EAGLE PHARMACEUTICALS, INC.
Form 10-Q
August 09, 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 June 30, 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 August 4, 2016: 15,636,387 shares.

NOTE REGARDING COMPANY REFERENCES

Throughout this report, “Eagle Pharmaceuticals,” the “Company,” “Eagle,” “we,” “us” and “our” refer to Eagle Pharmaceutica
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)

	June 30, 2016 (unaudited)	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$75,563	$79,083
Accounts receivable	52,027	26,267
Inventories	6,363	15,042
Prepaid expenses and other current assets	1,546	1,865
Total current assets	135,499	122,257
Property and equipment, net	2,813	2,205
Intangible assets, net	10,960	—
Other assets	94	143
Total assets	$149,366	$124,605
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$11,431	$3,857
Accrued expenses	23,336	24,405
Current portion of contingent consideration	1,012	—
Deferred revenue	—	6,000
Total current liabilities	35,779	34,262
Contingent consideration, less current portion	5,753	—
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of June 30, 2016 and December 31, 2015	—	—
Common stock, $0.001 par value; 50,000,000 shares authorized; 15,636,387 issued and outstanding as of June 30, 2016 and December 31, 2015	15	15
Additional paid in capital	202,729	197,440
Accumulated deficit	(94,910)	(107,112)
Total stockholders' equity	107,834	90,343
Total liabilities and stockholders' equity	$149,366	$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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenue:				
Product sales	$9,607	$ 3,730	$23,729	$ 6,786
Royalty income	31,311	2,272	40,779	5,525
License and other income	—	—	6,000	30,000
Total revenue	40,918	6,002	70,508	42,311
Operating expenses:				
Cost of revenue	11,473	3,348	26,062	9,296
Research and development	3,729	5,878	10,405	12,163
Selling, general and administrative	12,060	5,111	23,033	9,097
Gain on sale of asset	—	—	(1,750)	—
Total operating expenses	27,262	14,337	57,750	30,556
Income (Loss) from operations	13,656	(8,335)	12,758	11,755
Interest income	30	8	51	15
Interest expense	(3)	(3)	(4)	(4)
Total other income	27	5	47	11
Income (Loss) before income tax provision	13,683	(8,330)	12,805	11,766
Income tax (provision) benefit	(584)	153	(603)	(246)
Net Income (Loss)	$13,099	$ (8,177)	$12,202	$ 11,520
Earnings per share attributable to common stockholders:				
Basic	$0.84	$ (0.53)	$0.78	$ 0.77
Diluted	$0.80	$ (0.53)	$0.74	$ 0.73
Weighted average number of common shares outstanding:				
Basic	15,636,387	15,546,796	15,636,387	14,900,498
Diluted	16,466,020	15,546,796	16,526,596	15,876,397

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			5,289	—	5,289
Net income	—	—	—	12,202	12,202
Balance at June 30, 2016	15,637	$ 15	$ 202,729	$ (94,910)	$ 107,834

See accompanying notes to condensed financial statements.

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

	Six Months Ended June 30,	
	2016	2015
Cash flows from operating activities:		
Net (loss) income	$12,202	$11,520
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Depreciation expense	296	22
Amortization of intangible assets	260	—
Stock-based compensation	5,289	1,593
Change in fair value of contingent consideration	395	—
Gain on sale of diclofenac-misoprostol	(1,750)	—
Loss on disposal of fixed assets	—	273
Changes in operating assets and liabilities:		
Increase in accounts receivable	(25,760)	(1,026)
Decrease (increase) in inventories	8,679	(1,083)
Decrease in prepaid expenses and other current assets	319	81
Decrease (increase) in other assets	49	(59)
Increase in accounts payable	7,574	1,282
Decrease in deferred revenue	(6,000)	(260)
(Decrease) increase in accrued expenses and other liabilities	(1,069)	1,373
Net cash provided by operating activities	484	13,716
Cash flows from investing activities:		
Purchase of property and equipment	(904)	(327)
Purchase of short term investments	(62,000)	(89,999)
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	(4,004)	(90,326)
Cash flows from financing activities:		
Proceeds from common stock option exercise	—	1,096
Proceeds from issuance of common stock from follow-on public offering, net of issuance costs	—	54,331
Net cash provided by financing activities	—	55,427
Net (decrease) increase in cash	(3,520)	(21,183)
Cash and cash equivalents at beginning of period	79,083	34,869
Cash and cash equivalents at end of period	$75,563	$13,686
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Interest	$1	$4
Corporate taxes	—	187
Franchise taxes	107	78
Non-cash financing activities		
Accrued follow-on public offering costs	—	—
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 and six months ended June 30, 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. 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 also has a number of products currently under development and certain products may be subject to license agreements.

