

EAGLE PHARMACEUTICALS, INC.
Form 10-Q
November 01, 2018
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2018

OR

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

For the transition period from _____ to _____

Commission File Number 001-36306

Eagle Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

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

50 Tice Boulevard, Suite 315

Woodcliff Lake, NJ 07677

(201) 326-5300

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's
Principal Executive Offices)

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

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

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

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

Emerging growth company

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 October 25, 2018: 14,913,159 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.

TABLE OF CONTENTS

	Page
Part I - Financial Information	
Item 1. Condensed Consolidated Financial Statements (unaudited)	
Condensed Consolidated Balance Sheets as of September 30, 2018 and December 31, 2017	<u>1</u>
Condensed Consolidated Statements of Income for the three and nine months ended September 30, 2018 and 2017	<u>2</u>
Condensed Consolidated Statement of Changes in Stockholders' Equity for the nine months ended September 30, 2018	<u>3</u>
Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2018 and 2017	<u>4</u>
Notes to Condensed Consolidated Financial Statements	<u>5</u>
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>27</u>
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>38</u>
Item 4. <u>Controls and Procedures</u>	<u>38</u>
Part II - Other Information	
Item 1. <u>Legal Proceedings</u>	<u>39</u>
Item 1A. <u>Risk Factors</u>	<u>41</u>
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>41</u>
Item 3. <u>Defaults Upon Senior Securities</u>	<u>42</u>
Item 4. <u>Mine Safety Disclosures</u>	<u>42</u>
Item 5. <u>Other Information</u>	<u>42</u>
Item 6. <u>Exhibits</u>	<u>42</u>
<u>Signatures</u>	<u>44</u>

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

	September 30, 2018	December 31, 2017
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 91,226	\$ 114,657
Accounts receivable, net	78,461	53,821
Inventory	7,273	5,118
Prepaid expenses and other current assets	20,810	15,101
Total current assets	197,770	188,697
Property and equipment, net	2,553	6,820
Intangible assets, net	18,702	23,322
Goodwill	39,743	39,743
Deferred tax asset, net	9,314	11,354
Other assets	706	124
Total assets	\$ 268,788	\$ 270,060
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 7,544	\$ 11,981
Accrued expenses	22,867	15,391
Current portion of contingent consideration	—	15,055
Current portion of long-term debt	5,000	4,875
Total current liabilities	35,411	47,302
Contingent consideration, less current portion	—	709
Long-term debt, less current portion	39,312	42,905
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of September 30, 2018 and December 31, 2017	—	—
Common stock, \$0.001 par value; 50,000,000 shares authorized; 16,503,283 and 16,089,439 shares issued as of September 30, 2018 and December 31, 2017, respectively	16	16
Additional paid in capital	251,875	233,639
Retained earnings	45,597	26,284
Treasury stock, at cost, 1,582,666 and 1,241,695 shares as of September 30, 2018 and December 31, 2017, respectively	(103,423)	(80,795)
Total stockholders' equity	194,065	179,144
Total liabilities and stockholders' equity	\$ 268,788	\$ 270,060
See accompanying notes to condensed consolidated financial statements.		

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Revenue:				
Product sales	\$16,163	\$ 6,905	\$50,042	\$ 34,895
Royalty revenue	35,174	43,616	107,216	117,527
License and other revenue	—	12,500	—	37,500
Total revenue	51,337	63,021	157,258	189,922
Operating expenses:				
Cost of product sales	8,621	4,815	29,919	24,490
Cost of royalty revenue	4,370	6,850	13,440	18,990
Research and development	5,975	8,954	38,560	23,163
Selling, general and administrative	13,878	16,669	45,033	58,100
Restructuring charge	91	—	7,479	—
Asset impairment charge	—	7,235	2,704	7,235
Change in fair value of contingent consideration	—	(6,452)	(763)	(5,604)
Total operating expenses	32,935	38,071	136,372	126,374
Income from operations	18,402	24,950	20,886	63,548
Interest income	9	35	36	52
Interest expense	(743)	(527)	(2,118)	(594)
Total other expense, net	(734)	(492)	(2,082)	(542)
Income before income tax (provision) benefit	17,668	24,458	18,804	63,006
Income tax (provision) benefit	(3,628)	(9,027)	509	(20,148)
Net Income	\$14,040	\$ 15,431	\$19,313	\$ 42,858
Earnings per share attributable to common stockholders:				
Basic	\$0.94	\$ 1.03	\$1.30	\$ 2.82
Diluted	\$0.91	\$ 0.98	\$1.25	\$ 2.68
Weighted average number of common shares outstanding:				
Basic	15,011,159	15,047,917	14,903,945	15,174,426
Diluted	15,483,037	15,764,360	15,482,768	16,015,051

See accompanying notes to condensed consolidated financial statements.

EAGLE PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

(In thousands)

(unaudited)

	Common Stock Number of Shares	Amount	Additional Paid-In Capital	Treasury Stock	Retained Earnings	Total Stockholders' Equity
Balance at December 31, 2017	16,089	\$ 16	\$233,639	\$(80,795)	\$26,284	\$ 179,144
Stock-based compensation expense	—	—	14,512	—	—	14,512
Issuance of common stock upon exercise of stock option grants	414	—	8,601	—	—	8,601
Payments for employee net option exercises			(4,877)	—	—	(4,877)
Common stock repurchases	—	—	—	(22,628)	—	(22,628)
Net income	—	—	—	—	19,313	19,313
Balance at September 30, 2018	16,503	\$ 16	\$251,875	\$(103,423)	\$45,597	\$ 194,065

See accompanying notes to condensed consolidated financial statements.

EAGLE PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)
(unaudited)

	Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net income	\$19,313	\$42,858
Adjustments to reconcile net income to net cash provided by operating activities:		
Deferred income taxes	2,040	12,141
Depreciation expense	918	657
Amortization of intangible assets	1,916	2,135
Stock-based compensation	14,512	11,618
Change in fair value of contingent consideration	(763)	(5,604)
Amortization of debt issuance costs	282	128
Asset impairment charge	2,704	7,235
Non-cash restructuring charge	5,771	—
Changes in operating assets and liabilities:		
Increase in accounts receivable	(24,640)	(29,407)
Increase in inventories	(4,525)	(2,139)
(Increase) decrease in prepaid expenses and other current assets	(5,709)	3,227
(Increase) decrease in other assets	(582)	12
Decrease in accounts payable	(4,437)	(5,814)
Increase (decrease) in accrued expenses and other liabilities	7,476	(4,049)
Net cash provided by operating activities	14,276	32,998
Cash flows from investing activities:		
Purchase of property and equipment	(52)	(1,706)
Payment for intangible asset	—	(750)
Net cash used in investing activities	(52)	(2,456)
Cash flows from financing activities:		
Proceeds from common stock option exercise	8,601	4,165
Payments for employee net option exercises	(4,877)	—
Payment of debt financing costs	—	(1,192)
Proceeds from long-term debt	—	50,000
Payment of contingent consideration	(15,001)	—
Payment of debt	(3,750)	—
Repurchases of common stock	(22,628)	(38,790)
Net cash (used in) provided by financing activities	(37,655)	14,183
Net (decrease) increase in cash	(23,431)	44,725
Cash and cash equivalents at beginning of period	114,657	52,820
Cash and cash equivalents at end of period	\$91,226	\$97,545
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Income taxes	\$1,887	\$8,845
Interest	1,540	—

See accompanying notes to condensed consolidated financial statements.

