

**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 **March 31, 2019**

OR

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

For the transition period from _____ to _____

Commission File Number **001-36306**

Eagle Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of
Incorporation or Organization)

2834

(Primary Standard Industrial
Classification Code 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)

20-8179278

(I.R.S. Employer
Identification Number)

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	NASDAQ Global Market

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 <input checked="" type="checkbox"/>	Accelerated filer <input type="checkbox"/>	Non-accelerated filer <input type="checkbox"/>	Smaller reporting company <input type="checkbox"/>
Emerging growth company <input type="checkbox"/>			

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

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.

The number of shares outstanding of the registrant's common stock as of April 30, 2019: 13,929,470 shares.

NOTE REGARDING COMPANY REFERENCES

References to the "Company," "Eagle Pharmaceuticals," "Eagle," "we," "us" or "our" mean Eagle Pharmaceuticals, Inc., a Delaware corporation and its subsidiary, Eagle Biologics, Inc., and references to "Eagle Biologics" mean Eagle Biologics, Inc.

NOTE REGARDING TRADEMARKS

All trademarks, trade names and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

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

	March 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 102,139	\$ 78,791
Accounts receivable, net	63,930	66,486
Inventories	10,265	8,304
Prepaid expenses and other current assets	5,895	10,263
Total current assets	182,229	163,844
Property and equipment, net	2,333	2,397
Intangible assets, net	17,473	18,103
Goodwill	39,743	39,743
Deferred tax asset, net	14,109	13,822
Other assets	3,565	694
Total assets	\$ 259,452	\$ 238,603
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 16,786	\$ 9,917
Accrued expenses	22,436	23,519
Current portion of long-term debt	5,000	6,250
Total current liabilities	44,222	39,686
Other long-term liabilities	2,870	—
Long-term debt, less current portion	36,999	38,155
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of March 31, 2019 and December 31, 2018	—	—
Common stock, \$0.001 par value; 50,000,000 shares authorized; 16,519,728 and 16,504,283 shares issued as of March 31, 2019 and December 31, 2018, respectively	17	17
Additional paid in capital	262,084	256,458
Retained earnings	67,160	58,187
Treasury stock, at cost, 2,590,258 and 2,590,258 shares as of March 31, 2019 and December 31, 2018, respectively	(153,900)	(153,900)
Total stockholders' equity	175,361	160,762
Total liabilities and stockholders' equity	\$ 259,452	\$ 238,603

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended	
	March 31,	
	2019	2018
Revenue:		
Product sales	\$ 14,472	\$ 10,838
Royalty revenue	26,313	35,788
License and other revenue	9,000	—
Total revenue	49,785	46,626
Operating expenses:		
Cost of product sales	9,554	7,223
Cost of royalty revenue	3,546	4,585
Research and development	6,375	17,320
Selling, general and administrative	18,141	15,193
Total operating expenses	37,616	44,321
Income from operations	12,169	2,305
Interest income	494	27
Interest expense	(686)	(675)
Total other expense, net	(192)	(648)
Income before income tax (provision) benefit	11,977	1,657
Income tax (provision) benefit	(3,004)	959
Net Income	\$ 8,973	\$ 2,616
Earnings per share attributable to common stockholders:		
Basic	\$ 0.64	\$ 0.18
Diluted	\$ 0.62	\$ 0.17
Weighted average number of common shares outstanding:		
Basic	13,925,227	14,819,530
Diluted	14,418,211	15,478,335

See accompanying notes to condensed consolidated financial statements.

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

	Common Stock		Additional Paid-In Capital	Treasury Stock	Retained Earnings	Total Stockholders' Equity
	Number of Shares	Amount				
Balance at December 31, 2018	16,504	\$ 17	\$ 256,458	\$ (153,900)	\$ 58,187	\$ 160,762
Stock-based compensation expense	—	—	5,782	—	—	5,782
Issuance of common stock upon exercise of stock option grants	7	—	42	—	—	42
Payment of employee withholding tax upon vesting of stock-based awards	—	—	(198)	—	—	(198)
Issuance of common stock related to vesting of restricted stock units	9	—	—	—	—	—
Net income	—	—	—	—	8,973	8,973
Balance at March 31, 2019	<u>16,520</u>	<u>\$ 17</u>	<u>\$ 262,084</u>	<u>\$ (153,900)</u>	<u>\$ 67,160</u>	<u>\$ 175,361</u>

	Common Stock		Additional Paid-In Capital	Treasury Stock	Retained Earnings	Total Stockholders' Equity
	Number of Shares	Amount				
Balance at December 31, 2017	16,089	\$ 16	\$ 233,639	\$ (80,795)	\$ 26,284	\$ 179,144
Stock-based compensation expense	—	—	5,305	—	—	5,305
Issuance of common stock upon exercise of stock option grants	77	—	1,166	—	—	1,166
Payment of employee withholding tax for net option exercise	—	—	(3,051)	—	—	(3,051)
Common stock repurchases	—	—	—	(7,003)	—	(7,003)
Net income	—	—	—	—	2,616	2,616
Balance at March 31, 2018	<u>16,166</u>	<u>\$ 16</u>	<u>\$ 237,059</u>	<u>\$ (87,798)</u>	<u>\$ 28,900</u>	<u>\$ 178,177</u>

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2019	2018
Cash flows from operating activities:		
Net income	\$ 8,973	\$ 2,616
Adjustments to reconcile net income to net cash provided by operating activities:		
Deferred income taxes	(287)	(123)
Depreciation expense	503	341
Amortization expense	630	670
Stock-based compensation expense	5,782	5,305
Change in fair value of contingent consideration	—	27
Amortization of debt issuance costs	94	94
Changes in operating assets and liabilities which provided (used) cash:		
Accounts receivable	2,556	395
Inventories	(1,961)	(1,023)
Prepaid expenses and other current assets	4,368	1,518
Accounts payable	6,869	(2,628)
Accrued expenses and other liabilities	(1,083)	(2,289)
Other assets and other long-term liabilities, net	(263)	18
Net cash provided by operating activities	<u>26,181</u>	<u>4,921</u>
Cash flows from investing activities:		
Purchase of property and equipment	(177)	(19)
Net cash used in investing activities	<u>(177)</u>	<u>(19)</u>
Cash flows from financing activities:		
Proceeds from common stock option exercises	42	1,166
Payments related to employee net option exercises	—	(3,051)
Employee withholding taxes related to stock-based awards	(198)	—
Payment of contingent consideration	—	(15,001)
Payment of debt	(2,500)	—
Repurchases of common stock	—	(7,003)
Net cash used in financing activities	<u>(2,656)</u>	<u>(23,889)</u>
Net increase (decrease) in cash and cash equivalents	<u>23,348</u>	<u>(18,987)</u>
Cash and cash equivalents at beginning of period	<u>78,791</u>	<u>114,657</u>
Cash and cash equivalents at end of period	<u>\$ 102,139</u>	<u>\$ 95,670</u>
Supplemental disclosures of cash flow information:		
Cash (received) paid during the period for:		
Income taxes	\$ (6,490)	\$ 96
Interest	625	368

See accompanying notes to condensed consolidated financial statements.

EAGLE PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
(In thousands, except share and per share amounts)

1. Interim Condensed Consolidated Financial Statements

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 (the "SEC") for reporting on Form 10-Q. Accordingly, certain information and footnote disclosures required for complete financial statements are not included herein. The condensed consolidated balance sheet at December 31, 2018 was derived from audited financial statements, but certain information and footnote disclosures normally included in the Company's 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 months ended March 31, 2019 are not necessarily indicative of the results for the year ending December 31, 2019 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 the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on February 28, 2019. Unless otherwise indicated or required by context, reference throughout to the "Company," "Eagle Pharmaceuticals," "Eagle," "we," "us" or "our" mean Eagle Pharmaceuticals, Inc., a Delaware corporation and its subsidiary, Eagle Biologics, Inc., and references to "Eagle Biologics" mean Eagle Biologics, Inc.

2. Organization and Business Activities

Eagle Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on developing and commercializing injectable products, primarily in the critical care and oncology areas, mainly using the U.S. Food and Drug Administration's ("FDA's") 505(b)(2) New Drug Application ("NDA") regulatory pathway. The Company's business model is to develop proprietary innovations to FDA-approved injectable drugs, referred to as branded reference drugs, that offer favorable attributes to patients and healthcare providers. The Company has two products currently being sold in the United States under various license agreements in place with commercial partners; a ready-to-use formulation of Argatroban and rapidly infused bendamustine RTD 50ml solution ("BENDEKA"). In addition, the Company directly sells two products in the United States; Eagle's bendamustine RTD 500ml solution ("Big Bag" or "Belrapzo") and Ryanodex[®](dantrolene sodium) ("Ryanodex").The Company has a number of products currently under development and certain products may be subject to license agreements.