On February 13, 2015, the Company submitted a New Drug Application or 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 chronic lymphocytic leukemia ("CLL") and patients with non-Hodgkin's lymphoma ("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 an additional milestone payment. 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 process of finalizing the valuation of

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

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. The Company did not incur any significant acquisition related costs in connection with the Non-Alcohol Docetaxel Injection 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 is obligated to 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 ready-to-use ("RTU") bivalirudin ("EP-6101") in which the FDA stated it cannot approve the application in its present form and requested additional information from the Company. Discussions with the FDA to identify an appropriate pathway to approval are ongoing and could include a human study.

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.

On July 11, 2016 the FDA determined that no additional human safety and efficacy data is required for the submission of EP-4104 (dantrolene sodium) for exertional heatstroke ("EHS"), further confirming that a hybrid development

program comprised of clinical data from EHS patients and positive preclinical data from animal studies constitutes an adequate regulatory pathway for future NDA submission.

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

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

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.

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.

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

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). The Company is currently assessing the impact that this standard will have on our financial position and results of operations.

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.

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 June 30, 2016 and December 31, 2015. The fair value of the contingent consideration/accrued royalty is classified as Level 3 at

June 30, 2016.

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

Intangible Assets

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

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 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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Net revenues				
The Medicines Company	4 %	37 %	5 %	13 %
Sandoz, Inc.	5 %	30 %	4 %	7 %
Cephalon, Inc. (Teva) - See Revenue Recognition	80 %	— %	71 %	71 %
Par Pharmaceuticals Companies, Inc. - See Note 11	— %	— %	9 %	— %
Other	11 %	33 %	11 %	9 %
	100%	100%	100%	100%

	June 30, 2016	December 31, 2015

Accounts receivable				
The Medicines Company	16	%	35	%
Sandoz, Inc.	3	%	—	%
Cephalon, Inc. (Teva) - See Revenue Recognition	77	%	57	%
Other	4	%	8	%
	100	%	100	%

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

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 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 the three and six months ended June 30, 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 $3,318 and $1,612 for the three months ended June 30, 2016 and 2015, respectively, and $5,721 and $2,571 for the six months ended June 30, 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.

The Company's gross deferred tax assets primarily consist of net operating loss carry forwards (“NOLs”) and are required to record a valuation allowance against net deferred tax assets to the extent we conclude that it is more likely than not that taxable income generated in the future will be insufficient to utilize the future income tax benefit from net deferred tax assets (namely, the NOLs) prior to expiration. Since formation, the Company has concluded that it was more likely than not that taxable income in the future would be insufficient to utilize the future income tax benefit from net deferred tax assets (namely, the NOLs) prior to expiration.

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Each quarter, this conclusion is reviewed which requires significant management judgment. In the future, if available evidence changes the Company's conclusions, the related valuation allowance and tax expense will be adjusted at that time.

During the three months ended June 30, 2016 and 2015, the Company recorded an income tax provision of $584 and an income tax benefit of $153, respectively. The tax provision recorded in the three months ended June 30, 2016 was based upon the Company's estimated federal AMT and state tax liability. The Company recorded an income tax benefit in the three months ended June 30, 2015 due to the net loss incurred during the period.

During the six months ended June 30, 2016 and 2015, the Company recorded an income tax provision of $603 and $246, 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 (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 25 days for EP-3102 Bendeka and 60 days for EP-1101 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.

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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 an additional milestone payment. 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 an 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 milestone, if achieved, will be recognized in the period earned.

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 has entered into a supply agreement with Cephalon, pursuant to which the Company is 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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Risk-free interest rate	1.29% - 1.53%	1.42% - 2.09%	1.29% - 1.90%	1.42% - 2.09%
Volatility	31.56%	30.11%	31.31%	30.33%
Expected term (in years)	5.50 - 7.00 years	5.50 - 7.00 years	5.50 - 7.00 years	5.50 - 7.00 years
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

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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.

