EAGLE PHARMACEUTICALS, INC.
Form 10-Q
May 10, 2016

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 March 31, 2016
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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

The number of shares outstanding of the registrant’s common stock as of May 3, 2016: 15,636,387 shares.

Eagle Pharmaceuticals, Inc.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements, that involve risk and uncertainties. The words “may,” “will,” “plan,” “believe,” “expect,” “intend,” “anticipate,” “potential,” “should,” “estimate,” “predict,” “project,” 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.

These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the success, cost and timing of our product development activities and clinical trials;
- our ability to obtain and maintain regulatory approval of our products and product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product;
- our ability to obtain funding for our operations;
- our plans to research, develop and commercialize our products and product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- the size and growth potential of the markets for our products and product candidates, and our ability to serve those markets;
- our ability to successfully commercialize our products and product candidates;
- the rate and degree of market acceptance of our products and product candidates;
- our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators;
- the performance of our strategic collaborators and success of our current strategic collaborations;
- regulatory developments in the United States and foreign countries;
- the performance of our third-party suppliers and manufacturers;
- the success of competing drugs that are or become available;
- the loss of key scientific or management personnel;
- our use of the proceeds from our initial public offering; and subsequent follow-on offering;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates; and
- our ability to prevent or minimize the effects of Paragraph IV patent litigation.

In some cases, you can identify these statements by terms such as “anticipate,” “believe,” “could,” “estimate,” “expects,” “inter “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative of those terms, and similar expressio

These forward-looking statements reflect our management’s beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this Quarterly Report on Form 10-Q and are subject to risks and uncertainties. We discuss many of these risks in greater detail under the heading “Risk Factors.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

NOTE REGARDING COMPANY REFERENCES

Throughout this report, “Eagle Pharmaceuticals,” the “Company,” “we,” “us” and “our” refer to Eagle Pharmaceuticals, 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 BALANCE SHEETS
(In thousands, except share and per share amounts)

	March 31, 2016 (unaudited)	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$78,287	$79,083
Accounts receivable	26,526	26,267
Inventories	7,761	15,042
Prepaid expenses and other current assets	2,048	1,865
Total current assets	114,622	122,257
Property and equipment, net	2,869	2,205
Intangible assets, net	11,116	—
Other assets	94	143
Total assets	$128,701	$124,605
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$10,295	$3,857
Accrued expenses	19,561	24,405
Current portion of contingent consideration	1,012	—
Deferred revenue	—	6,000
Total current liabilities	30,868	34,262
Contingent consideration	5,517	—
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of March 31, 2016 and December 31, 2015	—	—
Common stock, $0.001 par value; 50,000,000 shares authorized; 15,636,387 issued and outstanding as of March 31, 2016 and December 31, 2015	15	15
Additional paid in capital	200,309	197,440
Accumulated deficit	(108,008)	(107,112)
Total stockholders' equity	92,316	90,343
Total liabilities and stockholders' equity	$128,701	$124,605

See accompanying notes to condensed financial statements.

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

	Three Months Ended March 31,	
	2016	2015
Revenue:		
Product sales	$14,122	$3,056
Royalty income	9,469	3,253
License and other income	6,000	30,000
Total revenue	29,591	36,309
Operating expenses:		
Cost of revenue	14,589	5,948
Research and development	6,676	6,285
Selling, general and administrative	10,973	3,986
Gain on sale of asset	(1,750)	—
Total operating expenses	30,488	16,219
Income (Loss) from operations	(897)	20,090
Interest income	21	7
Interest expense	(1)	(1)
Total other income	20	6
Income (Loss) before income tax provision	(877)	20,096
Income tax provision	(19)	(399)
Net Income (Loss)	$(896)	$19,697
Earnings per share attributable to common stockholders:		
Basic	$(0.06)	$1.38
Diluted	$(0.06)	$1.31
Weighted average number of common shares outstanding:		
Basic	15,636,387	14,247,019
Diluted	15,636,387	15,041,011

See accompanying notes to condensed financial statements.

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

	Common Stock Number of Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2015	15,637	15	$ 197,440	$ (107,112)	$ 90,343
Stock-based compensation expense			2,869	—	2,869
Net income	—	—	—	(896)	(896)
Balance at March 31, 2016	15,637	$ 15	$ 200,309	$ (108,008)	$ 92,316

See accompanying notes to condensed financial statements.

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

	Three Months Ended March 31,	
	2016	2015
Cash flows from operating activities:		
Net (loss) income	$(896)	$19,697
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Depreciation expense	140	12
Amortization of intangible assets	104	—
Stock-based compensation	2,869	384
Change in fair value of contingent consideration	159	—
Gain on sale of diclofenac-misoprostol	(1,750)	—
Loss on disposal of fixed assets	—	273
Changes in operating assets and liabilities:		
(Increase) decrease in accounts receivable	(259)	1,448
Decrease (increase) in inventories	7,281	(776)
(Increase) decrease in prepaid expenses and other current assets	(183)	300
Decrease in other assets	49	—
Increase in accounts payable	6,438	1,884
(Decrease) increase in deferred revenue	(6,000)	65
(Decrease) increase in accrued expenses and other liabilities	(4,844)	2,549
Net cash provided by operating activities	3,108	25,836
Cash flows from investing activities:		
Purchase of property and equipment	(804)	(43)
Purchase of short term investments	(62,000)	(15,998)
Cash used for acquisition	(4,850)	—
Proceeds from sale of diclofenac/misoprostol	1,750	—
Maturities of short term investments	62,000	—
Net cash used in investing activities	(3,904)	(16,041)
Cash flows from financing activities:		
Proceeds from common stock option exercise	—	564
Proceeds from issuance of common stock from follow-on public offering, net of issuance costs	—	54,696
Net cash provided by financing activities	—	55,260
Net (decrease) increase in cash	(796)	65,055
Cash and cash equivalents at beginning of period	79,083	34,869
Cash and cash equivalents at end of period	$78,287	$99,924
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Interest	$1	$1
Corporate taxes	—	—
Franchise taxes	107	53
Non-cash financing activities		
Accrued follow-on public offering costs	—	365
Contingent consideration on business acquisition	6,370	—

See accompanying notes to condensed financial statements.

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

1. Interim Condensed Financial Statements

The accompanying unaudited interim condensed 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. In the opinion of management, all adjustments (consisting only of normal recurring adjustments) necessary for the fair presentation of the financial information for the interim periods reported have been made. Results of operations for the three months ended March 31, 2016 are not necessarily indicative of the results for the year ending December 31, 2016 or any period thereafter. These unaudited interim condensed financial statements should be read in conjunction with the audited financial statements and related notes included in our annual report on Form 10-K for the fiscal year ended December 31, 2015, filed with the SEC on February 29, 2016.

2. Organization and Business Activities

Eagle Pharmaceuticals, Inc. (the "Company", or "Eagle") 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) 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 five products currently being sold in the United States under various license agreements in place with commercial partners, including a ready-to-use formulation of EP-1101 (argatroban) ("EP-1101"), Ryanodex® (dantrolene sodium) ("Ryanodex"), diclofenac-misoprostol, docetaxel injection non-alcohol formulation ("Non-Alcohol Docetaxel Injection") and EP-3102 (rapidly infused bendamustine RTD) ("EP-3102 Bendeka"). 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 an NDA to the FDA for EP-3102 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 EP-3102 Bendeka for treatment of patients with CLL and patients with NHL. Pursuant to the terms of the Cephalon License, Cephalon will be responsible for all U.S. commercial activities for the product including promotion and distribution, and the Company is responsible for obtaining and maintaining all regulatory approvals and conducting post-approval clinical studies. Additionally, under the terms of the Cephalon License, the Company received an upfront cash payment of $30 million, received a $15 million milestone payment in January 2016 related to the FDA approval of EP-3102 Bendeka in December 2015, and is currently eligible to receive up to $25 million in additional milestone payments. In addition, the Company is entitled to receive royalty payments of 20% of net sales of the product. 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 for a specified period.

On March 20, 2015, the Company completed an underwritten public offering (the "Follow-on Offering") of 1,518,317 shares of common stock, including the exercise by the underwriters of a 30-day option to purchase an additional 198,041 shares of common stock. Of the shares sold, 1,388,517 shares were issued and offered by the Company and 129,800 shares were offered by certain selling stockholders. All of the shares were offered at a price to the public of $42.00 per share. The net proceeds to Eagle from this offering, after deducting underwriting discounts and commissions and other offering expenses payable by Eagle, were approximately $54,331. Eagle did not receive any proceeds from the shares sold by the selling stockholders. The securities described above were offered pursuant to a shelf registration statement declared effective by the SEC on March 13, 2015.

On October 13, 2015, the Company entered into an exclusive U.S. licensing agreement (the "Teikoku Agreement") with Teikoku Pharma USA, Inc. ("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 an upfront cash payment of $250 upon execution of the agreement which was expensed in 2015 and is included in research and development expense and an additional payment of $4,850 upon FDA approval and NDA transfer to Eagle, which occurred in January 2016. In addition, the Company will pay 25% royalties on gross profits. The Company accounted for the transaction as a business combination in 2016 and is in the

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

process of finalizing the valuation of intangible assets and fair value of the contingent purchase price. As a result, the preliminary measurements of intangible assets are subject to change. The results of operations related to Non-Alcohol Docetaxel Injection have been included in the consolidated statements of income from the date of acquisition.

On November 4, 2015, the Company entered into a co-promotion agreement with Spectrum Pharmaceuticals, Inc. ("Spectrum") under which Spectrum's 32-person Corporate Accounts Sales Team will dedicate 80% of its time to selling and marketing up to six of the Company's products over a period of at least 18 months (the "Spectrum Agreement"). The Company will pay Spectrum a base fee of $12.8 million over 18 months, and additional payments of up to $9 million if specified targets for annual net sales of our products are met during the initial term of the Spectrum Agreement, for a potential total payment of up to $21.8 million during the initial term. The Company may extend the initial term of this agreement by six months to December 31, 2017 at its sole election. Any extensions after December 31, 2017 require mutual consent and will be for six months per extension.

