Party initiating the Enforcement Action under Section 9.8(a) and AOP does not join in such enforcement action, [***].

IX.9 Third Party Infringement Claims. If the Development, Manufacture, Commercialization, or other acts of exploitation of any Licensed Product in the Eagle Territory pursuant to this Agreement results in a claim, suit or proceeding alleging patent or other intellectual property infringement against a Party (or its Affiliates, or in the case of Eagle, its Sublicensees) (collectively, "**Infringement Actions**"), such Party shall [***] notify the other Party hereto in writing. Eagle shall have the right to direct and control the defense thereof, at its own expense (subject to AOP's indemnification obligations set forth in Section 13.2) with counsel of its choice. Eagle shall keep AOP informed of all material developments in connection with any such Infringement Action and take into good faith consideration AOP's views on the conduct of Infringement Actions. Eagle shall not enter into any settlement or consent decree that (i) requires any payment by or admits or imparts any other liability to AOP; or (ii) admits the invalidity or unenforceability of any Licensed Patent; or (iii) settle any Infringement Action in a manner that has a material adverse effect on the rights or interests of AOP or in a manner that imposes any costs or liability on, or involves any admission by, AOP, [***]. Eagle may treat any reasonable out-of-pocket costs, including reasonable attorneys' fees, damages and other liabilities, incurred in connection with such Infringement Action and which are (i) part of a final judgment or (ii) paid by Eagle in a settlement of the Infringement Action to which AOP has given its prior written consent and as entered into in compliance with this Section 9.9 as "**Third Party Payments.**"

IX.10 AOP Territory. AOP shall [***].

Article X
TERM AND TERMINATION

X.1 HSR and Other Government Filings.

(a) The Parties shall each, as promptly as practicable after the Execution Date, file or cause to be filed with the U.S. Federal Trade Commission ("**FTC**") and the U.S. Department of Justice ("**DOJ**") and any relevant foreign Governmental Authority any notifications required to be filed under the HSR Act (the "**HSR Filing**") or any similar Applicable (foreign) Laws with respect to the transactions contemplated hereby; provided that the Parties shall each make the HSR Filing within [***] after the Execution Date and shall each file any notifications or filings required to be filed under similar Applicable (foreign) Laws and regulations as promptly as reasonably practicable. The Parties shall use their reasonable best efforts to respond promptly to any requests for additional information made by such agencies, and to cause the waiting period (and any extension thereof) under the HSR Act to terminate or expire at the earliest possible date or obtain any required authorization or clearance under any similar Applicable (foreign) Laws after the date of filing. Eagle will be responsible for one hundred percent (100%) of the filing fees and each Party will be responsible for internal and out-of-pocket costs and expenses (including its own legal and other advice) in connection with the preparation and conduct of the HSR Filing and any filing under similar Applicable (foreign) Laws, including responding to the relevant Governmental Authorities.

(b) In connection with obtaining clearance under the HSR Act, each of AOP and Eagle shall (i) cooperate with each other in connection with any investigation or other inquiry relating to an HSR Filing and the transactions contemplated hereby, (ii) keep the other Party or its counsel informed of any communication received from or given to the FTC or DOJ relating to the HSR Filing and the transactions contemplated hereby (and provide a copy to the other Party if such communication is in writing), (iii) reasonably consult with each other in advance of any meeting or conference with the FTC or DOJ, and, to the extent permitted by the FTC or DOJ, give the other Party or its counsel the opportunity to attend and participate in such meetings and conferences, and (iv) permit the other Party or its counsel to review in advance, and in good faith consider the views of the other Party or its counsel and incorporating where appropriate, concerning, any submission, filing or communication (and documents submitted therewith) intended to be given to the FTC or DOJ. This Section 10.1(b) applies, *mutatis mutandis*, to filings under similar Applicable (foreign) Laws

X.2 Effective Date. Notwithstanding anything in this Agreement to the contrary, this Agreement (other than this ARTICLE X, which is binding and effective as of the Execution Date) shall not become effective until (i) the Parties' execution of the Supply Agreement, and (ii) the expiration or earlier termination of the waiting period (or any extension thereof) under the HSR Act in the United States, provided that neither the FTC nor the DOJ have commenced or threatened litigation to enjoin the transactions contemplated by this Agreement nor have the parties agreed with the FTC or DOJ to postpone closing (the date on which (i) and (ii) are fulfilled, the "**Effective Date**"). If, on the [***] after the date of filing under the HSR Act, the waiting period required thereunder has not expired, either Party shall have the right, on written notice to the other Party, to terminate this Agreement, and upon receipt of such notice by the terminating Party, this Agreement shall be null and void and have no further force and effect; provided, however, that [***] shall survive, in particular with respect to any rights that accrued to the benefit of a Party prior to such termination.

X.3 Term. On the Effective Date, the full Agreement and all its terms and provisions shall be automatically effective and binding on both Parties for [***] terminated in accordance with the termination provisions under this Agreement ("**Term**").