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

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

EAGLE PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(In thousands, except share and per share amounts)
(Unaudited)

The repurchases will be made using the Company's cash resources. In any period, cash used in financing activities related to shares repurchased may differ from the comparable change in stockholders' equity, reflecting timing differences between the recognition of share repurchase transactions and their settlement for cash. During the fourth quarter of 2018, the Company repurchased 1,000,134 shares of outstanding common stock for \$50 million pursuant to the ASR. The Company repurchased 1,348,563 shares of common stock for \$73.1 million during the year ended December 31, 2018 and an aggregate of 2,590,258 shares of common stock for \$153.9 million through March 31, 2019.

On November 16, 2016, the Company entered into a stock purchase agreement with Arsia Therapeutics, LLC ("Arsia SPA") to acquire Arsia Therapeutics, Inc., an early-stage biotechnology firm with proprietary viscosity-reducing technology and formulation know-how and subsequently renamed the subsidiary Eagle Biologics, Inc. ("Eagle Biologics"). Under the terms of the Arsia SPA, at closing the Company paid approximately \$27.2 million in cash and issued 40,200 shares of Eagle common stock worth \$3.0 million. The Company also agreed to pay up to \$48 million in additional payments upon the completion of certain milestones, for aggregate potential payments of \$78 million. As part of the agreement, Eagle Biologics founders and Massachusetts Institute of Technology professors Dr. Robert Langer and Dr. Alexander Klibanov, as well as other key members of the Eagle Biologics team, entered into consulting agreements with Eagle to develop new formulations and solve delivery challenges with large molecule products (see Note 4. Acquisitions).

On July 26, 2017, the Company received a Complete Response Letter from the FDA regarding its 505(b)(2) NDA for Ryanodex for the treatment of exertional heat stroke ("EHS"), in conjunction with external cooling methods. Based on our meeting with the FDA, the Company conducted an additional clinical trial in August 2018 during the Hajj pilgrimage, similar to the study conducted during the Hajj in 2015. On August 30, 2018, the Company announced the completion of enrollment of the Company's second clinical study to further evaluate the safety and efficacy of Ryanodex. During the 2018 Hajj, overall emergency room visits were dramatically decreased from previous years due to well-implemented crowd management, lower temperatures, lower humidity and other external factors. As a result, the number of EHS patients available for study enrollment was also significantly less than in previous years, and therefore much lower than anticipated. The preliminary assessment of patients enrolled is consistent with the data from the study conducted in 2015, in which patients dosed with RYANODEX plus Standard of Care ("SOC") showed an additive benefit compared to patients receiving SOC only. The Company intends to complete the analysis of the data and meet with the U.S. Food and Drug Administration to discuss next steps in 2019.

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

In March 2018, the Company announced that the United States Patent and Trademark Office ("USPTO") issued a new patent to the Company's Eagle Biologics division. Patent number 9,925,263 will expire in March 2036 and is the fourth patent issued in the Eagle Biologics family of patents.

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

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

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

On March 24, 2016, the FDA denied the Company's request for seven years of orphan drug exclusivity in the U.S., for BENDEKA. In April 2016, the Company filed a lawsuit against the FDA arguing that BENDEKA is entitled to orphan drug exclusivity as a

EAGLE PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(In thousands, except share and per share amounts)
(Unaudited)

matter of law (see Note 12. Legal Proceedings). On July 2, 2014, the FDA granted the Company orphan drug designations for BENDEKA for the treatment of CLL and indolent B-cell NHL. The designations were based on a plausible hypothesis that BENDEKA is “clinically superior” to a drug previously approved for the same indications. Generally, an orphan-designated drug is eligible for seven years of marketing exclusivity for the orphan-designated indications upon approval of the drug for those indications. On June 8, 2018, the U.S. District Court for the District of Columbia (the “Court”) issued a decision requiring the FDA to grant seven years of orphan drug exclusivity (“ODE”) in the U.S., for BENDEKA, and on July 8, 2018 the FDA granted such ODE through December 2022. In addition, on July 8, 2018, the FDA submitted a Motion to Alter or Amend the Judgement Pursuant to Rule 59(e), pursuant to which the FDA requested the Court amend its decision to make clear that the decision does not affect any applications referencing TREANDA. The FDA’s motion was denied by the Court on August 1, 2018 on the grounds that FDA was seeking an inappropriate advisory opinion. The Company continues to believe that an appropriate application of orphan drug exclusivity would first allow generic TREANDA entrants in December 2022, rather than November 2019, and expects to vigorously pursue the scope of its exclusivity grant.

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

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

As of March 29, 2019, the Company and TPIG executed an amendment to the BENDEKA License Agreement to terminate Teva’s obligation to pay future milestones and royalties on BENDEKA sales outside of the U.S., which included an upfront cash payment of \$9 million that was recorded as License and other revenue on the condensed consolidated statements of income for the three months ended March 31, 2019.

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

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

3. Summary of Significant Accounting Policies

Use of Estimates

These financial statements are presented in U.S. dollars and are prepared in accordance with U.S. GAAP. The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the 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. The Company’s critical accounting policies are those that are both most important to the Company’s financial condition and results of operations and require the most difficult, subjective or complex judgments on the part of management in their application,

EAGLE PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(In thousands, except share and per share amounts)
(Unaudited)

often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Because of the uncertainty of factors surrounding the estimates or judgments used in the preparation of the financial statements, actual results may materially vary from these estimates.

Reclassifications

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

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. All cash and cash equivalents are held in United States financial institutions. The carrying amount of cash and cash equivalents approximates its fair value due to its short-term nature.

The Company, at times, maintains balances with financial institutions in excess of the FDIC limit.

Fair Value Measurements

U.S. GAAP establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes the following fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value:

- Level 1: Quoted prices in active markets for identical assets or liabilities.
- Level 2: Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

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

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

The fair value of the contingent consideration/accrued royalty is classified as Level 3 for the periods presented.

Intangible Assets

Other Intangible Assets, Net

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

EAGLE PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(In thousands, except share and per share amounts)
(Unaudited)

value of the asset group. If impairment is indicated, the asset is written down by the amount by which the carrying value of the asset exceeds the related fair value of the asset with the related impairment charge recognized within the statements of income.

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

Goodwill

Goodwill represents the excess of purchase price over the fair value of net assets acquired in the Eagle Biologics acquisition. 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. The Company did not identify any impairment to goodwill during the periods presented.

Acquisition-Related Contingent Consideration

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

Concentration of Major Customers and Vendors

The Company is dependent on commercial partners to market and sell Argatroban and BENDEKA. The Company's customers for Argatroban and BENDEKA are its commercial and licensing partners; therefore, the Company's future revenues are highly dependent on these collaboration and distribution arrangements.

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

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

	Three Months Ended	
	March 31,	
	2019	2018
Net revenues		
Cephalon, Inc. (Teva) - See Revenue Recognition	84%	84%
Other	16%	16%
	<u>100%</u>	<u>100%</u>
	March 31,	December 31,
	2019	2018
Accounts receivable		
Cephalon, Inc. (Teva) - See Revenue Recognition	73%	61%
Other	27%	39%
	<u>100%</u>	<u>100%</u>

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Currently, for Argatroban, the Company uses one vendor as its sole source supplier. Because of the unique equipment and process for manufacturing, transferring manufacturing activities to an alternate supplier would be a time consuming and costly endeavor.

Inventories

Inventories are recorded at the lower of cost or expected net realizable value, with cost determined on a first-in first-out basis. The Company periodically reviews the composition of inventory in order to identify obsolete, slow-moving or otherwise non-saleable items. If non-saleable items are observed and there are no alternate uses for the inventory, the Company will record a write-down to net realizable value in the period that the decline in value is first recognized. In most instances, inventory is shipped from the Company's vendor directly to the Company's customers.

Property and Equipment

Property and equipment are stated at cost. Depreciation is recorded over the estimated useful lives of the assets utilizing the straight-line method. Leasehold improvements are being amortized over the shorter of their useful lives or the lease term.

Research and Development Expense

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

Costs for certain development activities, such as clinical studies, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by its vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the patterns of costs incurred, and are reflected in the 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 \$626 and \$895 for the three months ended March 31, 2019 and 2018, respectively.

