EAGLE PHARMACEUTICALS, INC.
Form 10-Q
August 11, 2014

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

FORM 10-Q

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

For the quarterly period ended June 30, 2014
OR

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.

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 August 8, 2014: 14,020,133 shares.

Eagle Pharmaceuticals, Inc.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements, that involve risk and uncertainties. The words “may,” “will,” “plan,” “believe,” “expect,” “intend,” “anticipate,” “potential,” “should,” “estimate,” “predict,” “project,” similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause actual results to differ materially from those projected in the forward-looking statements.

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

- the success, cost and timing of our product development activities and clinical trials;
- our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our ability to obtain funding for our operations;
- our plans to research, develop and commercialize our product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our ability to successfully commercialize our product candidates;
- the rate and degree of market acceptance of our product candidates;
- our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators;
- 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 the recent 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 Form 10Q and are subject to risks and uncertainties. We discuss many of these risks in greater detail under the heading “Risk Factors.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

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

NOTE REGARDING COMPANY REFERENCES

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

NOTE REGARDING TRADEMARKS

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

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EAGLE PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS

	June 30, 2014 (unaudited)	September 30, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$49,790,920	$10,455,565
Accounts receivable	6,712,244	5,124,182
Inventories	329,034	—
Prepaid expenses and other current assets	922,930	1,902,660
Total current assets	57,755,128	17,482,407
Property and equipment, net	359,509	402,286
Other assets	45,000	46,320
Deferred initial public offering costs	—	171,607
Total assets	$58,159,637	$18,102,620
LIABILITIES, SHARES SUBJECT TO REDEMPTION AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$2,520,523	$1,192,600
Accrued expenses	7,468,794	3,129,552
Deferred revenue	6,259,653	10,019,653
Total current liabilities	16,248,970	14,341,805
Redeemable Series C Preferred Stock warrants	—	1,706,829
Shares subject to redemption:		
Series A Convertible Preferred Stock, $0.001 par value; no shares and, 14,948,506 shares authorized at June 30, 2014 and September 30, 2013, respectively; no shares issued and outstanding as of June 30, 2014 and 14,948,506 shares issued and outstanding as of September 30, 2013	—	20,056,790
Series B Convertible Preferred Stock, $0.001 par value; no shares and 12,694,561 shares authorized, at June 30, 2014 and September 30, 2013, respectively; no shares issued and outstanding as of June 30, 2014 and 12,694,561 shares issued and outstanding as of September 30, 2013	—	30,089,853
Series B-1 Convertible Preferred Stock, $0.001 par value; no shares and 9,331,374 shares authorized at June 30, 2014 and September 30, 2013, respectively; no shares issued and outstanding as of June 30, 2014 and 9,331,374 shares issued and outstanding as of September 30, 2013	—	19,374,285
Series C Convertible Preferred Stock, $0.001 par value; no shares and 11,901,336 shares authorized at June 30, 2014 and September 30, 2013, respectively; no shares issued and outstanding as of June 30, 2014 and 11,023,232 shares issued and outstanding as of September 30, 2013	—	20,462,072
Commitments and contingencies		
Stockholders' Equity (Deficit):		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of June 30, 2014; no shares authorized, issued or outstanding as of September 30, 2013	—	—
Common stock, $0.001 par value; 50,000,000 and 80,000,000 shares authorized as of June 30, 2014 and September 30, 2013, respectively; 14,020,133 and 3,048,131 issued and outstanding as of June 30, 2014 and	14,020	3,048

September 30, 2013, respectively		
Additional paid in capital	136,970,460	14,203,995
Accumulated deficit	(95,073,813)	(102,136,057)
Total stockholders' equity (deficit)	41,910,667	(87,929,014)
Total liabilities, shares subject to redemption and stockholders' equity (deficit)	$58,159,637	$18,102,620

See accompanying notes to condensed financial statements.

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EAGLE PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS
(unaudited)