X.4 Termination for Material Breach. If either Party materially breaches this Agreement at any time, the non-breaching Party shall have the right to terminate this Agreement by written termination notice to the breaching Party, if such material breach is not cured within [***] after written breach notice is given by the non-breaching Party to the breaching Party specifying the breach, provided that in the event of a good faith dispute with respect to the existence of a material breach, this Agreement shall not be terminated unless it is finally determined under ARTICLE XIV that this Agreement was materially breached, and the breaching Party fails to cure such breach within [***] after such determination. For clarity, [***].

X.5 Termination for Bankruptcy. Either Party shall have the right to terminate this Agreement upon written notice to the other Party: (a) if such other Party is declared insolvent or bankrupt by a court of competent jurisdiction; (b) if a voluntary or involuntary petition in bankruptcy is filed in any court of competent jurisdiction against such other Party and such petition is not dismissed within [***] after filing; (c) if such other Party shall make or execute an assignment of substantially all of its assets for the benefit of creditors; or (d) substantially all of the assets of such other Party are seized or attached and not released within [***] thereafter.

X.6 Termination by Eagle. [***] Eagle shall have the right to terminate this Agreement, [***] prior written notice to AOP. Notwithstanding any other provision of this Agreement, during this [***], AOP shall have [***].

X.7 Termination by AOP for Failure to Make Upfront Payment. If Eagle fails to timely make the upfront payment to AOP as set forth under Section 6.1, AOP may terminate this Agreement by written termination notice to Eagle, if full payment is not made within [***] after written notice of non-payment is given to Eagle, and AOP may collect from Eagle the amount of US Dollars [***] as its sole and exclusive remedy besides the termination right. Any other failure of Eagle to make a payment due to AOP under this Agreement shall be considered a material breach.

X.8 Termination by AOP for Patent Challenge. AOP may terminate this Agreement in its entirety upon [***] written notice if Eagle or its Affiliates or Sublicensees, individually or in association with any other Third Party, commences a Patent Challenge. Notwithstanding the foregoing, [***].

X.9 Notice to AOP for Competitive Change of Control Over Eagle. Eagle shall, unless prohibited by Applicable Laws, immediately notify AOP in writing of any Competitive Change of Control over Eagle, as soon as Eagle reasonably expects such Competitive Change of Control over Eagle to occur.

X.10 Surviving Provisions. In case of a termination of this Agreement, [***] shall survive, in particular with respect to any rights that accrued to the benefit of a Party prior to such termination.

Article XI
EFFECT OF TERMINATION

XI.1 Accrued Obligations. The expiration or termination of this Agreement for any reason shall not release either Party from any liability which, at the time of such expiration or termination, has already accrued to the other Party prior to such expiration or termination, nor will any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, or at law or in equity, with respect to any breach of this Agreement that occurred prior to such expiration or termination.

XI.2 Return of Confidential Information. Within [***] after the Effective Date of any such termination, each Party shall promptly return to the other Party, or delete or destroy, all Confidential Information of the other Party; provided that (i) each Party may retain copies of the Confidential Information of the other Party to the extent [***]; (ii) each Party may retain one copy of the Confidential Information of the other Party [***] and (iii) neither Party shall be required to [***]. Upon any termination of this Agreement, Confidential Information comprising Licensed Know-How shall cease to be Confidential Information of Eagle, and thereafter shall be Confidential Information solely of AOP.

XI.3 Reversion of Rights. All rights and licenses granted to Eagle under this Agreement shall terminate and revert to AOP and Eagle shall no longer use the Licensed Intellectual Property, the AOP Trademarks, or any other trademark (except Eagle trademarks) used exclusively for the Commercialization of the Licensed Product in the Eagle Territory.

XI.4 Wind-Down Period. If this Agreement is terminated after the First Commercial Sale in the Eagle Territory, Eagle and its Affiliates may continue to Commercialize the Licensed Product for use in the Field in the Eagle Territory, in accordance with the terms and conditions of this Agreement, for a period [***] from the effective date of such termination (the "**Wind-Down Period**"). Notwithstanding any other provision of this Agreement, during this Wind-Down Period, Eagle's and its Affiliates' rights with respect to the Licensed Product shall be non-exclusive and AOP shall have the right to engage one or more partners(s) or distributor(s) of the Licensed Product in the Eagle Territory. During the Wind-Down Period, Eagle shall continue to make any and all Profit Share Payments and related reports to AOP for the Licensed Product sold by Eagle, its Affiliates, or its Sublicensees. After the Wind-Down Period, Eagle

and its Affiliates and Sublicensees shall not sell the Licensed Product or make any representation regarding their status as a licensee of AOP, or as distributor of the Licensed Product. Within [***] of expiration of the Wind-Down Period, Eagle shall notify AOP of any quantity of the Licensed Product remaining in Eagle's inventory and AOP shall have [***].