EAGLE PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(In thousands, except share and per share amounts)

(Unaudited)

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, 2017 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 and nine months ended September 30, 2018 are not necessarily indicative of the results for the year ending December 31, 2018 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, 2017, filed with the SEC on February 26, 2018. 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, 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") and Ryanode[®] (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 "Cephalon License") with Cephalon, Inc. ("Cephalon"), a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd. ("Teva"), for U.S. and Canadian rights to Bendeka for treatment of patients with chronic lymphocytic leukemia ("CLL") and patients with non-Hodgkin's lymphoma ("NHL"). Subsequently, with the consent of the Company, Cephalon assigned to Teva Pharmaceuticals International GmbH ("TPIG") all of Cephalon's rights and obligations under the Cephalon License. Accordingly, all references to "Cephalon" or to the "Cephalon License" and the related supply agreements for Bendeka should be read and construed as references to TPIG and to the license agreement and supply agreements for Bendeka to which the Company and TPIG are now parties. Pursuant to the terms of the Cephalon License, Cephalon will be responsible for all U.S. commercial activities for the product including promotion and distribution, and the Company is responsible for obtaining and maintaining all regulatory approvals and conducting post-approval clinical studies. In connection with the Cephalon License, the Company has entered into a supply agreement with Cephalon, pursuant to which the Company is responsible for supplying product to Cephalon. During the quarter-ended September 30, 2016, the Company entered into an amendment to the Cephalon License and supply agreements for Bendeka. The amendment expands the geographical scope of the rights granted under the original agreement to include territories outside the U.S. and Canada. Under the terms of the Cephalon License, the Company earned \$25 million in March 2017 for an additional sales-based milestone payment as TPIG

reached \$500 million of aggregate net sales of Bendeka. In addition, the Company is entitled to receive 25% royalty payments on net product sales.

On November 4, 2015, the Company entered into a Co-Promotion Agreement (the "Spectrum Agreement") with Spectrum Pharmaceuticals, Inc. ("Spectrum") under which Spectrum agreed to sell and market one of the Company's products through June 2017. The Company had the option to extend the initial term of this agreement by six months to December 31, 2017 at the Company's sole election. The Company elected not to exercise that option and the Spectrum agreement has expired.

EAGLE PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(In thousands, except share and per share amounts)

(Unaudited)

On August 9, 2016, the Company announced a share repurchase program approved by the Company's Board authorizing the repurchase of up to \$75.0 million of the Company's common stock (the "2016 Share Repurchase Program"). On August 9, 2017, the Company announced a new share repurchase program approved by the Board, under which the Company was authorized to repurchase up to an additional \$100 million of its outstanding common stock (the "2017 Share Repurchase Program"). On October 30, 2018, the Company announced a new 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"). 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 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. Under the 2016 Share Repurchase Program and 2017 Share Repurchase Program, prior to their termination, the Company repurchased 340,971 shares of common stock for \$22.6 million during the nine months ended September 30, 2018, and an aggregate of 1,582,666 shares of common stock for \$103.4 million through September 30, 2018.

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 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 agreements to work 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.

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 three-year \$50 million revolving credit facility and a three-year \$100 million term loan facility (which are collectively referred to as the “Amended Credit Facility”). At closing, which occurred on August 8, 2017, \$50 million of the term loan facility was drawn, and none of the revolving credit facility has been drawn. Although the Company had the option 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 (as defined above) and for

EAGLE PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(In thousands, except share and per share amounts)

(Unaudited)

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 3.00% 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 2.00% 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.

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

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

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

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

On October 23, 2017, the Company entered into an agreement with Worldwide Clinical Trials, Inc. to conduct a clinical trial for fulvestrant. A group study of healthy female subjects have been randomized across 12 sites. The study will evaluate the safety, tolerability, and pharmacokinetics of a single dose of fulvestrant for Injectable Suspension versus the reference drug administered by IM injection in the gluteal muscle.

On October 27, 2017, the FDA granted tentative approval for the Company's PEMFEXY™, a pemetrexed injection ready-to-dilute formulation ("Eagle's Pemfexy Product") for locally advanced or metastatic nonsquamous non-small cell lung cancer in combination with cisplatin; locally advanced or metastatic nonsquamous non-small cell lung cancer in patients whose disease has

EAGLE PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(In thousands, except share and per share amounts)

(Unaudited)

not progressed after four cycles of platinum-based first-line chemotherapy, as maintenance treatment; locally advanced or metastatic nonsquamous non-small cell lung cancer after prior chemotherapy as a single agent; and malignant pleural mesothelioma in patients whose disease is unresectable or who are otherwise not candidates for curative surgery in combination with cisplatin.

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

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

On March 24, 2016 the FDA denied the Company's request for seven years of orphan drug exclusivity in the U.S., for Bendeka. In April 2016, the Company filed a lawsuit against the FDA arguing that Bendeka is entitled to orphan drug exclusivity as a matter of law (see Note 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 September 26, 2018, the Company announced that the Compensation Committee of the Company's Board approved the appointment of David Pernock to the position of Chief Operating Officer effective as of September 1, 2018. In addition to his new role as Chief Operating Officer, Mr. Pernock has continued to serve as the Company's President.

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

EAGLE PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(In thousands, except share and per share amounts)

(Unaudited)

countermeasures research and development, to conduct a study to evaluate the neuroprotective effects of RYANODEX® (dantrolene sodium).

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

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, 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.

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.

EAGLE PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(In thousands, except share and per share amounts)

(Unaudited)

Intangible Assets

Other Intangible Assets, Net

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

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

Goodwill

Goodwill represents the excess of purchase price over the fair value of net assets acquired in the Eagle Biologics acquisition. 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. The Company earned a \$25 million sales-based milestone payment in March 2017 for Bendeka.

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

EAGLE PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(In thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended September 30, 2018		2017		Nine Months Ended September 30, 2018		2017	
Net revenues								
Cephalon, Inc. (Teva) - See Revenue Recognition	74	%	67	%	75	%	78	%
Cardinal Health	10	%	2	%	6	%	2	%
SymBio Pharmaceuticals Limited	—	%	20	%	—	%	7	%
Other	16	%	11	%	19	%	13	%
	100	%	100	%	100	%	100	%

	September 30, 2018		December 31, 2017	
Accounts receivable				
Cephalon, Inc. (Teva)	64	%	74	%
Oncology Supply	14	%	—	%
Other	22	%	26	%
	100	%	100	%

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.