Income Taxes

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

Revenue Recognition

Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a

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performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Sales, value add, and other taxes collected on behalf of third parties are excluded from revenue.

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

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

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

Royalty Revenue — The Company recognizes revenue from license arrangements with its commercial partners' net sales of products. In accordance with ASC 606-10-55-65, royalties are recognized when the subsequent sale of the commercial partner's products occurs. The Company's commercial partners are obligated to report their net product sales and the resulting royalty due to the Company within 25 days for BENDEKA and 60 days for Argatroban from the end of each quarter. Based on historical product sales, royalty receipts and other relevant information, the Company accrues royalty revenue each quarter and subsequently determines a true-up when it receives royalty reports from its commercial partners. Historically, these true-up adjustments have been immaterial.

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

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

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

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

Collaborative licensing and development revenue — The Company recognizes revenue from reimbursements received in connection with feasibility studies and development work for third parties when its contractual services are performed, provided collectability is reasonably assured. Its principal costs under these agreements include its personnel conducting research and development, its allocated overhead, as well as the research and development performed by outside contractors or consultants.

Upon termination of a collaboration agreement, any remaining non-refundable license fees received by the Company, which had been deferred, are generally recognized in full. All such recognized revenues are included in collaborative licensing and development revenue in its statements of income. The Company recognizes revenue from milestone payments received under collaboration agreements when earned, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, the Company has no further performance obligations relating to the event, and collectability is reasonably assured. If these criteria are not met, the Company recognizes milestone payments ratably over the remaining period of its performance obligations under the collaboration agreement.

Stock-Based Compensation

The Company accounts for stock-based compensation using the fair value provisions of ASC 718, Compensation - Stock Compensation that requires the recognition of compensation expense, using a fair-value based method, for costs related to all stock-based payments including stock options and restricted stock. This topic requires companies to estimate the fair value of the stock-based awards on the date of grant for options issued to employees and directors and record expense over the employees' service periods, which are generally the vesting period of the equity awards.

The Company accounts for stock-based compensation by measuring and recognizing compensation expense for all stock-based payments made to employees and directors based on estimated grant date fair values. The straight-line method is used to allocate compensation cost to reporting periods over each optionee's requisite service period, which is generally the vesting period. The fair value of the Company's stock-based awards to employees and directors is estimated using the Black-Scholes option valuation model, or Black-Scholes model. The Black-Scholes model requires the input of subjective assumptions, including the expected stock price volatility, the calculation of expected term, forfeitures and the fair value of the underlying common stock on the date of grant, among other inputs. The risk-free interest rate is determined with the implied yield currently available for zero-coupon U.S. government issues with a remaining term approximating the expected life of the options.

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.

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The anti-dilutive common shares equivalents outstanding at the three months ended March 31, 2019 and 2018 were as follows:

	Three Months Ended March 31,	
	2019	2018
Options	2,194,399	1,985,879
Total	2,194,399	1,985,879

The following table sets forth the computation for basic and diluted net income per share for the three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,	
	2019	2018
Numerator		
Numerator for basic and diluted earnings per share-net income	\$ 8,973	\$ 2,616
Denominator		
Basic weighted average common shares outstanding	13,925,227	14,819,530
Dilutive effect of stock options	492,984	658,805
Diluted weighted average common shares outstanding	14,418,211	15,478,335
Basic net income per share		
Basic net income per share	\$ 0.64	\$ 0.18
Diluted net income per share		
Diluted net income per share	\$ 0.62	\$ 0.17

Recent Accounting Pronouncements

Recent Accounting Pronouncements - Not Yet Adopted

In January 2017, the FASB issued guidance to simplify the measurement of goodwill. The guidance eliminates Step 2 from the goodwill impairment test. Instead, under the amendments in this guidance, an entity should perform its annual or interim goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. Additionally, an entity should consider income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss. The guidance also eliminates the requirements for any reporting unit with a zero or negative carrying amount to perform a qualitative assessment and if it fails that qualitative test, to perform Step 2 of the goodwill impairment test. An entity is required to disclose the amount of goodwill allocated to each reporting unit with a zero or negative carrying amount of net assets. The guidance is effective for public business entities for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, and early adoption is permitted for interim or annual goodwill impairment tests performed for testing dates after January 1, 2017. The guidance must be adopted on a prospective basis. We do not expect this guidance to have an impact on our condensed consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirement for Fair Value Measurement("ASU 2018-13"), which amends the disclosure requirements for fair value measurements. The amendments in ASU 2018-13 are effective for fiscal years beginning after December 15, 2019, with

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early adoption permitted. The Company is currently evaluating the potential impact that the adoption of ASU 2018-13 may have on the Company's financial position and results of operations.

Recently Adopted Accounting Pronouncements

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

4. Acquisitions

Eagle Biologics Acquisition

On November 16, 2016, the Company entered into a stock purchase agreement with Arsia Therapeutics, LLC ("Seller") ("Arsia SPA") to acquire Arsia Therapeutics, Inc., an early-stage biotechnology firm with proprietary viscosity-reducing technology and formulation know-how and subsequently renamed the subsidiary Eagle Biologics, Inc. ("Eagle Biologics"). Under the terms of the Arsia SPA, the Company paid approximately \$27.2 million in cash and 40,200 shares of Eagle common stock worth \$3.0 million at closing. The Company also agreed to pay up to \$48 million in additional payments upon the completion of certain milestones, for aggregate potential payments of \$78 million. As part of the agreement, Eagle Biologics founders and Massachusetts Institute of Technology professors, Dr. Robert Langer and Dr. Alexander Klivanov, as well as other key members of the Eagle Biologics team, entered into consulting agreements with the Company to develop new formulations and solve delivery challenges in the large molecules space.

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

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

Eagle Biologics' platform technology enables subcutaneous administration of high-dose biologics through improved formulation. Eagle Biologics has developed early-stage partnerships with major pharmaceutical companies to apply its technology to their biosimilar molecules, create subcutaneous versions of currently-marketed IV products and produce high-concentration formulations of clinical candidates. In addition to acquiring the technology platform, the Company plans to establish a Biologics Innovation Center in Kendall Square in Cambridge, Massachusetts.

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The following table summarizes the consideration transferred to acquire Eagle Biologics:

The aggregate consideration consisted of:		
Cash consideration paid	\$	27,209
Common stock issued (i)		3,046
Fair value of contingent consideration paid to seller (ii)		15,000
Total consideration	\$	<u>45,255</u>

(i) Under the Arsia SPA, the number of common shares to be issued to the Seller is equal to \$2.7 million divided by the average of the closing day price per share for the thirty (30) trading days prior to the date of closing. The average price of the common stock of 30 days prior to closing was \$68.18. Accordingly, the number of shares of common stock to be issued to the Seller was determined at 40,200 shares (\$2.7 million divided by \$68.18 per share). The fair value of the common stock issued to the Seller was determined based on the closing price of the Company's common stock on November 16, 2016.

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

5. Inventories

Inventories consist of the following:

	March 31,	December 31,
	2019	2018
Raw material	\$ 7,908	\$ 6,303
Work in process	1,715	1,776
Finished products	642	225
	<u>\$ 10,265</u>	<u>\$ 8,304</u>

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6. Balance Sheet Accounts

Prepaid and Other Current Assets

Prepaid and other current assets consist of the following:

	March 31, 2019	December 31, 2018
Advances to commercial manufacturers	\$ 3,256	\$ 2,700
Prepaid FDA user fee	1,266	1,540
Prepaid insurance	883	150
Prepaid income taxes	89	5,739
All other	401	134
Total Prepaid expenses and other current assets	<u>\$ 5,895</u>	<u>\$ 10,263</u>

Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2019	December 31, 2018
Royalties payable to commercial partners	\$ 7,195	\$ 7,139
Accrued research & development	1,131	1,245
Accrued professional fees	2,969	2,408
Accrued salary and other compensation	2,108	5,049
Accrued product costs	6,881	5,869
Accrued other	2,152	1,809
Total Accrued expenses	<u>\$ 22,436</u>	<u>\$ 23,519</u>

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

The Company leases its corporate office under a lease agreement that expires on June 30, 2020 with a renewal option period that would extend the term through June 30, 2025, if exercised. The Company also leases lab space under a lease agreement that expires on October 31, 2023. The Company estimated the right of use asset and the corresponding lease liability, on a discounted basis, as of the adoption date of January 1, 2019.

For the Company's two operating leases, the depreciation and interest expense components are combined and recognized ratably over the remaining term of the lease as research and development and selling, general and administrative in the Company's statements of income, respectively.