XI.5 Regulatory Filings. Eagle shall promptly assign and transfer to AOP the Regulatory Approvals together with all Regulatory Filings for the Licensed Product that are held or controlled by or under authority of Eagle, and shall take such actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights under the Regulatory Filings to AOP. Eagle shall cause each of its Affiliates or Sublicensees to transfer any such Regulatory Filings to AOP upon termination of this Agreement. If Applicable Laws prevent or delay the transfer of ownership of a Regulatory Filing to AOP, Eagle shall grant, and does hereby grant, to AOP an exclusive, royalty-free and irrevocable right of access and reference to such Regulatory Filing for the Licensed Product, and shall cooperate fully to make the benefits of such Regulatory Filings available to AOP and/or its designee(s). Within [***] after notice of termination, Eagle shall provide to AOP copies of all such Regulatory Filings, and of all Data Controlled by Eagle. AOP shall be free to use such Regulatory Filings and Data in the further Development and Commercialization of the Licensed Product in the Eagle Territory.

XI.6 Transition Assistance. Eagle shall cooperate with AOP and its designee(s) to facilitate a smooth, orderly and prompt transition of the Development and Commercialization of the Licensed Product in the Eagle Territory to AOP and/or its designee(s). This includes, without limitation, Eagle's obligation to cooperate (i) in the transition to AOP of the lead, or any other role Eagle or its Affiliates play, in any Clinical Studies or other clinical Development activities ongoing at the time of termination, if AOP chooses to take over such lead or other role in such Studies or such other activities, or (ii) in the winding-up and termination of such Clinical Studies or other activities if AOP so chooses.

XI.7 Non-Compete. For a period of [***], Eagle shall not, and shall cause its Affiliates not to, develop, use, make, have made, sell, have sold, offer for sale, export, import or otherwise commercialize [***] Competing Product.

XI.8 Costs and Expenses. [***].

Article XII
REPRESENTATIONS, WARRANTIES AND COVENANTS

XII.1 Representations and Warranties of AOP. AOP represents, warrants and covenants to Eagle that, as of the Execution Date:

(a) AOP is a corporation duly organized, validly existing and is in good standing under the laws of Austria, is qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the conduct of its business or the ownership of its properties requires such qualification and failure to have such would prevent AOP from performing its obligations under this Agreement;

(b) this Agreement is a legal and valid obligation binding upon AOP and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by AOP have been duly authorized by all necessary corporate action and do not and will not: (i) violate any law, rule, regulation, order, writ, judgment, decree, determination or award of any court, governmental body or administrative or other agency having jurisdiction over AOP; nor (ii) conflict with, or constitute a default under, any agreement, instrument or understanding, oral or written, to which AOP is a party or by which it is bound;

(c) AOP is the sole owner or otherwise has sufficient legal title or beneficial title or ownership or license with respect to the Licensed Patent Rights and the Licensed Know-How and has the full right and authority to grant the rights and licenses with respect to the Licensed Patent Rights and Licensed Know-How, without limitation or restriction;

(d) Exhibit 1.67 sets forth a true and complete list of all Patents owned by AOP or its Affiliates as of the Execution Date that Cover the Licensed Products in the Eagle Territory, and AOP has the full right and authority to grant to Eagle the rights or licenses granted under this Agreement regarding the Patents described in Exhibit 1.67, and to prosecute and enforce such Patents in accordance with ARTICLE IX;

(e) AOP has not previously granted and will not grant any right, license or interest in or to a Licensed Product, Licensed Know-How, or Licensed Patent Rights, or any portion thereof, that is in conflict with, limits or derogates from the rights or licenses granted to Eagle under this Agreement;

(f) the Licensed Patent Rights and the Licensed Know-How are free and clear of all liens, claims, security interests or other encumbrances of any kind and during the term of this Agreement, AOP shall not permit the Licensed Patent Rights or the Licensed Know-How to become encumbered by any liens, claims, security interests or other encumbrances that diminish the rights or licenses granted to Eagle under this Agreement;

(g) [***];

(h) all necessary consents, approvals and authorizations of all Regulatory Authorities, other Governmental Authorities and other persons or entities required to be obtained by AOP in order to enter into this Agreement have been obtained;

(i) to AOP's knowledge, [***];

(j) [***];

(k) AOP has not knowingly and intentionally withheld any Licensed Know-How that is reasonably material for Eagle's conduct of activities under this Agreement and, to AOP's knowledge, all Licensed Know-How provided to Eagle is free from any material inaccuracies;

(l) AOP has disclosed to Eagle all material information relating to the safety and efficacy of the Licensed Product known to it or its Affiliates;

(m) [***];

(n) to AOP's knowledge, AOP has complied with all Applicable Laws in all material respects, including any disclosure requirements, in connection with the filing, prosecution and maintenance of the Licensed Patent Rights and, to AOP's knowledge, none of the issued Licensed Patent Rights are invalid or unenforceable;

(o) the Licensed Patent Rights and Licensed Know-How are not subject to any funding agreement with any government or Governmental Authority; and

(p) to AOP's knowledge, none of the materials and documents provided to Eagle in the course of Eagle's due diligence preceding execution of this Agreement contained any untrue statement of material fact.