In addition to the services provided through the Spectrum Agreement and in line with our long-term strategy to build an internal commercial team, the Company hired approximately 12 direct sales representatives that will be a part of the Company's independent commercial organization. These representatives will be managed under the Spectrum sales team infrastructure for the duration of the Spectrum Agreement.

On January 11, 2016, the Company entered into an agreement with Albany Molecular Research, Inc. ("AMRI") to jointly develop and manufacture several select and complex parenteral drug products for registration and subsequent commercialization in the United States. Under the terms of the agreement, AMRI will develop and initially provide cGMP manufacturing and analytical support for the registration of the new product candidates. The costs of development are to be shared, with 37.5% paid by the Company and 62.5% paid by AMRI. The Company will be responsible for advancing the product candidates through clinical trials and regulatory submissions.

On March 18, 2016, the Company received a Complete Response Letter from the FDA for EP-6101 Kangio™ ready-to-use ("RTU") bivalirudin ("EP-6101 Kangio") in which the FDA stated it cannot approve the application in its present form and requested additional information from the Company.

On March 28, 2016 the FDA denied the Company's request for seven years of orphan drug exclusivity in the U.S., for EP-3102 Bendeka.

On March 29, 2016, the Company entered into an asset purchase agreement (the "Diclofenac Asset Purchase Agreement") pursuant to which the Company sold certain intellectual property related to diclofenac-misoprostol in the United States. In consideration of the assets and rights sold under the Diclofenac Asset Purchase Agreement, the Company received a one-time payment at closing of $1.75 million which was recognized a gain in the first quarter of 2016. In consideration of the rights granted under the agreement, the purchaser will pay the Company a 25% royalty on net profits of diclofenac-misoprostol in the territory for five years from the date of sale. The Company may continue to market diclofenac-misoprostol until such time that the purchaser is able to launch the product.

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 FINANCIAL STATEMENTS (Continued)
(In thousands, except share and per share amounts)
(Unaudited)

Accounting Guidance Not Yet Adopted

In May 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (ASU 2014-09), which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP.

In July 2015, the FASB finalized a one year delay in the effective date of this standard, which will now be effective for us on January 1, 2018, however early adoption is permitted any time after the original effective date, which for us is January 1, 2017. We have not yet selected a transition method and are currently evaluating the impact of ASU 2014-09 on our financial statements.

In November 2015, the FASB issued ASU 2015-17, which revises the guidance in ASC 740, Income Taxes, to simplify the presentation of deferred income taxes and require that deferred tax liabilities and assets be classified as non-current in the statement of financial position. The guidance is to be applied either prospectively or retrospectively, and is effective for reporting periods (interim and annual) beginning after December 15, 2016 for public companies. Early adoption is permitted. The implementation of this ASU is not expected to have a material impact on our financial position or results of operations.

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. We are currently assessing the potential impact of this ASU on our financial position and results of operations.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, Leases. The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement.

The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available.

In March 2016, the FASB issued ASU 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The amendments are intended to improve the accounting for employee share-based payments and affect all organizations that issue share-based payment awards to their employees. Several aspects of the accounting for share-based payment award transactions are simplified, including: (a) income tax consequences; (b) classification of awards as either equity or liabilities; and (c) classification on the statement of cash flows. For public companies, the amendments are effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. For private companies, the amendments are effective for annual periods

beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018. Early adoption is permitted for any organization in any interim or annual period. The Company is currently assessing the impact that this standard will have on our financial position and results of operations.

In March 2016, the FASB issued ASU 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net). The amendments relate to when another party, along with the entity, is involved in providing a good or service to a customer. Topic 606 Revenue from Contracts with Customers requires an entity to determine whether the nature of its promise is to provide that good or service to the customer (i.e., the entity is a principal) or to arrange for the good or service to be provided to the customer by the other party (i.e., the entity is an agent). The amendments are intended to improve the operability and understandability of the implementation guidance on principal versus agent considerations The effective date and transition of these amendments is the same as the effective date and transition of ASU 2014-09, Revenue from Contracts with Customers (Topic 606). Public entities should apply the amendments in ASU 2014-09 for annual reporting

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

periods beginning after December 15, 2017, including interim reporting periods therein (i.e., January 1, 2018, for a calendar year entity). The Company is currently assessing the impact that this standard will have on our financial position and results of operations.

The Company is currently evaluating the impact of its pending adoption of the new standard on its financial statements.

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 of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, accounts receivable, and accounts payable. The carrying values of these financial instruments approximate their fair values due to their short term maturities.

Short Term Investments

Investments consisted of U.S. Treasury securities that have an original maturity of greater than three months and typically less than 180 days. The Company's investments were classified as Level 1 and available-for-sale and are recorded at fair value, based upon quoted market prices. No gains or losses on investments are realized until the sale occurs or a decline in fair value is determined to be other-than-temporary. If a decline in fair value is determined to be other-than-temporary, an impairment charge is recorded and a new cost basis in the investment is established.

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, short term investments, accounts receivable and accounts payable approximate fair value due to their life being short term in nature, and are classified as Level 1 at March 31, 2016 and December 31, 2015. The fair value of the contingent consideration/accrued royalty is classified as Level 3 at March 31, 2016.

The Company is required by U.S. GAAP to record certain assets and liabilities at fair value on a recurring basis.

Intangible Assets

The Company capitalizes and includes in intangible assets the costs of trademark, developed technology and customer relationships. Intangible assets are recorded at fair value at the time of their acquisition and stated net of accumulated amortization. The Company amortizes its intangible assets that have finite lives using either the straight-line or accelerated method, based on the useful life of

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

the asset over which it is expected to be consumed utilizing expected undiscounted future cash flows. Amortization is recorded over the estimated useful lives. The Company evaluates the realizability of its definite lived intangible assets whenever events or changes in circumstances or business conditions indicate that the carrying value of these assets may not be recoverable based on expectations of future undiscounted cash flows for each asset group. If the carrying value of an asset or asset group exceeds its undiscounted cash flows, the Company estimates the fair value of the assets, generally utilizing a discounted cash flow analysis based on the present value of estimated future cash flows to be generated by the assets using a risk-adjusted discount rate. To estimate the fair value of the assets, the Company uses market participant assumptions pursuant to ASC 820, Fair Value Measurements. If the estimate of an intangible asset’s revised useful life is changed, the Company will amortize the remaining carrying value of the intangible asset prospectively over the revised useful life.

Valuation of Acquisition-Related Contingent Consideration

Contingent consideration related to a business combination is recorded at 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 (probability-weighted), 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 remeasured 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 operations.

Concentration of Major Customers and Vendors

The Company is dependent on commercial partners to market and sell EP-1101 and EP-3102 Bendeka. The Company relies on its partner Teva to market EP-3102 Bendeka. The Company's customers for EP-1101 are its commercial and licensing partners, therefore, the Company's future revenues are highly dependent on these collaboration and distribution arrangements.

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

	Three Months Ended March 31,	
	2016	2015
Net revenues		
The Medicines Company	6 %	9 %
Sandoz, Inc.	2 %	3 %
Cephalon, Inc. (Teva) - See Revenue Recognition	61 %	83 %
Par Pharmaceuticals Companies, Inc. - See Note 11	20 %	— %
Other	11 %	5 %
	100%	100%

	March 31, 2016	December 31, 2015
Accounts receivable		
The Medicines Company	32 %	35 %
Sandoz, Inc.	1 %	— %

Cephalon, Inc. (Teva) - See Revenue Recognition	57	%	57	%
Other	10	%	8	%
	100	%	100	%

Currently, for EP 1101 and EP-3102 Bendeka, the Company uses one vendor as its sole source supplier. Because of the unique equipment and process for manufacturing these products, transferring manufacturing activities to an alternate supplier would be

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a time consuming and costly endeavor, and there are only a limited number of manufacturers that are capable of performing this function for the Company.

Inventory

Inventories, which consist of finished products, are 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 computed 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.

Impairment of Long-Lived Assets

Long-lived assets and certain identifiable finite-lived intangible assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Determination of recoverability of long-lived assets is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. Measurement of an impairment loss for long-lived assets and certain identifiable intangible assets that management expects to hold and use is based on the fair value of the asset. When an impairment loss is recognized, the carrying amount of the asset is reduced to its estimated fair value. There were no impairment charges recognized in three months ended March 31, 2016 and 2015.

Research and Development Expense

Costs incurred for research and product development, including costs incurred for technology in the development stage, are expensed as incurred. Clinical study costs are accrued over the service periods specified in the contracts and adjusted as necessary based upon an ongoing review of the level of effort and costs actually incurred. Advance payments for goods or services that will be used for future research and development activities are deferred and capitalized. Such amounts are recognized as an expense as the related goods are delivered or services performed.

Advertising and Marketing

Advertising and marketing costs are expensed as incurred. Advertising and marketing costs were $2,404 and $959 for the three months ended March 31, 2016 and 2015, respectively.

Accounting for Income Taxes

The Company accounts for deferred taxes using the asset and liability method as specified by ASC 740, Income Taxes. Deferred income tax assets and liabilities are determined based on differences between the financial statement reporting and the tax basis of assets and liabilities, operating losses and tax credit carryforwards. Deferred income taxes are measured using the enacted tax rates and laws that are anticipated to be in effect when the differences are expected to reverse. The measurement of deferred income tax assets is reduced, if necessary, by a valuation allowance for any tax benefits which are not expected to be realized. The effect on deferred income tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted.

During the three months ended March 31, 2016 and 2015, the Company recorded an income tax provision of $19 and $399, respectively based upon its estimated federal AMT and state tax liability.

Revenue Recognition

Product revenue — The Company recognizes net revenue from EP-1101 and EP-3102 Bendeka supplied to its commercial partners and Non-Alcohol Docetaxel Injection, Ryanodex and diclofenac-misoprostol (see Note 11 "Asset Sales"), supplied to the end user, when the following four basic revenue recognition criteria under the related accounting guidance are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and

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(4) collectability is reasonably assured. Prior to the shipment of manufactured products, the Company conducts initial product release and stability testing in accordance with cGMP. The Company's commercial partners can return the products within contracted specified timeframes if the products do not meet the applicable inspection tests. The Company estimates its return reserves based on its experience with historical return rates. Historically, product returns have not been material. The Company has a no return policy for Ryanodex.