Inventory

Inventory is recorded at the lower of cost or market, 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.

EAGLE PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(In thousands, except share and per share amounts)

(Unaudited)

Advertising and Marketing

Advertising and marketing costs are expensed as incurred. Advertising and marketing costs were \$609 and \$2,568 for the three months ended September 30, 2018 and 2017, respectively, and \$2,622 and \$17,296 for the nine months ended September 30, 2018 and 2017.

Income Taxes

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

Revenue Recognition

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

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

EAGLE PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(In thousands, except share and per share amounts)

(Unaudited)

reversal of cumulative revenue under the contract will not occur. Estimates of variable consideration are made using the expected value method and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of the Company's anticipated performance and all information (historical, current and forecasted) that is reasonably available. The Company believes that the estimates it has established are reasonable based upon current facts and circumstances. Applying different judgments to the same facts and circumstances could result in the estimated amounts to vary.

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

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

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

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

As described above, under the terms of the Cephalon License, the Company received an upfront cash payment of \$30 million, received a milestone payment of \$15 million for regulatory approval, received a \$40 million milestone payment upon receipt of the J-Code and received \$25 million in an additional sales-based milestone payment for reaching \$500 million in net product sales of Bendeka. In 2015, the \$30 million upfront payment was allocated between the license issued to Cephalon and obtaining and maintaining regulatory approvals and conducting post-approval clinical studies using the Company's best estimate of selling price for each deliverable. The full \$30 million was recognized as income in the first quarter of 2015, as the Company substantially completed its requirements for obtaining regulatory approval, which consisted of filing an NDA on February 13, 2015, and the remaining obligations were estimated to require minimal effort. On December 7, 2015, the FDA approved Bendeka

(50 mL bendamustine hydrochloride) marking the achievement of a milestone which entitled the Company to a \$15 million payment which was received in January 2016. The Company received a \$40 million milestone payment in November 2016 upon receipt of the unique J-Code. Additionally, this event triggered an increase in the royalty rate from 20% to 25% of Bendeka net sales. In March 2017, the Company received a \$25 million sales-based milestone payment for reaching \$500 million in net product sales.

As discussed above, under the Symbio License Agreement, the Company earned an upfront non-refundable cash payment of \$12.5 million during the third quarter of 2017.

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 September 30, 2018.

EAGLE PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(In thousands, except share and per share amounts)

(Unaudited)

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.

The anti-dilutive common shares equivalents outstanding at the three and nine months ended September 30, 2018 and 2017 were as follows:

Three Months Ended September 30,		Nine Months Ended September 30,		
2018	2017	2018	2017	
Options	1,704,348	1,671,570	1,810,098	1,580,277

Total 1,704,348 1,671,570 1,810,098 1,580,277

14

EAGLE PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(In thousands, except share and per share amounts)

(Unaudited)

The following table sets forth the computation for basic and diluted net income per share for the three and nine months ended September 30, 2018 and 2017:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Numerator				
Numerator for basic and diluted earnings per share-net income	\$ 14,040	\$ 15,431	\$ 19,313	\$ 42,858
Denominator				
Basic weighted average common shares outstanding	15,011,155	15,047,917	14,903,945	15,174,426
Dilutive effect of stock options	471,878	716,443	578,823	840,625
Diluted weighted average common shares outstanding	15,483,033	15,764,360	15,482,768	16,015,051
Basic net income per share				
Basic net income per share	\$0.94	\$ 1.03	\$ 1.30	\$ 2.82
Diluted net income per share				
Diluted net income per share	\$0.91	\$ 0.98	\$ 1.25	\$ 2.68

Recent Accounting Pronouncements

Recent Accounting Pronouncements - Not Yet Adopted

In February 2016, the FASB issued guidance for accounting for leases. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. The guidance is effective for reporting periods beginning after December 15, 2018 and early adoption is permitted. We will adopt this guidance as of January 1, 2019. We are currently reviewing our leases and other contracts to determine the impact the adoption of this guidance will have on our consolidated financial statements. We currently expect that the adoption of this guidance will likely change the way we account for our operating leases and will likely result in recording the future benefits of those leases and the related minimum lease payments on our consolidated balance sheets.

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 consolidated financial statements.

In January 2017, the FASB issued guidance clarifying the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets or businesses. The guidance provides a screen to determine when an integrated set of assets and activities is not a business, provides a framework to assist entities in evaluating whether both an input and substantive process are present, and narrows the definition of the term output. The guidance is effective for public business entities for fiscal years beginning after December 15, 2017, including interim periods

15

EAGLE PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(In thousands, except share and per share amounts)

(Unaudited)

within those fiscal years, and early adoption is permitted. The guidance must be adopted on a prospective basis. We will consider the guidance for future transactions.

Recent Adopted Accounting Pronouncements

The Company adopted ASC 606, Revenue from Contracts with Customers with a date of initial application of January 1, 2018. As a result, the Company has updated its accounting policy for revenue recognition to reflect the new standard as detailed above. The adoption of ASC 606 represents a change in accounting principle that will more closely align revenue recognition with the delivery of the Company's services and will provide financial statement readers with enhanced disclosures. The Company applied Topic 606 using the modified retrospective method. The Company has elected to apply this initial application of the standard only to contracts that are not completed at the date of initial application. For contracts which were modified before the adoption date, the Company has not restated the contract for those modifications. Instead, the Company reflected the aggregate effect of all modifications when identifying the satisfied and unsatisfied performance obligations, determining the transaction price and allocating the transaction price, if necessary. The cumulative effect of initially applying the new revenue standard would be applied as an adjustment to the opening balance of retained earnings. The Company has analyzed this effect and found the adoption of the new guidance did not have a material impact on our consolidated financial statements and our recognition is consistent with our historical accounting policies.

In January 2016, the FASB issued ASU 2016-01, which revises the guidance in ASC 825-10, Recognition and Measurement of Financial Assets and Financial Liabilities, and provides guidance for the recognition, measurement, presentation, and disclosure of financial assets and liabilities. The guidance is effective for reporting periods (interim and annual) beginning after December 15, 2017, for public companies. The adoption of this guidance did not have a significant impact on our consolidated financial statements.

4. Acquisitions

Acquisition of Non-Alcohol Docetaxel Injection

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

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

During the year ended December 31, 2017, the Company recorded a change in the fair value of contingent consideration of \$6.2 million. This was primarily driven by adjustments to the fair values of the liabilities associated

with Non-Alcohol Docetaxel Injection, which was remeasured due to the loss of a customer and other market conditions identified during the third quarter of 2017 for the product and partially offset by accretion for the time value of money.

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

EAGLE PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(In thousands, except share and per share amounts)

(Unaudited)

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

Closing Balance December 31, 2017	Changes in fair value	Payment of contingent consideration	Closing Balance September 30, 2018
\$764	\$(763)	\$ (1)	\$ —

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

Eagle Biologics Acquisition

On November 16, 2016, the Company entered into a stock purchase agreement 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 agreements to work 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.