The anti-dilutive common shares equivalents outstanding at the three and six months ended June 30, 2016 and 2015 were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Options	1,448,172	1,836,327	1,359,519	1,556,815
Total	1,448,172	1,836,327	1,359,519	1,556,815

The following table sets forth the computation for basic and diluted net income (loss) per share for the three and six months ended June 30, 2016 and 2015:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Numerator				
Numerator for basic earnings per share-net (loss) income	$13,099	$ (8,177)	$12,202	$ 11,520
Numerator for diluted earnings per share-net (loss) income	$13,099	$ (8,177)	$12,202	$ 11,520
Denominator				
Basic weighted average common shares outstanding	15,636,387	15,546,796	15,636,387	14,900,498
Dilutive effect of stock options	829,633	—	890,209	975,899
Diluted weighted average common shares outstanding	16,466,020	15,546,796	16,526,596	15,876,397
Basic net (loss) income per share				
Basic net (loss) income per share	$0.84	$ (0.53)	$0.78	$ 0.77
Diluted net (loss) income per share				
Diluted net (loss) income per share	$0.80	$ (0.53)	$0.74	$ 0.73

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.

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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.
The following table represents a reconciliation of the change in the fair value measurement of the contingent consideration liability since acquisition through June 30, 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	395
Closing Balance June 30, 2016	$6,765

The following table displays the balance sheet classification of the contingent consideration liability account as of June 30, 2016 and the acquisition date, January 12, 2016:

	June 30, 2016	January 12, 2016
Accrued royalty payable	$1,012	$1,012
Long term royalty payable	5,753	5,358
Total acquisition related contingent consideration	$6,765	$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 $597 and a net loss of $2,179 in the three months ended June 30, 2016. The Company recorded product sales of Non-Alcohol Docetaxel Injection of $1,465 and a net loss of $3,047 in the six months ended June 30, 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.

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5. Inventories

Inventories consist of the following:

	June 30, 2016	December 31, 2015
Raw material	$5,518	$ 8,687
Work in process	—	6,044
Finished products	845	311
	$6,363	$ 15,042

During the three and six months ended June 30, 2016, the Company recorded inventory write-offs of $1.7 million included in cost of revenue and subject to reimbursement by our commercial partner.

6. Balance Sheet Accounts

Prepaid and Other Current Assets

Prepaid and other current assets consist of the following:

	June 30, 2016	December 31, 2015
Prepaid expenses and other current assets		
Prepaid product costs	$439	$ 85
Prepaid FDA user fee	190	551
Prepaid insurance	454	218
Prepaid research and development	9	283
Prepaid federal income taxes	126	508
All other	328	220
Total Prepaid expenses and other current assets	$1,546	$ 1,865

Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2016	December 31, 2015
Accrued expenses		
Royalties due to The Medicines Company	$7,750	$ 6,948
Royalties due to SciDose	3,717	1,637
Royalties due to Sandoz, Inc.	—	1,249
Accrued research & development	2,047	1,784
Accrued professional fees	1,471	792
Accrued salary and other compensation	2,382	2,242
Accrued product costs	4,955	9,232
Accrued provision for income tax	221	—
Accrued other	286	—
Deferred rent	507	521
Total Accrued expenses	$23,336	$ 24,405

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Deferred Revenue
Deferred revenue consists of the following:

	June 30, 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

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

	June 30, 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	$ (260)	$ 10,960	$ —	$ —	$ —
Total	18	$ 11,220	$ (260)	$ 10,960	$ —	$ —	$ —

Amortization expense was $156 and $0 for the three months ended June 30, 2016 and 2015, and $260 and $0 for the six months ended June 30, 2016 and 2015, respectively.
Based on finite-lived intangible assets recorded as of June 30, 2016, and assuming that the underlying assets will not be impaired and that the Company will not change the expected lives of the assets, future amortization expenses are estimated as follows:

	Estimated Amortization Expense
Year Ending December 31,	
2016 (remainder)	$ 312
2017	623
2018	623
2019	623
2020	623
All other	8,156
Total estimated amortization expense	$ 10,960

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

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"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. During the quarter ended June 30, 2016 the Company entered into an agreement with Jay Moorin and Alain Schreiber, M.D., in connection with their resignations from the Company’s board of directors, which resulted in a stock option modification. Under this agreement the Company reversed $319 in previously recognized expense for unvested options and recorded $160 in expense related to the acceleration of unvested options. The Company recognized share-based compensation in its statements of operations for the three and six months ended June 30, 2016 and 2015 as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Selling, general and administrative	$1,755	$762	$3,917	$962
Research and development	665	447	1,372	631
Total	$2,420	$1,209	$5,289	$