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2014	2013	2014	2013
Revenue:				
Product sales	$350,350	$2,489,310	$3,748,800	$3,689,640
Royalty income	1,941,526	2,585,719	8,774,407	5,349,289
Other income	3,500,000	—	3,765,000	—
Total revenue	5,791,876	5,075,029	16,288,207	9,038,929
Operating expenses:				
Cost of revenue	1,555,711	2,925,046	9,539,436	4,449,337
Research and development	4,545,158	1,632,280	10,927,912	6,375,896
Selling, general and administrative	2,673,405	1,251,051	5,471,727	6,130,634
Professional fee benefit	—	(1,993,099)	—	(1,993,099)
Total operating expenses	8,774,274	3,815,278	25,939,075	14,962,768
Income/(loss) from operations	(2,982,398)	1,259,751	(9,650,868)	(5,923,839)
Interest income	17,826	1,036	26,647	2,156
Interest expense	(4,812)	(16,018)	(6,244)	(309,121)
Deferred financing costs	—	(38,567)	—	(96,417)
Amortization of debt discount	—	(436,350)	—	(1,090,878)
Change in value of warrant liability	—	(15,608)	(573,582)	(15,608)
Other income	35,305	332	35,590	3,202
Total other income/(expense)	48,319	(505,175)	(517,589)	(1,506,666)
Net Income/(Loss) before income tax benefit	(2,934,079)	754,576	(10,168,457)	(7,430,505)
Income tax benefit	—	—	1,294,905	898,703
Net Income/(Loss)	$(2,934,079)	$754,576	$(8,873,552)	$(6,531,802)
Less dividends on Series A, B, B-1 and C Convertible Preferred Stock	—	(1,074,637)	(1,666,063)	(2,704,567)
Net loss attributable to common stockholders	$(2,934,079)	$(320,061)	$(10,539,615)	$(9,236,369)
Loss per share attributable to common stockholders Basic and diluted	$(0.21)	$(0.11)	$(1.23)	$(3.06)
Weighted average common shares outstanding Basic and diluted	14,020,133	3,048,131	8,590,719	3,020,889

See accompanying notes to condensed financial statements.

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EAGLE PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
(unaudited)

	Common Stock				Total
	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Stockholders' Equity (Deficit)
Balance at September 30, 2013	3,048,131	$3,048	$14,203,995	$(102,136,057)	$(87,929,014)
Stock-based compensation expense			381,736		381,736
Issuance of common stock in connection with initial public offering, including underwriter's over-allotment, net of offering costs and underwriter's discount	3,450,000	3,450	46,044,910		46,048,360
Conversion of Series A Preferred Stock (including accumulated dividends) to common stock in connection with initial public offering	2,332,051	2,332	20,374,290		20,376,622
Conversion of Series B Preferred Stock (including accumulated dividends) to common stock in connection with initial public offering	1,980,431	1,980	30,610,254		30,612,234
Conversion of Series B-1 Preferred Stock (including accumulated dividends) to common stock in connection with initial public offering	1,455,753	1,456	19,754,765		19,756,221
Conversion of Series C Preferred Stock (including accumulated dividends) to common stock in connection with initial public offering	1,719,693	1,720	20,901,092		20,902,812
Conversion of Redeemable Series C Preferred Stock warrants to common stock in connection with initial public offering	32,286	32	2,280,411		2,280,443
Issuance of common stock upon exercise of Redeemable Series C Preferred Stock warrants	1,788	2	20,866		20,868
Dividends on Convertible Preferred Stock and forfeitures of dividends on conversion to common			(17,601,859)	17,601,859	—
Net loss				(8,873,552)	(8,873,552)
Dividends on Convertible Preferred Stock				(1,666,063)	(1,666,063)
Balance at June 30, 2014	14,020,133	$14,020	$136,970,460	$(95,073,813)	$41,910,667

See accompanying notes to condensed financial statements.

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

	Nine Months Ended June 30,	
	2014	2013
Cash flows from operating activities:		
Net loss	$(8,873,552)	$(6,531,802)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	81,762	105,327
Stock-based compensation	381,736	329,920
Non-cash interest expense	—	309,121
Amortization of deferred financing costs	—	96,417
Amortization of debt discount	—	1,090,878
Change in fair value of warrant liability	573,582	15,608
Changes in operating assets and liabilities:		
(Increase) decrease in accounts receivable	(1,588,062)	1,263,875
Increase in inventories	(329,034)	(199,666)
Decrease (increase) in prepaid expenses and other current assets	979,730	(3,346,062)
Decrease in other assets	1,320	30,000
Increase in accounts payable	1,327,923	194,775
(Decrease) increase in deferred revenue	(3,760,000)	892,341
Increase in accrued expenses and other liabilities	4,489,848	185,681
Net cash used in operating activities	(6,714,747)	(5,563,587)
Cash flows from investing activities:		
Purchase of property and equipment	(38,815)	(30,675)
Proceeds from short term investments	—	1,500,000
Net cash (used in) provided by investing activities	(38,815)	1,469,325
Cash flows from financing activities:		
Proceeds from issuance of Series C preferred stock, net of offering costs of $159,727	—	9,828,737
Series C preferred stock offering costs	(1,179)	—
Proceeds from exercise of preferred stock warrants	20,868	—
Proceeds from issuance of common stock from initial public offering, net of issuance costs	46,069,228	—
Net cash provided by (used in) financing activities	46,088,917	9,828,737
Net increase (decrease) in cash	39,335,355	5,734,475
Cash and cash equivalents at beginning of period	10,455,565	5,066,886
Cash and cash equivalents at end of period	$49,790,920	$10,801,361
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Interest	$(6,244)	$—
Franchise taxes	9,295	2,335
Non-cash financing activities		
Conversion of note payable to Common Stock	—	10,062,296
Conversion of preferred stock and accrued dividends to Common stock	91,647,889	11,786,380
Preferred stock dividends	—	2,704,567
Conversion of redeemable warrant liability to Common stock	2,280,443	—

