EAGLE PHARMACEUTICALS, INC.
Form 10-Q
May 15, 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 March 31, 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 May 11, 2015: 15,538,943 shares.

Eagle Pharmaceuticals, Inc.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This 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,” “would,” and 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 recent 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 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)

	March 31, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$99,924	$34,869
Short-term investments	15,998	—
Accounts receivable	10,508	11,956
Inventories	2,018	1,242
Prepaid expenses and other current assets	1,340	1,640
Total current assets	129,788	49,707
Property and equipment, net	100	342
Other assets	45	45
Total assets	$129,933	$50,094
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$5,435	$3,501
Accrued expenses	15,029	12,165
Deferred revenue	6,585	6,520
Total current liabilities	27,049	22,186
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of March 31, 2015 and December 31, 2014	—	—
Common stock, $0.001 par value; 50,000,000 shares authorized; 15,509,179 and 14,036,680 issued and outstanding as of March 31, 2015 and December 31, 2014, respectively	15	14
Additional paid in capital	192,855	137,577
Accumulated deficit	(89,986)	(109,683)
Total stockholders' equity	102,884	27,908
Total liabilities and stockholders' equity	$129,933	$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 March 31,	
	2015	2014
Revenue:		
Product sales	$3,056	$1,175
Royalty income	3,253	3,565
License and other income	30,000	265
Total revenue	36,309	5,005
Operating expenses:		
Cost of revenue	5,948	3,360
Research and development	6,285	3,794
Selling, general and administrative	3,986	1,454
Total operating expenses	16,219	8,608
Income (Loss) from operations	20,090	(3,603)
Interest income	7	8
Interest expense	(1)	(1)
Change in value of warrant liability	—	(383)
Total other income (expense)	6	(376)
Income (Loss) before income tax (provision) benefit	20,096	(3,979)
Income tax (provision) benefit	(399)	1,295
Net Income (Loss)	$19,697	$(2,684)
Less dividends on Series A, B, B-1 and C Convertible Preferred Stock	—	(534)
Net income (loss) attributable to common stockholders	$19,697	$(3,218)
Earnings per share attributable to common stockholders:		
Basic	$1.38	$(0.36)
Diluted	$1.31	$(0.36)
Weighted average number of common shares outstanding:		
Basic	14,247,019	8,862,212
Diluted	15,041,011	8,862,212

See accompanying notes to condensed financial statements.

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Amount			
Balance at December 31, 2014	14,037	$ 14	$137,577	$(109,683)	$27,908
Stock-based compensation expense			384		384
Issuance of common stock upon exercise of stock option grants	84	—	564		564
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				19,697	19,697
Balance at March 31, 2015	15,510	$ 15	$192,855	$(89,986)	$102,884

See accompanying notes to condensed financial statements.

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

	Three Months Ended March 31,	
	2015	2014
Cash flows from operating activities:		
Net income (loss)	$19,697	$(2,684)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation expense	12	29
Stock-based compensation	384	140
Change in fair value of warrant liability	—	383
Loss on disposal of fixed assets	273	—
Changes in operating assets and liabilities:		
Decrease (increase) in accounts receivable	1,448	(1,228)
(Increase) in inventories	(776)	—
Decrease (increase) in prepaid expenses and other current assets	300	(464)
Decrease in other assets	—	1
Increase in accounts payable	1,884	112
Increase (decrease) in deferred revenue	65	(325)
Increase in accrued expenses and other liabilities	2,549	1,965
Net cash provided by (used in) operating activities	25,836	(2,071)
Cash flows from investing activities:		
Purchase of property and equipment	(43)	(28)
Purchase of short term investments	(15,998)	—
Net cash used in investing activities	(16,041)	(28)
Cash flows from financing activities:		
Series C preferred stock offering costs	—	(1)
Proceeds from common stock option exercise	564	—
Proceeds from exercise of preferred stock warrants	—	21
Proceeds from issuance of common stock from follow-on public offering, net of issuance costs	54,696	—
Proceeds from issuance of common stock from initial public offering, net of issuance costs	—	46,985
Net cash provided by financing activities	55,260	47,005
Net increase in cash	65,055	44,906
Cash and cash equivalents at beginning of period	34,869	9,974
Cash and cash equivalents at end of period	$99,924	$54,880
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Interest	$1	$1
Financing costs	—	5,158
Franchise taxes	53	8
Non-cash financing activities		
Accrued follow-on public offering costs	365	—
Accrued initial public offering costs	—	414
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 months ended March 31, 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 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 $90.0 million in additional milestone payments. In addition, we are 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 License, Eagle has agreed to enter into a supply agreement with Cephalon, pursuant to which Eagle will be responsible for supplying product to Cephalon for a specified period.

In connection with the Cephalon License, 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, under which Eagle agreed to enter into a Consent Judgment regarding the ‘270 patent.

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 us, were approximately $54,331. We did not receive any proceeds from the shares sold by the selling stockholders. The securities described above were offered by us pursuant to a shelf registration statement declared effective by the Securities Exchange Commission on March 13, 2015.
These financial statements are presented in U.S. dollars and are prepared under accounting principles generally accepted in the United States of America (“U.S. GAAP”).
3. Summary of Significant Accounting Policies
Use of Estimates
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.

The standard is effective for annual periods beginning after December 15, 2016, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our financial statements and have not yet determined the method by which we will adopt the standard in 2017.

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

Reclassifications

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

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. All cash and cash equivalents are held in United States financial institutions. The carrying amount of cash and cash equivalents approximates its fair value due to its short-term nature.

The Company, at times, maintains balances with financial institutions in excess of the FDIC limit.

Fair Value 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 had an original maturity of greater than three months. 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 March 31, 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 March 31, 2015.

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

Concentration of Major Customers and Vendors

The Company's customers are its commercial and licensing partners. The Company is dependent on these commercial partners to market and sell Argatroban; therefore, the Company's future revenues are highly dependent on these collaboration and distribution arrangements. The Company received a $30.0 million upfront payment during the quarter ended March 31, 2015 under the terms of the Cephalon License- see revenue recognition below.

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

	Three Months Ended March 31,			
	2015		2014	
Net revenues				
The Medicines Company	9	%	29	%
Sandoz, Inc.	3	%	71	%
Cephalon, Inc. (Teva) - See Revenue Recognition	83	%	—	%
Other	5	%	—	%
	100	%	100	%
	March 31, 2015		December 31, 2014	
Accounts receivable				
The Medicines Company	76	%	61	%
Sandoz, Inc.	15	%	35	%
Other	9	%	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 March 31, 2015 the Company had $1,400 in inventories related to product that was not yet available to be sold but could be converted to other uses.

