EAGLE PHARMACEUTICALS, INC.
Form 10-Q
November 12, 2015

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 September 30, 2015
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 o | Accelerated filer o | Non-accelerated filer x (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 November 10, 2015: 15,589,844 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 product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our ability to obtain funding for our operations;
- our plans to research, develop and commercialize our product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our ability to successfully commercialize our product candidates;
- the rate and degree of market acceptance of our product candidates;
- our ability to develop sales and marketing capabilities, whether alone or with current or 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 expectations regarding the period during which we qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (“JOBS Act”);
- 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 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)
(unaudited)

| | September 30, 2015 | December 31, 2014 |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $71,979 | $34,869 |
| Short term investments | 24,000 | — |
| Accounts receivable | 12,218 | 11,956 |
| Inventories | 7,348 | 1,242 |
| Prepaid expenses and other current assets | 4,757 | 1,640 |
| Total current assets | 120,302 | 49,707 |
| Property and equipment, net | 1,803 | 342 |
| Other assets | 111 | 45 |
| Total assets | $122,216 | $50,094 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | $14,148 | $3,501 |
| Accrued expenses | 14,439 | 12,165 |
| Deferred revenue | 6,000 | 6,520 |
| Total current liabilities | 34,587 | 22,186 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of September 30, 2015 and December 31, 2014 | — | — |
| Common stock, $0.001 par value; 50,000,000 shares authorized; 15,589,844 and 14,036,680 issued and outstanding as of September 30, 2015 and December 31, 2014, respectively | 15 | 14 |
| Additional paid in capital | 195,945 | 137,577 |
| Accumulated deficit | (108,331) | (109,683) |
| Total stockholders' equity | 87,629 | 27,908 |
| Total liabilities and stockholders' equity | $122,216 | $50,094 |

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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| Revenue: | | | | |
| Product sales | $3,314 | $877 | $10,099 | $2,402 |
| Royalty income | 2,422 | 1,934 | 7,947 | 7,440 |
| License and other income | — | — | 30,000 | 3,765 |
| Total revenue | 5,736 | 2,811 | 48,046 | 13,607 |
| Operating expenses: | | | | |
| Cost of revenue | 3,753 | 2,175 | 13,049 | 7,090 |
| Research and development | 6,911 | 5,888 | 19,073 | 14,227 |
| Selling, general and administrative | 5,460 | 3,854 | 14,557 | 7,981 |
| Total operating expenses | 16,124 | 11,917 | 46,679 | 29,298 |
| Income (Loss) from operations | (10,388) | (9,106) | 1,367 | (15,691) |
| Interest income | 8 | 4 | 22 | 30 |
| Interest expense | (5) | (2) | (9) | (8) |
| Change in value of warrant liability | — | — | — | (383) |
| Other income | — | — | — | 35 |
| Total other income (expense) | 3 | 2 | 13 | (326) |
| Income (Loss) before income tax benefit(provision) | (10,385) | (9,104) | 1,380 | (16,017) |
| Income tax benefit (provision) | 218 | — | (28) | 1,295 |
| Net Income (Loss) | $(10,167) | $(9,104) | $1,352 | $(14,722) |
| Less dividends on Series A, B, B-1 and C Convertible Preferred Stock | — | — | — | (534) |
| Net income (loss) attributable to common stockholders | $(10,167) | $(9,104) | $1,352 | $(15,256) |
| Earnings per share attributable to common stockholders: | | | | |
| Basic | $(0.65) | $(0.65) | $0.09 | $(1.24) |
| Diluted | $(0.65) | $(0.65) | $0.08 | $(1.24) |
| Weighted average number of common shares outstanding: | | | | |
| Basic | 15,589,818 | 14,021,933 | 15,132,797 | 12,320,311 |
| Diluted | 15,589,818 | 14,021,933 | 16,123,729 | 12,320,311 |

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, 2014 | 14,037 | $ 14 | $137,577 | $ (109,683 ) | $ 27,908 |
| Stock-based compensation expense | | | 2,942 | — | 2,942 |
| Issuance of common stock upon exercise of stock option grants | 164 | — | 1,096 | — | 1,096 |
| Issuance of common stock in connection with follow-on public offering, including underwriter's over-allotment, net of offering costs and underwriter's discount | 1,389 | 1 | 54,330 | — | 54,331 |
| Net income | — | — | — | 1,352 | 1,352 |
| Balance at September 30, 2015 | 15,590 | $ 15 | $195,945 | $ (108,331 ) | $ 87,629 |

See accompanying notes to condensed financial statements.