XII.2 Representations and Warranties of Eagle. Eagle represents and warrants to AOP that, as of the Execution Date:

(a) Eagle is a corporation duly organized, validly existing and is in good standing under the laws of the State of Delaware, U.S.A., is qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the conduct of its business or the ownership of its properties requires such qualification and failure to have such would prevent Eagle from performing its obligations under this Agreement;

(b) this Agreement is a legal and valid obligation binding upon Eagle and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by Eagle have been duly authorized by all necessary corporate action and do not and will not: (i) violate any law, rule, regulation, order, writ, judgment, decree, determination or award of any court, governmental body or administrative or other agency having jurisdiction over Eagle; nor (ii) conflict with, or constitute a default under, any agreement, instrument or understanding, oral or written, to which Eagle is a party or by which it is bound;

(c) all necessary consents, approvals and authorizations of all Regulatory Authorities, other Governmental Authorities and other persons or entities required to be obtained by Eagle in order to enter into this Agreement have been obtained;

(d) Eagle has not previously granted and will not grant any right, license or interest in or to Eagle Background Know-How, Eagle Background Patents, Eagle Non-Product-Specific Collaboration Know-How, and Eagle Non-Product-Specific Collaboration Patents, or any portion thereof, that is in conflict with, limits or derogates from the rights or licenses granted to AOP under this Agreement; and

(e) Eagle Background Know-How, Eagle Background Patents, and all portions thereof, are free and clear of all liens, claims, security interests or other encumbrances of any kind and during the term of this Agreement, Eagle shall not permit them, Eagle Non-Product-Specific Collaboration Know-How and Eagle Non-Product-Specific Collaboration Patents, to become encumbered by any liens, claims, security interests or other encumbrances that could diminish AOP's rights under the Agreement;

(f) [***];

(g) to Eagle's knowledge, [***];

(h) [***];

(i) to Eagle's knowledge, none of the materials and documents provided to preceding execution of this Agreement contained any untrue statement of material fact.

XII.3 Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTIES OF ANY KIND EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT OR VALIDITY OF INTELLECTUAL PROPERTY RIGHTS.

XII.4 Effective Date. During the period from the Execution Date until the Effective Date, each Party shall promptly inform the other Party in writing if and when it or any of its Affiliates becomes aware that the representations and warranties made pursuant to Section 12.1 or 12.2 as of the Execution

Date are no longer true and correct in any material respects if made on and as of the date of such notice. Upon receipt of such notice, the notified Party shall have the right, on written notice to the notifying Party, to terminate this Agreement at any point prior to the Effective Date or within [***] thereafter, in the event that the notified Party determines in good faith that the applicable change to the status of the representations and warranties as of the Execution Date would be reasonably likely to have a material adverse effect, and upon receipt of such notice by the notifying Party, this Agreement shall be null and void and have no further force and effect; provided, however, [***] shall survive, in particular with respect to any rights that accrued to the benefit of a Party prior to such termination.

Article XIII
INDEMNIFICATION; RECALLS

XIII.1 Indemnification of AOP. Eagle shall indemnify and hold harmless each of AOP, its Affiliates, and the directors, officers, shareholders and employees of such entities and the successors and assignees of any of the foregoing (the "**AOP Indemnitees**"), from and against any and all liabilities, damages, penalties, fines, costs, expenses [***] ("**Liabilities**") incurred by any AOP Indemnitee as a result of any claims, actions, suits or proceedings brought by a Third Party (a "**Third Party Claim**") against an AOP Indemnitee, arising from, or occurring as a result of: (a) the Development, Manufacture or Commercialization of any Licensed Product by Eagle, its Affiliates or Sublicensees; (b) any breach of any representations or warranties by Eagle; and (c) any breach by Eagle or failure by Eagle to perform an agreement assigned to Eagle, [***]; except to the extent such Third Party Claims fall within the scope of AOP's indemnification obligations set forth in Section 13.2 below or result from the material fault of an AOP Indemnitee.

XIII.2 Indemnification of Eagle. AOP shall indemnify and hold harmless each of Eagle, its Affiliates and Sublicensees and the directors, officers and employees of Eagle, its Affiliates and Sublicensees and the successors and assignees of any of the foregoing (the "**Eagle Indemnitees**"), from and against any and all Liabilities incurred by any Eagle Indemnitee as a result of any Third Party Claims against an Eagle Indemnitee, arising from, or occurring as a result of (a) the Development, Manufacture or Commercialization of any Licensed Product by AOP, its Affiliates or (sub)licensees prior to the Effective Date; (b) any breach of any representations, warranties or covenants by AOP; except to the extent such Third Party Claims fall within the scope of Eagle's indemnification obligations set forth in Section 13.1 or result from the material fault of an Eagle Indemnitee.

XIII.3 Procedure. A Party that intends to claim indemnification under this ARTICLE XIII (the "**Indemnitee**") shall promptly notify the other Party (the "**Indemnitor**") in writing of any Third Party Claim, in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have sole control of the defense or settlement thereof, except as set forth in Section 9.9. The indemnity arrangement in this Section 13.3 shall not apply to amounts paid in settlement of any action with respect to a Third Party Claim, if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld or delayed unreasonably. The failure to deliver written notice to the Indemnitor within [***], if prejudicial to its ability to defend such action, shall relieve such Indemnitor of any liability to the Indemnitee under this Section 13.3, but the omission to so deliver written notice to the Indemnitor shall not relieve the Indemnitor of any liability that it may have to any Indemnitee otherwise than under this Section 13.3. The Indemnitee under this Section 13.3 shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Third Party Claim covered by this indemnification.