See accompanying notes to condensed financial statements.

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EAGLE PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(Financial information as of June 30, 2014 and for the three and nine months ended June 30, 2014 and 2013 is 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. It is recommended that these condensed financial statements be read in conjunction with the financial statements and related notes that appear in Eagle Pharmaceuticals, Inc.'s (the "Company") final prospectus filed by the Company with the SEC on February 13, 2014, relating to the Company's Registration Statement on Form S-1 (File No. 001-36306) for the Company's initial public offering. In the opinion of management, all adjustments (consisting only of normal recurring adjustments) necessary for the fair presentation of the financial information for the interim periods reported have been made. Results of operations for the three and nine months ended June 30, 2014 are not necessarily indicative of the results for the year ending September 30, 2014 or any period thereafter.

2. Organization and Business Activities

Eagle Pharmaceuticals, Inc. is a pharmaceutical company focused on the development and commercialization of specialty and generic pharmaceutical products, primarily in the injectable arena within the hospital segment. The Company has agreements in place with development partners under which products will be jointly developed and profits from the sales of the products will be shared by the parties. The Company has a number of products currently under development and one currently being sold in the United States.

On February 18, 2014, the Company closed its initial public offering 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 $46,069,228. Included in this amount is $20,868 received from the exercise of Series C preferred stock warrants for 1,788 shares of common stock.

In connection with the initial public offering, 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 initial public offering date, all outstanding shares of preferred stock converted into 7,487,928 shares of common stock and the 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 for the next twelve months. Following these transactions, the Company's total issued common stock as of June 30, 2014 was 14,020,133 shares.

3. Summary of Significant Accounting Policies

Use of Estimates

The preparation of condensed 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 condensed 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 condensed financial statements, actual results may materially vary from these estimates.

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EAGLE PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)
(Financial information as of June 30, 2014 and for the three and nine months ended June 30, 2014 and 2013 is unaudited)

Accounting Guidance Not Yet Adopted

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

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 consolidated financial statements and have not yet determined the method by which we will adopt the standard in 2017.

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.

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 and cash equivalents are classified as Level 1 at June 30, 2014 and September 30, 2013.

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 (See Note 6) 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.

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NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)
(Financial information as of June 30, 2014 and for the three and nine months ended June 30, 2014 and 2013 is unaudited)

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 public offering were net exercised in connection with the initial public offering. There were no outstanding warrants as of June 30, 2014.

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, from which all of its current revenues are currently derived; therefore, the Company's future revenues are highly dependent on these collaboration and distribution arrangements.

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

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2014	2013	2014	2013
Net revenues				
The Medicines Company	51 %	42 %	42 %	53 %
Sandoz, Inc.	49 %	58 %	58 %	47 %
	100 %	100 %	100 %	100 %

	June 30, 2014	September 30, 2013
Accounts receivable		
The Medicines Company	84 %	58 %
Sandoz, Inc.	15 %	40 %
Other	1 %	2 %
	100 %	100 %

Currently, for argatroban, the Company uses one vendor as its sole source of 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 an Abbreviated New Drug Application (an "ANDA") 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 could 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 June 30, 2014 the Company had $329,034 in inventories related to product that was not yet available to be sold. On July 22, 2014, the Company received FDA

approval for the sale of the product.