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

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2015 | 2014 |
| Cash flows from operating activities: | | |
| Net income (loss) | $1,352 | $(14,722) |
| Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities: | | |
| Depreciation expense | 31 | 73 |
| Stock-based compensation | 2,942 | 528 |
| Change in fair value of warrant liability | — | 383 |
| Loss on disposal of fixed assets | 273 | — |
| Changes in operating assets and liabilities: | | |
| Increase in accounts receivable | (262) | (704) |
| Increase in inventories | (6,106) | (1,294) |
| Increase in prepaid expenses and other current assets | (3,117) | (1,342) |
| (Increase) decrease in other assets | (66) | — |
| Increase in accounts payable | 10,647 | 1,713 |
| Decrease in deferred revenue | (520) | (3,435) |
| Increase in accrued expenses and other liabilities | 1,907 | 4,934 |
| Net cash provided by (used in) operating activities | 7,081 | (13,866) |
| Cash flows from investing activities: | | |
| Purchase of property and equipment | (1,398) | (39) |
| Purchase of short term investments | (105,999) | (19,999) |
| Maturities of short term investments | 81,999 | — |
| Net cash used in investing activities | (25,398) | (20,038) |
| Cash flows from financing activities: | | |
| Series C preferred stock offering costs | — | (1) |
| Proceeds from common stock option exercise | 1,096 | 65 |
| Proceeds from exercise of preferred stock warrants | — | 21 |
| Proceeds from issuance of common stock from follow-on public offering, net of issuance costs | 54,331 | — |
| Proceeds from issuance of common stock from initial public offering, net of issuance costs | — | 46,567 |
| Net cash provided by financing activities | 55,427 | 46,652 |
| Net increase in cash | 37,110 | 12,748 |
| Cash and cash equivalents at beginning of period | 34,869 | 9,974 |
| Cash and cash equivalents at end of period | $71,979 | $22,722 |
| Supplemental disclosures of cash flow information: | | |
| Cash paid during the period for: | | |
| Interest | $(9) | $(8) |
| Corporate taxes | 482 | — |
| Franchise taxes | 91 | 8 |
| Non-cash operating activities | | |
| Landlord contribution to leasehold improvements recorded as deferred rent | 367 | — |
| Non-cash financing activities | | |
| Conversion of preferred stock and accrued dividends to Common stock | — | 91,648 |
| Conversion of redeemable warrant liability to Common stock | — | 2,280 |

See accompanying notes to condensed financial statements.

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 nine months ended September 30, 2015 are not necessarily indicative of the results for the year ending December 31, 2015 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 September 30, 2014, filed with the Securities and Exchange Commission on December 22, 2014.

On January 20, 2015, the Board of Directors of the Company authorized a change in the Company's fiscal year end from September 30th to December 31st. The change was intended to better align the Company's fiscal year with the business cycles of other specialty pharmaceutical companies. As a result of the change in fiscal year, the Company's 2015 fiscal year began on January 1, 2015 and will end on December 31, 2015.

As a result of the change in fiscal year, on February 17, 2015 the Company filed a Transition Report on Form 10-Q covering the transition period from October 1, 2014 to December 31, 2014.

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 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 three products currently being sold in the United States under various license agreements in place with commercial partners, including Ryanodex®, Diclofenac-misoprostol, launched in January 2015, and a ready-to-use formulation of Argatroban. The Company has a number of products currently under development and certain products may be subject to license agreements.

On February 18, 2014, the Company closed its initial public offering (the "IPO") whereby the Company sold 3,350,000 shares of common stock, at a public offering price of $15.00 per share, before underwriting discounts and expenses. On March 18, 2014, the underwriters exercised an over-allotment option granted in connection with the offering of 100,000 shares of common stock at the initial public offering price, less the underwriter discount. The aggregate net proceeds received by the Company from the offering were $46,069. Included in this amount is $21 received from the exercise of Series C preferred stock warrants for 1,788 shares of common stock.

In connection with the IPO, the Company's Board of Directors approved a one-for-6.41 reverse stock split of the Company's common stock (that resulted in a proportional adjustment to the conversion ratio of the preferred stock warrants). All references to common stock, common stock equivalents and per share amounts have been changed retroactively in these condensed financial statements and accompanying footnotes have been retroactively adjusted for all periods presented to give effect to this reverse stock split, including reclassifying an equal amount to the reduction in par value of common stock to additional paid-in capital.