XIII.4 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, CONSEQUENTIAL, OR INDIRECT DAMAGES, INCLUDING LOST PROFITS, ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT,

REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 13.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 13.1 OR 13.2, AND THE FOREGOING LIMITATIONS SHALL NOT APPLY WITH RESPECT TO DAMAGES RESULTING FROM A PARTY'S WILLFUL MISCONDUCT OR GROSS NEGLIGENCE OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE VIII.

Article XIV
DISPUTE RESOLUTION

XIV.1 Referral to Senior Executives. The Parties recognize that disputes as to certain matters relating to or in connection with this Agreement may from time to time arise during the term of this Agreement (each, including any dispute arising with respect to the interpretation, enforcement, termination or invalidity of this Agreement, a "**Dispute**"). If any such Dispute cannot be resolved by good faith negotiations, [***].

XIV.2 Arbitration. Any Dispute that is not resolved pursuant to Section 14.1 shall be finally settled by arbitration in accordance with [***]. The seat of the arbitration shall be [***]. The language of the proceedings shall be English. If so requested by the arbitrator, any evidence originally in a language other than English shall be submitted with a certified English translation accompanied by an original or true copy thereof. Any decision and/or award of the arbitrator may be entered in any court of competent jurisdiction for judicial recognition of the decision and an order of enforcement. The arbitration proceedings and the decision of the arbitrator shall be deemed the Confidential Information of both Parties subject to ARTICLE VIII. If a party asserted to be in breach under Section 10.4 disputes the asserted breach, this Agreement shall not be terminated and the license herein shall not be affected as a result of the disputed breach unless and until it has been determined in accordance with this Section 14.2 that this Agreement was materially breached, and such breach is not cured within [***] after such determination or such longer period as the arbitrator may establish. The Parties agree that they shall share equally the [***].

XIV.3 Interim Relief. Notwithstanding anything in Sections 14.1 or 14.2 to the contrary, each Party shall have the right to apply, for a temporary restraining order, preliminary injunction or other similar interim or conservatory relief, as necessary to protect the rights or property of such Party, (i) to any court of competent jurisdiction pending the selection of the arbitrator or pending the arbitrator's determination of the merits of any Dispute, or (ii) to an emergency arbitrator appointed [***] prior to the constitution of an arbitral tribunal. Nothing in the preceding sentence shall be interpreted as limiting the powers of the arbitrator(s) with respect to any Dispute subject to arbitration under this Agreement.

XIV.4 Jury Waiver. EACH PARTY, TO THE EXTENT PERMITTED BY LAW, KNOWINGLY, VOLUNTARILY, AND INTENTIONALLY WAIVES ITS RIGHT TO A TRIAL BY JURY IN ANY ACTION OR OTHER LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT AND THE TRANSACTIONS IT CONTEMPLATES AND AGREES TO ARBITRATE AS SET FORTH IN SECTION 14.2 (ARBITRATION). THIS WAIVER APPLIES TO ANY ACTION OR LEGAL PROCEEDING, WHETHER SOUNDING IN CONTRACT, TORT OR OTHERWISE.

Article XV
GENERAL PROVISIONS

XV.1 Force Majeure. Except with regard to obligations to pay money, neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay (again: except for a failure or delay in making a money payment pursuant to this Agreement) is caused by or results from events beyond the reasonable control of the non-performing Party, including fire, flood, earthquake, hurricane, embargo, shortage, epidemic, pandemic, quarantine, war, act of war (whether war be declared or not), terrorist act, insurrection, riot, civil commotion, strike, lockout or other labor disturbance (whether involving the workforce of the non-performing Party or of any other Person) or act, omission or delay in acting by any Governmental Authority, including due to a clinical hold pursuant to 21 C.F.R. §312.42, as amended (and any equivalent in any jurisdiction outside the United States). The non-performing Party shall notify the other Party of such force majeure by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than necessary to resolve such force majeure event and the non-performing Party shall use diligent efforts to remedy its inability to perform. If a condition constituting force majeure exists for more than [***], the parties shall meet to negotiate a mutually satisfactory solution to the problem. The Party not affected by the force majeure situation shall have the right to terminate this Agreement upon [***] written notice from the failure of reaching a mutually satisfactory solution to the force majeure situation.

XV.2 Governing Law. This Agreement and all questions regarding its validity or interpretation, or the breach or performance of this Agreement, shall be governed by, and construed and enforced in accordance with, the laws of [***], without reference to conflict of law provisions or principles. The Parties hereby agree that the provisions of the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement and are strictly excluded.

XV.3 Data Protection.