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

	Preliminary fair value
Cash consideration paid	\$ 27,209
Common stock issued (i)	3,046
Fair value of contingent consideration payable to seller (long term) (ii)	16,100
Total consideration	\$ 46,355

(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 Closing Date. 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

17

EAGLE PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(In thousands, except share and per share amounts)

(Unaudited)

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.

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 (ii) 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.

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

Closing Balance December 31, 2017	Changes in fair value	Payment of contingent consideration	Closing Balance September 30, 2018
\$15,000	\$	-\$ (15,000)	\$ —

5. Inventory

Inventory consists of the following:

	September 30, 2018	December 31, 2017
Raw material	\$ 6,944	\$ 2,489
Work in process	—	931
Finished products	329	1,698
	\$ 7,273	\$ 5,118

EAGLE PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(In thousands, except share and per share amounts)

(Unaudited)

6. Balance Sheet Accounts

Prepaid and Other Current Assets

Prepaid and other current assets consist of the following:

	September 30, 2018	December 31, 2017
Advances to commercial manufacturers	\$ 5,012	\$ 2,389
Prepaid FDA user fee	1,240	1,369
Prepaid insurance	389	116
Prepaid income taxes	12,498	9,597
Prepaid research and development	—	1,069
All other	1,671	561
Total Prepaid expenses and other current assets	\$ 20,810	\$ 15,101

Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2018	December 31, 2017
Royalties payable to commercial partners	\$ 6,335	\$ 4,310
Accrued research & development	3,160	936
Accrued professional fees	1,740	1,254
Accrued salary and other compensation	4,119	4,811
Accrued product costs	4,843	2,657
Accrued restructuring costs	1,600	—
Accrued other	1,070	1,423
Total Accrued expenses	\$ 22,867	\$ 15,391

EAGLE PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(In thousands, except share and per share amounts)

(Unaudited)

7. Intangible Assets, Net

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

		September 30, 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	(1,360)	—	13,640
Developed technology	5	8,100	(3,038)	—	5,062
Total		\$34,320	\$ (5,679)	\$ (9,939)	\$ 18,702
		December 31, 2017			
	Useful Life (In Years)	Gross Carrying Amount	Accumulated Amortization	Impairment Charge	Net Book Value
Docetaxel product rights	10	\$ 11,220	\$ (1,164)	\$ (7,235)	\$ 2,821
Ryanodex intangible	20	15,000	(777)	—	14,223
Developed technology	5	8,100	(1,822)	—	6,278
Total		\$34,320	\$ (3,763)	\$ (7,235)	\$ 23,322

Amortization expense was \$599 and \$711 for the three months ended September 30, 2018 and 2017, respectively, and \$1,916 and \$2,135 for the nine months ended September 30, 2018 and 2017, respectively.

Intangible Asset Impairment

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

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

Estimated Amortization Expense for Intangible Assets

Based on definite-lived intangible assets recorded as of September 30, 2018, 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:

EAGLE PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(In thousands, except share and per share amounts)

(Unaudited)

Year Ending December 31,	Estimated Amortization Expense
2018 (remainder)	\$ 599
2019	2,520
2020	2,666
2021	2,623
2022	1,369
Thereafter	8,925
Total estimated amortization expense	\$ 18,702

8. Common Stock and Stock-Based Compensation

Common Stock

On August 9, 2016, the Company announced a share repurchase program approved by the Company's Board authorizing the repurchase of up to \$75.0 million of the Company's common stock (the "2016 Share Repurchase Program"). On August 9, 2017, the Company announced a new share repurchase program approved by the Board, under which the Company was authorized to repurchase up to an additional \$100 million of its outstanding common stock (the "2017 New Share Repurchase Program"). 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 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.

Under the 2016 Share Repurchase Program and 2017 Share Repurchase Program, the Company repurchased the following shares of common stock with cash resources during the nine months ended September 30, 2018:

Shares of common stock repurchased	340,971
Value of common stock repurchased	\$22,628

Stock-Based Compensation

In December 2007, the Company's board of directors approved the 2007 Incentive Compensation Plan (the "2007 Plan") enabling the Company to grant multiple stock-based awards to employees, directors and consultants, the most

common being stock options and restricted stock awards. In November 2013, the Company's board of directors approved the 2014 Equity Incentive Plan (the "2014 Plan") which became effective on February 11, 2014. The 2007 Plan was terminated upon the effectiveness of the 2014 Plan and all shares available for issuance under the 2007 Plan were made available under the 2014 Plan. The 2014 Plan provides for the awards of incentive stock options, non-qualified stock options, restricted stock, restricted stock units and other stock-based

EAGLE PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(In thousands, except share and per share amounts)

(Unaudited)

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. At the Company's annual meeting of stockholders held on August 4, 2015, the stockholders approved an amendment to the 2014 Plan to, among other things, increase the number of shares of common stock authorized for issuance thereunder by 500,000 shares.

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

A summary of stock option, RSU and PSU activity under the 2014 Plan during the nine months ended September 30, 2018 and 2017 is presented below:

	Stock Options	RSUs	PSUs
Outstanding at December 31, 2016	2,324,918	—	—
Granted	925,329	—	—
Options Exercised/RSUs Vested/PSUs Vested	(180,516)	—	—
Forfeited or expired	(107,102)	—	—
Outstanding at September 30, 2017	2,962,629	—	—
Outstanding at December 31, 2017	2,786,568	—	—
Granted	652,625	64,080	127,080
Options Exercised/RSUs Vested/PSUs Vested	(499,592)	—	—
Forfeited or expired	(391,609)	(9,861)	(9,861)
Outstanding at September 30, 2018	2,547,992	54,219	117,219

Stock Options

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Risk-free interest rate	2.72% - 2.90%	1.79% - 2.18%	2.30% - 2.94%	1.79% - 2.42%
Volatility	43.76%	34.35%	43.76%	36.97%
Expected term (in years)	6.08 years	5.50 - 7.00 years	5.50 - 6.08 years	5.50 - 7.00 years
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

RSUs

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

PSUs

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

EAGLE PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(In thousands, except share and per share amounts)

(Unaudited)

The Company recognized stock-based compensation in its condensed consolidated statements of income for the three and nine months ended September 30, 2018 and 2017 as follows:

	Three Months		Nine Months	
	Ended		Ended September	
	September 30,	30,	2018	2017
	2018	2017	2018	2017
Stock options	\$3,514	\$3,728	\$11,725	\$11,618
RSUs	176	—	513	—
PSUs	782	—	2,274	—
Stock-based compensation expense	\$4,472	\$3,728	\$14,512	\$11,618
Selling, general and administrative	\$3,641	\$2,795	\$11,418	\$8,662
Research and development	831	933	3,094	2,956
Stock-based compensation expense	\$4,472	\$3,728	\$14,512	\$11,618

9. Commitments

Our future material contractual obligations include the following:

Obligations	Total	2018	2019	2020	2021	2022	Beyond
Operating leases (1)	\$4,904	\$265	\$1,256	\$978	\$699	\$703	\$1,003
Credit facility	45,000	1,250	5,000	38,750	—	—	—
Purchase obligations (2)	30,974	6,195	24,779	—	—	—	—
Total obligations	\$80,878	\$7,710	\$31,035	\$39,728	\$699	\$703	\$1,003

(1) The Company leases its office and lab spaces under lease agreements that expire on June 30, 2020, October 31, 2023 and December 31, 2027. Rental expense was \$135 and \$184, for the three months ended September 30, 2018 and 2017, and \$423 and \$503 for the nine months ended September 30, 2018 and 2017, respectively. The remaining future lease payments under the operating lease are \$4,904 as of September 30, 2018, payable monthly through June 30, 2020, October 31, 2023 and December 31, 2027.