On the IPO closing date, all outstanding shares of preferred stock converted into 7,487,928 shares of common stock and all outstanding warrants were net exercised for 32,286 shares common stock at the initial public offering price. These transactions produced a significant increase in the number of shares outstanding which will impact the year-over-year comparability of the Company's (loss) earnings per share calculations. Additionally, in connection with the closing of the IPO, the Company amended and restated its articles of incorporation to decrease the number of authorized shares of common and undesignated preferred stock to 50,000,000 and 1,500,000, respectively.

On February 13, 2015, Eagle 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 the Company's bendamustine hydrochloride (HCl) rapid infusion product for treatment of patients with chronic lymphocytic leukemia and patients with indolent B-cell non-Hodgkin lymphoma. Pursuant to the terms of the Cephalon License, Cephalon will be

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

responsible for all U.S. commercial activities for the product including promotion and distribution, and Eagle will be responsible for obtaining and maintaining all regulatory approvals and conducting post-approval clinical studies.

Under the terms of the Cephalon License, Eagle received an upfront cash payment of $30.0 million, and Eagle is currently eligible to receive up to $80.0 million in additional milestone payments. In addition, Eagle is entitled to receive royalty payments in the double digit range on net sales of the product, if approved by the FDA. In connection with the Cephalon License, Eagle entered into a supply agreement with Cephalon, pursuant to which Eagle will be responsible for supplying product to Cephalon for a specified period. Additionally, on February 13, 2015, Eagle and Cephalon entered into a Settlement and License Agreement (the "Cephalon Settlement Agreement"), 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 and Cephalon filed a consent judgment between Cephalon and Eagle acknowledging the validity and enforceability of the ‘270 patent (the "Consent Judgment").

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 Securities Exchange Commission on March 13, 2015.

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.

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 the Company 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 condensed consolidated financial statements.

Reclassifications

Certain reclassifications have been made to prior year amounts to conform with the current year presentation.

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

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 and short term investments are classified as Level 1 at September 30, 2015 and December 31, 2014.

The Company is required by U.S. GAAP to record certain assets and liabilities at fair value on a recurring basis. The guidance in ASC 815 required that the Company mark the value of its warrant liability to market and recognize the change in valuation in its statement of operations each reporting period. Determining the warrant liability to be recorded required the Company to develop estimates to be used in calculating the fair value of the warrant.

Since these preferred stock warrants did not trade in an active securities market, the Company recognized a warrant liability and estimated the fair value of these warrants using a Probability-Weighted Expected Returns valuation model. Therefore, the warrant liability was considered a Level 3 measurement. All warrants outstanding immediately prior to the IPO were net exercised in connection with the IPO. There were no outstanding warrants as of September 30, 2015.

Concentration of Major Customers and Vendors

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

on these collaboration and

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

distribution arrangements. The Company received a $30 million upfront payment during February 2015 under the terms of the Cephalon License- See "revenue recognition" below for more detail.

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| Net revenues | | | | |
| The Medicines Company | 37 % | 50 % | 15 % | 26 % |
| Sandoz, Inc. | 28 % | 42 % | 10 % | 45 % |
| Cephalon, Inc. (Teva) - See Revenue Recognition | — % | — % | 62 % | — % |
| Hikma Pharmaceuticals | — % | — % | — % | 28 % |
| Other | 35 % | 8 % | 13 % | 1 % |
| | 100 % | 100 % | 100 % | 100 % |

| | September 30, 2015 | December 31, 2014 |
|---|---|---|
| Accounts receivable | | |
| The Medicines Company | 76 % | 61 % |
| Sandoz, Inc. | 13 % | 35 % |
| Other | 11 % | 4 % |
| | 100 % | 100 % |

Currently, for Argatroban, the Company uses one vendor as its sole source supplier. Because of the unique equipment and process for manufacturing Argatroban, transferring manufacturing activities for Argatroban 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.

Pre-Launch Inventory

The Company capitalizes inventory costs associated with certain products prior to regulatory approval and product launch, based on management's judgment of reasonably certain future commercial use and net realizable value, when it is reasonably certain that the pre-launch inventories will be saleable. The determination to capitalize is made once the Company (or its third party development partners) has filed a New Drug Application (an "NDA") that has been acknowledged by the FDA as containing sufficient information to allow the FDA to conduct its review in an efficient and timely manner and management is reasonably certain that all regulatory and legal hurdles will be cleared. This determination is based on the particular facts and circumstances relating to the expected FDA approval of the drug product being considered, and accordingly, the time frame within which the determination is made varies from product to product. The Company may be required to write down previously capitalized costs related to pre-launch inventories upon a change in such judgment, or due to a denial or delay of approval by regulatory bodies, or a delay in commercialization, or other potential factors. As of September 30, 2015 the Company had $6,960 in inventories related to product that was not yet available to be sold but could be converted to other uses.