(a) The Parties are – and will make their employees – aware of, consent to, and acknowledge that (i) the respective other Party may collect, process, transmit and use (personal) data according to Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 ("GDPR") and other Applicable Laws on data protection such as information on personal or material circumstances of an identified or an identifiable individual in the performance of this Agreement and the Supply Agreement and to comply with that other Party's obligation to report to the responsible authorities and/or disclose mandatory details; and (ii) such data may be stored in the other Party's database for the performance of this Agreement and the Supply Agreement, and that it may – if applicable and necessary – be transmitted to the other Party's Affiliates. The Parties and, if applicable, their employees have been informed about their rights according to the GDPR and other Applicable Laws on data protection, including their right to revoke the above given consent at any time and to have their (personal) data deleted or rectified. The Parties acknowledge that the other Party's obligation to report and/or disclose mandatory information remains irrespective of a revocation of such consent.

(b) With regard to personal data relating to other data subjects than the Parties and their employees ("**Third Party Personal Data**") including, but not limited to, clinical trial data, each Party shall ensure that is permitted under the GDPR and other Applicable Laws on data protection to disclose such Third Party Personal Data to the other Party for the other Party's processing of such Third Party Personal Data in the performance of this Agreement and the Supply Agreement. Given the sensitivity of such Third Party Personal Data, each Party will put the necessary technical and organizational measures in place to preserve its security at all times.

(c) Prior to any disclosure or transfer of personal data under this Agreement or the Supply Agreement, the Parties will enter into data processing and data transfer agreements, each as applicable and required by the GDPR and other Applicable Laws on data protection.

XV.4 Waiver of Breach. The failure of either Party at any time or times to require performance of any provision hereof shall in no manner affect its rights at a later time to enforce the same. No waiver by either Party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

XV.5 Modification. No amendment or modification of any provision of this Agreement shall be effective unless in writing signed by both Parties hereto. No provision of this Agreement shall be varied, contradicted or explained by any oral agreement, course of dealing or performance or any other matter not set forth in an agreement in writing and signed by both Parties hereto.

XV.6 Severability. In the event any provision of this Agreement should be held invalid, illegal, or unenforceable in any jurisdiction, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions of this Agreement shall remain in full force and effect in such jurisdiction. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction.

XV.7 Entire Agreement; Amendments. This Agreement (including the Exhibits attached hereto) constitutes the complete, final and entire agreement between the Parties relating to the subject matter hereof and supersede all prior and contemporaneous agreements, representations and/or understandings, including the Prior CDA. The foregoing shall not be interpreted as a waiver of any remedies available to either Party as a result of any breach, prior to the Effective Date, by the other Party of its obligations under the Prior CDA. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

XV.8 Notices. Unless otherwise agreed by the Parties or specified in this Agreement, all communications between the Parties relating to, and all written documentation to be prepared and provided under, this Agreement shall be in the English language. Any notice between the Parties required or permitted under this Agreement shall be in writing in the English language, and (a) delivered personally, (b) sent by air mail or express courier service providing evidence of receipt, postage pre-paid where applicable, or (c) by electronic transmission (complete transmission confirmed and a copy promptly sent by another permissible method of providing notice described in paragraph (a) or (b) above), to the following addresses of the Parties (or such other address for a Party as may be specified by like notice):

To AOP:

AOP Orphan Pharmaceuticals GmbH
Leopold-Ungar-Platz 2
A-1190 Vienna
Attention: [***]
Electronic mail: [***]

To Eagle:

Eagle Pharmaceuticals, Inc.
50 Tice Blvd, Suite 315
Woodcliff Lake, NJ 07677
Attention: [***]
Electronic mail: [***]

With a copy to:

AOP Orphan Pharmaceuticals GmbH
Leopold-Ungar-Platz 2
A-1190 Vienna
Attention: [***]
Electronic mail: [***]

With a copy to:

Cooley LLP
One Freedom Square
Reston Town Center
11951 Freedom Drive
Reston, Virginia 20190-5656
Attn: [***]
Electronic mail: [***]

Any notice required or permitted to be given concerning this Agreement shall be effective upon receipt by the Party to whom it is addressed.

XV.9 Assignment.

(a) Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment or transfer without the other Party's consent to (i) its Affiliates or (ii) a Third Party successor to substantially all of the business of such Party to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other transaction.

(b) Any permitted assignee shall assume all obligations of its assignor under this Agreement. Subject to the foregoing, this Agreement shall inure to the benefit of each Party, its successors and permitted assignees. Any purported assignment of this Agreement in contravention of this Section 15.9 shall be null and void.

XV.10 No Partnership or Joint Venture. Nothing in this Agreement is intended, or shall be deemed, to establish a joint venture or partnership between Eagle and AOP. Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other Party, or to bind the other Party to any contract, agreement or undertaking with any Third Party.