Inventory

Inventories are recorded at the lower of cost or market, with cost determined on a first-in, first-out basis and consists of finished products. The Company periodically reviews the composition of inventory in order to identify obsolete, slow-moving or otherwise

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

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.

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 $959 and immaterial for the three months ended March 31, 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 three months ended March 31, 2014, the Company sold New Jersey state net operating loss (NJ NOL) carry forwards, which resulted in the recognition of a $1,295 tax benefit.

During the three months ended March 31, 2015, the Company recorded a provision for income taxes of $399 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

EAGLE PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)
(In thousands, except share and per share amounts)
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tests.The Company estimates its return reserves based on its experience with historical return rates. Historically, product returns have not been material. The Company has a no return policy for Ryanodex®.

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

Royalties — The Company recognizes revenue from royalties based on its commercial partners' net sales of products. Royalties are recognized as earned in accordance with contract terms when they can be reasonably estimated and collectability is reasonably assured. The Company's commercial partners are obligated to report their net product sales and the resulting royalty due to the Company within 60 days from the end of each quarter. Based on historical product sales, royalty receipts and other relevant information, the Company accrues royalty revenue each quarter and subsequently determines a true-up when it receives royalty reports from its commercial partners. Historically, these true-up adjustments have been immaterial.

License revenue — The Company analyzes each element of our licensing agreements to determine the appropriate revenue recognition. The terms of the license agreement may include payment to us of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. The Company recognizes revenue from upfront payments over the period of significant involvement under the related agreements unless the fee is in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation exists under the contract.

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

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

As described above, under the terms of the Cephalon License, the Company received an upfront cash payment of $30.0 million, and is eligible to receive up to $90.0 million in additional milestone payments. The $30.0 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 $30.0 million was recognized as income in the quarter ended March 31, 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 have 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 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 the well as research and development performed by outside contractors or consultants.

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

Upon termination of a collaboration agreement, any remaining non-refundable license fees received by the Company, which had been deferred, are generally recognized in full. All such recognized revenues are included in collaborative licensing and development revenue in its statements of operations. The Company recognizes revenue from milestone payments received under collaboration agreements when earned, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, the Company has no further performance obligations relating to the event, and collectability is reasonably assured. If these criteria are not met, the Company recognizes milestone payments ratably over the remaining period of its performance obligations under the collaboration agreement.

Stock-Based Compensation

The Company accounts for stock-based compensation using the fair value provisions of ASC 718, Compensation — Stock Compensation that requires the recognition of compensation expense, using a fair-value based method, for costs related to all stock-based payments including stock options and restricted stock. This topic requires companies to estimate the fair value of the stock-based awards on the date of grant for options issued to employees and directors. The Company uses a Black-Scholes valuation model as the most appropriate valuation method for pricing these options. Awards for consultants are accounted for under ASC 505-50, Equity Based Payments to Non-Employees. Any compensation expense related to consultants is marked-to-market over the applicable vesting period as they vest. There are customary limitations on the sale or transfer of the stock.

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

	Three Months Ended March 31,	
	2015	2014
Risk-free interest rate	1.63% - 1.92%	1.75% - 8.25%
Volatility	30.38%	64.00%
Expected term (in years)	5.50 - 7.00 years	6.02 - 10.00 years
Expected dividend yield	0.0%	0.0%

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

Earnings (Loss) Per Share

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

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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 months ended March 31, 2015 and 2014 were as follows:

	Three Months Ended March 31,	
	2015	2014
Series A	—	1,088,294
Series B	—	924,200
Series B-1	—	679,350
Series C	—	802,522
Series C warrants	—	68,719
Options	118,619	841,104
Total	118,619	4,404,189

The following table sets forth the computation for basic and diluted net income (loss) per share for the three months ended March 31, 2015 and 2014:

	Three Months Ended March 31,	
	2015	2014
Numerator		
Numerator for basic earnings per share-net income (loss)	$19,697	$(3,218)
Numerator for diluted earnings per share-net income (loss)	$19,697	$(3,218)
Denominator		
Basic weighted average common shares outstanding	14,247,019	8,862,212
Dilutive effect of stock options	793,992	—
Diluted weighted average common shares outstanding	15,041,011	8,862,212
Basic net income (loss) per share		
Basic net income (loss) per share	$1.38	$(0.36)
Diluted net income (loss) per share		
Diluted net income (loss) per share	$1.31	$(0.36)

4. Inventories

Inventories consist of the following:

	March 31, 2015	December 31, 2014
Raw material - pre launch inventory	$1,414	$—
Finished products	604	1,242
	$2,018	$1,242

During the three months ended March 31, 2015, the Company recorded total write-offs of $1.1 million attributable to expiring Ryanodex inventory.

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

5. Balance Sheet Accounts

Prepaid and Other Current Assets

Prepaid and other current assets consist of the following:

	March 31, 2015	December 31, 2014
Prepaid expenses and other current assets		
Prepaid product costs	$321	$1,020
Prepaid FDA user fee	99	148
Prepaid insurance	628	183
Prepaid equipment	118	—
All other	174	289
Total Prepaid expenses and other current assets	$1,340	$1,640

Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2015	December 31, 2014
Accrued expenses		
Royalties due to The Medicines Company	$6,434	$5,880
Royalties due to SciDose	3,028	2,308
Accrued research & development	1,031	1,307
Accrued professional fees	537	502
Accrued salary and other compensation	733	1,025
Accrued product costs	1,363	839
Accrued payroll withholding tax payable	809	—
Accrued provision for income tax	399	—
Accrued insurance	421	—
All other	274	304
Total Accrued expenses	$15,029	$12,165

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

Deferred Revenue
Deferred revenue consists of the following:

	March 31, 2015	December 31, 2014
Deferred revenue		
The Medicines Company	$585	$520
Deferred Revenue for ongoing business	585	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	$6,585	$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. The Company has reserved and made available 974,311 shares of common stock for issuance under the 2014 Plan.
The Company recognized share-based compensation in its statements of operations for the three months ended March 31, 2015 and 2014 as follows:

	Three Months Ended March 31,	
	2015	2014
Selling, general and administrative	$200	$144
Research and development	184	140
Total	$384	$284

7. Commitments
At March 31, 2015, the Company has purchase obligations in the amount of $4,535 which represent the contractual commitments under a Contract Manufacturing and Supply Agreement with a supplier. The obligation under the supply agreement is primarily for finished product and research and development.
The Company leases its office space under a lease agreement that originally expired on May 31, 2015 (the "Original Term"). Rental expense was $68 and $72 for the three months ended March 31, 2015 and 2014. As of March 31, 2015, the remaining future lease payments under the operating lease for the Original Term was $45 as of March 31, 2015, payable monthly through May 31, 2015. On March 16, 2015, the Company amended its existing lease extending its term through June 30, 2020. The future lease payments under the amended operating lease are $2,062 as of March 31, 2015, payable monthly beginning June 1, 2015 through June 30, 2020.