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

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Lease related disclosures consist of the following:

	March 31, 2019
Right of Use (ROU) Asset, net included with Other assets	\$ 2,871
Lease liability included with Other long-term liabilities	\$ 2,871
Q1 2019 Depreciation of ROU Asset	\$ 261
Q1 2019 related Rent Expense	\$ 287
Operating cash flows from operating leases	\$ 287
Operating lease costs	\$ 287
Weighted-average remaining lease term - operating leases	2.8 years
Weighted-average discount rate - operating leases	6.4%

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

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

7. Intangible Assets, Net

The gross carrying amounts and net book value of the Company's intangible assets are as follows:

		March 31, 2019			
	Useful Life (In Years)	Gross Carrying Amount	Accumulated Amortization	Impairment Charge	Net Book Value
Ryanodex intangible	20	\$ 15,000	\$ (1,780)	\$ —	\$ 13,220
Developed technology	5	8,100	(3,847)	—	4,253
Total		\$ 23,100	\$ (5,627)	\$ —	\$ 17,473

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

Amortization expense was \$630 and \$670 for the three months ended March 31, 2019 and 2018, respectively.

Intangible Asset Impairment

During the year ended December 31, 2017, the Company experienced a decline in customer contracts and saw a drop in market pricing for Non-Alcohol Docetaxel Injection. Accordingly, the Company estimated the fair value of the Company's Non-Alcohol

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Docetaxel Injection product and determined the carrying amount of the intangible asset was no longer fully recoverable, resulting in a pre-tax, non-cash asset impairment charge of \$7.2 million during the year ended December 31, 2017.

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

Estimated Amortization Expense for Intangible Assets

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

	Estimated Amortization Expense
Year Ending December 31,	
2019 (remainder)	1,890
2020	2,666
2021	2,623
2022	1,369
2023	1,369
Thereafter	7,556
Total estimated amortization expense	\$ 17,473

8. Common Stock and Stock-Based Compensation

Common Stock

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

In connection with the 2018 Share Repurchase Program, on October 30, 2018, the Company entered into the ASR with JPMorgan to repurchase an aggregate of \$50 million of the Company’s common stock. Under the terms of the ASR, the Company paid \$50 million to JPMorgan on November 1, 2018, and received 702,988 shares, representing approximately 80% of the notional amount of the ASR, based on the closing price of \$56.90 on October 29, 2018. Upon settlement of the ASR, the final number of shares repurchased were trued up based on the average of the daily volume weighted average share prices of the Company’s common stock, less a discount, during the term of the ASR. The Company received 297,146 additional shares on December 6, 2018, the termination date, for a total of 1,000,134 shares from the ASR.

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Stock-Based Compensation

In November 2013, the Company's board of directors approved the 2014 Equity Incentive Plan (the "2014 Plan") which became effective on February 11, 2014. The 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 three months ended March 31, 2018, the Company introduced a new long-term incentive program with the objective to better align the stock-based awards granted to management with the Company's 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 restricted stock units ("RSUs") and performance-based stock units ("PSUs"). PSUs are comprised of awards that vest upon achievement of certain share price appreciation conditions.

A summary of stock option, RSU and PSU activity under the 2014 Plan during the three months ended March 31, 2019 and 2018 is presented below:

	Stock Options	RSUs	PSUs
Outstanding at December 31, 2017	2,786,568	—	—
Granted	631,625	64,080	127,080
Options Exercised/RSUs Vested/PSUs Vested	(134,715)	—	—
Forfeited or expired	(215,108)	(9,000)	(9,000)
Outstanding at March 31, 2018	<u>3,068,370</u>	<u>55,080</u>	<u>118,080</u>
Outstanding at December 31, 2018	2,556,365	54,219	117,219
Granted	550,433	211,829	—
Options Exercised/RSUs Vested/PSUs Vested	(4,914)	(13,555)	—
Forfeited or expired	(9,588)	(531)	(709)
Outstanding at March 31, 2019	<u>3,092,296</u>	<u>251,962</u>	<u>116,510</u>

Stock Options

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

	Three Months Ended	
	March 31,	
	2019	2018
Risk-free interest rate	2.57% - 2.61%	2.30% - 2.71%
Volatility	50.47%	43.76%
Expected term (in years)	5.98 years	5.50 - 6.08 years
Expected dividend yield	0.0%	0.0%

RSUs

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

PSUs

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

The Company recognized stock-based compensation in its condensed consolidated statements of income for the three months ended March 31, 2019 and 2018 as follows:

	Three Months Ended March 31,	
	2019	2018
Stock options	\$ 4,428	\$ 4,427
RSUs	608	162
PSUs	746	716
Stock-based compensation expense	<u>\$ 5,782</u>	<u>\$ 5,305</u>
Selling, general and administrative	\$ 4,639	\$ 4,045
Research and development	1,143	1,260
Stock-based compensation expense	<u>\$ 5,782</u>	<u>\$ 5,305</u>

9. Commitments

Our future material contractual obligations include the following:

Obligations	Total	2019	2020	2021	2022	2023	Beyond
Operating leases (1)	\$ 3,374	\$ 859	\$ 864	\$ 583	\$ 583	\$ 485	\$ —
Credit facility	42,500	3,750	5,000	33,750	—	—	—
Purchase obligations (2)	38,810	38,810	—	—	—	—	—
Total obligations	<u>\$ 84,684</u>	<u>\$ 43,419</u>	<u>\$ 5,864</u>	<u>\$ 34,333</u>	<u>\$ 583</u>	<u>\$ 485</u>	<u>\$ —</u>

(1) The Company leases its office and lab spaces under lease agreements that expire on June 30, 2020 and October 31, 2023. Rental expense was \$287 and \$184, for the three months ended March 31, 2019 and 2018. The remaining future lease payments under the operating lease are \$3,374 as of March 31, 2019, payable monthly through June 30, 2020 and October 31, 2023.

(2) At March 31, 2019, the Company has purchase obligations in the amount of \$38,810 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.

10. Debt

On August 8, 2017, the Company entered into an Amended and Restated Credit Agreement (the "Amended Credit Agreement"), with JPMorgan Chase Bank, N.A., as administrative agent (the "Agent") and the lenders party thereto, which amended and restated the Company's existing credit agreement, dated as of January 26, 2017. The Amended Credit Agreement provides for a 3-year \$50 million revolving credit facility and a 3-year \$100 million term loan facility (which are collectively referred to as the "Amended Credit Facility"). As of March 31, 2019, the Company has \$0.5 million of unamortized deferred debt issuance costs as part of long-term debt in its condensed consolidated balance sheets.

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At closing, \$50 million of the term loan facility was drawn, and none of the revolving credit facility has been drawn. Although the Company was permitted to make one other draw on the term loan facility on or before February 4, 2018, the Company elected not to draw down further on the term loan facility. The Amended Credit Facility includes a \$5 million letter of credit subfacility. The Company anticipates that the draw at closing and future draws under the Amended Credit Facility, if any, will be used to finance the 2018 Share Repurchase Program and for other corporate purposes. Loans under the Amended Credit Facility bear interest, at the Company's option, at a rate equal to either (a) the LIBOR rate, plus an applicable margin ranging from 2.25% to 3.0% per annum, based upon the total net leverage ratio (as defined in the Amended Credit Agreement), or (b) the prime lending rate, plus an applicable margin ranging from 1.25% to 2.0% per annum, based upon the total net leverage ratio. The Company is required to pay a commitment fee on the unused portion of the Amended Credit Facility at a rate ranging from 0.35% to 0.45% per annum based upon the total net leverage ratio. The Company is permitted to terminate or reduce the revolving commitments or term commitments of the lenders and to make voluntary prepayments at any time subject to break funding payments. The Company is required to make mandatory prepayments of outstanding indebtedness under the Amended Credit Agreement (a) upon receipt of proceeds from certain sales, transfers or other dispositions, casualty and other condemnation events and the incurrence of certain indebtedness other than indebtedness permitted, subject to customary reinvestment exceptions and (b) in the case that the aggregate amount of all outstanding loans and letters of credit issued under the Amended Credit Facility exceed the aggregate commitment of all lenders under the Amended Credit Facility. The Company is obligated to repay the term loan facility on the last day of each March, June, September and December in an aggregate principal amount equal to 2.5% during the term of the loan.

Debt Maturities	as of March 31, 2019	
2019 (remainder)	\$	3,750
2020		5,000
2021		33,750
Total debt	\$	42,500

11. Income Taxes

	Three Months Ended March 31,	
	2019	2018
Income tax (provision) benefit	\$ (3,004)	\$ 959
Effective tax rate	25%	(58)%

For interim periods, we recognize an income tax (provision) benefit 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 temporary and estimated permanent differences, and certain discrete items whose tax effect, when material, is recognized in the interim period in which they occur.

