EAGLE PHARMACEUTICALS, INC.
Form 10-Q
August 07, 2018

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

FORM 10-Q

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

For the quarterly period ended June 30, 2018
OR

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

For the transition period from _____ to _____
Commission File Number 001-36306

Eagle Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in its Charter)

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

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

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

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

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

Large accelerated filer x	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Emerging growth company o

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

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

The number of shares outstanding of the registrant’s common stock as of July 31, 2018: 15,055,924 shares.

NOTE REGARDING COMPANY REFERENCES

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

NOTE REGARDING TRADEMARKS

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

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

	June 30, 2018 (unaudited)	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$100,247	$114,657
Accounts receivable, net	69,403	53,821
Inventory	6,444	5,118
Prepaid expenses and other current assets	25,502	15,101
Total current assets	201,596	188,697
Property and equipment, net	2,773	6,820
Intangible assets, net	19,302	23,322
Goodwill	39,743	39,743
Deferred tax asset, net	9,817	11,354
Other assets	706	124
Total assets	$273,937	$270,060
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$18,266	$11,981
Accrued expenses	23,222	15,391
Current portion of contingent consideration	—	15,055
Current portion of long-term debt	6,250	4,875
Total current liabilities	47,738	47,302
Contingent consideration, less current portion	—	709
Long-term debt, less current portion	40,468	42,905
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of June 30, 2018 and December 31, 2017	—	—
Common stock, $0.001 par value; 50,000,000 shares authorized; 16,457,575 and 16,089,439 issued as of June 30, 2018 and December 31, 2017, respectively	16	16
Additional paid in capital	245,470	233,639
Retained earnings	31,559	26,284
Treasury stock, at cost, 1,413,984 and 1,241,695 shares as of June 30, 2018 and December 31, 2017, respectively	(91,314)	(80,795)
Total stockholders' equity	185,731	179,144
Total liabilities and stockholders' equity	$273,937	$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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenue:				
Product sales	$23,041	$ 12,704	$33,879	$ 27,990
Royalty revenue	36,255	37,404	72,043	73,911
License and other revenue	—	—	—	25,000
Total revenue	59,296	50,108	105,922	126,901
Operating expenses:				
Cost of product sales	14,074	8,910	21,298	19,675
Cost of royalty revenue	4,485	4,910	9,070	12,140
Research and development	15,265	6,684	32,585	14,209
Selling, general and administrative	15,987	23,280	31,153	41,431
Restructuring charge	7,388	—	7,388	—
Asset impairment charge	2,704	—	2,704	—
Change in fair value of contingent consideration	(790)	422	(763)	848
Total operating expenses	59,113	44,206	103,435	88,303
Income from operations	183	5,902	2,487	38,598
Interest income	1	14	27	17
Interest expense	(701)	(40)	(1,376)	(67)
Total other expense, net	(700)	(26)	(1,349)	(50)
(Loss) income before income tax benefit (provision)	(517)	5,876	1,138	38,548
Income tax benefit (provision)	3,176	(1,373)	4,137	(11,121)
Net Income	$2,659	$ 4,503	$5,275	$ 27,427
Earnings per share attributable to common stockholders:				
Basic	$0.18	$ 0.30	$0.36	$ 1.80
Diluted	$0.17	$ 0.28	$0.34	$ 1.70
Weighted average number of common shares outstanding:				
Basic	14,879,040	15,219,777	14,849,449	15,238,729
Diluted	15,446,827	16,100,615	15,473,727	16,135,276

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	—	—	10,040	—	—	10,040
Issuance of common stock upon exercise of stock option grants	369	—	6,668	—	—	6,668
Payments for employee net option exercises			(4,877)	—	—	(4,877)
Common stock repurchases	—	—	—	(10,519)	—	(10,519)
Net income	—	—	—	—	5,275	5,275
Balance at June 30, 2018	16,458	$ 16	$245,470	$(91,314)	$31,559	$ 185,731

See accompanying notes to condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2018	2017
Cash flows from operating activities:		
Net income	$ 5,275	$ 27,427
Adjustments to reconcile net income to net cash provided by operating activities:		
Deferred income taxes	1,537	8,368
Depreciation expense	683	432
Amortization of intangible assets	1,316	1,423
Stock-based compensation	10,040	7,890
Change in fair value of contingent consideration	(763)	848
Amortization of debt issuance costs	188	66
Asset impairment charge	2,704	—
Non-cash restructuring charge	5,788	—
Changes in operating assets and liabilities:		
Increase in accounts receivable	(15,582)	(11,036)
Increase in inventories	(3,427)	(848)
Increase in prepaid expenses and other current assets	(10,705)	(307)
Increase in other assets	(582)	(26)
Increase (decrease) in accounts payable	6,285	(2,568)
Increase (decrease) in accrued expenses and other liabilities	7,831	(6,557)
Net cash provided by operating activities	10,588	25,112
Cash flows from investing activities:		
Purchase of property and equipment	(19)	(884)
Net cash used in investing activities	(19)	(884)