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

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

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.

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 $1,310 and $1,820 for the three months ended September 30, 2015 and 2014, respectively, and $3,880 and $2,485 for the nine months ended September 30, 2015 and 2014, respectively.

Redeemable Convertible Preferred Stock

The carrying value of redeemable convertible preferred stock was increased by periodic accretions, using the interest method so that the carrying amount would equal the redemption amount at the earliest redemption date.

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 received approval to sell a portion of the Company's New Jersey net operating losses ("NOL's") as part of the Technology Business Tax Certificate Program sponsored by The New Jersey Economic Development Authority. Under the program, emerging biotechnology firms with unused net operating loss carryovers and unused research and development credits are allowed to sell these benefits to other firms.

During the nine months ended September 30, 2014, the Company sold New Jersey state NOL carry forwards, which resulted in the recognition of a $1,295 tax benefit.

During the nine months ended September 30, 2015, the Company recorded an income tax provision of $28 based upon its estimated federal AMT and state tax liability.

Revenue Recognition

Product revenue — The Company recognizes net revenue from Argatroban supplied to its commercial partners and Ryanodex® and Diclofenac-misoprostol 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®.

EAGLE PHARMACEUTICALS, INC.
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(In thousands, except share and per share amounts)
(Unaudited)

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, and is eligible to receive up to $80 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 the New Drug Application on February 13, 2015, and the remaining obligations were estimated to require minimal effort. The remaining milestones, if achieved, will be recognized in the period earned.

In addition, the Company is entitled to receive royalty payments in the double digit range of net sales of the product, if approved by the FDA. 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

EAGLE PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)
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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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| Risk-free interest rate | 1.68% - 1.71% | 1.89% - 1.89% | 1.42% - 2.09% | 1.69% - 2.21% |
| Volatility | 31.17% | 53.71% | 30.33% | 54.58% |
| Expected term (in years) | 5.58 - 6.08 years | 6.08 - 6.08 years | 5.50 - 7.00 years | 5.50 - 7.00 years |
| Expected dividend yield | 0.0% | 0.0% | 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.

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

The dilutive and anti-dilutive common shares equivalents outstanding at the three and nine months ended September 30, 2015 and 2014 were as follows:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| Series A | — | — | — | 362,765 |
| Series B | — | — | — | 308,067 |
| Series B-1 | — | — | — | 226,450 |
| Series C | — | — | — | 267,507 |
| Series C warrants | — | — | — | 22,906 |
| Options | 1,882,171 | 1,144,751 | 1,665,494 | 995,540 |
| Total | 1,882,171 | 1,144,751 | 1,665,494 | 2,183,235 |

The following table sets forth the computation for basic and diluted net income (loss) per share for the three and nine months ended September 30, 2015 and 2014:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| Numerator | | | | |
| Numerator for basic earnings per share-net income (loss) | $(10,167) | $(9,104) | $1,352 | $(15,256) |
| Numerator for diluted earnings per share-net income (loss) | $(10,167) | $(9,104) | $1,352 | $(15,256) |
| Denominator | | | | |
| Basic weighted average common shares outstanding | 15,589,818 | 14,021,933 | 15,132,797 | 12,320,311 |
| Dilutive effect of stock options | — | — | 990,932 | — |
| Diluted weighted average common shares outstanding | 15,589,818 | 14,021,933 | 16,123,729 | 12,320,311 |
| Basic net income (loss) per share | | | | |
| Basic net income (loss) per share | $(0.65) | $(0.65) | $0.09 | $(1.24) |
| Diluted net income (loss) per share | | | | |
| Diluted net income (loss) per share | $(0.65) | $(0.65) | $0.08 | $(1.24) |

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

4. Inventories

Inventories consist of the following:

| | September 30, 2015 | December 31, 2014 |
|---|---|---|
| Raw material - pre launch inventory | $2,791 | $— |
| Work in process - pre launch inventory | 4,169 | — |
| Finished products | 388 | 1,242 |
| | $7,348 | $1,242 |

During the nine months ended September 30, 2015, the Company recorded total write-offs of $1.1 million attributable to expiring Ryanodex inventory.