The provision for income taxes was based on the applicable federal and state tax rates for those periods. The effective tax rate for the three months ended March 31, 2019 reflects the impact of certain non-deductible executive compensation partially offset by credits for research and development activity. The effective tax rate for the three months ended March 31, 2018 reflects tax benefits related to stock option exercises in the period as well as credits for research and development activity.

Deferred income tax assets at March 31, 2019 consist 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.

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

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history, and subjective estimates and assumptions. The Company reflects interest and penalties attributable to income taxes, to the extent they arise, as a component of income tax provision or benefit.

12. Legal Proceedings

In addition to the below legal proceedings, from time to time, the Company may be a party to litigation and subject to claims incident to the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, the Company currently believes that the final outcome of these ordinary course matters will not have a material adverse effect on the Company's business. Regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources and other factors.

Commercial Litigation

In Re: Taxotere (Docetaxel)

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

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

Eagle v. Burwell

On April 27, 2016, the Company filed an action in the U.S. District Court for the District of Columbia against the FDA and other federal defendants seeking an order requiring the FDA to recognize orphan drug exclusivity for BENDEKA for the treatment of CLL and indolent B-cell NHL. On June 8, 2018, the Court issued a decision requiring the FDA to recognize seven years of orphan drug exclusivity in the U.S. for BENDEKA, and on July 6, 2018 the FDA recognized such ODE until December 7, 2022. In addition, on July 6, 2018, the FDA submitted a Motion to Alter or Amend the Judgement Pursuant to Rule 59(e), pursuant to which the FDA requested that the Court amend its decision to make clear that the decision does not affect any applications referencing TREANDA. The FDA's motion was denied by the Court on August 1, 2018 on the grounds that the FDA had not satisfied the standard for altering or amending the judgment. The FDA and two intervenors have appealed the Court's final judgment to the U.S. Court of Appeals for the District of Columbia Circuit. The briefing schedule issued by the Court of Appeals provides for briefing in those appeals to be completed by June 24, 2019. On February 20, 2019, the FDA issued a decision in favor of the Company, regarding the scope of exclusivity for BENDEKA. Pursuant to the decision and provided that the Court's decision is not reversed upon appeal, no bendamustine product used to treat the same indications (including generic versions of TREANDA) may launch in the United States until December 7, 2022 unless it is clinically superior to BENDEKA. The Company expects to vigorously pursue the scope of its exclusivity grant.

Eagle v. Eli Lilly

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

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Patent Litigation

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

On August 14, 2017, Lilly filed suit against the Company in the United States District Court for the Southern District of Indiana (the “Indiana Suit”). Lilly alleged patent infringement based on the filing of the Company’s 505(b)(2) NDA seeking approval to manufacture and sell the Company’s EP-5101. EP-5101, if finally approved by FDA, will be a branded alternative to Alimta®, which is indicated (in combination with cisplatin) (a) for the treatment of patients with malignant pleural mesothelioma, or (b) for the initial treatment of locally advanced or metastatic nonsquamous non-small cell lung cancer. Alimta® also is indicated as a single-agent for the treatment of patients with locally advanced or metastatic nonsquamous non-small cell lung cancer after prior chemotherapy. Alimta® also is indicated for maintenance treatment of patients with locally advanced or metastatic nonsquamous non-small cell lung cancer whose disease has not progressed after four cycles of platinum-based first-line chemotherapy.

On September 8, 2017, Eagle moved to dismiss the Indiana Suit for improper venue. On September 11, 2017, Lilly voluntarily dismissed the Indiana Suit. It then filed a complaint in the United States District Court for the District of Delaware, alleging similar patent infringement claims (the “Delaware Suit”). Eagle answered and filed various counterclaims in the Delaware Suit on October 3, 2017. Lilly answered Eagle’s counterclaims on October 24, 2017. The Court held a scheduling conference on December 11, 2017 and set trial in the Delaware Suit to begin on September 9, 2019. On May 31, 2018, Eagle filed a Motion for Judgment on the Pleadings, which the Court denied on October 26, 2018. On January 23, 2019, the Court held a Markman hearing. On March 21, 2019, the Court entered its claim construction ruling. Trial is scheduled to begin on September 9, 2019. The Delaware Suit is pending.

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. - (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. Four companies - Slayback Pharma Limited Liability Company (“Slayback”), Apotex Inc. and Apotex Corp. (“Apotex”), Fresenius Kabi USA, LLC (“Fresenius”), and Mylan Laboratories Limited (“Mylan”) - 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”) a 505(b)(2) NDA.

The Company, Cephalon, Inc. and/or Teva Pharmaceuticals International GMBH (together the “Patentees”), filed separate suits against Slayback, Apotex, Fresenius, Mylan and Hospira 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”)), and July 19, 2018 (Hospira). 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. The parties stipulated to dismiss without prejudice U.S. Patent No. 8,791,270 as to Apotex, Fresenius, Mylan and Slayback on July 24, 2018, August 2, 2018, August 3, 2018, and January 4, 2019, 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. The Slayback I, Slayback II, Apotex, Fresenius and Mylan cases have been consolidated for all purposes, with trial scheduled to begin September 3, 2019. 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. Hospira filed a motion to dismiss the case, which was fully briefed on November 16, 2018. All seven cases are pending.

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The FDA is stayed from approving Apotex's, Fresenius', Mylan's ANDA's, and Hospira's 505(b)(2) application until the earlier of (1) January 7, 2020, January 14, 2020, April 30, 2020, and December 20, 2020, respectively (the "30-month stay dates"); and (2) a court decision that each of the challenged patents is not infringed, invalid or unenforceable. The 30-month stay dates may be shortened or lengthened if either party to the action fails to reasonably cooperate in expediting the action. The FDA cannot approve Slayback's ANDA until March 2033.

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

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

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

Slayback filed a 505(b)(2) NDA referencing Eagle's Big Bag. Slayback's NDA includes challenges to one or more of the Big Bag Orange Book-listed patents. On December 11, 2018, the Company filed a suit against Slayback in the United States District Court for the District of Delaware, alleging patent infringement of U.S. Patent Nos. 9,265,831, 9,572,796, 9,572,797 and 10,010,533. On December 13, 2018, Slayback answered the Complaint and filed various counterclaims. On January 4, 2019, Slayback filed a Motion for Judgment on the Pleadings. The Company answered on February 4, 2019. This case is pending.

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

On May 31, 2018, Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (together "Par") filed suit against the Company in the United States District Court for the District of Delaware. Par alleged patent infringement based on the filing of the Company's ANDA seeking approval to manufacture and sell the Company's vasopressin product. The Company's vasopressin product, if approved by FDA, will be an alternative to Vasotric, 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. A Markman Hearing is scheduled for July 1, 2019. Trial is scheduled to begin May 18, 2020. This suit is pending.

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

On March 27, 2019, the Company filed suit against Accord Healthcare, Inc. in the United States District Courts for the District of New Jersey, and the District of North Carolina, alleging patent infringement of U.S. Patent Nos. 7,589,106 and 7,687,516.

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

The following information should be read in conjunction with the unaudited financial information and the notes thereto included in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on February 28, 2019. Unless otherwise indicated or required by context, reference throughout to "Eagle," the "Company," "we," "our," or "us" refer to financial information and transactions of Eagle Pharmaceuticals, Inc.

Forward-Looking Information

This Quarterly Report on Form 10-Q contains forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that involve risks and uncertainties. The words "may," "will," "plan," "believe," "expect," "intend," "anticipate," "potential," "should," "estimate," "predict," "project," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause actual results to differ materially from those projected in the forward-looking statements.

Readers are cautioned that these forward-looking statements are only predictions and are subject to risks, uncertainties, and assumptions that are difficult to predict, including those identified under Part I, Item 1A. "Risk Factors," in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on February 28, 2019, as updated in our Quarterly Reports on Form 10-Q subsequently filed during the current fiscal year. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. Furthermore, such forward-looking statements speak only as of the date of this report. We undertake no obligation to revise or update any forward-looking statements for any reason, except as required by law.