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EAGLE PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)
(Financial information as of June 30, 2014 and for the three and nine months ended June 30, 2014 and 2013 is unaudited)

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.
Deferred Financing Costs
Prior to the initial public offering, costs relating to obtaining Convertible Notes were capitalized and amortized over the term of the related debt using the straight line method. Amortization of deferred financing costs charged to interest expense was $0, $38,567, $0 and $96,416 for the three and nine months ended June 30, 2014 and 2013, respectively. The unamortized balance as of June 30, 2014 and September 30, 2013 is $0.
Deferred Initial Public Offering Costs
Costs incurred of $2,073,694 related to the initial public offering, consisting primarily of professional fees, were deferred until the completion of the offering at which time such costs, as well as underwriters' fees paid, were netted against proceeds received and reclassified to Additional paid-in capital.
Advertising and Marketing
Advertising and marketing costs are expensed as incurred. Advertising and marketing costs were $596,024, $0, $685,937 and $117,977 for the three and nine months ended June 30, 2014 and 2013, respectively.
Redeemable Convertible Preferred Stock
The carrying value of redeemable convertible preferred stock was increased by periodic accretions, using the interest method so that the carrying amount would equal the redemption amount at the earliest redemption date.
Accounting for Income Taxes
The Company accounts for deferred taxes using the asset and liability method as specified by ASC 740, Income Taxes. Deferred income tax assets and liabilities are determined based on differences between the financial statement reporting and the tax basis of assets and liabilities, operating losses and tax credit carryforwards. Deferred income taxes are measured using the enacted tax rates and laws that are anticipated to be in effect when the differences are expected to reverse. The measurement of deferred income tax assets is reduced, if necessary, by a valuation allowance for any tax benefits which are not expected to be realized. The effect on deferred income tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted.
The Company received approval to sell a portion of the Company's New Jersey net operating losses ("NOL's") as part of the Technology Business Tax Certificate Program sponsored by The New Jersey Economic Development Authority. Under the program, emerging biotechnology firms with unused net operating loss carryovers and unused research and development credits are allowed to sell these benefits to other firms.
During the nine months ended June 30, 2014 and 2013, the Company sold New Jersey state net operating loss (NJ NOL) carry forwards, which resulted in the recognition of $1,294,905 and $898,703 in tax benefits, respectively.
Revenue Recognition
Product Revenue — The Company recognizes net revenue from products manufactured and supplied to its commercial partners, when the following four basic revenue recognition criteria under the related accounting guidance are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. Prior to the shipment of manufactured products, the Company conducts initial product

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release and stability testing in accordance with cGMP. The Company's commercial partners can return the products within contracted specified timeframes if the products do not meet the applicable inspection tests. The Company estimates its return reserves based on its experience with historical return rates. Historically, product returns have not been material.

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.

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.

The Company recognizes revenues from non-refundable up-front license fees received under collaboration agreements ratably over the performance period as determined under the collaboration agreement (estimated development period in the case of development agreements, and contract period or longest patent life in the case of supply and distribution agreements). If the estimated performance period is subsequently modified, the Company will modify the period over which the upfront license fee is recognized accordingly on a prospective basis. 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. No such revenue was recorded in 2014 or 2013.

See Note 10 regarding Asset Sales related to Other Income of $3,500,000 recognized in June 2014.

Stock-Based Compensation

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

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

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2014	2013	2014	2013
Risk-free interest rate	2.11% - 2.16%	.82% - 3.23%	1.77% - 2.16%	.95% - 2.47%
Volatility	56.84%	64.00%	64.00%	36.58% - 39.65%
Expected term (in years)	6.59 - 10.00 years	6.08 - 10.00 years	6.07 - 10.00 years	6.08 - 9.81 years
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

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The risk-free rate assumption was based on U.S. Treasury instruments whose term was consistent with the expected term of the stock options. The expected stock price volatility was determined by examining the historical volatilities for industry peers as the Company did not have any 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.

Net Loss Per Share

Basic loss per common share is computed based on the weighted average number of shares outstanding during the period. Diluted loss per share is computed in a manner similar to the basic 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. Since the Company has incurred net losses for all periods, basic loss per share and diluted loss per share are the same.

The anti-dilutive common shares equivalents outstanding at the three and nine months ended June 30, 2014 and 2013 were as follows:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2014	2013	2014	2013
Series A	—	2,332,059	1,104,226	2,332,059
Series B	—	1,980,429	937,730	1,980,429
Series B-1	—	1,455,750	689,295	1,455,750
Series C	—	1,719,690	814,270	1,719,690
Series C warrants	—	147,254	69,725	147,254
Options	990,330	705,655	891,393	850,749
Total	990,330	8,340,837	4,506,639	8,485,931

4. Inventories

Inventories consist of the following at June 30, 2014 and September 30, 2013:

	June 30, 2014	September 30, 2013
Raw material- pre launch inventory	$329,034	$—
	$329,034	$—

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5. Balance Sheet Accounts

Prepaid and Other Current Assets

Prepaid and other current assets consist of the following:

	June 30, 2014	September 30, 2013
Prepaid expenses and other current assets		
Prepaid Product Costs	$—	$730,003
Prepaid FDA User Fee	—	1,023,291
Prepaid Insurance	514,141	117,510
All Other	408,789	31,856
Total Prepaid expenses and other current assets	$922,930	$1,902,660

Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2014	September 30, 2013
Accrued expenses		
Royalties Due to The Medicines Company	$4,301,683	$1,724,061
Royalties Due to SciDose	859,868	546,756
Accrued Research & Development	815,057	282,682
Accrued Professional Fees	419,242	274,566
Accrued Salary	244,158	169,568
Accrued Product Costs	4,000	62,737
All Other	824,786	69,182
Total Accrued expenses	$7,468,794	$3,129,552

Deferred Revenue

Deferred revenue consists of the following:

	June 30, 2014	September 30, 2013
Deferred revenue		
The Medicines Company	$259,653	$519,653
Deferred Revenue for ongoing business	259,653	519,653
Hikma Pharmaceuticals, Co. Ltd. (See Note 10)	—	3,500,000
Par Pharmaceuticals Companies, Inc.	5,500,000	5,500,000
Par Pharmaceuticals Companies, Inc./Tech Transfer	500,000	500,000
Deferred Revenue from Asset Sales (See Note 10)	6,000,000	9,500,000
Total Deferred revenue	$6,259,653	$10,019,653

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6. Notes Payable

Convertible Notes

The Company entered into a Convertible Note and Warrant Purchase Agreement (the "Convertible Note Agreements"), pursuant to which it issued $9,662,755 of Convertible Notes (the "Convertible Notes") to existing preferred stockholders. The loan funding was completed in two tranches on August 2, 2012 and September 26, 2012, respectively. Holders of the Convertible Notes were entitled to cumulative interest at an annual rate of 6%. Such interest accrued daily and was cumulative from the respective date. In addition, the holders received warrants to purchase preferred stock, which accrued at a monthly rate of 2% of the principal amount until the completion of a Qualified Financing, as defined in the Convertible Note Agreement, or August 1, 2013, whichever was sooner.

The Convertible Notes and associated accrued interest were due and payable on August 1, 2013, unless the Convertible Notes converted earlier. Conversion could occur, upon certain triggering events or the holder elects to convert. Principal and interest accrued shall convert into shares of preferred stock: a) upon the attainment of a Qualified Financing, or b) on August 1, 2013, whichever is sooner. Upon conversion pursuant to (a), the aggregate amount converted will be divided by the offering price of the Qualified Financing to arrive at the amount of preferred stock that will be issued. Upon conversion pursuant to (b), the aggregate amount converted will be divided by $1.82 to arrive at the amount of preferred stock that will be issued.

The Series C Preferred Share financing (See Note 6) represented a Qualified Financing whereby the Convertible Notes for those participating investors converted to Series C Preferred Shares.

The Convertible Notes agreement was structured such that a portion of the shares of the Company's Series A preferred stock, Series B preferred stock and Series B-1 preferred stock, collectively the "Special Conversion Preferred", held by a holder, that did not participate in the financing to the full extent of its pro rata share of preferred stock ownership (a "Non-Fully Participating Holder"), was converted into shares of the Company's Common Stock, and any dividends accumulated to date were forfeited.

The option for existing preferred stockholders to participate in the Convertible Notes expired on October 1, 2012. On October 2, 2012, 8,943,447 shares of preferred stock held by Non-Fully Participating Holders were converted into 1,395,226 shares of Common Stock.

Warrants

Prior to the initial public offering, the Company accounted for the warrants as liability instruments. The Company estimated the initial fair value of the 944,210 warrants to be $654,527 using a Probability-Weighted Expected Returns valuation model. At each reporting period, any changes to the fair value of the warrants were recorded in the statements of operations. As of June 30, 2014 and September 30, 2013, warrants to purchase 0 and 944,210 shares of common stock, respectively, were outstanding in connection with the warrants.

The valuation model considered three scenarios. Two of the scenarios assumed a stockholder exit, either through sale, or dissolution. The third scenario assumed operations continue as a private company and no exit transaction occurred. The following assumptions were used in the valuation: exercise price of $1.82; implied stock price of $1.82; expected volatility of 64%; expected dividend rate of 6%; risk free interest rate of 0.83% and expiration date of six years.

The following was a description of the key terms of the warrants per the warrant purchase agreement:

- Exercise period — Exercisable, in whole or in part, during the six year term commencing on the earliest to occur of: (a) the consummation of a Qualified Financing, (b) immediately prior to the consummation of a Change of Control (but subject to and contingent upon such consummation of a Change of Control) and (c) the date one year after the Initial Closing or August 1, 2013.
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Exercise Price — The purchase price for the Warrant Shares issuable was: (a) $1.82, or (b) the offering price of a Qualified Financing should this occur prior to August 1, 2013.