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

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 (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 Hydrochloride Injection, a ready-to-dilute concentrate solution (“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 the Company’s bendamustine product 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 a Consent Judgment regarding the ‘270 patent. As part of the Cephalon Settlement Agreement, Cephalon has agreed to waive its orphan drug exclusivities for the treatment of patients with chronic lymphocytic leukemia and patients with indolent B-cell non-Hodgkin lymphoma with EP-3102.

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. “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), (“bendamustine RTD”) and orphan drug designation on EP-3102 Bendamustine RTD 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 pursuant to separate agreements market Argatroban. 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; while 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, along with greater working capital requirements to support this strategy.

Recent Developments

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

On February 13, 2015, we 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 our 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 responsible for all U.S. commercial activities for the product including promotion and distribution, and we will be responsible for obtaining and maintaining all regulatory approvals and conducting post-approval clinical studies.

Additionally, under the terms of the Cephalon License, we received an upfront cash payment of $30.0 million, and are currently eligible to receive up to $90.0 million in additional milestone payments. In addition, we are 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, we have agreed to enter into a supply agreement with Cephalon, pursuant to which we will be responsible for supplying product to Cephalon for a specified period.

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

On February 13, 2015, we submitted a New Drug Application (NDA) to the FDA for EP-3102 our rapid infusion bendamustine product which was accepted for filing by the FDA. The Prescription Drug User Fee Act (PDUFA) goal date for a decision on this NDA by the FDA is December 2015.

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

the selling stockholders. The securities described above were offered by us pursuant to a shelf registration statement declared effective by the SEC on March 13, 2015.

On April 7, 2015, the United States Patent and Trademark Office ("USPTO") granted us Patent No. 9,000,021 for the use of bendamustine for treating patients requiring restricted fluid and/or sodium intake. This patent expires in March 2033.

Financial Operations Overview

Revenue

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

Product Sales. We recognize revenues from product sales of Ryanodex®, Argatroban and Diclofenac-misoprostol. Ryanodex® and Diclofenac-misoprostol, launched in January 2015, are sold directly to wholesalers, hospitals and surgery centers through a third party logistics partner and Argatroban revenues are through sales to our commercial partners. Sales to our commercial partners are typically made at little or no profit for resale.

Royalty Income. We recognize revenue from royalties based on our commercial partners' net sales of products, typically calculated as a percentage of the net selling price, which is net of discounts, returns and allowances incurred by our commercial partners. Royalty Income is recognized as earned in accordance with contract terms when it can be reasonably estimated and collectability is reasonably assured.

License Revenue. We analyze each element of our licensing agreement 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. We recognize 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.

Collaborative Arrangements. We recognize revenue from reimbursement received in connection with feasibility studies and development work for third parties. Our principal costs under these arrangements include our personnel conducting research and development, and our allocated overhead, as well as research and development performed by outside contractors or consultants.

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

Currently, most of our product sales are from Argatroban and Ryanodex® and royalty income is derived from the sale of Argatroban to, and the resale by, two commercial partners, Sandoz and The Medicines Company. The primary factors that determine our revenues derived from Argatroban are:

- the level of orders submitted by our commercial partners — Sandoz and The Medicines Company;
- the level of institutional demand for Argatroban;
- unit sales prices; and
- the amount of gross-to-net sales adjustments realized by our marketing partners.

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

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

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

We also have generated collaborative licensing and development revenue from our collaboration arrangements with third parties. Revenues have been generated from the achievement of milestones pursuant to, or other payments made under, arrangements related to the divestiture of non-core assets, namely Diclofenac-misoprostol tablets, a generic

product candidate sold to Hikma, and EP-2101 (topotecan), which was licensed to Pfizer.

Cost of Revenue

Cost of revenue consists of the costs associated with producing our products for our commercial partners. In particular, our cost of revenue includes production costs of Argatroban and Ryanodex® paid to a contract manufacturing organization coupled with shipping and customs charges, as well as royalty expense. Cost of revenue may also include the effects of product recalls, if applicable.

Research and Development

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

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

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

Selling, General and Administrative

Selling, general and administrative costs consist primarily of salaries, benefits and other related costs, including stock-based compensation for executive, finance, selling and operations personnel. Included in selling costs are expenses related to our contracted sales organization and marketing of Ryanodex®. General and administrative expenses include facility and related costs, professional fees for legal, consulting, tax and accounting services, insurance, selling, market research, advisory board and key opinion leaders, depreciation and general corporate expenses. We expect that our selling, general and administrative expenses will increase with the continued development and potential commercialization of our product candidates particularly as we begin to commercialize our own products in the United States, as well as increased expenses associated with being a public company.

Other Income (Expense)

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

Income Tax Benefit

Income tax benefit primarily consists of proceeds from the sale of our New Jersey state net operating losses which is net of any minimum state taxes paid.

Income Tax Provision

Income tax provision reflects management's best assessment of estimated future taxes to be paid.

Results of Operations

Comparison of Three Months Ended March 31, 2015 and 2014

Revenues

	Three Months Ended March 31,		Increase/ (Decrease)
	2015	2014	
	(in thousands)		
Product sales	$3,056	$1,175	$1,881
Royalty income	3,253	3,565	(312)
License and other income	30,000	265	29,735
Total revenue	$36,309	$5,005	$31,304

Total revenue increased $31.3 million in the three months ended March 31, 2015 to $36.3 million as compared to $5.0 million in the three months ended March 31, 2014.

Product sales increased $1.9 million in the three months ended March 31, 2015 to $3.1 million as compared to $1.2 million in the three months ended March 31, 2014. This increase was due to Ryanodex®, launched in August 2014, which resulted in net product sales of $1.6 million for the three months ended March 31, 2015.