Overview

Our business model is to develop proprietary innovations to FDA-approved, injectable drugs that offer commercial and/or functional advantages to currently available alternatives. We have historically been, and will continue to primarily be, focused on developing and commercializing injectable drugs, primarily in the critical care and oncology areas, using the United States Food and Drug Administration ("FDA")'s 505(b)(2) New Drug Application ("NDA") regulatory pathway. With our addition of Eagle Biologics, we hope to apply our proven market strategy to offer "biobetter" formulations, and to rapidly develop novel biologic products under the pathway provided by the Biologics Price Competition and Innovation Act. In addition, we plan to continue to market and/or commercialize our products through marketing partners and/or through our growing internal direct sales force.

Our product portfolio now includes four approved products: Argatroban, Ryanodex® (dantrolene sodium) ("Ryanodex"), rapidly infused bendamustine RTD 50ml solution ("BENDEKA") and Eagle's bendamustine RTD 500ml solution ("Big Bag"). We have three commercial partners: Chiesi USA, Inc. ("Chiesi") and Sandoz Inc. ("Sandoz"), who, pursuant to separate agreements, market Argatroban and Teva Pharmaceutical Industries Ltd. ("Teva"), which, through its subsidiary Cephalon, Inc. ("Cephalon"), markets BENDEKA®. BENDEKA was commercially launched by Teva in January 2016. We launched Big Bag in May 2018 with our commercial team immediately after receiving FDA approval.

We currently have multiple product candidates in advanced stages of development and/or under review for approval by the FDA. Additionally, we have other product candidates under a collaborative agreement. Our advanced product candidates are EP-4104 (dantrolene sodium for exertional heat stroke ("EHS")) ("EP-4104"), EP-5101 (PEMFEXY™, a pemetrexed injection ready-to-dilute formulation) ("EP-5101") and EGL-5385-C-1701 (fulvestrant).

Recent Developments

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

In March 2018, the Company announced that the United States Patent and Trademark Office (USPTO) issued a new patent to the Company's Eagle Biologics division. Patent number 9,925,263 will expire in March 2036 and is the fourth patent issued in the Eagle Biologics family of patents.

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

On April 16, 2018, the Company announced the FDA's acceptance of our ANDA filing for vasopressin injection, 1ml. This product is the generic version of Endo International plc's original Vasostrict® formulation, which is indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines. Vasostrict had approximately \$450 million in brand sales in 2018.

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

On March 24, 2016 the FDA denied the Company's request for seven years of orphan drug exclusivity in the U.S., for BENDEKA. In April 2016, the Company filed a lawsuit against the FDA arguing that BENDEKA is entitled to orphan drug exclusivity as a matter of law (see Note 12. Legal Proceedings). On July 2, 2014, the FDA granted the Company orphan drug designations for BENDEKA for the treatment of CLL and indolent B-cell NHL. The designations were based on a plausible hypothesis that BENDEKA is "clinically superior" to a drug previously approved for the same indications. Generally, an orphan-designated drug is eligible for seven years of marketing exclusivity for the orphan-designated indications upon approval of the drug for those indications. On June 8, 2018, the U.S. District Court for the District of Columbia (the "Court") issued a decision requiring the FDA to grant seven years of orphan drug exclusivity (ODE) in the U.S., for BENDEKA, and on July 8, 2018 the FDA granted such ODE through December 2022. In addition, on July 8, 2018, the FDA submitted a Motion to Alter or Amend the Judgement Pursuant to Rule 59(e), pursuant to which the FDA requested the Court amend its decision to make clear that the decision does not affect any applications referencing TREANDA. The FDA's motion was denied by the Court on August 1, 2018 on the grounds that FDA was seeking an inappropriate advisory opinion. The Company continues to believe that an appropriate application of orphan drug exclusivity would first allow generic TREANDA entrants in December 2022, rather than November 2019, and expects to vigorously pursue the scope of its exclusivity grant.

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

On July 26, 2017, we received a Complete Response Letter from the FDA regarding our 505(b)(2) NDA for Ryanodex for the treatment of exertional heat stroke ("EHS"), in conjunction with external cooling methods. Based on our meeting with the FDA, the Company conducted an additional clinical trial in August 2018 during the Hajj pilgrimage, similar to the study conducted during the Hajj in 2015. On August 30, 2018, we announced the completion of enrollment of our second clinical study to further evaluate the safety and efficacy of Ryanodex. During the 2018 Hajj, overall emergency room visits were dramatically decreased from previous years due to well-implemented crowd management, lower temperatures, lower humidity and other external factors. As a result, the number of EHS patients available for study enrollment was also significantly less than in previous years, and therefore much lower than anticipated. The preliminary assessment of patients enrolled is consistent with the data from the study conducted in 2015, in which patients dosed with RYANODEX plus Standard of Care ("SOC") showed an additive benefit compared to patients receiving SOC only. We intend to complete the analysis of the data and meet with the U.S. Food and Drug Administration to discuss next steps in 2019.

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

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

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

On November 27, 2018, the Company announced positive results of a pre-clinical study conducted to evaluate the effects of Ryanodex in Acute Radiation Syndrome.

On April 15, 2019, we announced an expansion of our BENDEKA License Agreement. Under the terms of the revised agreement, beginning on October 1, 2019, Eagle's royalty payment will increase from 25% to 30% of BENDEKA net U.S. sales, provided that BENDEKA's orphan drug exclusivity has not been rescinded, withdrawn or waived by such date. The royalty rate will increase by one percentage point on each anniversary of October 1, 2019 until it reaches 32%, and it will remain at 32% thereafter. The revised agreement also extends the U.S. BENDEKA royalty term until it is no longer sold in the United States. The previous U.S. royalty term was set to expire in 2025.

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

Financial Operations Overview

Revenue

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

Product Sales. Through March 31, 2019, we have recognized revenues from product sales of BENDEKA, Argatroban, Ryanodex, and Big Bag. Sales of BENDEKA are sold to our commercial partner Teva. Argatroban is sold directly to our commercial partners Chiesi and Sandoz. Sales to our commercial partners are typically made at little or no profit for resale. Ryanodex and Big Bag have been 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 pay a chargeback, representing the difference between the price invoiced to the wholesaler and the customer contract price.

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

License and other revenue.

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

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

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

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

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

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

- the effectiveness of our sales force;
- the level of orders submitted by wholesalers, hospitals and surgery centers;

- the level of institutional demand for our products; and
- unit sales prices, net of any sales reserves.

Cost of Revenues

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

Research and Development

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

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

Selling, General and Administrative

Selling, general and administrative costs consist primarily of salaries, benefits and other related costs, including stock-based compensation for executive, finance, sales and operations personnel. Selling, general and administrative expenses also include facility and related costs, professional fees for legal, consulting, tax and accounting services, insurance, selling, marketing, market research, advisory board and key opinion leaders, depreciation and general corporate expenses.

Income Taxes

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

Results of Operations

Comparison of Three Months Ended March 31, 2019 and 2018

Revenues

	Three Months Ended March 31,		
	2019	2018	Increase/(Decrease)
	(in thousands)		
Product sales	\$ 14,472	\$ 10,838	\$ 3,634
Royalty revenue	26,313	35,788	(9,475)
License and other revenue	9,000	—	9,000
Total revenue	<u>\$ 49,785</u>	<u>\$ 46,626</u>	<u>\$ 3,159</u>

Total revenue increased \$3.2 million in the three months ended March 31, 2019 to \$49.8 million as compared to \$46.6 million in the three months ended March 31, 2018.

Product sales increased \$3.6 million in the three months ended March 31, 2019 as compared to the three months ended March 31, 2018 primarily driven by the FDA approval and launch of Big Bag in May 2018 accompanied by an increase in product sales of BENDEKA of \$1.6 million. The increased sales were partially offset by decreases in product sales of Non-Alcohol Docetaxel Injection of \$0.8 million due to its discontinuation in September 2018 and of Ryanodex of \$0.4 million due to volume decrease.

Royalty revenue decreased \$9.5 million in the three months ended March 31, 2019 as compared to the three months ended March 31, 2018 as a result of lower royalties on Teva's sales of BENDEKA of \$8.0 million and lower royalties on sales of Argatroban of \$1.5 million.

License and other revenue in the three months ended March 31, 2019 represents an upfront cash payment of \$9.0 million upon execution of an amendment to the BENDEKA License Agreement to terminate Teva's obligation to pay future milestones and royalties on BENDEKA sales outside of the U.S.

Cost of Revenue

	Three Months Ended March 31,		
	2019	2018	Increase/(Decrease)
	(in thousands)		
Cost of product sales	\$ 9,554	\$ 7,223	\$ 2,331
Cost of royalty revenue	3,546	4,585	(1,039)
Total cost of revenue	<u>\$ 13,100</u>	<u>\$ 11,808</u>	<u>\$ 1,292</u>

Cost of revenue increased by \$1.3 million to \$13.1 million in the three months ended March 31, 2019 as compared to \$11.8 million in the three months ended March 31, 2018.