- No Rights as Stockholders — Prior to the exercise of the warrants, no holder of warrants (solely in its capacity as a holder of warrants) is entitled to any rights as a stockholder of the Company, including, without limitation, the right to vote, receive notice of any meeting of stockholders or receive dividends, allotments or other distributions.

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In February 2014, proceeds in the amount of $20,868 were received from the exercise of Series C preferred stock warrants for 1,788 common shares. In addition, Redeemable Series C preferred stock warrants were net exercised for 32,286 shares common stock upon the closing of the initial public offering.

Warrant Liability

On February 18, 2014, the initial public offering date, the estimated fair value of the Convertible Note warrant liability was $2,280,378 which resulted in a charge to other income and expense of $382,630. The change in the value of the warrant liability was $0, $15,608, $573,582, and $15,608 for the three and nine months ended June 30, 2014 and 2013, respectively. As of September 30, 2013, the estimated fair value of the Convertible Note warrant liability was $1,706,829 which resulted in a charge to other income and expense of $1,052,302 for the year ended September 30, 2013. Upon the completion of the qualified offering, the warrants became exercisable into Series C Preferred Shares. The increase in the fair value of the warrant liability is primarily attributable to the liquidation preference of the Series C Preferred Shares to receive 2 times the original investment upon a liquidation event under certain circumstances.

Debt Discount

In connection with the Convertible Notes described above and as a result of the warrants issued with the Convertible Notes, the Company determined that a discount to the debt should be recorded in the amount of $654,528, representing its fair value and recorded as a discount to the debt instrument and amortized over the life of the instrument. The amount recorded as interest expense during the three and nine months ended June 30, 2014 and 2013 was approximately $0, $218,000, $0, and $545,000, respectively. Due to the conversion of the Convertible Notes to preferred stock, the balance of the unamortized debt discount was written off during the year ended September 30, 2013, resulting in interest expense of $545,000.

Beneficial Conversion Feature

A convertible financial instrument includes a beneficial conversion feature if the effective conversion price is less than the Company's market price of preferred stock on the commitment date. The effective price paid for a share is the amount allocated to the convertible instrument, divided by the number of shares the holder is entitled to upon conversion. If the convertible financial instrument is issued with warrants and/or other detachable instruments, the amount allocated to the convertible instrument is the face amount less the allocation to the detachable instruments. In connection with the Convertible Notes described above and as a result of the warrants issued with the Convertible Notes, the Company determined that the conversion rate represented a beneficial conversion feature. Accordingly, a discount on the notes was recorded in the amount of $654,528. The discount was amortized ratably with a corresponding non-cash charge to interest expense. The amount recorded as interest expense during the three and nine months ended June 30, 2014 and 2013 was approximately$0, $218,000, $0, and $545,000, respectively. Due to the conversion of the Convertible Notes to preferred stock, the balance of the unamortized beneficial conversion feature was written off during the year ended September 30, 2013, resulting in interest expense of $545,000.

7. Shares Subject to Redemption — Convertible Preferred Stock

Series A Convertible preferred stock

On March 8, 2007, the Company issued 20,237,911 shares of Series A Convertible preferred stock, par value $0.001 (the "Series A preferred stock"). The outstanding shares of the Series A preferred stock (as amended in connection with the issuance of the Series B preferred stock) is redeemable after August 11, 2013 at a redemption price per share equal to the Original Issue Price of $0.971 per share plus accrued but unpaid dividends (see "Redemption" below). The outstanding Series A convertible preferred stock converted into 2,332,051 shares of common stock upon the closing of the initial public offering. The outstanding shares of the Series A preferred stock were recorded at their estimated fair value of $19,651,000 which equaled the sale price on the date of issuance. The amount was adjusted for

net offering costs of $179,806. The fair value of the Series A preferred stock had been increased through periodic accretions using the interest method for dividends (see "Preferred Stock Dividends" below) so that the carrying value equals the redemption amount on the redemption date. Accumulated dividends on the Series A preferred stock as of June 30, 2014 and September 30, 2013 were $0 and $5,721,608 respectively. The liquidation value of the Series A preferred stock was $0 and $20,236,596 as of June 30, 2014 and September 30, 2013, respectively. The accumulated dividend through the closing date of the initial public offering on February 18, 2014 of the Series A preferred stock was $97,261.