Royalty income decreased $(0.3) million in the three months ended March 31, 2015 to $3.3 million as compared to $3.6 million in the three months ended March 31, 2014, as a result of decreased end use sales of Argatroban by our commercial partners.

License and other income increased $29.7 million in the three months ended March 31, 2015 to $30.0 million as compared to $0.3 million in the three months ended March 31, 2014, as a result of the licensing agreement with Cephalon.

Cost of Revenue

	Three Months Ended March 31,		Increase
	2015	2014	
	(in thousands)		
Cost of revenue	$5,948	$3,360	$2,588

Cost of net revenues increased by $2.6 million to $5.9 million in the three months ended March 31, 2015 from $3.3 million in the three months ended March 31, 2014. This $2.6 million net increase in cost of revenues was mainly attributable to product sales of Ryanodex® and an increase in royalty expense to SciDose related to the licensing agreement with Cephalon. We recognized $3.2 million and $2.4 million in royalty expense for the three months ended March 31, 2015 and 2014, respectively.

Cost of revenue related to Ryanodex® was approximately $1.6 million, of which $0.2 million was for royalty expense, $1.1 million for expiring inventory, $0.2 million was related to product sales and $0.1 million for other expenses incurred including predominantly certain regulatory and other expenses to our third party logistics partner.

Research and Development

	Three Months Ended March 31,		Increase/ (Decrease)
	2015	2014	
	(in thousands)		
EP-6101 (bivalirudin)	$797	$854	$(57)
EP-3101 (bendamustine RTD)	731	779	(48)
EP-3102 (bendamustine rapid infusion)	2,646	496	2,150
Ryanodex® (dantrolene sodium)	226	535	(309)
Pemetrexed	457	—	457
Diclofenac-misoprostol	18	300	(282)
All other projects	62	31	31
Salary and other personnel related expenses	1,348	799	549
Total Research and Development	$6,285	$3,794	$2,491

Research and development expenses increased $2.5 million in the three months ended March 31, 2015 to $6.3 million as compared to $3.8 million in the three months ended March 31, 2014. Expenses in the three months ended March 31, 2015 were higher than in the three months ended March 31, 2014 as a result of an increase in project spending for EP-3102 (bendamustine rapid infusion), Pemetrexed, and salaries and other personnel related expenses offset by a decrease in project spending for Ryanodex® and Diclofenac-misoprostol.

Selling, General and Administrative

	Three Months Ended March 31,		Increase
	2015	2014	
	(in thousands)		
Selling, general and administrative	$3,986	$1,454	$2,532

Selling, general and administrative expenses increased $2.5 million in the three months ended March 31, 2015 to $4.0 million as compared to $1.5 million in the three months ended March 31, 2014. This increase is related to a $0.9 million increase in marketing related to Ryanodex® (dantrolene sodium), increase of $0.8 million of professional fees, $0.6 million increase in general and administrative salary and personnel related expenses and a $0.2 million increase in insurance and miscellaneous expenses.

Other Income (Expense)

	Three Months Ended March 31,		Increase/ (Decrease)
	2015	2014	
	(in thousands)		
Interest income	$7	$8	$(1)
Interest expense	(1)	(1)	—
Change in value of warrant liability	—	(383)	383
Total other income/(expense), net	$6	$(376)	$382

Other income and (expense) increased by $0.4 million in the three months ended March 31, 2015 to income of $6.0 thousand as compared to an expense of $0.4 million in the three months ended March 31, 2014. The increase in other income and (expense) was due to the recognition of the change in value of the warrant liability during three months ended March 31, 2014. These convertible notes and warrants converted to common stock in connection with the initial public offering in February 2014.

Income Tax (Provision) Benefit

Income tax (provision) benefit decreased $0.9 million in the three months ended March 31, 2015 to a provision of $0.4 million as compared to a benefit of $1.3 million for the three months ended March 31, 2014. The decrease in

income tax (provision) benefit

was due to the sale of our New Jersey State net operating losses during the three months ended March 31, 2014, offset by the tax provision resulting from the Company recognizing net income in the current quarter.

Net Income (Loss)

Net income for the three months ended March 31, 2015 was $19.7 million as compared to net loss of $(2.7) million in the three months ended March 31, 2014, as a result of the factors discussed above.

Liquidity and Capital Resources

On February 18, 2014, we closed our initial public offering whereby 3,350,000 shares of common stock were sold, 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 $46.1 million.

On March 20, 2015, we completed the Follow-on Offering described above under the heading "Recent Developments". As previously indicated, the net proceeds to us from this offering, after deducting underwriting discounts and commissions and other offering expenses payable by us, were approximately $54.3 million.

Our primary uses of cash are to fund working capital requirements, product development costs and operating expenses. Historically, we have funded our operations primarily through private placements of preferred stock and convertible notes and out-licensing product rights. Cash and cash equivalents were $99.9 million and $54.9 million as of March 31, 2015 and March 31, 2014, respectively. In addition, we have short term investments in U.S. Treasury Bills of $16.0 million at March 31, 2015.

For the three months ended March 31, 2015, we realized net income of $19.7 million. As of March 31, 2015, we had a working capital surplus of $102.7 million. For the three months ended March 31, 2014, we incurred a net loss of $(2.7) million. We have sustained significant losses since our inception on January 2, 2007 and had accumulated a deficit of $90.0 million as of March 31, 2015.

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

Operating Activities:

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

At March 31, 2015, our cumulative receivables related to royalty income consist of approximately $8.0 million in receivables from The Medicines Company and $1.2 million in receivables from Sandoz.

Based on our agreement with The Medicines Company, our cumulative receivables related to that agreement will continue to aggregate in future periods. Our agreement with The Medicines Company does not contemplate the ability for the parties to net settle amounts receivable or payable. Nonetheless, the Company has periodically collected from

The Medicines Company amounts that would be equal to the net amount of receivables due from The Medicines Company, but, because it is unclear whether such cash receipt is intended to be settlement of the net receivable or only a partial payment towards the gross receivable, the Company has presented these receivables and payables in gross amounts on its condensed financial statements. As a result, the cumulative receivable from The Medicines Company, as reduced by the cash received from The Medicines Company, aggregates from period-to-period and has never been fully offset by those actual cash payments. At March 31, 2015, we recorded a receivable of approximately $8.0 million and a payable of $6.5 million to The Medicines Company (based upon a 50% revenue split on Sandoz sales). The net receivable due from The Medicines Company for the quarter ended March 31, 2015 therefore is $1.5 million. The

receivable of $1.5 million from The Medicines Company as of March 31, 2015 therefore represents the net cumulative receivable of the Company.