Revenues from product sales to end users are recorded net of provisions for estimated chargebacks, rebates, returns (if applicable), prompt pay discounts and other deductions, such as shelf stock adjustments, which can be reasonably estimated. When sales provisions are not considered reasonably estimable by Eagle, the revenue is deferred to a future period when more information is available to evaluate the impact.

Royalties — The Company recognizes revenue from royalties based on its commercial partners' net sales of products. Royalties are recognized as earned in accordance with contract terms when they can be reasonably estimated and collectability is reasonably assured. The Company's commercial partners are obligated to report their net product sales and the resulting royalty due to the Company within 60 days 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 revenue — The Company analyzes each element of our licensing agreements to determine the appropriate revenue recognition. The terms of the license agreement may include payment to us of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. The Company recognizes revenue from upfront payments over the period of significant involvement under the related agreements unless the fee is in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation exists under the contract.

When a sale combines multiple elements upon performance of multiple services, the Company allocates revenue for transactions that include multiple elements to each unit of accounting based on its relative selling price, and recognizes revenue for each unit of accounting when the revenue recognition criteria have been met. The Company follows the selling price hierarchy as outlined in the guidance Revenue Recognition (ASC Topic 605) - Multiple-Deliverable Revenue Arrangements. The guidance provides a hierarchy to determine the selling price to be used for allocating revenue to deliverables: (i) vendor-specific objective evidence (“VSOE”), (ii) third-party evidence (“TPE”) if available and when VSOE is not available, and (iii) best estimate of the selling price (“BESP”) if neither VSOE nor TPE is available. The Company uses BESP to determine the standalone selling price for such deliverables. The Company has an established process for developing BESP, which incorporates pricing practices, historical selling prices, the effect of market conditions as well as entity-specific factors. Estimated selling price is monitored and evaluated on a regular basis to ensure that changes in circumstances are accounted for in a timely manner.

The Company recognizes milestone payments as revenue upon the achievement of specified milestones only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions are not met, we defer the milestone payment and recognize it as revenue over the estimated period of performance under the contract.

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 and is eligible to receive up to $25 million in additional milestone payments. 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 February 2015, as the Company substantially completed its requirements for obtaining regulatory approval, which consisted of filing a New Drug Application, or NDA, on February 13, 2015, and the remaining obligations were estimated to require minimal effort. On December 7, 2015, the FDA approved EP-3102 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 remaining milestones, if achieved, will be recognized in the period earned.

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In addition, the Company is entitled to royalty payments equal to 20% of net sales of the product. In connection with the Cephalon License, the Company agreed to enter into a supply agreement with Cephalon, pursuant to which the Company will be responsible for supplying product to Cephalon for a specified period.

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, and 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 operations. 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. The Company uses a Black-Scholes valuation model as the most appropriate valuation method for pricing these options. Awards for consultants are accounted for under ASC 505-50, Equity Based Payments to Non-Employees. Any compensation expense related to consultants is marked-to-market over the applicable vesting period as they vest. There are customary limitations on the sale or transfer of the stock.

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

	Three Months Ended March 31,	
	2016	2015
Risk-free interest rate	1.29% - 1.90%	1.63% - 1.92%
Volatility	31.31%	30.38%
Expected term (in years)	5.50 - 7.00 years	5.50 - 7.00 years
Expected dividend yield	0.0%	0.0%

The risk-free rate assumption was based on U.S. Treasury instruments whose term was consistent with the expected term of the stock options. The expected stock price volatility was determined by examining the historical volatilities for industry peers as the Company did not have sufficient trading history for its common stock. Industry peers consist of those companies in the pharmaceutical industry similar in size, stage of life-cycle and financial leverage. The expected term of stock options represents the average of the vesting period and the contractual life of the option for employees and the life of the option for consultants. The expected dividend assumption is based on the Company's history and expectation of future dividend payouts. Changes in the estimated forfeiture rates are reflected prospectively.

Earnings (Loss) Per Share

Basic earnings (loss) 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 (loss) per share, except that the weighted-average number of shares outstanding is increased to include all common shares, including those with the potential to be issued by virtue of warrants, options, convertible debt and other such convertible instruments. Diluted earnings per share contemplate a complete conversion to common shares of all convertible instruments only if they are dilutive in nature with regards to earnings per share.

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The anti-dilutive common shares equivalents outstanding at the three months ended March 31, 2016 and 2015 were as follows:

	Three Months Ended March 31,	
	2016	2015
Options	2,510,702	118,619
Total	2,510,702	118,619

The following table sets forth the computation for basic and diluted net income (loss) per share for the three months ended March 31, 2016 and 2015:

	Three Months Ended March 31,	
	2016	2015
Numerator		
Numerator for basic earnings per share-net (loss) income	$(896)	$ 19,697
Numerator for diluted earnings per share-net (loss) income	$(896)	$ 19,697
Denominator		
Basic weighted average common shares outstanding	15,636,387	14,247,019
Dilutive effect of stock options	—	793,992
Diluted weighted average common shares outstanding	15,636,387	15,041,011
Basic net (loss) income per share		
Basic net (loss) income per share	$(0.06)	$ 1.38
Diluted net (loss) income per share		
Diluted net (loss) income per share	$(0.06)	$ 1.31

Note 4. Acquisitions

Acquisition of Docetaxel-Injection, Non-Alcohol Formula

On October 13, 2015, the Company entered into the Teikoku Agreement with Teikoku to market, sell and distribute Non-Alcohol Docetaxel Injection, an investigational product intended for the treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma, and head and neck cancer. The NDA for Non-Alcohol Docetaxel Injection for these indications was approved by the FDA on December 22, 2015. Under the terms of the agreement, the Company paid an upfront cash payment of $250 upon execution of the agreement which was expensed in 2015 and was included in research and development expense and an additional payment of $4,850 upon FDA approval and NDA transfer to the Company which occurred on January 12, 2016. In addition, the Company will pay 25% royalties on gross profits. The Company accounted for the transaction as a purchase of a business in 2016, in accordance with FASB Accounting Standard Codification 805 Business Combinations.

The Company is in the process of finalizing the valuation of intangible assets and fair value of the contingent purchase price. As a result, the preliminary measurements of fair value of the contingent consideration payments on the acquisition date was $6,370 as of the acquisition date and the total amount capitalized as an intangible asset was $11,220. The Company estimated the fair value of this contingent consideration based on forecasted revenues reflecting the Company's own assumptions concerning future revenue from such product. 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.

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The following table represents a reconciliation of the change in the fair value measurement of the contingent consideration liability since acquisition through March 31, 2016 which was recorded in selling, general and administrative expense in the condensed statements of operations:

Opening Balance January 12, 2016	$6,370
Changes in fair value	159
Closing Balance March 31, 2016	$6,529

The following table displays the balance sheet classification of the contingent consideration liability account as of March 31, 2016 and the acquisition date, January 12, 2016:

	March 31, 2016	January 12, 2016
Accrued royalty payable	$1,012	$1,012
Long term royalty payable	5,517	5,358
Total acquisition related contingent consideration	$6,529	$6,370

The results of operations related to Docetaxel Non-Alcohol Injection have been included in the consolidated statements of income from the date of acquisition. Pro forma results of operations have not been presented because the effect of Docetaxel Non-Alcohol Injection was not material. The Company recorded product sales of Non-Alcohol Docetaxel Injection of $868 and a net loss of $867 in the three months ended March 31, 2016. The Company did not incur any significant acquisition related costs in connection with the Non-Alcohol Docetaxel injection acquisition. The fair value measurement of contingent consideration is based on significant inputs not observed in the market and thus represents a Level 3 measurement. 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.

5. Inventories

Inventories consist of the following:

	March 31, 2016	December 31, 2015
Raw material	$5,208	$ 8,687
Work in process	—	6,044
Finished products	2,553	311
	$7,761	$ 15,042

6. Balance Sheet Accounts

Prepaid and Other Current Assets

Prepaid and other current assets consist of the following:

	March 31, 2016	December 31, 2015
Prepaid expenses and other current assets		
Prepaid product costs	$134	$ 85

Prepaid FDA user fee	373	551
Prepaid insurance	651	218
Prepaid research and development	194	283
Prepaid income taxes	489	508
All other	207	220
Total Prepaid expenses and other current assets	$2,048	$ 1,865

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Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2016	December 31, 2015
Accrued expenses		
Royalties due to The Medicines Company	$7,166	$ 6,948
Royalties due to SciDose	1,474	1,637
Royalties due to Sandoz, Inc.	813	1,249
Accrued research & development	1,258	1,784
Accrued professional fees	817	792
Accrued salary and other compensation	1,149	2,242
Accrued product costs	5,918	9,232
Accrued other	428	—
Deferred rent	538	521
Total Accrued expenses	$19,561	$ 24,405

Deferred Revenue

Deferred revenue consists of the following:

	March 31, 2016	December 31, 2015
Deferred revenue		
Par Pharmaceuticals Companies, Inc. (See Note 11)	$ —	$ 5,500
Par Pharmaceuticals Companies, Inc./Tech Transfer	—	500
Deferred Revenue from Asset Sales	—	6,000
Total Deferred revenue	$ —	$ 6,000

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7. Intangible Asset

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

	March 31, 2016				December 31, 2015		
	Useful Life (In Years)	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Docetaxel product rights	18	$ 11,220	$ (104)	$ 11,116	$ —	$ —	$ —
Total	18	$ 11,220	$ (104)	$ 11,116	$ —	$ —	$ —

Amortization expense was $104 and $0 for three months ended March 31, 2016 and 2015, respectively.