XV.11 Interpretation. The captions to the several Articles and Sections of this Agreement are not a part of this Agreement, but are included for convenience of reference and shall not affect its meaning or interpretation. In this Agreement: (a) the word "including" shall be deemed to be followed by the phrase "without limitation" or like expression; (b) the singular shall include the plural and vice versa; (c) masculine, feminine and neuter pronouns and expressions shall be interchangeable; and (d) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or.". Each accounting term used herein that is not specifically defined herein shall have the meaning given to it under generally accepted cost accounting principles, but only to the extent consistent with its usage and the other definitions in this Agreement. This Agreement has been prepared jointly by the Parties and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

XV.12 Performance by Affiliates. Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

XV.13 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

XV.14 Counterparts; Other Matters. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Each Party may execute this Agreement only by wet ink signature. In addition, wet ink signatures of authorized signatories of any Party will be deemed to be original signatures and will be valid and binding. Wet ink signature counterparts must be transmitted to the respective other Party by delivery in person or via internationally recognized overnight delivery, or by registered or certified mail (postage prepaid, return receipt requested). This Agreement is established in the English language. Any translation in another language shall be deemed for convenience only and shall never prevail over the original English version.

[Remainder of this page intentionally blank.]

IN WITNESS WHEREOF, the Parties have executed this License Agreement as of the date first set forth above.

AOP ORPHAN PHARMACEUTICALS GmbH

By: [***]

Name: [***]

Title: [***]

By: [***]

Name: [***]

Title: [***]

EAGLE PHARMACEUTICALS, INC.

By: [***]

Name: [***]

Title: [***]

Exhibit 1.43 – [***]

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Exhibit 1.67 – [***]

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Exhibit 6.4 – [***]

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Exhibit 6.5 – [***]

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Exhibit 8.7. – Press Release

For Immediate Release

Eagle Pharmaceuticals Announces Licensing Agreement with AOP Orphan for U.S. Commercial Rights to Landiolol, a Beta-1 Adrenergic Blocker

-- Eagle poised to facilitate regulatory pathway for approval in the U.S. based on existing data from Japanese and European studies, with no additional clinical work expected –

-- Anticipates filing new drug application ("NDA") in Q1 2022, with expected ten-month review, based on well-defined feedback from U.S. Food and Drug Administration provided during AOP Orphan's Type C meeting --

-- Landiolol, a leading hospital emergency use product, is approved in Europe for the treatment of non-compensatory sinus tachycardia and tachycardic supraventricular arrhythmias --

-- Eagle to support seeking the approval of Landiolol for the short-term reduction of ventricular rate in patients with supraventricular tachycardia, including atrial fibrillation and atrial flutter in the U.S.

--

-- Studies of additional indications, including sepsis and other cardioprotective indications, have begun in Europe, with the potential to be pursued in the U.S. --

-- Enrollment of study of pediatric patients with supraventricular tachycardia is under way in Europe and will serve as the basis for initial pediatric study plans for a future FDA submission --

-- Company expects five years of new chemical entity exclusivity --

WOODCLIFF LAKE, NJ—August ___, 2021—Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced that it has entered into a licensing agreement with AOP Orphan Pharmaceuticals GmbH ("AOP Orphan"), a privately owned Austrian company devoted to the treatment of rare and special diseases, for the commercial rights to its product, Landiolol in the United States. Landiolol, a leading hospital emergency use product, is currently approved in Europe for the treatment of non-compensatory sinus tachycardia and tachycardic supraventricular arrhythmias. The Company will support the submission of a new drug application ("NDA") to the U.S. Food and Drug Administration ("FDA") seeking approval for Landiolol for the short-term reduction of ventricular rate in patients with supraventricular tachycardia ("SVT"), including atrial fibrillation and atrial flutter.

Landiolol is a short-acting, ultra-high selective beta-1 adrenoceptor blocker developed by AOP Orphan that has a selective effect on heart rate over cardiac contractility. Landiolol is available in two forms (20 mg/2ml concentrate, 300 mg powder) and is designed for use in emergency, cardiac critical care, operating room, and intensive care settings. It is registered in several European countries for the treatment of non-compensatory sinus tachycardia and tachycardic supraventricular arrhythmias. The drug uses a proprietary dosing algorithm to facilitate the administration.

Under the terms of the agreement, Eagle will facilitate the U.S. regulatory pathway for the approval of Landiolol. In addition, Eagle will be responsible for the U.S. commercialization of the product upon approval. Landiolol, which has not previously been marketed in the U.S., is covered by several patents, and the Company anticipates five years of new chemical entity ("NCE") exclusivity.

Landiolol is already commercially available in Japan (Onoact(®)) and several European markets as RAPIBLOC®. A review of multiple clinical studies suggests that Landiolol is a useful option for the rapid short-term control of tachyarrhythmias (Syed YY. Landiolol: A Review in Tachyarrhythmias. Drugs. 2018 Mar;78(3):377-388. doi: 10.1007/s40265-018-0883-9. PMID: 29470800.). A Type C meeting was held with FDA in July 2020, at which time AOP Orphan proposed a submission strategy in which it would provide summaries of pre-existing safety and efficacy data and a meta-analysis of published randomized controlled trials. FDA tentatively agreed with this methodological approach and deemed data sets adequate to support a proposed NDA.