We believe that our accounts receivable as of March 31, 2015, after taking into account netting of receivables and payables related to The Medicines Company, are reasonably collectible, and given the payment terms, will be collected in approximately 90 days, and thus would not have a material effect on our liquidity.

Net cash used in operating activities for the three months ended March 31, 2014 was $2.0 million. Net loss for the period was $2.7 million offset by non-cash adjustments of approximately $0.6 million from the change in the value of the warrant liability, depreciation and stock-based compensation expense. Net changes in working capital increased cash from operating activities by approximately $0.1 million, due to an increase in accounts receivable of $1.2 million, an increase in prepaid expenses and other current assets of $0.5 million and an increase in accounts payable and accrued expenses of $2.1 million. This was offset by a decrease in deferred revenue of $0.3 million. Accounts payable and accrued expenses increased primarily due to accrued royalties and accrued expenses related to the initial public offering. The total amount of accounts receivable at March 31, 2014 was approximately $7.8 million, which included approximately $0.9 million of product sales and approximately $6.5 million of royalty income, all with payment terms of 45 days and approximately $0.4 million of other receivables. For royalty income, the 45-day period starts at the end of the quarter upon receipt of the royalty statement detailing the amount of sales in the prior completed quarter, and, for product sales, the period starts upon delivery of product.

Investing Activities:

In the three months ended March 31, 2015 and 2014, we invested $43 thousand and $28 thousand, respectively, for the purchase of property and equipment.

In the three months ended March 31, 2015 and 2014, we invested $16.0 million and $0, respectively, of short term investments.

Financing Activities:

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

Net cash provided by financing activities for the three months ended March 31, 2014 was $47.0 million, primarily resulting from the issuance of Common Stock from the initial public offering and the exercise of warrants of $20.9 thousand.

Contractual Obligations

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

	Total	2015	2016	2017	2018	2019	Beyond
Operating lease obligations	$2,107	230	417	417	417	417	209

Recent Accounting Pronouncements

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

The standard is effective for annual periods beginning after December 15, 2016, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our financial statements and have not yet determined the method by which we will adopt the standard in 2017.

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

Off-Balance Sheet Arrangements

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

Impact of Inflation

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. Our exposure to market risk is confined to our cash and cash equivalents. As of March 31, 2015 we had cash and cash equivalents of $99.9 million. We do not engage in any hedging activities against changes in interest rates. Because of the short-term maturities of our cash and cash equivalents and short-term investments, we do not believe that a change in market rates would have any significant impact on the realized value of our investments. We may, however, require additional financing to fund future obligations and no assurance can be given that the terms of future sources of financing will not expose us to material market risk.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on their evaluation at March 31, 2015, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended March 31, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II-OTHER INFORMATION

Item 1. Legal Proceedings

Cephalon (U.S. Patent No. 8,445,524)

On October 21, 2013, Cephalon Inc. ("Cephalon"), a subsidiary of Teva, filed a lawsuit in the United States District Court for the District of Delaware alleging that our tentatively approved bendamustine hydrochloride injection infusion product infringes one of its patents, U.S. Patent No. 8,445,524. On November 15, 2013, we filed an Answer and Counterclaims seeking Declaration of Non-infringement. On December 9, 2013, Cephalon filed an Answer to our counterclaims. At Cephalon’s request, the court dismissed this suit with prejudice on November 10, 2014.

Cephalon (U.S. Patent No. 8,791,270)

On July 29, 2014, Patent No. 8,791,270 was issued to Cephalon, and was subsequently listed in the FDA’s Orange Book for the referenced listed drug Treanda®. On August 12, 2014, Cephalon filed a lawsuit against us in the United Stated District Court for the District of Delaware alleging infringement by our NDA filing of U.S. Patent No. 8,791,270. On September 3, 2014, we filed an Answer and Counterclaims seeking a Declaration of Non-infringement and/or Invalidity. On September 15, 2014, Cephalon filed an Answer to our counterclaims. On October 31, 2014, our lawsuit was consolidated with twenty-five other lawsuits Cephalon had filed against sixteen defendants who seek to manufacture generic Treanda®.

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

Also, on February 13, 2015, the Company submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for EP-3102, its rapid infusion bendamustine product, which was accepted by the FDA on April 14, 2015. The Prescription Drug User Fee Act (PDUFA) goal date for a decision on this NDA by the FDA is December 2015.

Additionally, the Company received an upfront cash payment of $30.0 million, and is currently eligible to receive up to $90.0 million in additional milestone payments. In addition, the Company will 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 and Cephalon have agreed to enter into a supply agreement, pursuant to which the Company will be responsible for supplying product to Cephalon for a specified period.

In connection with the entry into the License, on February 13, 2015, the Company 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, under which the Company has agreed to enter into a Consent Judgment regarding the ‘270 patent. As part of the Cephalon Settlement Agreement, Cephalon has agreed to waive its orphan drug exclusivities for the treatment of patients with chronic lymphocytic leukemia and patients with indolent B-cell non-Hodgkin lymphoma with EP-3102.

Other

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

Item 1a. Risk Factors

Except for the risk factors set forth below, there have been no material changes from the Company’s risk factors and uncertainties disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2014. For a complete discussion of the Company's risk factors, refer to Part I, Item 1A, “Risk Factors,” contained in the Company’s Annual Report on Form 10-K for the period ended September 30, 2014.

We have incurred significant losses since our inception and we may continue to incur significant losses for the foreseeable future and may never be profitable.

We have a limited operating history. To date, we have focused primarily on developing a broad product portfolio and have obtained regulatory approval for three products. Some of our product candidates will require substantial additional development time and resources before we would be able to receive regulatory approvals, implement commercialization strategies and begin generating revenue from product sales. We have net income of $19.7 million for the three months ended March 31, 2015, however, we may not generate significant revenue from sales of our product candidates in the near-term, if ever. As of March 31, 2015, we had an accumulated deficit of $90.0 million.