Based on finite-lived intangible assets recorded as of March 31, 2016, and assuming the underlying assets will not be impaired and that the Company will not change the expected lives of the assets, future amortization expenses are estimated as follows:

	Estimated Amortization Expense
Year Ending December 31,	
2016 (remainder)	$ 468
2017	623
2018	623
2019	623
2020	623
All other	8,156
Total estimated amortization expense	$ 11,116

8. Common Stock and Stock-Based Compensation

In December 2007, the Company's board of directors approved the 2007 Incentive Compensation Plan (the "2007 Plan") enabling the Company to grant multiple stock based awards to employees, directors and consultants, the most common being stock options and restricted stock awards. In November 2013, the Company's board of directors approved the 2014 Equity Incentive Plan (the "2014 Plan") which became effective on February 11, 2014. The 2007 Plan was terminated upon the effectiveness of the 2014 Plan and all shares available for issuance under the 2007 Plan were made available under the 2014 Plan. The 2014 Plan provides for the awards of incentive stock options, non-qualified stock options, restricted stock, restricted stock units and other stock-based awards. Awards generally vest equally over a period of four years from grant date. Vesting is accelerated under a change in control of the Company or in the event of death or disability to the recipient. In the event of termination, any unvested shares or options are forfeited. At the Company's annual meeting of stockholders held on August 4, 2015, the stockholders approved an amendment to the 2014 Plan to, among other things, increase the number of shares of common stock authorized for issuance thereunder by 500,000 shares. After accounting for such increase, the Company has reserved and made available 2,035,598 shares of common stock for issuance under the 2014 Plan.

The Company recognized share-based compensation in its statements of operations for the three months ended March 31, 2016 and 2015 as follows:

	Three Months

	Ended March 31,	
	2016	2015
Selling, general and administrative	$2,162	$200
Research and development	707	184
Total	$2,869	$384

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9. Commitments

At March 31, 2016, the Company has purchase obligations in the amount of $21,345 which represent 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.

The Company leases its office space under a lease agreement that expires on June 30, 2020. Rental expense was $162 and $68 for the three months ended March 31, 2016 and 2015, respectively. The future lease payments under the operating lease are $2,396 as of March 31, 2016, payable monthly through June 30, 2020.

	Total	2016	2017	2018	2019	2020	Beyond
Operating lease obligations	$2,396	423	564	564	564	281	—
Purchase obligations	$21,345	21,345					

10. Legal Proceedings

Claims and lawsuits may be filed against the Company from time to time. Although the results of pending claims are always uncertain, the Company believes that it has adequate reserves or adequate insurance coverage in respect of these claims, but no assurance can be given as to the sufficiency of such reserves or insurance coverage in the event of any unfavorable outcome resulting from such actions.

In September 2013, the Company filed an NDA under Section 505(b)(2) for EP-3101(bendamustine RTD) ("EP-3101"), the Company's bendamustine hydrochloride injection, in a ready-to-dilute concentrate solution, product ("bendamustine RTD") and notified Cephalon, the holder of Treanda®, the referenced approved drug in our application, of the Company's 505(b)(2) filing and paragraph IV certification. Cephalon filed a patent infringement lawsuit against the Company in the United States District Court for the District of Delaware on October 21, 2013 to defer the approval of the bendamustine indication alleging that the Company's tentatively approved bendamustine hydrochloride injection infusion product infringes one of its patents, U.S. Patent No. 8,445,524 (the "First Cephalon Lawsuit").

In July 2014, the FDA had granted tentative approval and orphan drug designation to the Company’s NDA for patented bendamustine RTD for the treatment of NHL.

In September 2014, Cephalon moved to dismiss with prejudice the First Cephalon Lawsuit.

On August 12, 2014, Cephalon filed a second lawsuit in the District of Delaware alleging that bendamustine RTD infringes Cephalon’s newly-issued U.S. Patent No. 8,791,270 (the "Second Cephalon Lawsuit").

On February 13, 2015, the Company and Cephalon entered into the Cephalon Settlement Agreement pursuant to which the parties agreed to settle the Second Cephalon Lawsuit, under which the Company has agreed to enter into the Consent Judgment regarding the ‘270 patent. As part of the Cephalon Settlement Agreement, Cephalon has agreed to waive its orphan drug exclusivities for the treatment of patients with chronic lymphocytic leukemia and patients with indolent B-cell non-Hodgkin lymphoma with EP-3102 Bendeka.

In February 2016, The Medicines Company (“MDCO”) filed a complaint against the Company, SciDose LLC and TherDose Pharma Pvt. Ltd. (collectively the “Defendants”) relating to the Defendants’ work on a novel ready-to-use bivalirudin injection product (the “Bivalirudin Product”). The suit cites the May 7, 2008 License and Development Agreement (the “LDA”) between the Defendants and MDCO. In the lawsuit, MDCO alleges that the Company violated the terms of the LDA by, inter alia, developing the Bivalirudin Product, and that the Company's Bivalirudin Product infringes two patents that are jointly-owned by the Company and MDCO and violates an exclusive license that MDCO claims exists under the LDA. The Company disputes the allegations and believes it has meritorious defenses

to all of MDCO's allegations.

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 EP-3102 Bendeka for the treatment of CLL and indolent B-cell NHL. The Company believes EP-3102 Bendeka is entitled to orphan drug exclusivity as a matter of law, and that the FDA's decision violates federal law and is inconsistent with the holding of the U.S. District Court

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for the District of Columbia in Depomed Inc. v. U.S. Department of Health and Human Services. The FDA has not yet responded to the Company's complaint.

11. Asset Sales

During fiscal year 2010 and 2011, the Company divested another non-core product and received proceeds of $6,500, comprised of $5,500 as a signing milestone which was previously recorded in deferred revenues and $500 for the initiation of Tech Transfer of which $250 previously remained in deferred revenues and a second payment of $500 for the completion of the Tech Transfer of which $250 previously remained in deferred revenues. Under the terms of this agreement, the licensor must obtain all of the following milestones with regard to the filing of the product in order for the Company to earn the revenues. These milestones are a) the receipt of an approval letter from the FDA, b) acknowledgment from the FDA that no further clinical studies will be needed and c) an approval letter from the FDA.

The Company, through various requests for information, was informed by the licensor in 2016 that it had voluntarily withdrawn the filing of the product application from the FDA in a prior year. Under the terms of the agreement, the milestones required to earn the $6,000 previously included in deferred revenue, were with regard to the filing. The voluntary withdrawal of the filing by the licensor relieved the Company of further obligation with regard to performance under the milestones. During the quarter ended March 31, 2016, the Company recognized the $6,000 as Other revenue.

On March 29, 2016, the Company entered into the Diclofenac Asset Purchase Agreement pursuant to which the Company sold certain intellectual property related to diclofenac-misoprostol in the United States. In consideration of the assets and rights sold under the Diclofenac Asset Purchase Agreement, the Company received a one-time payment at closing of $1.75 million, which was recognized as a gain in the first quarter of 2016. In consideration of the rights granted under the Diclofenac Asset Purchase Agreement, the purchaser will pay the Company a 25% royalty on net profits of diclofenac-misoprostol in the territory for five years from the date of sale. The Company may continue to market diclofenac-misoprostol until such time that the purchaser is able to launch.

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, filed with the SEC on February 29, 2016.

Forward-Looking Information

This Quarterly Report on Form 10-Q contains forward-looking statements, that involve risk and uncertainties. The words "may," "will," "plan," "believe," "expect," "intend," "anticipate," "potential," "should," "estimate," "predict," "project," 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 below, under Part II, Item 1A. See "Risk Factors" and elsewhere herein. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. We undertake no obligation to revise or update any forward-looking statements for any reason.

Overview

We are a specialty pharmaceutical company focused on developing and commercializing injectable products utilizing the U.S. Food and Drug Administration's ("FDA's") 505(b)(2) regulatory pathway. Our business model is to develop proprietary innovations to FDA-approved, injectable drugs that offer longer commercial duration at attractive prices. For each of our products, we intend to enter the market no later than the first generic drug, allowing us to substantially convert the market to our product by addressing the needs of stakeholders who ultimately use our products. We believe we can further extend commercial duration through new intellectual property protection and/or orphan drug exclusivity and three years of regulatory exclusivity as provided under the Hatch-Waxman Act, as applicable.

Our product portfolio now includes five approved products: EP-1101 (argatroban) (“EP-1101”), Ryanodex®(dantrolene sodium) (“Ryanodex”), docetaxel injection, non-alcohol formulation (“Non-Alcohol Docetaxel Injection”), diclofenac-misoprostol, and EP-3102 (rapidly infused bendamustine RTD) (“EP-3102 Bendeka”). We have three commercial partners: Teva Pharmaceutical Industries Ltd. ("Teva"), who through their subsidiary Cephalon, Inc. ("Cephalon"), markets EP-3102 Bendeka, The Medicines Company (“MDCO”) and Sandoz Inc. (“Sandoz”), who pursuant to separate agreements market EP-1101. Our recently approved EP-3102 Bendeka was commercially launched by Teva in January 2016.

We intend to market and commercialize certain of our products through our recent co-promotion agreement with Spectrum Pharmaceuticals, Inc. ("Spectrum") while continuing to grow our commercial organization.
We currently have four product candidates in advanced stages of development, and/or under review for approval by the FDA. Additionally, we have other exploratory candidates under a collaborative agreement entered into in January 2016 with Albany Molecular Research, Inc. ("AMRI"). Our four advanced candidates are EP-3101 (bendamustine RTD) ("EP-3101"), EP-6101 Kangio™ ready-to-use ("RTU") bivalirudin ("EP-6101 Kangio"), EP-4104 (dantrolene sodium) (“EP-4104”) for exertional heat stroke ("EHS"), and EP-5101 (pemetrexed) (“EP-5101”). Our leading near-term product candidate is EP-6101 Kangio™, a patented liquid intravenous form of Angiomax for percutaneous transluminal angioplasty. In March of 2016 we received a Complete Response Letter from the FDA stating that while their initial review of our New Drug Application, or NDA, for EP-6101 Kangio was complete, they could not approve the application in its present form and are requesting additional information. We are working with the FDA to provide the additional requested information. EP-3101 is tentatively approved and we may begin commercializing in May 2016. Both EP-5101 and the potential label expansion of Ryanodex into EHS may address unmet medical needs in major specialty markets.

Recent Developments
On January 20, 2015, our board of directors authorized a change in our fiscal year end from September 30, 2014 to December 31, 2014. The change was intended to better align our fiscal year with the business cycles of other specialty pharmaceutical companies. As a result of the change starting in fiscal year 2015, our 2015 fiscal year began on January 1 and ended on December 31.