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Series B Convertible Preferred Stock

On August 11, 2008, the Company issued 16,052,343 shares of Series B Convertible preferred stock, par value $0.001 (the "Series B preferred stock"). The Series B preferred stock is redeemable as described above for the Series A preferred stock at a redemption price per share equal to the Original Issue Price of $1.82 per share plus accrued but unpaid dividends (see "Redemption" below). The outstanding Series B convertible preferred stock converted into 1,980,431 shares of common stock upon the closing of the initial public offering. The outstanding shares of the Series B preferred stock were recorded at their estimated fair value of $29,215,266, which equaled the sale price on the date of issuance. The amount was adjusted for net offering costs of $125,714. The fair value of the Series B preferred stock had been increased through periodic accretions using the interest method so that the carrying value equals the redemption amount on the redemption date. Accumulated dividends on redeemable shares as of June 30, 2014, and September 30, 2013 were $0 and $7,111,465, respectively. The liquidation value of the Series B preferred stock is $0 and $30,215,567 as of June 30, 2014 and September 30, 2013, respectively. The accumulated dividend through the closing date of the initial public offering on February 18, 2014 was $172,971.

Series B-1 Convertible Preferred Stock

The Company consummated an offering of Series B-1 Convertible preferred stock, par value $0.001 (the "Series B-1 Preferred Stock") to its existing investors in two stages in February 2011 and July 2011. The Company issued an aggregate of 10,177,085 shares of Series B-1 preferred stock. The Series B-1 preferred stock is redeemable at a redemption price per share equal to the Original Issue Price of $1.82 per share plus accrued but unpaid dividends (see "Redemption" below). The outstanding series B-1 convertible preferred stock converted into 1,455,753 shares of common stock upon the closing of the initial public offering. The outstanding shares of the Series B-1 preferred stock were recorded at their estimated fair value of $17,522,294 which equaled the sale price on the date of issuance. The amount was adjusted for net offering costs of $144,250. On August 2, 2012, the Company entered into a Payoff and Exchange Agreement with an Officer/Director. The Company accepted a total of 549,451 shares of Series B-1 preferred stock in exchange for satisfaction of the principal amount of debt. The total number of outstanding shares of Series B-1 preferred stock was 9,627,634 as of September 30, 2012. The fair value of the Series B preferred stock had been increased through periodic accretions using the interest method so that the carrying value equals the redemption amount on the redemption date. Accumulated dividends on redeemable shares were $0 and $2,535,434 as of June 30, 2014 and September 30, 2013, respectively. The liquidation value of the Series B-1 preferred stock is $0 and $19,518,535 as of June 30, 2014 and September 30, 2013, respectively. The accumulated dividend through the closing date of the initial public offering on February 18, 2014 of the Series B-1 preferred stock was $125,096.

Series C Convertible Preferred Stock

The Company consummated an offering of Series C Convertible preferred stock, par value $0.001 (the "Series C preferred stock") on April 11, 2013. The Company issued an aggregate of 11,023,232 shares of Series C preferred stock. The Series C preferred stock is redeemable at a redemption price per share equal to the Original Issue Price of $1.82 per share plus accrued but unpaid dividends (see "Redemption" below). The outstanding series C convertible preferred stock converted into 1,719,693 shares of common stock upon the closing of the initial public offering. The outstanding shares of the Series C preferred stock were recorded at their estimated fair value of $20,062,296 which equaled the sale price on the date of issuance. The amount was adjusted for net offering costs of $167,465. The fair value of the Series C preferred stock had been increased through periodic accretions using the interest method so that the carrying value equals the redemption amount on the redemption date. Accumulated dividends on redeemable shares were $0 and $567,241 as of June 30, 2014 and September 30, 2013, respectively. The liquidation value of the Series C preferred stock is $0 and $20,629,537 as of June 30, 2014 and September 30, 2013, respectively. The accumulated dividend through closing date of the initial public offering on February 18, 2014 of the Series C preferred

stock was $138,513.

On October 2, 2012, holders of preferred stock who elected not to participate in the Convertible Notes (see "Notes Payable") had their preferred stock shares convert to Common stock. Upon conversion from preferred to common, the investors forfeited all accumulated dividends from their investment date. 5,289,405 shares of Series A preferred stock were converted into 825,177 shares of Common stock and $1,718,102 in accumulated dividends was forfeited, 3,357,782 shares of Series B preferred stock were converted into 532,832 shares of Common Stock and $1,519,922 in accumulated dividends was forfeited, and 296,260 shares of Series B-1 preferred stock were converted into 46,218 shares of Common stock and $48,572 in accumulated dividends was forfeited. Concurrent with the conversion, the Company reduced the amounts authorized for the Series A, Series B, and Series B-1 preferred stock to 14,948,506 shares, 12,694,561 shares and 9,331,374 shares, respectively.