We have devoted most of our financial resources to product development. To date, we have financed our operations primarily through the sale of equity and debt securities. The size of our future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenue. To date, only Argatroban, Ryanodex® and diclofenac-misoprostol have been commercialized, and if our product candidates are not successfully developed or commercialized, or if revenue is insufficient following marketing approval, we will not achieve profitability and our business may fail. Even if we successfully obtain regulatory approval to market our product candidates in the United States, our revenue is also dependent upon the size of the markets outside of the United States, as well as our ability to obtain market approval and achieve commercial success in those jurisdictions.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to fully predict the timing or amount of our expenses, but we expect to continue to incur substantial expenses, which we expect to increase as we expand our development activities and product portfolio. As a result of the foregoing, we expect to continue to incur significant and increasing losses and negative cash flows for the foreseeable future, which may increase compared to past periods. We believe that our existing cash and cash equivalents, together with interest thereon, may only be sufficient to fund our operations for a minimum of twelve months.

We are heavily dependent on the success of our lead product candidates EP-3101 (bendamustine RTD), EP-3102 (bendamustine rapid infusion), EP-6101 (bivalirudin) and EP-4104 (dantrolene for EHS). We cannot give any assurance that we will receive regulatory approval for such product candidates, which is necessary before they can be commercialized.

Our business and future success are substantially dependent on our ability to successfully and timely develop, obtain regulatory approval for, and commercialize our lead product candidates EP-3101 (bendamustine RTD), EP-3102 (bendamustine rapid infusion), and EP-4104 (dantrolene for EHS). Any delay or setback in the development of any of these product candidates could adversely affect our business. Our planned development, approval and commercialization of these product candidates may fail to be completed in a timely manner or at all. Our other product candidates, EP-6101 (bivalirudin) and EP-5101 (pemetrexed), are at an earlier development stage and it will require additional time and resources to develop and seek regulatory approval for such product candidates and, if we are successful, to proceed with commercialization. We cannot provide assurance that we will be able to obtain approval for any of our product candidates from the FDA or any foreign regulatory authority or that we will obtain such approval in a timely manner. For example, in August 2009, we submitted our product EP-2101 (topotecan) for approval in the United States under the 505(b)(2) regulatory pathway, referencing the brand product, Hycamtin. Ultimately, the FDA determined that it could not approve the application as submitted due to the amount of active drug per vial in our product and the potential for unintentional overdose. Based on the FDA's feedback and our determination that the market for topotecan had become overly competitive with multiple players, we decided not to continue to pursue product approval and we do not currently have plans to commercialize EP-2101 (topotecan). Additionally as of September 30, 2014 we have decided not to commercialize EP-2101.

An NDA submitted under Section 505(b)(2) subjects us to the risk that we may be subject to a patent infringement lawsuit that would delay or prevent the review or approval of our product candidate.

Our product candidates will be submitted to the FDA for approval under Section 505(b)(2) of the FDCA. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies that were not conducted by, or for, the applicant and on which the applicant has not obtained a right of reference. The 505(b)(2) application would enable us to reference published literature and/or the FDA's

previous findings of safety and effectiveness for the branded reference drug. For NDAs submitted under Section 505(b)(2) of the FDCA, the patent certification and related provisions of the Hatch-Waxman Act apply. In accordance with the Hatch-Waxman Act, such NDAs may be required to include certifications, known as paragraph IV certifications, that certify that any patents listed in the Patent and Exclusivity Information Addendum of the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, with respect to any product referenced in the 505(b)(2) application, are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505(b)(2) NDA.

Under the Hatch-Waxman Act, the holder of patents that the 505(b)(2) application references may file a patent infringement lawsuit after receiving notice of the paragraph IV certification. Filing of a patent infringement lawsuit against the filer of the 505(b)(2) applicant within 45 days of the patent owner's receipt of notice triggers a one-time, automatic, 30-month stay of the FDA's ability

to approve the 505(b)(2) NDA, unless patent litigation is resolved in the favor of the paragraph IV filer or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all. In addition, a 505(b)(2) application will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, or NCE, listed in the Orange Book for the referenced product has expired. The FDA may also require us to perform one or more additional clinical studies or measurements to support the change from the branded reference drug, which could be time consuming and could substantially delay our achievement of regulatory approvals for such product candidates. The FDA may also reject our future 505(b)(2) submissions and require us to file such submissions under Section 505(b)(1) of the FDCA, which would require us to provide extensive data to establish safety and effectiveness of the drug for the proposed use and could cause delay and be considerably more expensive and time consuming. These factors, among others, may limit our ability to successfully commercialize our product candidates.

Companies that produce branded reference drugs routinely bring litigation against abbreviated new drug application, or ANDA, or 505(b)(2) applicants that seek regulatory approval to manufacture and market generic and reformulated forms of their branded products. These companies often allege patent infringement or other violations of intellectual property rights as the basis for filing suit against an ANDA or 505(b)(2) applicant. Likewise, patent holders may bring patent infringement suits against companies that are currently marketing and selling their approved generic or reformulated products.

Litigation to enforce or defend intellectual property rights is often complex and often involves significant expense and can delay or prevent introduction or sale of our product candidates. If patents are held to be valid and infringed by our product candidates in a particular jurisdiction, we would, unless we could obtain a license from the patent holder, be required to cease selling in that jurisdiction and may need to relinquish or destroy existing stock in that jurisdiction. There may also be situations where we use our business judgment and decide to market and sell our approved products, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts, which is known as an "at-risk launch." The risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement may include, among other things, damages measured by the profits lost by the patent owner and not necessarily by the profits earned by the infringer. In the case of a willful infringement, the definition of which is subjective, such damages may be increased up to three times. Moreover, because of the discount pricing typically involved with bioequivalent and, to a lesser extent, 505(b)(2), products, patented branded products generally realize a substantially higher profit margin than bioequivalent and, to a lesser extent, 505(b)(2), products, resulting in disproportionate damages compared to any profits earned by the infringer. An adverse decision in patent litigation could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

We have very limited sales, marketing or distribution experience and have only recently started the initial phases of developing an internal commercial organization. Although we have begun to establish a small, focused, specialty sales and marketing organization to promote Ryanodex® in the United States, we currently have no such organization or capabilities, and the cost of establishing and maintaining such an organization may exceed the benefit of doing so. We have very limited prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We also intend to enter into strategic partnerships with third parties to commercialize our product candidates both inside and outside of the United States and have recently entered into a strategic partnership with Cephalon, a wholly owned subsidiary of Teva, to commercialize our bendamustine hydrochloride (HCl) rapid infusion, if approved. We may have limited or no control over the sales, marketing and distribution activities of Cephalon. Our future revenues may depend heavily on the success of the efforts of Cephalon.