On February 13, 2015, we submitted an NDA to the FDA for EP-3102 Bendeka which was approved by the FDA on December 7, 2015. Also, on February 13, 2015, we entered into an Exclusive License Agreement (the "Cephalon License") with Cephalon, Inc. for U.S. and Canadian rights to EP-3102 Bendeka for treatment of patients with CLL and patients with NHL. Pursuant to the terms of the Cephalon License, Cephalon is responsible for all U.S. commercial activities for the product including promotion and distribution, and we are responsible for obtaining and maintaining all regulatory approvals and conducting post-approval clinical studies. Additionally, under the terms of the Cephalon License, we received an upfront cash payment of $30 million, received a $15 million milestone payment in January 2016, related to the FDA approval of EP-3102 Bendeka in December 2015 and are currently eligible to receive up to $25 million in additional milestone payments. In addition, we are entitled to receive royalty payments of 20% of net sales of the product. In connection with the Cephalon License, we have entered into a supply agreement with Cephalon, pursuant to which we will be responsible for supplying product to Cephalon for a specified period.

In connection with the Cephalon License, on February 13, 2015, we entered into a Settlement and License Agreement (the "Cephalon Settlement Agreement") with Cephalon, pursuant to which the parties agreed to settle the pending patent infringement claims against each other regarding Cephalon's US Patent No. 8,791,270, under which we agreed to enter into a Consent Judgment regarding the ‘270 patent. As part of the Cephalon Settlement Agreement, Cephalon has agreed to waive its orphan drug exclusivities for the treatment of patients with CLL and patients with NHL with EP-3102 Bendeka.

On March 20, 2015, we completed an underwritten public offering (the "Follow-on Offering") of 1,518,317 shares of common stock, including the exercise by the underwriters of a 30-day option to purchase an additional 198,041 shares

of common stock. Of the shares sold, 1,388,517 shares were issued and offered by the Company and 129,800 shares were offered by certain selling stockholders. All of the shares were offered at a price to the public of $42.00 per share. The net proceeds from this offering, after deducting underwriting discounts and commissions and other offering expenses payable by us, were approximately $54.3 million. We did not receive any proceeds from the shares sold by the selling stockholders. The securities described above were offered by us pursuant to a shelf registration statement declared effective by the SEC on March 13, 2015.

On April 7, 2015 and May 19, 2015, the United States Patent and Trademark Office (“USPTO”) granted us Patents No. 9,000,021 and No. 9,034,908 for our rapid infusion bendamustine, for treating patients requiring restricted fluid and/or sodium intake. These patents extend to March 2033.

On May 20, 2015, we submitted an NDA to the FDA for our ready-to-use Bivalirudin product which was accepted for filing by the FDA. On March 18, 2016, we received a Complete Response Letter from the FDA for our NDA for EP-6101 Kangio stating

that the FDA could not approve the application in its present form and requested additional information. We are currently working with the FDA to provide the requested information.

On September 29, 2015, the USPTO granted us Patent No. 9,144,568, which pertains to the use of EP-3102 Bendeka. The patent extends to March 2033.

On October 13, 2015, we entered into an exclusive U.S licensing agreement (the "Teikoku Agreement"), whereby Teikoku Pharma USA, Inc. ("Teikoku") granted to us a royalty-bearing, exclusive right and license under and to Teikoku's patent rights and know how to make, use, market, commercialize, and offer for sale Non-Alcohol Docetaxel Injection described in NDA 205934. Pursuant to the agreement, and after the FDA's approval of NDA 205934 which happened on December 22, 2015, Teikoku also assigned NDA 205934 to us. In consideration for the license and assignment, we made an upfront payment to Teikoku upon signing and an additional milestone payment of $4.85 million upon Teikoku's submission of the NDA transfer letter to the FDA in February 2016. In addition, we will pay to Teikoku a royalty based on the gross margin generated by the product which was launched in February 2016. The royalty owed to Teikoku will be reduced by a double-digit percentage for any sales in a period during which the product is not covered by a valid claim within the Teikoku patent rights. We accounted for the transaction as a business combination and are in the process of finalizing the valuation of intangible assets and fair value of the contingent purchase price. As a result, the preliminary measurements of intangible assets are subject to change. The results of Non-Alcohol Docetaxel Injection operations have been included in the consolidated statements of income from the date of acquisition. The Company did not incur any significant acquisition related costs in connection with the Non-Alcohol Docetaxel acquisition.

On November 4, 2015, we entered into a co-promotion agreement with Spectrum (the "Spectrum Agreement"), under which Spectrum's 32-person Corporate Accounts Sales Team will dedicate 80% of its time to selling and marketing up to six of the Company's products over a period of at least 18 months. We will pay Spectrum a base fee of $12.8 million over 18 months, and additional payments of up to $9 million if specified targets for annual net sales of our products are met during the initial term of the Spectrum Agreement, for a potential total payment of up to $21.8 million during the initial term. We may extend the initial term of this agreement by six months to December 31, 2017 at our sole election. Any extensions after December 31, 2017 require mutual consent and will be for six months per extension.

In addition to the services provided through the Spectrum Agreement and in line with our long-term strategy to build an internal commercial team, we hired approximately 12 direct sales representatives that will be a part of our independent commercial organization. These representatives will be managed under the Spectrum sales team infrastructure for the duration of the Spectrum Agreement.

On January 11, 2016, we entered into an agreement with AMRI to jointly develop and manufacture several select and complex parenteral drug products for registration and subsequent commercialization in the United States. Under the terms of the agreement, AMRI will develop and initially provide cGMP manufacturing and analytical support for the registration of the new product candidates and the cost are to be shared, 37.5% paid by Eagle and 62.5% paid by AMRI. We will be responsible for advancing the product candidates through clinical trials and regulatory submissions.

On March 29, 2016, we entered into an asset purchase agreement (the "Diclofenac Asset Purchase Agreement") pursuant to which we sold certain intellectual property related to diclofenac-misoprostol in the United States. In consideration of the assets and rights sold under the Diclofenac Asset Purchase Agreement, we received a one-time payment at closing of $1.75 million. We recognized a gain in the first quarter of 2016 of $1.75 million on the sale of diclofenac-misoprostol. In consideration of the rights granted under the agreement, the purchaser will pay us a 25% royalty on net profits of diclofenac-misoprostol in the territory covered in the agreement for five years from the date of sale. We may continue to market diclofenac-misoprostol until such time that the purchaser is able to launch the product.

On July 2, 2014, the FDA granted us orphan drug designations for EP-3102 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. If granted, orphan drug exclusivity for Bendeka would run for seven years from December 7, 2015, the date Bendeka was approved. However, the FDA issued a letter decision to us on March 24, 2016, taking the position that Bendeka is not currently eligible for orphan drug exclusivity because it has not been demonstrated to be clinically superior to the drug previously approved for the same indications. In April 2016, we filed a lawsuit against the FDA (see Legal Proceedings).

Financial Operations Overview

Revenue

Revenue includes product sales, royalty income and license and other income. Revenue results are difficult to predict, and any shortfall in revenue or delay in recognizing revenue could cause operating results to vary significantly from quarter to quarter and year to year.

We recognize revenues from product sales of EP-3102 Bendeka, Ryanodex, EP-1101, Non-Alcohol Docetaxel Injection, and diclofenac-misoprostol. Sales of EP-3102 Bendeka are sold to our commercial partner Teva. Non-Alcohol Docetaxel Injection, launched in February 2016 and diclofenac-misoprostol, launched in January 2015, are sold directly to wholesalers, hospitals and surgery centers through a third party logistics partner and EP-1101 is sold directly to our commercial partners. Sales to our commercial partners are typically made at little or no profit for resale. Diclofenac-misoprostol was divested in March 2016, and we may continue to market diclofenac-misoprostol until such time that the purchaser is able to launch the product.

Royalty Income. We recognize revenue from royalties based on Teva's net sales of EP-3102 Bendeka from Teva and Sandoz and MDCO's nest sales of EP-1101, typically calculated as a percentage of the net selling price, which is net of discounts, returns and allowances incurred by our commercial partners. Royalty income is recognized as earned in accordance with contract terms when it can be reasonably estimated and collectability is reasonably assured. Pursuant to the divestiture of diclofenac-misoprostol, we will receive a 25% royalty on net profits from the purchaser.

License and other income. We recognize license revenue from Teva related to EP-3102 Bendeka.

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.

Currently, our product sales are from EP-3102 Bendeka, Non-Alcohol Docetaxel Injection, EP-1101, Ryanodex and diclofenac-misoprostol, and royalty income is derived from the sale of EP-3102 Bendeka through our commercial partner Teva, and EP-1101 to, and the resale by, two commercial partners, Sandoz and MDCO. The primary factors that determine our revenues derived from EP-3102 Bendeka are:

- the rate at which Teva can convert the current market to Bendeka
- the level of institutional demand
- unit sales prices; and
- the level of orders submitted by wholesalers, hospitals and surgery centers;

The primary factors that may determine our revenues derived from EP-1101 are:

- the level of orders submitted by our commercial partners, Sandoz and MDCO;
- the level of institutional demand for EP-1101;
- unit sales prices; and
- the amount of gross-to-net sales adjustments realized by our marketing partners.

The primary factors that may determine our revenues derived from Ryanodex and Non-Alcohol Docetaxel Injection and our future products are:

- the effectiveness of our contracted sales force and co-promotion partner, Spectrum;
- the level of orders submitted by wholesalers, hospitals and surgery centers;
- the level of institutional demand for our products;
- unit sales prices; and
- the amount of gross-to-net sales and chargebacks.

Chargebacks. We typically enter into agreements with group purchasing organizations acting on behalf of their hospital members, in connection with the hospitals' purchases of products. Based on these agreements, most of our hospital customers have the right to receive a discounted price for products and volume-based rebates on product purchases. In the case of discounted pricing, we typically receive a chargeback, representing the difference between the contract acquisition list price and the discounted price.

Cost of Revenue

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, as well as royalty expense. Cost of revenue may also include the effects of product recalls, if applicable.

Research and Development

Our research and development expenses consist of expenses incurred in developing, testing, manufacturing and seeking regulatory approval of our product candidates, including: expenses associated with regulatory submissions, clinical trials and manufacturing, including additional expenses in preparing for the commercial manufacture of products including Ryanodex (launched in August 2014), EP-3101, EP-3102 Bendeka, EP-4104, EP-5101, and EP-6101 Kangio™ and and Non-Alcohol Docetaxel Injection; payments made to third-party clinical research organizations, contract laboratories and independent contractors; payments made to consultants who perform research and development on our behalf and assist us in the preparation of regulatory filings; payments made to third-party investigators who perform research and development on our behalf and clinical sites where such research and development is conducted; expenses incurred to maintain technology licenses; and facility, maintenance, allocated rent, utilities, depreciation and amortization and other related expenses. Additionally, expenses include salaries, benefits and other related costs, including stock-based compensation for research and development personnel.