"This is an exciting near-term opportunity for Eagle, with the potential to file an NDA in the first quarter of next year. The clinical advantages of Landiolol are well recognized within the medical community, and we look forward to advancing this asset for FDA approval in the United States. Our deep understanding of the U.S. regulatory landscape, along with our established research and development infrastructure, will be valuable in accelerating the program. Once approved, we plan to leverage our current sales force and relationships in the critical care setting to promote the product. There is broad potential to expand the portfolio of future indications for Landiolol's use," stated Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals.

"With this license agreement, we are solidifying our hospital and critical care product portfolio, as we look to capitalize on multiple near- and longer-term opportunities. As we have stated, executing on our growth strategy for Eagle beyond 2021 has been a priority. With the anticipated launch of vasopressin, the February 2022 launch of PEMFEXY, the recent launch of bendamustine in Japan, our current pipeline, and now the future potential Landiolol launch, we believe we have a firm foundation for sustained future growth," concluded Tarriff.

"The step into the American market forms the basis for further expansion of AOP Orphan. I am convinced that with an experienced partner like Eagle, we will succeed in making Landiolol available to patients in the U.S. as well," stated Georg Fischer, Chief Executive Officer of AOP Orphan.

The management of rapid heart rate (tachycardia) in critically ill patients can be quite complicated regardless of the underlying cause, which may include shock, arrhythmias, heart failure, and the postoperative setting. Beta blockers, also known as beta-adrenergic blocking agents, are a class of drugs that works by blocking the neurotransmitters norepinephrine and epinephrine from binding to receptors. These neurotransmitters contribute to the development of tachycardia. The β-1 receptor beta blockers are used frequently in critical care settings to manage tachycardia; however, the available β-1 beta blockers in the U.S. also can have the unwanted effects of decreasing the contractility, or muscle strength, of the heart, and of lowering blood pressure.

Landiolol has the potential to become a cornerstone therapy in the management of these patients. It is ultra short acting, with a rapid on and off effect that allows clinicians to balance heart rate control and blood pressure more precisely. In addition, it predominantly affects heart rate without much effect on cardiac contractility and blood pressure. The Company believes that clinicians will welcome Landiolol as a key therapeutic tool for the more precise management of tachycardia in the critical care setting.

There are additional clinical settings for which Landiolol has the potential to improve patient management. Enrollment is under way in Europe for a trial of Landiolol in patients with tachycardia and septic shock, and importantly, the product is also being studied in a pediatric population, for whom no beta-blocker drug products are approved in the U.S. for ventricular rate control. The U.S. FDA has tentatively agreed that this study could form the basis for initial pediatric study plan (“iPSP”) for a future submission to FDA.

“We believe that we can expedite and prepare a compelling submission for approval of this important cardioprotective therapeutic,” stated Judith Ng-Cashin, MD, Chief Medical Officer of Eagle Pharmaceuticals

Terms of the Agreement

The agreement is subject to regulatory clearance. Under the terms of the agreement, Eagle will make an upfront payment of $5 million, followed by additional payments upon regulatory approval(s) and based upon commercial sales.

About Eagle Pharmaceuticals, Inc.

Eagle is a fully integrated pharmaceutical company with research and development, clinical, manufacturing and commercial expertise. Eagle is committed to developing innovative medicines that result in meaningful improvements in patients’ lives. Eagle’s commercialized products include RYANODEX®, BENDEKA®, BELRAPZO®, and its oncology and CNS/metabolic critical care pipeline includes product candidates with the potential to address underserved therapeutic areas across multiple disease states. Additional information is available on Eagle’s website at www.eagleus.com.

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AOP Orphan Pharmaceuticals GmbH is an international pharmaceutical company with its registered office in Vienna and a focus on rare and special diseases. Over the past 25 years, the company has become an established provider of integrated therapy solutions from its headquarters in Vienna. This development has been made possible by a continually high level of investment in research and development on the one hand and a highly consistent and pragmatic orientation towards the needs of all our stakeholders on the other - especially the patients and their families but also the doctors and care professionals treating them. In the third quarter of 2020, AOP Orphan took over Amomed and SciPharm, two European health care companies, continuing its consistent path of growth into a pan-European health care group specializing in rare and special diseases.

Agreement is subject to regulatory clearance.

Investor Relations for Eagle Pharmaceuticals, Inc.:
Lisa M. Wilson
In-Site Communications, Inc.
T: 212-452-2793
E: lwilson@insitecony.com

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Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Scott Tarriff, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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 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: November 9, 2021

/s/ Scott Tarriff

Scott Tarriff
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Brian J. Cahill, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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 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: November 9, 2021

/s/ Brian J. Cahill

Brian J. Cahill
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**, Chief Executive Officer of Eagle Pharmaceuticals, Inc. (the "Company"), and **Brian J. Cahill**, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2021, (the "Quarterly 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 Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned have set their hands hereto as of the 9th day of November 2021.

By: /s/ Scott Tarriff

Scott Tarriff
Chief Executive Officer
(Principal Executive Officer)

By: /s/ Brian J. Cahill

Brian J. Cahill
Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification accompanies the Form 10-Q 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-Q), irrespective of any general incorporation language contained in such filing.