We may have difficulty establishing additional relationships with third parties on terms that are acceptable to us, or in all of the regions where we wish to commercialize our products, or at all. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

In addition to the agreements we have for Argatroban and bendamustine hydrochloride (HCl) rapid infusion, we may enter into agreements with third parties to market Ryanodex® (dantrolene sodium) and diclofenac-misoprostol outside the United States. Additionally, we may enter into agreements with third parties to market our products, as well as Argatroban, outside the United States. We expect that we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We expect to have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. For example, Argatroban is currently marketed in the United States by, among others, GlaxoSmithKline, or GSK, West-Ward Pharmaceuticals, or West-Ward, and Teva Pharmaceutical Industries Ltd., or Teva, and bendamustine is marketed in the United States by Cephalon under the brand name Treanda®. Further, makers of branded reference drugs could also enhance their own formulations in a manner that competes with our enhancements of these drugs. Cephalon has obtained approval for a ready to dilute, or RTD, version of Treanda® which will compete with our EP-3101 (bendamustine RTD) product.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products or drug delivery technologies that are more effective or less costly than Argatroban and Ryanodex® or any product candidate that we are currently developing or that we may develop. In addition, our competitors may file citizens' petitions with the FDA in an attempt to persuade the FDA that our products, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

We believe that our ability to successfully compete will depend on, among other things:

- the efficacy and safety of our products and product candidates, including as relative to marketed products and product candidates in development by third parties;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- the ability to maintain a good relationship with regulatory authorities;
- the ability to commercialize and market any of our product candidates that receive regulatory approval;

- the price of our products, including in comparison to branded or generic competitors;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;
- the ability to protect intellectual property rights related to our products and product candidates;
- the ability to manufacture on a cost-effective basis and sell commercial quantities of our products and product candidates that receive regulatory approval; and
- acceptance of any of our products and product candidates that receive regulatory approval by physicians and other health care providers.

If our competitors market products that are more effective, safer or less expensive than our product candidates, if any, or that reach the market sooner than our product candidates, if any, we may enter the market too late in the cycle and may not achieve commercial

success. In addition, the biopharmaceutical industry is characterized by rapid technological change. Because we have limited research and development capabilities, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

We rely on third parties to manufacture commercial supplies of Argatroban, Ryanodex®, Diclofenac-misoprostol and clinical supplies of our product candidates, and we intend to rely on third parties to manufacture commercial supplies of any other approved products. The commercialization of any of our products could be stopped, delayed or made less profitable if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices or fail to maintain or achieve satisfactory regulatory compliance.

We do not own any manufacturing facilities, and we do not currently, and do not expect in the future, to independently conduct any aspects of our product manufacturing and testing, or other activities related to the clinical development and commercialization of our product candidates. We currently rely, and expect to continue to rely, on third parties with respect to these items, and control only certain aspects of their activities.

Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it could delay our product candidate development and commercialization activities. Our reliance on these third parties reduces our control over these activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards and any applicable trial protocols. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we will not be able to complete, or may be delayed in completing, clinical trials required to support future regulatory submissions and approval of our product candidates.

Our products and product candidates are highly reliant on very complex sterile techniques and personnel aseptic techniques. The facilities used by our third-party manufacturers to manufacture our products and product candidates must be approved by the applicable regulatory authorities pursuant to inspections that will be conducted after we submit our NDA to the FDA. If any of our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the applicable regulatory authorities' strict regulatory requirements, or pass regulatory inspection, they will not be able to secure or maintain regulatory approval for the manufacturing facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Quality problems in manufacturing are linked to a majority of shortages of sterile injectable drugs. Some of the largest manufacturers of sterile injectable drugs have had serious quality problems leading to the temporary voluntary closure or renovations of major production facilities. Further, as we scale up manufacturing of our product candidates and conduct required stability testing, product packaging, equipment and process-related issues may require refinement or resolution in order for us to proceed with our planned clinical trials and obtain regulatory approval for commercialization of our product candidates. In the future, for example, we may identify impurities in the product manufactured for us for commercial supply, which could result in increased scrutiny by the regulatory agencies, delays in our clinical program and regulatory approval, increases in our operating expenses, or failure to obtain or maintain approval for our product candidates. If the FDA or any other applicable regulatory authority does not approve these facilities to manufacture our products or if they withdraw any such approval in the future, or if our suppliers or third-party manufacturers decide they no longer want to manufacture our products, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our products or product candidates.

More generally, manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to make product candidates available for clinical trials and development purposes or to further commercialize Argatroban, Ryanodex® and Diclofenac-misoprostol or commercialize any of our other

product candidates in the United States would be jeopardized. Any delay or interruption in our ability to meet commercial demand may result in the loss of potential revenues and could adversely affect our ability to gain market acceptance for approved products. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. Regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

The occurrence of any of these factors could have a material adverse effect on our business, results of operations, financial condition and prospects.

The design, development, manufacture, supply, and distribution of our product candidates is highly regulated and technically complex.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP and equivalent foreign standards. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. The development, manufacture, supply, and distribution of Argatroban and Ryanodex®, as well as our other product candidates, is highly regulated and technically complex. We, along with our third-party providers, must comply with all applicable regulatory requirements of the FDA and foreign authorities.

We, or our contract manufacturers, must supply all necessary documentation in support of our regulatory filings for our product candidates on a timely basis and must adhere to the FDA's good laboratory practices, or GLP, and cGMP regulations enforced by the FDA through its facilities inspection program, and the equivalent standards of the regulatory authorities in other countries. Any failure by our third-party manufacturers to comply with cGMP or failure to scale-up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must also pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities in any country may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities and quality systems do not pass a pre-approval plant inspection, FDA approval of our product candidates, or the equivalent approvals in other jurisdictions, will not be granted.

Regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or biological product or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be materially harmed.

We rely on limited sources of supply for Argatroban, Ryanodex®, Diclofenac-misoprostol and for our product candidates, and any disruption in the chain of supply may impact production and sales of Argatroban and cause delay in developing and commercializing our product candidates.