Clinical trial expenses for our product candidates are and will continue to be a significant component of our research and development expenses. Product candidates in later stage clinical development generally have higher research and development expenses than those in earlier stages of development. We coordinate clinical trials through a number of contracted investigational sites and recognize the associated expense based on a number of factors, including actual and estimated subject enrollment and visits, direct pass-through costs and other clinical site fees.

We expect to incur additional research and development expenses as we accelerate the development of our product portfolio, both internally and through our joint development agreement with AMRI, as applicable. These expenditures are subject to numerous uncertainties regarding timing and cost to completion. Completion of clinical trials may take several years or more and the length of time generally varies according to the type, complexity, novelty and intended use of a product candidate.

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, selling and operations personnel. Included in selling costs are expenses related to our contracted sales organization and marketing related to the product launch of Non-Alcohol Docetaxel Injection in early 2016. General and administrative expenses include facility and related costs, professional fees for legal, consulting, tax and accounting services, insurance, selling, market research, advisory board and key opinion leaders, depreciation and general corporate expenses.

We expect that our selling, general and administrative expenses will increase with the potential of further commercialization of our product candidates particularly as we begin to commercialize our products through our co-promotion agreement with Spectrum and continue to grow our commercial organization.

Other Income and Expense

Other income (expense) consists primarily of interest income, interest expense and changes in value of our warrant liability. Interest income consists of interest earned on our cash and cash equivalents. Interest expense consists primarily of cash and non-cash interest costs related to our issuance of convertible notes, including the amortization of debt discounts and deferred financing costs.

Results of Operations

Comparison of Three Months Ended March 31, 2016 and 2015

Revenues

	Three Months Ended March 31,		Increase/(Decrease)
	2016	2015	
	(in thousands)		
Product sales	$14,122	$3,056	$ 11,066
Royalty income	9,469	3,253	6,216
License and other income	6,000	30,000	(24,000)
Total revenue	$29,591	$36,309	$ (6,718)

Total revenue decreased $6.7 million in the three months ended March 31, 2016 to $29.6 million as compared to $36.3 million in the three months ended March 31, 2015.

Product sales increased $11.1 million in the three months ended March 31, 2016 to $14.1 million as compared to $3.0 million in the three months ended March 31, 2015. This increase was due to $10.3 million in net product sales of Bendeka (launched in January 2016), $0.9 million in net product sales of Non-Alcohol Docetaxel Injection (launched in February 2016), an increase of $0.4 million in net product sales of diclofenac-misoprostol (launched in January 2015), and an increase of $0.3 million in net product sales of Ryanodex (launched in August 2014). These increases were offset by a decrease in Argatroban product sales of $0.8 million.

Royalty income increased $6.2 million in the three months ended March 31, 2016 to $9.5 million as compared to $3.3 million in the three months ended March 31, 2015, as a result of the launch of EP-3102 Bendeka in January 2016.

License and other income decreased $24.0 million in the three months ended March 31, 2016 to $6.0 million as compared to $30.0 million in the three months ended March 31, 2015 as a result of the upfront cash payment upon entering the Cephalon License. License and other income for the three months ended March 31, 2016 was comprised of $6.0 million earned from an asset sale in fiscal 2010 that was previously recorded as deferred revenue.

Cost of Revenue

	Three Months Ended March 31,		Increase
	2016	2015	
	(in thousands)		
Cost of revenue	$14,589	$5,948	$ 8,641

Cost of revenue increased by $8.6 million to $14.5 million in the three months ended March 31, 2016 from $5.9 million in the three months ended March 31, 2015. This $8.6 million net increase resulted from $0.3 million in cost of revenue for Non-Alcohol Docetaxel Injection (launched in February 2016), an increase of $10.3 million related to the cost of EP-3102 Bendeka product sales (launched in January 2016), and an increase of $0.2 million in cost of revenue for diclofenac-misoprostol (launched in January 2015). These increases were offset by a decrease of $0.9 million in cost of revenue for Ryanodex (launched in August 2014) due to spoiled inventory, and a decrease of $1.3 million in EP-1101 cost of revenue due to decreased product sales.

Research and Development

	Three Months Ended March 31,		Increase/ (Decrease)
	2016	2015	
	(in thousands)		
EP-6101 Kangio™ (bivalirudin)	$3,106	$797	$ 2,309
EP-3101 (bendamustine RTD)	25	731	(706)
EP-3102 Bendeka (bendamustine rapid infusion)	134	2,646	(2,512)
EP-4104 (dantrolene sodium)	764	226	538
EP-5101 (pemetrexed)	242	457	(215)
Diclofenac-misoprostol	—	18	(18)
All other projects	242	62	180
Salary and other personnel related expenses	2,163	1,348	815
Total Research and Development	$6,676	$6,285	$ 391

Research and development expenses increased $0.4 million in the three months ended March 31, 2016 to $6.7 million as compared to $6.3 million in the three months ended March 31, 2015. Expenses in the three months ended March 31, 2016 were higher than in the three months ended March 31, 2015 as a result of an increase in project spending for the successful completion of the clinical treatment portion of the safety and efficacy study of EP-4104 (dantrolene sodium) for exertional heatstroke, and an increase in project spending for EP-6101 Kangio. Salary and other personnel-related expenses increased due to increased staffing and higher overall compensation costs. The increased spending for these projects was offset by a decrease in project spending for EP-3101 and EP-3102 Bendeka due to product approval in December 2015.

Selling, General and Administrative

	Three Months Ended March 31,		Increase
	2016	2015	
	(in thousands)		
Selling, general and administrative	$10,973	$3,986	$ 6,987

Selling, general and administrative expenses increased $7.0 million in the three months ended March 31, 2016 to $11.0 million as compared to $4.0 million in the three months ended March 31, 2015. This increase is related to a $1.4 million increase in sales and marketing expenses, $3.4 million increase in selling, general and administrative salary and personnel related expenses, $1.3 million increase in professional fees, $0.2 million increase in facilities expenses, $0.2 million increase in travel expenses, $0.2 million increase related to interest related to the acquisition of Non-Alcohol Docetaxel Injection and $0.3 million increase in miscellaneous expenses.

Gain on sale of asset

On March 29, 2016, we entered into the Diclofenac Asset Purchase Agreement pursuant to which we sold certain intellectual property related to diclofenac-misoprostol in the United States. In consideration of the assets and rights sold under the Diclofenac Asset Purchase Agreement, we received a one-time payment at closing of $1.75 million included in operating expenses.

Other Income (Expense)

	Three Months Ended March 31,	Increase

	2016	2015	
	(in thousands)		
Interest income	$21	$ 7	$ 14
Interest expense	(1)	(1)	—
Total other income/(expense), net	$20	$ 6	$ 14

Other income and expense increased by $14 thousand in the three months ended March 31, 2016 to income of $20 thousand as compared to income of $6 thousand in the three months ended March 31, 2015. The increase in other income and expense was due to the increase in interest income.

Income Tax Benefit

In the three months ended March 31, 2016 and 2015, the Company recorded an income tax provision of $19 thousand and $0.4 million, respectively, based upon its estimated federal AMT and state tax liability.

Net Income (Loss)

Net loss for the three months ended March 31, 2016 was $0.9 million as compared to net income of $19.7 million in the three months ended March 31, 2015, as a result of the factors discussed above.

Liquidity and Capital Resources

On March 20, 2015, we completed an underwritten public offering (the "Follow-on Offering") of 1,518,317 shares of common stock, including the exercise by the underwriters of a 30-day option to purchase an additional 198,041 shares of common stock. Of the shares sold, 1,388,517 shares were issued and offered by the Company and 129,800 shares were offered by certain selling stockholders. All of the shares were offered at a price to the public of $42.00 per share. The net proceeds from this offering, after deducting underwriting discounts and commissions and other offering expenses payable by us, were approximately $54.3 million. We did not receive any proceeds from the shares sold by the selling stockholders. The securities described above were offered by us pursuant to a shelf registration statement declared effective by the SEC on March 13, 2015.

Our primary uses of cash are to fund working capital requirements, product development costs and operating expenses. Historically, we have funded our operations primarily through public offerings of common stock and private placements of preferred stock and convertible notes and out-licensing product rights. Cash and cash equivalents were $78.3 million and $99.9 million as of March 31, 2016 and March 31, 2015, respectively.

For the three months ended March 31, 2016, we incurred a net loss of $0.9 million. As of March 31, 2016, we had a working capital surplus of $83.8 million. For the three months ended March 31, 2015, we realized net income of $19.7 million. We have sustained significant losses since our inception on January 2, 2007 and have accumulated a deficit of $108.0 million as of March 31, 2016.

We believe that future cash flows from operations, together with proceeds from the initial and follow-on public offerings will be sufficient to fund our currently anticipated working capital requirements through 2017. No assurance can be given that operating results will improve, out-licensing of products will be successful or that additional financing could be obtained on terms acceptable to us.

Operating Activities:

Net cash provided by operating activities for the three months ended March 31, 2016 was $3,108. Net loss for the period was $0.9 million offset by non-cash adjustments of approximately $1.5 million from depreciation, amortization of intangible assets, stock-based compensation expense, royalty interest related to the Non-Alcohol Docetaxel Injection acquisition and gain on sale of diclofenac-misoprostol. Net changes in working capital decreased cash from operating activities by approximately $2.5 million, due to an increase in accounts receivable of $0.3 million, an increase in prepaid expenses and other current assets of $0.2 million, an increase in accounts payable of $6.4 million, a decrease in other assets of $0.1 million, a decrease in inventories of $7.3 million, a decrease in deferred revenue of $6.0 million and a decrease in accrued expenses and other liabilities of $4.8 million. The total amount of accounts receivable at March 31, 2016 was approximately $26.5 million, which included approximately $10.5 million of product sales and approximately $16.0 million of royalty income, all with payment terms of 45 days. For royalty income, the 45-day period starts at the end of the quarter upon receipt of the royalty statement detailing the amount of sales in the prior completed quarter, and, for product sales, the period starts upon delivery of product.