(2) At September 30, 2018, the Company has purchase obligations in the amount of \$30,974 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 three-year \$50 million revolving credit facility and a three-year \$100 million term loan facility (which are collectively referred to as the "Amended Credit Facility"). The Company recorded \$0.3 million of debt extinguishment costs related to the amendment included in selling, general and administrative expenses during the year ended December 31, 2017. As of September 30, 2018, the Company has \$0.7 million of unamortized deferred debt issuance costs as part of long-term debt in its condensed consolidated balance sheets.

EAGLE PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(In thousands, except share and per share amounts)

(Unaudited)

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 3.00% 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 2.00% 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.

	as of
Debt Maturities	September
	30, 2018
2018 (remainder)	\$ 1,250
2019	5,000
2020	38,750
Total debt	\$ 45,000

11. Income Taxes

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Income tax (provision) benefit	\$(3,628)	\$(9,027)	\$509	\$(20,148)
Effective tax rate	21	% 37	% (3)% 32

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.

Our effective tax rate for the three and nine months ended September 30, 2018 was impacted primarily by the Tax Cuts and Jobs Act of 2017, which was enacted on December 22, 2017 and lowered the U.S. corporate tax rate from 35% to 21%, beginning in 2018. Our effective tax rate for the three and nine months ended September 30, 2018 and 2017 reflects the tax benefit of stock option exercises in the period and credits for research and development activity. Deferred income tax assets at September 30, 2018 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 September 30, 2018. 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

EAGLE PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(In thousands, except share and per share amounts)

(Unaudited)

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, we may be a party to litigation and subject to claims incident to the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we currently believe that the final outcome of these ordinary course matters will not have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Commercial Litigation

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 grant us 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 grant seven years of orphan drug exclusivity 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 the FDA was seeking an inappropriate advisory opinion. The FDA and two intervenor's have provided notice that they intend to appeal the Court's decision.

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 September 13, 2018, Lilly moved the court to stay the case. That motion and this case are pending.

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

EAGLE PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(In thousands, except share and per share amounts)

(Unaudited)

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. 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 and Mylan on July 24, 2018, August 2, 2018, and August 3, 2018, respectively. Slayback, Apotex, Fresenius, and Mylan answered their Complaints and some filed various counterclaims on September 29, 2017 (Slayback I), February 12, 2018 (Slayback II), November 27, 2017, September 15, 2017, and February 14, 2018, respectively. The Patentees answered the Slayback I, Slayback II, Fresenius, and Apotex counterclaims on October 20, 2017, March 5, 2018, October 6, 2017, and December 18, 2017, respectively.

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. All seven cases are pending.

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

EAGLE PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(In thousands, except share and per share amounts)

(Unaudited)

Slayback Pharma Limited Liability Company (“Slayback”) filed an ANDA referencing Eagle's bendamustine RTD 500ml solution (“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. That 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 Abbreviated New Drug Application (“ANDA”) seeking approval to manufacture and sell the Company’s vasopressin product. The Company’s vasopressin product, if finally approved by FDA, will be an alternative to Vasostriect, 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. The Parties submitted a proposed scheduling order, with trial proposed to begin May 18, 2020. This suit is pending.

13. Restructuring

As part of its ongoing organizational review, the Company engaged in a restructuring initiative to rationalize its product portfolio and focus its physical sites. These measures included the discontinuation of manufacture and distribution of Non-Alcohol Docetaxel Injection in June 2018 and plans to rationalize research and development operations. Charges consist of inventory and related reserves, certain asset impairment charges related to property, plant and equipment, and personnel related costs. The restructuring charges of \$91 and \$7,479 for the three and nine months ended September 30, 2018 have been recorded to Restructuring charge on the Condensed Consolidated Statements of Income. The Company also recorded an asset impairment charge for the remaining Intangible asset for Non-Alcohol Docetaxel Injection of \$2,704 as well as an adjustment to remove the contingent consideration of \$790 on the related line items in the Statements of Income for the nine months ended September 30, 2018. The liability related to this restructuring initiative is included in Accrued expenses in the Condensed Consolidated Balance Sheet and is related to unsettled payments for inventory and related costs amounting to \$1.6 million. No payments were made in the third quarter of 2018 related to this liability. The Company expects to incur additional expenses related to this restructuring initiative. The Company anticipates substantially all related cash payments will be made by the end of 2018.

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, 2017, filed with the SEC on February 26, 2018. 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, 2017, filed with the SEC on February 26, 2018, as updated in our Quarterly Reports on Form 10-Q subsequently filed during the current fiscal year, including this report. 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 third 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 \$400 million in brand sales in 2017.

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.

On September 26, 2018, we announced that the Compensation Committee of the Company’s Board approved the appointment of David Pernock to the position of Chief Operating Officer effective as of September 1, 2018. In addition to his new role as Chief Operating Officer, Mr. Pernock has continued to serve as the Company’s President.

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.

Financial Operations Overview

Revenue

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

Product Sales. We recognize revenues from product sales of Bendeka, Ryanodex, Argatroban, Non-Alcohol Docetaxel Injection, and diclofenac-misoprostol. 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, Non-Alcohol Docetaxel Injection, and diclofenac-misoprostol are sold directly to wholesalers, hospitals and surgery centers through a third party logistics partner. Diclofenac-misoprostol was divested in March 2016; however, we continued to market diclofenac-

misoprostol through the first quarter of 2018 until such time that the purchaser was able to launch the product. As part of a restructuring initiative, we ceased selling Non-Alcohol Docetaxel Injection by September 30, 2018.

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

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

License and other revenue.

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

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

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

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

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

The primary factors that may determine our revenues derived from Non-Alcohol Docetaxel Injection, Ryanodex and diclofenac-misoprostol 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 September 30, 2018 and 2017

Revenues

	Three Months Ended		Increase/(Decrease)
	September 30, 2018	September 30, 2017	
	(in thousands)		
Product sales	\$ 16,163	\$ 6,905	\$ 9,258
Royalty revenue	35,174	43,616	(8,442)
License and other revenue	—	12,500	(12,500)
Total revenue	\$ 51,337	\$ 63,021	\$ (11,684)

Total revenue decreased \$11.7 million in the three months ended September 30, 2018 to \$51.3 million as compared to \$63.0 million in the three months ended September 30, 2017.