5. Balance Sheet Accounts

Prepaid and Other Current Assets

Prepaid and other current assets consist of the following:

| | September 30, 2015 | December 31, 2014 |
|---|---|---|
| Prepaid expenses and other current assets | | |
| Prepaid product costs | $68 | $1,020 |
| Prepaid FDA user fee | 716 | 148 |
| Prepaid insurance | 331 | 183 |
| Prepaid research and development | 3,000 | — |
| Prepaid income taxes | 483 | — |
| All other | 159 | 289 |
| Total Prepaid expenses and other current assets | $4,757 | $1,640 |

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

Accrued expenses consist of the following:

| | September 30, 2015 | December 31, 2014 |
|---|---|---|
| Accrued expenses | | |
| Royalties due to The Medicines Company | $7,584 | $5,880 |
| Royalties due to SciDose | 1,524 | 2,308 |
| Accrued research & development | 1,360 | 1,307 |
| Accrued professional fees | 639 | 502 |
| Accrued salary and other compensation | 1,345 | 1,025 |
| Accrued product costs | 1,365 | 839 |
| Accrued provision for income tax | — | — |
| Accrued insurance | 142 | — |
| Deferred rent | 480 | — |
| All other | — | 304 |
| Total Accrued expenses | $14,439 | $12,165 |

Deferred Revenue

Deferred revenue consists of the following:

| | September 30, 2015 | December 31, 2014 |
|---|---|---|
| Deferred revenue | | |
| The Medicines Company | $— | $520 |
| Deferred Revenue for ongoing business | — | 520 |
| Par Pharmaceuticals Companies, Inc. | 5,500 | 5,500 |
| Par Pharmaceuticals Companies, Inc./Tech Transfer | 500 | 500 |
| Deferred Revenue from Asset Sales | 6,000 | 6,000 |
| Total Deferred revenue | $6,000 | $6,520 |

6. 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.

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

The Company recognized share-based compensation in its statements of operations for the three and nine months ended September 30, 2015 and 2014 as follows:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| Selling, general and administrative | $1,050 | $112 | $2,012 | $262 |
| Research and development | 299 | 112 | 930 | 266 |
| Total | $1,349 | $224 | $2,942 | $528 |

7. Commitments

At September 30, 2015, the Company has purchase obligations in the amount of $9,397 which represent the contractual commitments under a 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 $180 and $68 for the three months ended September 30, 2015 and 2014, respectively, and $343 and $208 for the nine months ended September 30, 2015 and 2014, respectively. The future lease payments under the operating lease are $2,556 as of September 30, 2015, payable monthly through June 30, 2020.

8. 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 a New Drug Application under Section 505(b)(2) for 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 New Drug Application 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.

9. Subsequent Events

On October 13, 2015, the Company entered into an exclusive U.S. licensing agreement with Teikoku Pharma USA, Inc. ("Teikoku") to market, sell and distribute Docetaxel Injection Concentrate, Non-Alcohol Formula, 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 Docetaxel Injection for these indications is currently under review with the FDA and the Prescription Drug User Fee Act action date is December 27, 2015. Under the terms of the agreement, the Company paid an upfront cash payment, will pay a near-term milestone based upon the timing of an FDA approval and double-digit royalties on gross profits.

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NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)
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On November 4, 2015, the Company entered into a co-promotion agreement with Spectrum Pharmaceuticals ("Spectrum") under which the Spectrum 32-person Corporate Accounts Sales Team will dedicate 80 percent 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 the Products are met during the initial term of the Spectrum Agreement, for a potential total payment of up to $22 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.

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 December 22, 2014.

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 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 three approved products, Argatroban, Ryanodex® (dantrolene sodium) and Diclofenac-misoprostol. We were granted tentative approval for EP-3101 (patented Bendamustine Hydrochloride Injection, ready-to-dilute concentrate solution, which we refer to as "bendamustine RTD") and orphan drug designation on EP-3102 ("bendamustine rapid infusion"), for the treatment of chronic lymphocytic leukemia ("CLL") and indolent B-cell non-Hodgkin's lymphoma ("NHL"). We currently have five advanced product candidates and three commercialized products. We began commercializing Diclofenac-misoprostol in January 2015.

We have two commercial partners, The Medicines Company and Sandoz Inc., ("Sandoz"), who market Argatroban pursuant to separate agreements. As a result of our commercialization strategy, we have been able to minimize certain expenses, but also are required to share royalty revenues from Argatroban with our commercial partners.

We may commercialize our future products independently in the United States. Outside of the United States, we intend to utilize partners for the commercialization of our products. As part of our strategy for Ryanodex®, we have contracted a specialty sales force who is targeting group purchasing organizations, hospital groups and key stakeholders in acute care settings and primary hospitals. We expect the impact on our results of operations of this commercialization strategy will be that we will receive revenue from direct sales and royalty income will be a less significant part of our revenues. This commercialization strategy will also result in higher infrastructure and selling expenses