At March 31, 2016, our cumulative receivables related to royalty income consisted of approximately $8.3 million in receivables from MDCO and $7.7 million in receivables from Cephalon.

Based on our agreement with MDCO, our cumulative receivables related to that agreement will continue to aggregate in future periods. Our agreement with MDCO does not contemplate the ability for the parties to net settle amounts

receivable or payable. Nonetheless, the Company has periodically collected from MDCO amounts that would be equal to the net amount of receivables due from MDCO, but, because it is unclear whether such cash receipt is intended to be settlement of the net receivable or only a partial payment towards the gross receivable, the Company has presented these receivables and payables in gross amounts on its condensed financial statements. As a result, the cumulative receivable from MDCO, as reduced by the cash received from MDCO, aggregates from period-to-period and has never been fully offset by those actual cash payments. At March 31, 2016, we recorded

a receivable of approximately $8.3 million and a payable of $7.2 million to MDCO (based upon a 50% revenue split on Sandoz sales). The net receivable due from MDCO for the quarter ended March 31, 2016 therefore is $1.1 million. The receivable of $1.1 million from MDCO as of March 31, 2016 therefore represents the net cumulative receivable of the Company.

We believe that our accounts receivable as of March 31, 2016, after taking into account netting of receivables and payables related to MDCO, are reasonably collectible, and given the payment terms, will be collected in approximately 90 days, and thus would not have a material effect on our liquidity.

Net cash provided by operating activities for the three months ended March 31, 2015 was $25.8 million. Net income for the period was $19.7 million offset by non-cash adjustments of approximately $0.7 million from depreciation, stock-based compensation expense and retirement of fixed assets. Net changes in working capital increased cash from operating activities by approximately $5.4 million, due to an increase in inventories of $(0.8) million, an increase in accounts payable of $1.9 million, an increase in deferred revenue of $0.1 million, and an increase in accrued expenses and other liabilities of $2.5 million. We experienced a decrease in accounts receivable of $1.4 million and a decrease in prepaid expenses and other current assets of $0.3 million. Accounts payable and accrued expenses increased primarily due to accrued royalties, accrued provision for income tax and accrued expenses related to the follow-on public offering. The total amount of accounts receivable at March 31, 2015 was approximately $10.5 million, which included approximately $1.3 million of product sales and approximately $9.2 million of royalty income, all with payment terms of 45 days. For royalty income, the 45-day period starts at the end of the quarter upon receipt of the royalty statement detailing the amount of sales in the prior completed quarter, and, for product sales, the period starts upon delivery of product.

Investing Activities:

In the three months ended March 31, 2016, we invested $0.8 million in purchases of property and equipment, invested and redeemed $62.0 million of short term investments. We purchased Non-Alcohol Docetaxel Injection for $4.8 million and divested diclofenac-misoprostol and received $1.8 million

In the three months ended and March 31, 2015, we invested $16.0 million, in short term investments and invested $43 thousand in the purchase of property and equipment.

Financing Activities:

Net cash provided by financing activities for the three months ended March 31, 2016 was $0. Net cash provided by financing activities for the three months ended March 31, 2015 was $55.3 million, primarily resulting from the issuance of Common Stock from the follow-on public offering of $54.7 million and stock option exercises of $0.6 million.

Contractual Obligations

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

	Total	2016	2017	2018	2019	2020	Beyond
Operating lease obligations	$2,396	423	564	564	564	281	—
Purchase obligations	$21,345	21,345					

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (ASU 2014-09), which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP.

In July 2015, the FASB finalized a one year delay in the effective date of this standard, which will now be effective for us on January 1, 2018, however early adoption is permitted any time after the original effective date, which for us is January 1, 2017. We have not yet selected a transition method and are currently evaluating the impact of ASU 2014-09 on our financial statements.

In November 2015, the FASB issued ASU 2015-17, which revises the guidance in ASC 740, Income Taxes, to simplify the presentation of deferred income taxes and require that deferred tax liabilities and assets be classified as non-current in the statement of financial position. The guidance is to be applied either prospectively or retrospectively, and is effective for reporting periods (interim and annual) beginning after December 15, 2016 for public companies. Early adoption is permitted. The implementation of this ASU is not expected to have a material impact on our financial position or results of operations.

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. We are currently assessing the potential impact of this ASU on our financial position and results of operations.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, Leases. The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement.

The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available.

In March 2016, the FASB issued ASU 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The amendments are intended to improve the accounting for employee share-based payments and affect all organizations that issue share-based payment awards to their employees. Several aspects of the accounting for share-based payment award transactions are simplified, including: (a) income tax consequences; (b) classification of awards as either equity or liabilities; and (c) classification on the statement of cash flows. For public companies, the amendments are effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. For private companies, the amendments are effective for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018. Early adoption is permitted for any organization in any interim or annual period. We are currently assessing the impact that this standard will have on our financial position and results of operations.

In March 2016, the FASB issued ASU 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net). The amendments relate to when another party, along with the entity, is involved in providing a good or service to a customer. Topic 606 Revenue from Contracts with Customers requires an entity to determine whether the nature of its promise is to provide that good or service to the customer (i.e., the entity is a principal) or to arrange for the good or service to be provided to the customer by the other party (i.e., the entity is an agent). The amendments are intended to improve the operability and understandability of the implementation guidance on principal versus agent considerations The effective date and transition of these amendments is the same as the effective date and transition of ASU 2014-09, Revenue from Contracts with Customers (Topic 606). Public entities should apply the amendments in ASU 2014-09 for annual reporting periods beginning after December 15, 2017, including interim reporting periods therein (i.e., January 1, 2018, for a calendar year entity). We are currently assessing the impact that this standard will have on our financial position and results of operations.

We are currently evaluating the impact of our pending adoption of the new standard on our financial statements.

No accounting standards or interpretations issued recently are expected to have a material impact on our financial position, operation or cash flow.

Off-Balance Sheet Arrangements

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

Impact of Inflation

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

Critical Accounting Policies and Estimates

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

and conditions. In addition, our reported financial condition and results of operations could vary due to a change in the application of a particular accounting standard.

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

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

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

Our significant accounting policies are more fully described in note 3 to our financial statements included in this quarterly report on Form 10-Q. Not all of these significant accounting policies, however, require that we make estimates and assumptions that we believe are “critical accounting estimates.” We have discussed our accounting policies with the audit committee of our board of directors, and we believe that our estimates relating to revenue recognition, accounting for fair value of warrant liabilities and share-based compensation described below are “critical accounting estimates.”

Revenue Recognition

Revenue recognition determines the timing of certain expenses, such as commissions and royalties. Revenue results are difficult to predict, and any shortfall in revenue or delay in recognizing revenue could cause operating results to vary significantly from quarter to quarter and year to year. Royalty revenues, based on net sales by licensees, are recorded as revenue for the period in which those sales are made by the licensees. License fees are recorded over the life of the license. Deferred revenue is recognized upon the achievement of milestones. Other deferred revenue is amortized over the life of the underlying agreement.

We recognize revenue in accordance with SEC Staff Accounting Bulletin, or SAB, No. 104, Revenue Recognition, and Statement of Financial Accounting Standards, or ASC 605, Revenue Recognition.

Product sales. We recognize net revenues from products manufactured and supplied to our commercial partners, when the following four basic revenue recognition criteria under the related accounting guidance are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. Prior to the shipment of our manufactured products, we conduct initial product release and stability testing in accordance with current good manufacturing practices, or cGMP. Our commercial partners can return the products within contracted specified timeframes if the products do not meet the applicable inspection tests. We estimate our return reserves based on our experience with historical return rates. Historically, our product returns have not been material.

Royalty income. We recognize revenue from royalties based on our commercial partners' net sales of products. Royalties are recognized as earned in accordance with contract terms when they can be reasonably estimated and collectability is reasonably assured. Our commercial partners are obligated to report their net product sales and the resulting royalty due to us within 60 days from the end of each quarter. Based on historical product sales, royalty receipts and other relevant information, we accrue royalty revenue each quarter and subsequently true-up when we receive royalty reports from our commercial partners.

Collaborative arrangements. We recognize revenue from reimbursements received in connection with feasibility studies and development work for third parties when our contractual services are performed, provided collectability is reasonably assured. Our principal costs under these arrangements include our personnel conducting research and development, and our allocated overhead, as well as research and development performed by outside contractors or consultants.

We recognize revenues from non-refundable up-front license fees received under collaboration arrangements ratably over the performance period as determined under the collaboration agreement (estimated development period in the case of development arrangements, and contract period or longest patent life in the case of supply and distribution arrangements). If the estimated performance period is subsequently modified, we will modify the period over which

the up-front license fee is recognized accordingly on a prospective basis. Upon termination of a collaboration agreement, any remaining non-refundable license fees received by us, which had been deferred, are generally recognized in full. All such recognized revenues are included in collaborative licensing and development revenue in our statements of operations. We recognize revenue from milestone payments received under collaboration arrangements when earned, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, we have no further performance obligations relating to the event and collectability is reasonably assured. If these criteria are not met, we recognize milestone payments ratably over the remaining period of our performance obligations under the collaboration agreement.

Stock-based compensation. We account for stock-based compensation under ASC, 718 "Accounting for Stock Based

Compensation." All stock-based awards granted to non-employees are accounted for at their fair value in accordance with ASC 718, and ASC 505, " Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services," under which compensation expense is generally recognized over the vesting period of the award. Determining the amount of stock-based compensation to be recorded requires us to develop estimates of fair values of stock options as of the grant date.