Product sales increased \$9.3 million in the three months ended September 30, 2018 primarily driven by the FDA approval and launch of Big Bag in May 2018 accompanied by increases in product sales of Bendeka of \$3.4 million and Ryanodex of \$0.3 million. The increased sales were partially offset by decreases in product sales of \$1.2 million for Argatroban, \$0.8 million for Non-Alcohol Docetaxel Injection and \$0.5 million for diclofenac-misoprostol. The Company sold certain intellectual property related to diclofenac-misoprostol in March 2016.

Royalty revenue decreased \$8.4 million in the three months ended September 30, 2018 as a result of lower royalties on Bendeka of \$7.6 million and Argatroban of \$0.8 million.

License and other revenue decreased as we realized a \$12.5 million upfront cash payment earned under the SymBio License Agreement during the three months ended September 30, 2017.

Cost of Revenue

	Three Months Ended		Increase/(Decrease)
	September 30, 2018	September 30, 2017	
	(in thousands)		
Cost of product sales	\$ 8,621	\$ 4,815	\$ 3,806

Cost of royalty revenue	4,370	6,850	(2,480)
Total cost of revenue	\$12,991	\$11,665	\$	1,326

31

Cost of revenue increased by \$1.3 million to \$13.0 million in the three months ended September 30, 2018 as compared to \$11.7 million in the three months ended September 30, 2017.

Cost of product sales increased \$3.8 million in the three months ended September 30, 2018 to \$8.6 million as compared to \$4.8 million in the three months ended September 30, 2017, primarily as a result of increased product sales of Big Bag and Bendeka, offset by decreased product sales of Argatroban, Non-Alcohol Docetaxel Injection, and diclofenac-misoprostol.

Cost of royalty revenue decreased \$2.5 million in the three months ended September 30, 2018 to \$4.4 million as compared to \$6.9 million in the three months ended September 30, 2017, primarily as a result of the decrease in royalty revenue for Bendeka and Argatroban.

Research and Development

Three Months		Decrease
Ended		
September 30,		
2018	2017	
(in thousands)		

Research and development \$5,975 \$8,954 \$(2,979)

Research and development expenses decreased \$3.0 million in the three months ended September 30, 2018 to \$6.0 million as compared to \$9.0 million in the three months ended September 30, 2017. The decrease primarily resulted from a decrease in project spending for EP-5101 and EGL-5385-C-1701 relating to the clinical study nearing completion. These decreases were offset by increased spend for EP-4104 for the clinical trial conducted in August 2018 during the Hajj pilgrimage.

Selling, General and Administrative

Three Months		Decrease
Ended		
September 30,		
2018	2017	
(in thousands)		

Selling, general and administrative \$13,878 \$16,669 \$(2,791)

Selling, general and administrative expenses decreased \$2.8 million in the three months ended September 30, 2018 to \$13.9 million as compared to \$16.7 million in the three months ended September 30, 2017. This decrease is primarily related to a decrease in legal fees and sales and marketing spend as we incurred significant preparation costs for the launch of Ryanodex for exertional heat stroke during the three months ended September 30, 2017.

Other Income (Expense)

Three Months		Decrease / Increase
Ended		
September 30,		
2018	2017	
(in thousands)		

Interest income \$9 \$35 \$(26)

Interest expense (743) (527) (216)

Total other expense, net \$(734) \$(492) \$(242)

Interest expense increased in the three months ended September 30, 2018 as compared to the three months ended September 30, 2017 due to cash interest on our debt and the amortization of debt issuance costs incurred on long-term

debt for a full quarter as we entered into the Amended Credit Agreement on August 8, 2017.

32

Income tax provision

	Three Months Ended		
	September 30, 2018	2017	
	(in thousands)		
Provision for income taxes	\$(3,628)	\$(9,027)	
Effective tax rate	21	% 37	%

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 September 30, 2018 and 2017 reflects tax benefits related to stock option exercises in the period as well as credits for research and development activity (see Note to Condensed Consolidated Financial Statements - Note 11. Income Taxes).

Net Income

Net income for the three months ended September 30, 2018 was \$14.0 million as compared to net income of \$15.4 million in the three months ended September 30, 2017, as a result of the factors discussed above.

Comparison of Nine Months Ended September 30, 2018 and 2017

Revenues

	Nine Months Ended		Increase/ (Decrease)
	September 30, 2018	2017	
	(in thousands)		
Product sales	\$50,042	\$34,895	\$ 15,147
Royalty revenue	107,216	117,527	(10,311)
License and other revenue	—	37,500	(37,500)
Total revenue	\$157,258	\$189,922	\$(32,664)

Total revenue decreased \$32.7 million in the nine months ended September 30, 2018 to \$157.2 million as compared to \$189.9 million in the nine months ended September 30, 2017.

Product sales increased \$15.1 million in the nine months ended September 30, 2018, primarily driven by the FDA approval and launch of Big Bag in May 2018 accompanied by increases in product sales of Bendeka of \$3.8 million and Ryanodex of \$2.2 million. The increased sales were partially offset by decreases in product sales of \$3.7 million for Argatroban, \$2.0 million for Non-Alcohol Docetaxel Injection and \$1.2 million for diclofenac-misoprostol. The Company sold certain intellectual property related to diclofenac-misoprostol in March 2016.

Royalty revenue decreased \$10.3 million as a result of lower royalties on Argatroban of \$1.7 million and Bendeka of \$8.6 million.

License and other revenue for the nine months ended September 30, 2017 comprised of a \$25.0 million milestone under the Cephalon agreement related to Teva reaching \$500 million in cumulative net sales of Bendeka and a \$12.5 million upfront cash payment earned under the SymBio License Agreement.

Cost of Revenue

	Nine Months Ended September 30,		Increase/ (Decrease)
	2018	2017	

Cost of product sales	29,919	24,490	\$ 5,429
Cost of royalty revenue	13,440	18,990	(5,550)
Total cost of revenue	\$43,359	\$43,480	\$ (121)

Cost of revenue decreased by \$0.1 million to \$43.4 million in the nine months ended September 30, 2018 as compared to \$43.5 million in the nine months ended September 30, 2017.

Cost of product sales increased \$5.4 million in the nine months ended September 30, 2018 to \$29.9 million as compared to \$24.5 million in the nine months ended September 30, 2017, primarily as a result of increased product sales of Big Bag and Bendeka, offset by decreased product sales of Argatroban, Non-Alcohol Docetaxel Injection, and diclofenac-misoprostol.

Cost of royalty revenue decreased \$5.6 million due to the \$25.0 million milestone realized under the Cephalon agreement, related to Teva reaching \$500 million in cumulative net sales of Bendeka, and the \$12.5 million upfront cash payment earned under the Symbio License Agreement during the nine months ended September 30, 2017.