We currently have relationships with only one third party for the manufacture of each of our most advanced product candidates and for our commercial supply of Argatroban. These include development relationships with Zydus BSV Pharma Pvt. Ltd. for our EP-3101 (bendamustine RTD) product and AAIPharma Services Corp. for our dantrolene product and a supply agreement with Cipla Limited for supply of Diclofenac-misoprostol and Argatroban product to The Medicines Company and Sandoz under their agreements with us for commercialization of Argatroban. 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 we believe are capable of performing this function for us. Switching finished drug suppliers may involve substantial cost and could result in a delay in our desired clinical and commercial timelines. If any of these

single-source manufacturers breaches or terminates their agreements with us, we would need to identify an alternative source for the manufacture and supply of product candidates to us for the purposes of our development and commercialization of the applicable products. Identifying an appropriately qualified source of alternative supply for any one or more of these product candidates could be time consuming, and we may not be able to do so without incurring material delays in the development and commercialization of our product candidates, which could harm our financial position and commercial potential for our products. Any alternative vendor would also need to be qualified through an NDA supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if we appoint a new manufacturer for supply of our product candidates that differs from the manufacturer used for clinical development of such product candidates. For our other product candidates, we expect that only one supplier will initially be qualified as a vendor with the FDA. If supply from the approved vendor is interrupted, there could be a significant disruption in commercial supply.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of components and active pharmaceutical ingredient on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

If any of our current strategic collaborators fail to perform their obligations or terminate their agreements with us, the development and commercialization of the product candidates under such agreements could be delayed or terminated and our business could be substantially harmed.

On February 13, 2015, we entered into an exclusive license agreement, which we refer to as the Cephalon agreement, with Cephalon, a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd., for U.S. and Canadian rights to the our 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 agreement, Cephalon will be responsible for all U.S. commercial activities for the product including promotion and distribution, and we will be responsible for obtaining and maintaining all regulatory approvals and conducting post-approval clinical studies.

This strategic collaboration may not be scientifically or commercially successful due to a number of important factors, including the following:

- If our development efforts for our product do not result in a successful commercial product, or we fail to obtain or maintain any regulatory approvals, we may not receive all anticipated milestone and royalty payments.
- Cephalon has significant discretion in determining the efforts and resources that it will apply to their strategic collaboration with us. The timing and amount of any cash payments, milestones and royalties that we may receive under such agreements will depend on, among other things, the efforts, allocation of resources and the commercialization of our product by Cephalon under the Cephalon agreement;
- Cephalon currently markets a competitive bendamustine product, Treanda, in the United States. In addition, it is possible that Cephalon may develop and commercialize, either alone or with others, or be acquired by a company that has, products that are similar to or competitive with the product candidates that they license from us;
- Cephalon may change the focus of their commercialization efforts or pursue higher-priority programs;
- Cephalon may terminate its strategic collaboration with us on short notice, which could make it difficult for us to attract new strategic collaborators or adversely affect how we are perceived in the scientific and financial communities;
- Cephalon has the right to maintain or defend our intellectual property rights licensed to them in their territories, and, although we may have the right to assume the maintenance and defense of our intellectual property rights if they do not, our ability to do so may be compromised by our strategic collaborators' acts or omissions; and
- Cephalon may not comply with all applicable regulatory requirements, or fail to report safety data in accordance with all applicable regulatory requirements.
- If Cephalon fails to effectively commercialize our product, we may not be able to replace them with another collaborator.
- If our agreement with Cephalon terminates, we are required to pay them a portion of our future profits on the product.

Any of these events could have a material adverse effect on our business, results of operations and our ability to achieve future profitability, and could cause our stock price to decline.

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

As of March 31, 2015 we had a total of 30 full-time and one part time employees in the United States and one full time consultant in India. As our company matures, we expect to expand our employee base to increase our managerial, scientific and engineering, operational, sales, marketing, financial and other resources and to hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our

management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to sell Argatroban and Ryanodex® and commercialize our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage any future growth.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability. The use of our product candidates in clinical trials (if any), and the sale of Argatroban, Ryanodex® or diclofenac-misoprostol and any product candidates for which we obtain marketing approval, exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with Argatroban, Ryanodex® or diclofenac-misoprostol, and other approved future products and our product candidates. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical study participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for Argatroban, Ryanodex® and diclofenac-misoprostol and our product candidates, if approved for commercial sale.

Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

The patents and the patent applications that we have covering our products are limited to specific formulations, methods of use and processes, and our market opportunity for Argatroban and Ryanodex® and our product candidates may be limited by the lack of patent protection for the active ingredients and by competition from other formulations and delivery methods that may be developed by competitors.

Patent protection on the active ingredient in Argatroban has expired, and there is therefore no composition of matter patent protection available for the active ingredient in Argatroban. This is also the case with respect to our other product candidates. We have obtained, and continue to seek to obtain patent protection of other aspects of Argatroban and our product candidates, including specific formulations, methods of use and processes, which may not be as effective as composition of matter coverage in preventing work-arounds by competitors. As a result, generic products that do not infringe the claims of our issued patents covering formulations, methods of use and processes are, or may be, available while we are marketing our products. Competitors who obtain the requisite regulatory approval will be able to commercialize products with the same active ingredients as Argatroban and such other product candidates so long as the competitors do not infringe any process, use or formulation patents that we have developed for our products, subject to any regulatory exclusivity we may be able to obtain for our products.

The number of patents and patent applications covering products containing the same active ingredient as Argatroban and our product candidates indicates that competitors have sought to develop and may seek to commercialize competing formulations that may not be covered by our patents and patent applications. The commercial opportunity for Argatroban and our product candidates could be significantly harmed if competitors are able to develop and commercialize alternative formulations of Argatroban and our product candidates that are different from ours and do not infringe our issued patents covering our products.

Ryanodex® (dantrolene sodium), Argatroban and diclofenac-misoprostol have been approved by the FDA, and we anticipate that other product candidates will be approved by the FDA in the future. For our current products on the market, and future products once they are on the market, one or more third parties may also challenge the patents that we control covering our products, which could result in the invalidation or unenforceability of some or all of the relevant patent claims of our issued patents covering our products. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with

these requirements.

Ryanodex® (dantrolene sodium), Argatroban and diclofenac-misoprostol have been approved by the FDA, and we anticipate that other product candidates will be approved by the FDA in the future. Once our products are on the market, one or more third parties may also challenge the patents that we control covering our products in court or the US PTO, which could result in the invalidation or unenforceability of some or all of the relevant patent claims of our issued patents covering our products.

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering one of our products or product candidates, the defendant could counterclaim that the patent covering our product or product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability

of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors that control the prosecution and maintenance of our licensed patents fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Our initial public offering was completed in February 2014 at a public offering price of $15.00 per share followed by a secondary offering in March 2015 at a public offering price of $42.00 per share. The trading price of our common stock is likely to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

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