We account for stock-based compensation by measuring and recognizing compensation expense for all stock-based payments made to employees and directors based on estimated grant date fair values. We use the straight-line method to allocate compensation cost to reporting periods over each optionee's requisite service period, which is generally the vesting period. We estimate the fair value of our stock-based awards to employees and directors 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 and the fair value of the underlying common stock on the date of grant, among other inputs. The risk-free interest rate was 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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

During the three months ended March 31, 2016, 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 year ended December 31, 2015.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as such term is defined in Rule 13a-15(e) under the Securities Exchange Act

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

Based on their evaluation at March 31, 2016, 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 quarter ended March 31, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II-OTHER INFORMATION

Item 1. Legal Proceedings

The Medicines Company

In February 2016, MDCO filed a complaint against us, SciDose LLC and TherDose Pharma Pvt. Ltd. (collectively the "Defendants") relating to the Defendants' work on a novel ready-to-use bivalirudin injection product (the "Bivalirudin Product"). The suit cites the May 7, 2008 License and Development Agreement (the "LDA") between the Defendants and MDCO. In the lawsuit, MDCO alleges that we violated the terms of the LDA by, inter alia, developing the Bivalirudin Product, and that our Bivalirudin Product infringes two patents that are jointly-owned by us and MDCO and violates an exclusive license that MDCO claims exists under the LDA. We dispute the allegations and believe we have meritorious defenses to all of MDCO's allegations.

Eagle v. FDA

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 EP-3102 Bendeka for the treatment of CLL and indolent B-cell NHL. The Company believes EP-3102 Bendeka is entitled to orphan drug exclusivity as a matter of law, and that the FDA's decision violates federal law and is inconsistent with the holding of the U.S. District Court for the District of Columbia in Depomed Inc. v. U.S. Department of Health and Human Services. The FDA has not yet responded to the Company's complaint.

The Company cannot reasonably predict the outcome of these legal proceedings, nor can it estimate the amount of loss, or range of loss, if any, that may result from these proceedings. As such the Company is not currently able to estimate the impact of the above litigations on its financial position or results of operations.

Other

From time to time we are party to legal proceedings in the course of our business in addition to those described above. We do not, however, expect such other legal proceedings to have a material adverse effect on our business, financial condition or results of operations.

Item 1a. Risk Factors

Except for the risk factors set forth below, there have been no material changes from the Company's risk factors and uncertainties disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2015. For a complete discussion of the Company's risk factors, refer to Part I, Item 1A, "Risk Factors," contained in the Company's Annual Report on Form 10-K for the period ended December 31, 2015.

We have a history of operating losses and have only recently achieved profitability. If we cannot sustain profitability, our business, prospects, operating results and financial condition would be materially harmed.

To date, we have focused primarily on developing a broad product portfolio and have obtained regulatory approval for five products. Some of our product candidates will require substantial additional development time and resources before we would be able to receive regulatory approvals, implement commercialization strategies and begin generating revenue from product sales. Although we had net income of $2.6 million for the year ended December 31, 2015, we had a net loss of $(896) thousand for the three months ended March 31, 2016, and have incurred significant net losses prior to 2015. As of March 31, 2016, we had an accumulated deficit of $108 million.

We have devoted most of our financial resources to product development, and may not generate significant revenue from sales of our product candidates in the near-term, if ever. To date, only EP-1101, diclofenac-misoprostol, Ryanodex, Non-Alcohol Docetaxel Injection and EP-3102 Bendeka have been commercialized.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to fully predict the timing or amount of our expenses, but we expect to continue to incur substantial expenses, which

we expect to increase as we expand our development activities and product portfolio. As a result of the foregoing, we may incur losses and negative

cash flows in the future. We believe that our existing cash and cash equivalents, together with interest thereon, is sufficient to fund our operations for a minimum of twelve months.

Risks Related to Regulatory Approval

We cannot give any assurance that we will receive regulatory approval for our product candidates, which is necessary before they can be commercialized.

Our business and future success are substantially dependent on our ability to successfully and timely develop, obtain regulatory approval for, and commercialize our product candidates. Any delay or setback in the development of any of these product candidates could adversely affect our business. Our planned development, approval and commercialization of these product candidates may fail to be completed in a timely manner or at all. We cannot provide assurance that we will be able to obtain approval for any of our product candidates from the FDA or any foreign regulatory authority or that we will obtain such approval in a timely manner. For example, our leading near-term product candidate is EP-6101 Kangio, a patented liquid intravenous form of Angiomax for percutaneous transluminal angioplasty. In March of 2016 we received a Complete Response Letter from the FDA stating that while their initial review of our NDA for EP-6101 Kangio was complete, they could not approve the application in its present form and are requesting additional information. We are working with the FDA to provide the additional requested information, but there can be no assurance that the FDA will ultimately approve the NDA.

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

Our strategy is to have our drugs enter the market no later than the first generic to the applicable branded reference drug. We expect to compete against branded reference drugs and to compete with their generic counterparts that will be sold for a lower price. Although we believe that our products and product candidates will be clinically differentiated from branded reference drugs and their generic counterparts, if any, it is possible that such differentiation will not impact our market position. If we are unable to achieve significant differentiation for our products or product candidates against other drugs, the opportunity for our products and product candidates to achieve premium pricing and be commercialized successfully would be adversely affected. For example, in April 2016, CMS determined that the existing "J-Code" reimbursement for Treanda adequately describes EP-3102 Bendeka. A shared J-Code reimbursement could result in accelerated erosion of EP-3102 Bendeka pricing in the event of a generic Treanda market.

In addition to existing branded reference drugs and the related generic products, the FDA or other applicable regulatory authorities may approve generic products that compete directly with our products or product candidates, if approved. Once an NDA, including a 505(b)(2) application, is approved, the product covered thereby becomes a "listed drug" which can, in turn, be cited by potential competitors in support of approval of an ANDA. The FDCA, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as our products or product candidate and that the generic product is bioequivalent to ours, meaning it is absorbed in the body at the same rate and to the same extent as our products or product candidate. These generic equivalents, which must meet the same quality standards as branded pharmaceuticals, would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product is typically lost to the generic product. Accordingly, competition from generic equivalents of our products or product candidates would materially adversely impact our ability to successfully commercialize our product candidates or negatively impact our ability to gain market acceptance and market share for our products.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our

business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. To date, we have obtained regulatory approval for five products, and we have three product candidates in advanced stages of development and other exploratory candidates under a collaborative agreement entered into in January 2016. However, it is possible that none

of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval in the United States or other jurisdictions.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree that our changes to branded reference drugs meet the criteria for the 505(b)(2) regulatory pathway or foreign regulatory pathways;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective or comparable to its branded reference product for its proposed indication;
- the results of any clinical trials we conduct may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change significantly in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would harm our business, results of operations and prospects significantly.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could harm the commercial prospects for our product candidates.

We have limited experience using the 505(b)(2) regulatory pathway to submit an NDA or any similar drug approval filing to the FDA, and we cannot be certain that any of our product candidates will receive regulatory approval. For example, our leading near-term product candidate is EP-6101 Kangio, a patented liquid intravenous form of Angiomax for percutaneous transluminal angioplasty. In March of 2016 we received a Complete Response Letter from the FDA stating that while their initial review of our NDA for EP-6101 Kangio was complete, they could not approve the application in its present form and are requesting additional information. We are working with the FDA to provide the additional requested information, but there can be no assurance that the FDA will ultimately approve the NDA. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such products, if approved.

Risks Related to Commercialization of Our Products and Product Candidates

If we are unable to establish sales and marketing capabilities or if our commercial partners do not adequately perform, the commercial opportunity for our products may be diminished.

Although we have begun to establish a commercial organization to promote certain of our approved products in the United States, we currently have limited experience, and the cost of establishing and maintaining such an organization may exceed the benefit of doing so. We have very limited prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team.

On November 4, 2015, we entered into the Spectrum Agreement under which Spectrum’s 32-person Corporate Accounts Sales Team will dedicate 80% of its time to selling and marketing up to six of our products over a period of at least 18 months. We, Spectrum and any other commercialization partner we engage may not be able to attract, hire,

train and retain qualified sales and sales management personnel in the future. If we or they are not successful in maintaining an effective number of qualified sales personnel, our ability to effectively market and promote our products may be impaired. Even if we or Spectrum are able to effectively build and maintain such sales personnel, such efforts may not be successful in commercializing our products.

The efforts of our partners in many instances are likely to be outside our control. If we are unable to maintain our commercial partnerships or to effectively establish alternative arrangements for our products, our business could be adversely affected. In addition, despite our arrangement with Spectrum, we still may not be able to cover all of the prescribing physicians for our

products at the same level of reach and frequency as our competitors, and we ultimately may need to further expand our selling efforts in order to effectively compete.

Risks Related to Our Business Operations and Industry

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of March 31, 2016 we had a total of 62 full-time and two part-time employees in the United States and two full-time consultants in India. As our company matures, we expect to expand our employee base to increase our managerial, scientific and engineering, operational, sales, marketing, financial and other resources and to hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to sell our products and commercialize our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Risks Related to Ownership of Our Common Stock

We expect that our stock price may fluctuate significantly.

Our initial public offering was completed in February 2014 at a public offering price of $15.00 per share. The trading price of our common stock has fluctuated significantly in the past and is likely to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- any delay in filing an NDA for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA's review of that NDA;
- failure to successfully execute our commercialization strategy with respect to our approved products or any other approved product in the future;
- adverse results or delays in clinical trials, if any;
- significant lawsuits, including patent or stockholder litigation;
- inability to obtain additional funding;
- failure to successfully develop and commercialize our product candidates;
- changes in laws or regulations applicable to our product candidates;
- inability to obtain adequate product supply for our product candidates, or the inability to do so at acceptable prices;
- unanticipated serious safety concerns related to the use of our products or any of our product candidates;
- adverse regulatory decisions;
- introduction of new products or technologies by our competitors;
- failure to meet or exceed product development or financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future; trading volume of our common stock; and
- changes in the collective short interest in our common stock.

The stock market in general, and The NASDAQ Stock Market, or NASDAQ, in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of listed companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

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

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

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and NASDAQ and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds
None.

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 filed or furnished as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

SIGNATURES

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

EAGLE PHARMACEUTICALS, INC.

DATED: May 10, 2016 By: /s/ Scott Tarriff

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

DATED: May 10, 2016 By: /s/ David E. Riggs

David E. Riggs
Chief Financial Officer
(Principal Accounting and Financial Officer)

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
3.1 (1)	Amended and Restated Certificate of Incorporation
3.2 (1)	Amended and Restated Bylaws
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
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) Incorporated by reference to the Registrant’s Registration Statement on Form S-1 (File No. 333-92984), as amended.