Research and Development

	Nine Months Ended September 30,		Increase
	2018	2017	

Research and development	38,560	23,163	\$ 15,397
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Research and development expenses increased \$15.4 million in the nine months ended September 30, 2018 to \$38.6 million as compared to \$23.2 million in the nine months ended September 30, 2017. The increase primarily resulted from an increase in project spending for EGL-5385-C-1701 relating to the clinical study, which completed randomization of 600 subjects in the first quarter of 2018, as well as higher salary and personnel-related expenses.

Selling, General and Administrative

	Nine Months Ended September 30,		Decrease
	2018	2017	

Selling, general and administrative	\$45,033	\$58,100	\$(13,067)
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Selling, general and administrative expenses decreased \$13.1 million in the nine months ended September 30, 2018 to \$45.0 million as compared to \$58.1 million in the nine months ended September 30, 2017. This decrease is principally related to a \$14.7 million decrease in sales and marketing spend in preparation for the launch of Ryanodex for exertional heat stroke and fees related to our co-promotion agreement during the six months ended June 30, 2017 and \$1.1 million decrease in professional fees. These decreases were partially offset by a \$3.1 million increase in salary and personnel-related expenses, including stock-based compensation expense, as we build out areas to support the growing needs of the business and sales force.

Restructuring Charge

As part of an ongoing organizational review, we began a restructuring initiative to rationalize our product portfolio and focus our physical sites. This initiative includes the discontinuation of manufacture and distribution of Non-Alcohol Docetaxel Injection, which occurred in June 2018, and plans to rationalize research and development operations. Charges consist of inventory and related reserves of \$4.0 million, certain asset impairment charges related to property, plant and equipment of \$3.4 million, and \$0.1 million related to personnel related costs resulting in a total restructuring charge of \$7.5 million for the nine months ended September 30, 2018.

Asset Impairment Charge

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

Change in Fair Value of Contingent Consideration

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

Contingent consideration gain of \$0.8 million was recorded during the nine months ended September 30, 2018. This was primarily driven by adjustments to the fair values of the liabilities associated with Non-Alcohol Docetaxel Injection, which was remeasured as a result of the discontinuation of the product and partially offset by accretion for the time value of money.

Other Income (Expense)

	Nine Months Ended		Increase
	September 30, 2018	September 30, 2017	
	(in thousands)		
Interest income	\$36	\$52	\$(16)
Interest expense	(2,118)	(594)	(1,524)
Total other income (expense), net	\$(2,082)	\$(542)	\$(1,540)

Interest expense increased in the nine months ended September 30, 2018 related to interest incurred on long-term debt and the amortization of debt issuance costs. We entered into the Amended Credit Agreement on August 8, 2017.

Provision for Income Taxes

	Nine Months Ended	
	September 30, 2018	September 30, 2017
	(in thousands)	
Income tax (benefit) provision	\$509	\$(20,148)
Effective tax rate	(3)%	32 %

The benefit (provision) for income taxes was based on the applicable federal and state tax rates for those periods. The effective tax rate for the nine months ended September 30, 2018 and 2017 reflects tax benefits related to stock option exercises in the period as well as credits for research and development activity (see Note to Condensed Consolidated Financial Statements - Note 11. Income Taxes).

Net Income

Net income for the nine months ended September 30, 2018 was \$19.3 million as compared to net income of \$42.9 million in the nine months ended September 30, 2017, as a result of the factors discussed above.

Liquidity and Capital Resources

Our primary uses of cash are to fund working capital requirements, product development costs and operating expenses. Cash and cash equivalents were \$91.2 million and \$97.5 million as of September 30, 2018 and September 30, 2017, respectively.

For the nine months ended September 30, 2018, we realized net income of \$19.3 million. As of September 30, 2018, we had a working capital surplus of \$162.4 million. For the nine months ended September 30, 2017, we realized net income of \$42.9 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 Credit Facility, for general corporate purposes and any strategic acquisitions.

Operating Activities:

Net cash provided by operating activities for the nine months ended September 30, 2018 was \$14.3 million. Net income for the period was \$19.3 million offset by non-cash adjustments of approximately \$27.4 million from deferred income taxes, depreciation, amortization of intangible assets, stock-based compensation expense, amortization of debt issuance costs, change in fair value of contingent consideration, asset impairment charge and fair value adjustment related to restructuring. Net changes in working capital decreased cash from operating activities by approximately \$32.4 million, due to an increase in accounts receivable of \$24.6 million, an increase in inventory of \$4.5 million, an increase in prepaid expenses and other current assets of \$5.7 million, an increase in other assets of \$0.6 million, an increase in accrued expenses and other liabilities of \$7.4 million, and a decrease in accounts payable of \$4.4 million. The total amount of accounts receivable at September 30, 2018 was approximately \$78.5 million, which included approximately \$43.3 million of product sales and \$35.2 million of 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. Net cash provided by operating activities for the nine months ended September 30, 2017 was \$33.0 million. Net income for the period was \$42.9 million offset by non-cash adjustments of approximately \$28.3 million from deferred income taxes, depreciation, amortization of intangible assets, stock-based compensation expense, asset impairment charge, amortization of debt issuance costs, and change in fair value of contingent consideration. Net changes in working capital decreased cash from operating activities by approximately \$38.2 million, due to an increase in accounts receivable of \$29.4 million, an increase in inventories of \$2.1 million, a decrease in prepaid expenses and other current assets of \$3.2 million, a decrease in accounts payable of \$5.8 million, and a decrease in accrued expenses and other liabilities of \$4.1 million. The total amount of accounts receivable at September 30, 2017 was approximately \$71.6 million, which included approximately \$15.5 million of product sales and \$56.1 million of royalty and milestone income.

Investing Activities:

In the nine months ended September 30, 2018, we invested \$0.1 million in purchases of property and equipment. In the nine months ended September 30, 2017, we invested \$1.7 million in purchases of property and equipment and paid \$0.8 million related to the purchase of the Ryanodex intangible.

Financing Activities:

Net cash used in financing activities for the nine months ended September 30, 2018 was \$37.7 million, primarily resulting from a \$15 million payment of contingent consideration in connection with the Arsia Amendment, \$22.6 million in cash settlements on repurchases of common stock, \$3.8 million payment of debt financing costs and a \$4.9 million payment of employee withholding tax for net option exercises. This was offset by the issuance of common stock for stock option exercises of \$8.6 million.

Net cash used in financing activities for the nine months ended September 30, 2017 was \$14.2 million, primarily resulting from \$50.0 million in proceeds from long-term debt and the issuance of common stock for stock option exercises of \$4.1 million. This was offset by \$38.9 million in cash settlements on repurchases of common stock and \$1 million payment of debt financing costs.