Cost of product sales increased \$2.3 million in the three months ended March 31, 2019 to \$9.6 million as compared to \$7.2 million in the three months ended March 31, 2018, primarily as a result of increased product sales of Big Bag and BENDEKA, partially offset by decreased product sales of Argatroban and the discontinuation of Non-Alcohol Docetaxel Injection in September 2018.

Cost of royalty revenue decreased \$1.0 million in the three months ended March 31, 2019 to \$3.5 million as compared to \$4.6 million in the three months ended March 31, 2018, primarily as a result of the decrease in royalty revenue for BENDEKA and Argatroban.

Research and Development

	Three Months Ended March 31,		Decrease
	2019	2018	
	(in thousands)		
Research and development	\$ 6,375	\$ 17,320	\$ (10,945)

Research and development expenses decreased \$10.9 million in the three months ended March 31, 2019 to \$6.4 million as compared to \$17.3 million in the three months ended March 31, 2018. The decrease primarily resulted from a decrease in project spending for EGL-5385-C-1701 (the Company's fulvestrant formulation) relating to the clinical study which completed randomization of 600 subjects in the first quarter of 2018. This decrease was partially offset by increased spend related to the Company's vasopressin injection ANDA filing.

Selling, General and Administrative

	Three Months Ended March 31,		Decrease
	2019	2018	
	(in thousands)		
Selling, general and administrative	\$ 18,141	\$ 15,193	\$ 2,948

Selling, general and administrative expenses increased \$2.9 million in the three months ended March 31, 2019 to \$18.1 million as compared to \$15.2 million in the three months ended March 31, 2018. This increase is primarily related to an increase of \$2.1 million in external legal fees related to ongoing litigation matters and sales and marketing spend as we incurred additional sales force costs for \$0.8 million during the three months ended March 31, 2019.

Other Income (Expense)

	Three Months Ended March 31,		Decrease / Increase
	2019	2018	
	(in thousands)		
Interest income	\$ 494	\$ 27	\$ 467
Interest expense	(686)	(675)	(11)
Total other expense, net	\$ (192)	\$ (648)	\$ 456

Interest income increased \$0.5 million in the three months ended March 31, 2019 primarily due to the Company investing additional cash in a money market fund throughout the three months ended March 31, 2019 as compared to the three months ended March 31, 2018.

Interest expense increased in the three months ended March 31, 2019 as compared to the three months ended March 31, 2018 due to cash interest on our long-term debt accruing at a marginally higher rate.

Income tax provision

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	
(Provision) benefit for income taxes	\$ (3,004)	\$ 959
Effective tax rate	25%	(58)%

The provision for income taxes was based on the applicable federal and state tax rates for those periods. The effective tax rate for the three months ended March 31, 2019 reflects the impact of certain non-deductible executive compensation partially offset by credits for research and development activity. The effective tax rate for the three months ended March 31, 2018 reflects tax benefits related to stock option exercises in the period as well as credits for research and development activity.

Net Income

Net income for the three months ended March 31, 2019 was \$9.0 million as compared to net income of \$2.6 million in the three months ended March 31, 2018, as a result of the factors discussed above.

Liquidity and Capital Resources

Our primary uses of cash are to fund working capital requirements, product development costs and operating expenses. Cash and cash equivalents were \$102.1 million and \$95.7 million as of March 31, 2019 and March 31, 2018, respectively.

For the three months ended March 31, 2019, we realized net income of \$9.0 million. As of March 31, 2019, we had a working capital surplus of \$138.0 million. For the three months ended March 31, 2018, we realized net income of \$2.6 million.

We believe that future cash flows from operations will be sufficient to fund our currently anticipated working capital requirements.

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

Operating Activities:

Net cash provided by operating activities for the three months ended March 31, 2019 was \$26.2 million. Net income for the period was \$9.0 million enhanced by non-cash adjustments of approximately \$6.7 million from deferred income taxes, depreciation, amortization of intangible assets, stock-based compensation expense, and amortization of debt issuance costs. Net changes in working capital increased cash from operating activities by approximately \$10.5 million, due to changes in working capital accounts. The total amount of accounts receivable at March 31, 2019 was approximately \$63.9 million, which included approximately \$27.0 million related to product sales and \$36.9 million related to royalty 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.

Investing Activities:

In the three months ended March 31, 2019, we invested \$0.2 million in purchases of property and equipment.

Financing Activities:

Net cash used in financing activities for the three months ended March 31, 2019 was \$2.7 million, primarily resulting from payment of debt of \$2.5 million and payment of employee withholding tax for net option exercises.

Contractual Obligations

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

Obligations	Total	2019	2020	2021	2022	2023	Beyond
Operating leases (1)	\$ 3,374	\$ 859	\$ 864	\$ 583	\$ 583	\$ 485	\$ —
Credit facility	42,500	3,750	5,000	33,750	—	—	—
Purchase obligations (2)	38,810	38,810	—	—	—	—	—
Total obligations	\$ 84,684	\$ 43,419	\$ 5,864	\$ 34,333	\$ 583	\$ 485	\$ —

(1) The Company leases its office and lab spaces under lease agreements that expire on June 30, 2020 and October 31, 2023. Rental expense was \$135 and \$184, for the three months ended March 31, 2019 and 2018, respectively.

(2) At March 31, 2019, the Company has purchase obligations in the amount of \$38,810 which represents the contractual commitments under contract manufacturing and supply agreements with suppliers. The obligation under the supply agreement is primarily for finished product, inventory, and research and development.

Recent Accounting Pronouncements

Recent Accounting Pronouncements - Not Yet Adopted

In January 2017, the FASB issued guidance to simplify the measurement of goodwill. The guidance eliminates Step 2 from the goodwill impairment test. Instead, under the amendments in this guidance, an entity should perform its annual or interim goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. Additionally, an entity should consider income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss. The guidance also eliminates the requirements for any reporting unit with a zero or negative carrying amount to perform a qualitative assessment and if it fails that qualitative test, to perform Step 2 of the goodwill impairment test. An entity is required to disclose the amount of goodwill allocated to each reporting unit with a zero or negative carrying amount of net assets. The guidance is effective for public business entities for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, and early adoption is permitted for interim or annual goodwill impairment tests performed for testing dates after January 1, 2017. The guidance must be adopted on a prospective basis. We do not expect this guidance to have an impact on our condensed consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirement for Fair Value Measurement (“ASU 2018-13”) which amends the disclosure requirements for fair value measurements. The amendments in ASU 2018-13 are effective for fiscal years beginning after December 15, 2019, with early adoption permitted. The Company is currently evaluating the potential impact that the adoption of ASU 2018-13 may have on the Company's financial position and results of operations.

Recently Adopted Accounting Pronouncements

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

Off-Balance Sheet Arrangements

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

or capital resources.

Impact of Inflation

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

During the three months ended March 31, 2019, 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 on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on February 28, 2019.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (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. In designing and evaluating our disclosure controls and procedures, management recognized 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 March 31, 2019, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective.

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 March 31, 2019 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 12. Legal Proceedings in the Condensed Consolidated Financial Statements included in Part I, Item 1 of this report are incorporated into this Part II, Item 1 by reference.

Item 1A. Risk Factors

You should carefully consider the factors discussed in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2018, which could materially affect our business, financial condition, cash flows or future results. There have been no material changes in our risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2018. The risks described in our Annual Report on Form 10-K for the year ended December 31, 2018 are not the only risks facing our company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition or future results.

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

There were no purchases or sales of equity securities by the Company during the three months ended March 31, 2019.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

The exhibits listed below are filed or furnished (as applicable) as part of, or incorporated by reference into, this Quarterly Report on Form 10-Q.

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
10.1*	(1) <u>Fourth Amendment to the Exclusive License Agreement, dated April 12, 2019, by and between Eagle Pharmaceuticals, Inc., a Delaware corporation and Teva Pharmaceuticals International GmbH, a company formed under Swiss law</u>
31.1	(1) <u>Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
31.2	(1) <u>Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
32.1	(1) <u>Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

(1) Filed herewith.

* Portions of this exhibit have been omitted.