Cash flows from financing activities:						
Proceeds from common stock option exercise	6,668			4,130		
Payments for employee net option exercises	(4,877		)	—		
Payment of debt financing costs	—			(482		)
Payment of contingent consideration	(15,001		)	—		
Payment of debt	(1,250		)	—		
Repurchases of common stock	(10,519		)	(25,311		)
Net cash used in financing activities	(24,979		)	(21,663		)
Net (decrease) increase in cash	(14,410		)	2,565		
Cash and cash equivalents at beginning of period	114,657			52,820		
Cash and cash equivalents at end of period	$	100,247		$	55,385	
Supplemental disclosures of cash flow information:						
Cash paid during the period for:						
Income taxes	$	1,831		$	5,585	
Interest	529			—		

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 six months ended June 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 Ryanodex® (dantrolene sodium) ("Ryanodex").The Company has a number of products currently under development and certain products may be subject to license agreements.

On February 13, 2015, the Company submitted a New Drug Application ("NDA") to the FDA for Bendeka, which was approved by the FDA on December 7, 2015. Also on February 13, 2015, the Company entered into an Exclusive License Agreement (the “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 of directors authorizing the repurchase of up to $75.0 million of the Company's common stock (the "Share Repurchase Program"). On August 9, 2017, the Company announced a new share repurchase program approved by the Board, under which the Company may repurchase up to an additional $100 million of its outstanding common stock (the "New Share Repurchase Program"). Under the Share Repurchase Program and the New Share Repurchase Program, the Company is authorized to repurchase shares through open market purchases, privately-negotiated transactions or otherwise in accordance with applicable federal securities laws, including through Rule 10b5-1 trading plans and under Rule 10b-18 of the Exchange Act. The Share Repurchase Programs have no time limit and may be suspended or discontinued completely at any time. The specific timing and amount of repurchases will vary based on available capital resources and other financial and operational performance, market conditions, securities law limitations, and other factors. The repurchases will be made using the Company's cash resources. In any period, cash used in financing activities related to shares repurchased may differ from the comparable change in stockholders' equity, reflecting timing differences between the recognition of share repurchase transactions and their settlement for cash. The Company repurchased 172,289 shares of common stock for $10.5 million during the six months ended June 30, 2018, and an aggregate of 1,413,984 shares of common stock for $91.3 million through June 30, 2018.

On November 16, 2016 the Company entered into a stock purchase agreement to acquire Arsia Therapeutics, Inc. ("Arsia"), an early-stage biotechnology firm with proprietary viscosity-reducing technology and formulation know-how and subsequently renamed the subsidiary Eagle Biologics, Inc. ("Eagle Biologics"). Under the terms of the stock purchase agreement, 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 the recent meeting with the FDA, the Company has agreed on a path forward and plans to conduct an additional clinical trial in August 2018 during the Hajj pilgrimage, similar to the study conducted during the Hajj in 2015.

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 New Share Repurchase Program (as defined above) 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.

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

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. The Company expects the study to be completed by fall 2018.

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 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.

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

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.

At June 30, 2018, the Company was owed approximately $4.2 million from its CEO related to the tax withholdings on options exercised on June 29, 2018. Following the interceding weekend, the funds were received on July 3, 2018. It is not the practice of the Company to extend personal loans or extend other forms of credit to the CEO or other officers and directors of the Company.

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 will cease selling the product by September 30, 2018.

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.

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

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.

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.

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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:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net revenues				
Cephalon, Inc. (Teva) - See Revenue Recognition	70 %	77 %	76 %	83 %
Oncology Supply	14 %	— %	8 %	— %
Other	16 %	23 %	16 %	17 %
	100%	100%	100%	100%

	June 30, 2018	December 31, 2017
Accounts receivable		
Cephalon, Inc. (Teva)	66 %	74 %
Oncology Supply	14 %	0 %
Other	20 %	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

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

Property and Equipment

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

Research and Development Expense

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

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

Advertising and Marketing

Advertising and marketing costs are expensed as incurred. Advertising and marketing costs were $1,118 and $8,792 for the three months ended June 30, 2018 and 2017, respectively, and $2,013 and $14,728 for the six months ended June 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

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

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

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

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the

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

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

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inherent uncertainty of the occurrence of these future events, the Company will not recognize revenue from the milestone until there is not a high probability of a reversal of revenue, which typically occurs near or upon achievement of the event.

As described above, under the terms of the Cephalon License, the Company received an upfront cash payment of $30 million, received a milestone payment of $15 million for regulatory approval, received a $40 million milestone upon receipt of the J-Code and received a $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 June 30, 2018.

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.

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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 six months ended June 30, 2018 and 2017 were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Options	1,884,614	1,581,586	1,892,614	1,552,064
Total	1,884,614	1,581,586	1,892,614	1,552,064

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Numerator				
Numerator for basic and diluted earnings per share-net income	$2,659			