Contractual Obligations

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

Obligations	Total	2018	2019	2020	2021	2022	Beyond
Operating leases (1)	\$4,904	\$265	\$1,256	\$978	\$699	\$703	\$1,003
Credit facility	45,000	1,250	5,000	38,750	—	—	—
Purchase obligations (2)	30,974	6,195	24,779	—	—	—	—
Total obligations	\$80,878	\$7,710	\$31,035	\$39,728	\$699	\$703	\$1,003

(1) The Company leases its office and lab spaces under lease agreements that expire on June 30, 2020, October 31, 2023 and December 31, 2027. Rental expense was \$135 and \$184, for the three months ended September 30, 2018 and 2017, and \$423 and \$503 for the nine months ended September 30, 2018 and 2017, respectively. The remaining future lease payments under the operating lease are \$4,904 as of September 30, 2018, payable monthly through June 30, 2020, October 31, 2023 and December 31, 2027.

36

(2) At September 30, 2018, the Company has purchase obligations in the amount of \$30,974 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 February 2016, the FASB issued guidance for accounting for leases. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. The guidance is effective for reporting periods beginning after December 15, 2018 and early adoption is permitted. We will adopt this guidance as of January 1, 2019. We are currently reviewing our leases and other contracts to determine the impact the adoption of this guidance will have on our consolidated financial statements. We currently expect that the adoption of this guidance will likely change the way we account for our operating leases and will likely result in recording the future benefits of those leases and the related minimum lease payments on our consolidated balance sheets.

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 consolidated financial statements.

In January 2017, the FASB issued guidance clarifying the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets or businesses. The guidance provides a screen to determine when an integrated set of assets and activities is not a business, provides a framework to assist entities in evaluating whether both an input and substantive process are present, and narrows the definition of the term output. The guidance is effective for public business entities for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, and early adoption is permitted. The guidance must be adopted on a prospective basis. We will consider the guidance for future transactions.

Recent Adopted Accounting Pronouncements

The Company adopted ASC 606, Revenue from Contracts with Customers with a date of initial application of January 1, 2018. As a result, the Company has updated its accounting policy for revenue recognition to reflect the new standard. The adoption of ASC 606 represents a change in accounting principle that will more closely align revenue recognition with the delivery of the Company's services and will provide financial statement readers with enhanced disclosures. The Company applied Topic 606 using the modified retrospective method. The Company has elected to apply this initial application of the standard only to contracts that are not completed at the date of initial application. For contracts which were modified before the adoption date, the Company has not restated the contract for those modifications. Instead, the Company reflected the aggregate effect of all modifications when identifying the satisfied and unsatisfied performance obligations, determining the transaction price and allocating the transaction price, if necessary. The cumulative effect of initially applying the new revenue standard would be applied as an adjustment to the opening balance of retained earnings. The Company has analyzed this effect and found the adoption of the new guidance did not have a material impact on our consolidated financial statements and our recognition is consistent

with our historical accounting policies.

In January 2016, the FASB issued ASU 2016-01, which revises the guidance in ASC 825-10, Recognition and Measurement of Financial Assets and Financial Liabilities, and provides guidance for the recognition, measurement, presentation, and disclosure of financial assets and liabilities. The guidance is effective for reporting periods (interim and annual) beginning after December 15, 2017, for public companies. The adoption of this guidance did not have a significant impact on our consolidated financial statements.

37

Off-Balance Sheet Arrangements

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

Impact of Inflation

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

During the nine months ended September 30, 2018, 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, 2017, filed with the SEC on February 26, 2018.

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 September 30, 2018, 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 September 30, 2018 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

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

Commercial Litigation

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 grant us 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 grant seven years of orphan drug exclusivity 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 the FDA was seeking an inappropriate advisory opinion. The FDA and two intervenor's have provided notice that they intend to appeal the Court's decision.

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 September 13, 2018, Lilly moved the court to stay the case. That motion and this case are pending.

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. 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 and Mylan on July 24, 2018, August 2, 2018, and August 3, 2018, respectively. Slayback, Apotex, Fresenius, and Mylan answered their Complaints and some filed various counterclaims on September 29, 2017 (Slayback I), February 12, 2018 (Slayback II), November 27, 2017, September 15, 2017, and February 14, 2018, respectively. The Patentees answered the Slayback I, Slayback II, Fresenius, and Apotex counterclaims on October 20, 2017, March 5, 2018, October 6, 2017, and December 18, 2017, respectively. 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. All seven cases are pending.

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 bendamustine RTD 500ml solution (“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. That 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 Abbreviated New Drug Application ("ANDA") seeking approval to manufacture and sell the Company's vasopressin product. The Company's vasopressin product, if finally approved by FDA, will be an alternative to Vasopressin, 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. The Parties submitted a proposed scheduling order, with trial proposed to begin May 18, 2020. This suit is pending.

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, 2017, 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, 2017. The risks described in our Annual Report on Form 10-K for the year ended December 31, 2017 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

Issuer Purchases of Equity Securities

The following table provides information about purchases of our equity securities during the three months ended September 30, 2018:

Period	Total Number of Shares Purchased (1)(2)(3)(4)(5)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Programs (dollars in thousands)
July 1, 2018 to July 31, 2018	—	\$ —	—	\$ 88,669
August 1, 2018 to August 31, 2018	153,797	\$ 72.28	153,797	77,553
September 1, 2018 to September 30, 2018	14,885	\$ 67.15	14,885	76,553
Total	168,682	\$ 71.83	168,682	

(1) All shares repurchased by the Company in this table were repurchased pursuant to the Share Repurchase Programs, described below and elsewhere in this Quarterly Report on Form 10-Q.

(2) On August 9, 2016, the Company announced a share repurchase program approved by the Company’s Board authorizing the repurchase of up to \$75.0 million of the Company’s common stock (the “2016 Share Repurchase Program”). Under the 2016 Share Repurchase Program, the Company was authorized to repurchase shares through open market purchases, privately-negotiated transactions or otherwise in accordance with applicable federal securities laws, including through Rule 10b5-1 trading plans and under Rule 10b-18 of the Exchange Act. The 2016 Share Repurchase Program was terminated by the Company’s Board in connection with its approval of the 2018 Share Repurchase Program in October 2018.

(3) On August 9, 2017, the Company announced a new share repurchase program approved by the Board, under which the Company may repurchase up to \$100 million of its outstanding common stock (the “2017 Share Repurchase Program”). Under the 2017 Share Repurchase Program, the Company may repurchase shares through open market purchases, privately-negotiated transactions or otherwise in accordance with applicable federal securities laws, including through Rule 10b5-1 trading plans and under Rule 10b-18 of the Exchange Act. The 2017 Share Repurchase Program was terminated by the Company’s Board in connection with its approval of the 2018 Share Repurchase Program in October 2018.

(4) 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.

(5) 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 will pay \$50 million to JP Morgan on November 1, 2018, and receive approximately 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 will be 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 expects the ASR to be completed in the fourth quarter of 2018. As of September 30, 2018, the Company had 14.9 million common shares outstanding.

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
3.1	<u>Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed February 20, 2014)</u>
3.2	<u>Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed February 20, 2014)</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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized

EAGLE PHARMACEUTICALS, INC.

DATED: November 1, 2018 By: /s/ Scott Tarriff

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

DATED: November 1, 2018 By: /s/ Pete A. Meyers

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