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: May 7, 2019

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

DATED: May 7, 2019

By: /s/ Pete A. Meyers
Pete A. Meyers
Chief Financial Officer
(Principal Accounting and Financial Officer)

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE EAGLE PHARMACEUTICALS, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO EAGLE PHARMACEUTICALS, INC. IF PUBLICLY DISCLOSED.**

FOURTH AMENDMENT TO EXCLUSIVE LICENSE AGREEMENT

This amendment (“**Amendment**”) is entered into as of April 12, 2019 (the “**Fourth Amendment Effective Date**”) by and between Eagle Pharmaceuticals, Inc., a Delaware corporation (“**Eagle**”) and Teva Pharmaceuticals International GmbH, a company formed under Swiss law (“**TPIG**”). Eagle and TPIG are sometimes referred to herein, individually, as a “**Party**” or, collectively, as “**Parties**”.

WHEREAS, Eagle and Cephalon, Inc., a Delaware corporation and an Affiliate of TPIG (“**Cephalon**”), entered into an exclusive license agreement dated February 13, 2015 (the “**License Agreement**”) under which Eagle granted Cephalon certain licenses to Develop, Manufacture and Commercialize Licensed Compounds and Licensed Products (referring to Eagle’s bendamustine product for Short Infusion known as EP-3102 and any existing or future improved or modified versions of such compound discovered, conceived, created or otherwise Controlled by Eagle or any of its Affiliates) in the Field in the Territory of the United States and Canada.

WHEREAS, pursuant to an assignment and assumption agreement dated October 12, 2015 made between Cephalon and TPIG and acknowledged and consented to by Eagle (the “**Assignment and Assumption Agreement**”), Cephalon has assigned, and TPIG has assumed, all Cephalon’s rights and obligations under the License Agreement. Accordingly, all references to Cephalon in the License Agreement should be read and construed as references to TPIG.

WHEREAS, in connection with the License Agreement, Eagle and TPIG made and entered into a Supply Agreement on October 12, 2015, as amended (the “**Supply Agreement**”).

WHEREAS, contemporaneously with the execution of this Amendment, the Parties are executing a Second Amendment to the Supply Agreement to clarify responsibilities and rights relating to supply allocation and any transfer of manufacturing knowledge.

WHEREAS, the Parties seek to amend the License Agreement to re-allocate Royalty and certain litigation expenses.

WHEREAS, capitalized terms used herein and not defined have the meanings given to such terms in the License Agreement.

NOW, THEREFORE, in consideration of the mutual promises and covenants set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties, intending to be legally bound, agree to amend the License Agreement as follows:

1. Amendments to License Agreement
1. Section 1.65 of the License Agreement is hereby modified to read:

“**Royalty Term**” means with respect to a Licensed Product (i) for the United States, the period commencing upon the First Commercial Sale of such Licensed Product and continuing for so long as the Licensed Product is sold and (ii) for Canada and the Additional Territory, on a country-by-country basis, the period commencing upon the First Commercial Sale of such Licensed Product in such country and ending on the tenth (10th) anniversary thereof.
2. Section 9.3.1 of the License Agreement is hereby amended by adding the following sentence at the end of the section:

Provided that Eagle’s orphan drug exclusivity for BENDEKA is not rescinded, withdrawn or waived prior to October 1, 2019, on and after October 1, 2019, the royalty rate in the United States shall be 30%, and shall increase by 1% on October 1, 2020, and by an additional 1% on October 1, 2021; provided, however, that the royalty rate will be reduced by five percentage points with respect to any calendar quarter during which Eagle has over-allocated supply in its favor as set forth in Section 2.6(d) of the Supply Agreement, as amended.
3. In Section 10.4,

Section 10.4.4 is hereby amended in its entirety, as follows:

Damages. Other than with respect to the Hospira Litigation, in the event that TPIG exercises the rights conferred under Section 10.4.1 and recovers any damages, payments or other sums in such action or proceeding or in settlement thereof, such damages or other sums recovered will first be applied to all out-of-pocket costs and expenses incurred by the Parties in connection therewith (including, for purposes of this Section 10.4.4, attorney's fees) [***]% to TPIG and [***]% to Eagle in accordance with their contribution pursuant to Section 10.4.5 below and, then, the remaining recovery (if any) will be treated as Net Sales hereunder and subject to the terms and conditions set forth in Section 9.3.

In the event that Eagle exercises the rights conferred under Section 10.4.2 and recovers any damages, payments or other sums in such action or proceeding or in settlement thereof, such damages or other sums recovered will be retained one hundred percent (100%) by Eagle.

With respect to the Hospira Litigation, in the event that Eagle recovers any damages, payments or other sums in such action or proceeding or in settlement thereof, such damages or other sums recovered will first be applied to all out-of-pocket costs and expenses incurred by the Parties in connection therewith (including, for purposes of this Section 10.4.4, attorney's fees) [***]% to TPIG and [***]% to Eagle in accordance with their contribution pursuant to Section 10.4.6 below, and, then, the remaining recovery (if any) will be shared [***]% to TPIG and [***]% to Eagle.

and a new Section 10.4.5 and a new Section 10.4.6 are hereby inserted reading as follows:

10.4.5 *Bendeke-related litigation expenses.* TPIG shall reimburse Eagle up to \$[***] for BENDEKA-related ANDA patent litigation expenses through March 31, 2019; provided that such expenses are directly related to BENDEKA and consistent with [***]'s historical billing practices. For clarity, BENDEKA-related expenses do not include any litigation expenses related to *Eagle Pharmaceuticals, Inc., Teva Pharmaceuticals International GmbH, and Cephalon, Inc. v. Hospira, Inc.*, Case No. 18-1074-CC (D. Del. July 19, 2018) (the "Hospira Litigation"), which are specified in Section 10.4.6. Notwithstanding the provisions of Section 10.4.1, the Parties shall split BENDEKA-related ANDA patent litigation expenses of the Parties incurred from April 1, 2019 and onward with TPIG paying [***]% and Eagle paying [***]%. The Parties shall meet in good faith to discuss litigation strategy for any future ANDA or 505(b)(2) patent litigation. If TPIG decides to lead any such future patent litigation in accordance with Section 10.4.1, TPIG and Eagle will share said expenses of the Parties with TPIG paying [***]% and Eagle paying [***]%, notwithstanding the provisions of Section 10.4.1. To the extent that either Party funds a portion of an existing or future BENDEKA-related patent litigation, such Party shall also have the right to consent to any settlement. The Parties shall promptly meet with outside counsel regarding the BENDEKA-related patent litigation to determine the legal budget for the next 12-month period. The Parties shall meet with outside counsel on an at least annual basis to coordinate legal budgets for each successive 12-month period during which the BENDEKA-related patent litigation is ongoing.

10.4.6 *Hospira-related litigation expenses.* Notwithstanding the provisions of Section 10.4.2, the Parties shall [***] split the Hospira Litigation expenses of the Parties incurred from April 1, 2019 and onward, with TPIG paying [***]% and Eagle paying [***]%, and TPIG shall have the right to consent to any settlement of such Hospira Litigation. The Parties shall promptly meet with outside counsel regarding the Hospira Litigation to determine the legal budget for the next 12-month period. The Parties shall meet with outside counsel on an at least annual basis to coordinate legal budgets for each successive 12-month period during which the Hospira Litigation is ongoing.

2. Representations, Warranties and Covenants

As a material inducement for the other Party's entry into this Amendment, each Party repeats and confirms that as of the Fourth Amendment Effective Date its representations, warranties and covenants to the other Party set out in Section 12 of the License Agreement.

3. Governing Law

This Fourth Amendment will be governed by, and enforced and construed in accordance with, the laws of the State of New York, without regard to its conflict of law provisions.

4. The License Agreement shall continue in full force and effect subject to the terms of this Fourth Amendment.

IN WITNESS WHEREOF, the Parties have caused this Fourth Amendment to be executed by their respective duly authorized representatives as of the Fourth Amendment Effective Date.

EAGLE PHARMACEUTICALS, INC.

By: /s/ Scott Tariff
Name: Scott Tarriff
Title: CEO

By: /s/ Pete Meyers
Name: Pete Meyers
Title: CFO

TEVA PHARMACEUTICALS INTERNATIONAL GmbH

By: /s/ Naama Bar Am
Name: Naama Bar Am
Title: General Manager

By: /s/ Jana Noldeke
Name: Jana Noldeke, MSc, PhD
Title: Managing Officer

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: May 7, 2019

/s/ Scott Tarriff

Scott Tarriff
Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Pete A. Meyers, 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: May 7, 2019

/s/ Pete A. Meyers

Pete A. Meyers
Chief Financial Officer
(Principal Accounting and Financial Officer)

**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 **Pete A. Meyers**, 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 March 31, 2019, (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 7th day of May 2019.

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

By: /s/ Pete A. Meyers
Pete A. Meyers
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.