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8. Common Stock and Stock-Based Compensation

In December 2007, the Company's Board of Directors approved the 2007 Incentive Compensation Plan (the "2007 Plan") enabling the Company to grant multiple stock based awards to employees, directors and consultants, the most common being stock options and restricted stock awards. In November 2013, the Company's Board of Directors approved the 2014 Equity Incentive Plan (the "2014 Plan") which became effective on February 11, 2014. The 2007 Plan was terminated upon the effectiveness of the 2014 Plan and all shares available for issuance under the 2007 Plan were made available under the 2014 Plan. The 2014 Plan provides for the awards of incentive stock options, non-qualified stock options, restricted stock, restricted stock units and other stock-based awards. Awards generally vest equally over a period of four years from grant date. Vesting is accelerated under a change in control of the Company or in the event of death or disability to the recipient. In the event of termination, any unvested shares or options are forfeited. 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 and nine months ended June 30, 2014 and 2013 as follows:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2014	2013	2014	2013
Selling, general and administrative	$77,628	$84,583	$190,878	$252,626
Research and development	85,872	43,730	190,858	77,293
Total	$163,500	$128,313	$381,736	$329,919

9. License Agreements of Development and Commercialization Rights

Development

The Company has entered into several product development agreements with development partners whereby the Company acquired the exclusive rights in the United States and, in most cases, worldwide rights to a total of thirty-three products for ten years following first commercial sale of each product. The Company will share varying percentages of the profits after, in most cases, recapturing development, legal and certain operating costs, from the sales of the products with the development partners if the products are commercialized. The Company expenses these costs as incurred.

Commercialization Rights

In May 2008, the Company entered into a collaborative product development agreement with a Branded product company, whereby the Company has agreed to develop a product for the Brand Company. Under the terms of the agreement, the Brand Company acquired the exclusive worldwide rights to market the product for ten years following approval. The Company will receive a royalty on net sales of the product, dependent upon the achievement of certain goals. In addition, the Company received $750,000 upon signing which was non-refundable and recorded as revenue in the year it was received and it will receive milestones of up to $13,000,000 upon the achievement of certain goals. The Brand Company is also required to pay all out of pocket costs related to the project and also made payments to the Company totaling $2,000,000 for the development of the product, payable at $200,000 per month commencing in April 2008. In July 2013, an arbitration settlement between the two companies was reached. The Company then terminated the contract; therefore no additional revenues will be recognized.

10. Asset Sales

On March 28, 2012, the Company entered into an Asset Purchase Agreement (“APA”) with Hikma Pharmaceutical Co. LTD, or Hikma. Under the terms of the agreement, Hikma acquired exclusive U.S. rights to market diclofenac/misoprostol following regulatory approval. The Company received $3,500,000 upon signing the

APA. This amount was included in deferred revenue until FDA approval, since it was otherwise refundable. In addition, the Company was entitled to receive another $1,000,000 upon regulatory approval, validation batch manufacturing with inventory released for launch, and sufficient launch inventory. Before approval, this approval milestone was to be reduced for each generic competitor that received regulatory approval (excluding an "authorized generic" version of the Brand Product); however, the milestone was not to be reduced to an amount less than $500,000. The Company was to receive a royalty on Net Profits of the product for a period of ten years from the date of the first commercial sale of the product, with the royalty percentage varying depending upon certain events and competition.

On June 24, 2013, Hikma filed a lawsuit against the Company in the United States District Court for the Southern District of New York alleging that the Company (a) breached the Hikma, APA by failing to refund the purchase price following Hikma's purported termination of the Hikma APA as a result of the Company failing to receive timely ANDA approval, and (b) intentionally failed to disclose alleged manufacturing product defects to Hikma. The Company believed that it did not fail to receive timely ANDA approval and therefore that Hikma was not entitled to (a) terminate the Hikma APA or (b) receive a refund of the purchase price. The Company also believed that it did not intentionally fail to disclose alleged manufacturing product defects to Hikma. If Hikma had prevailed on its claims, the Company could have been required to return the $3,500,000 purchase price plus interest, as well as other damages. The Company could not estimate the possible loss or range of loss related to the Hikma litigation beyond the $3,500,000 purchase price.

On March 14, 2014, the Company received FDA approval of our Abbreviated New Drug Application for diclofenac/misoprostol tablets. The Company had not yet recognized the $3,500,000 as revenue since it was required to submit additional data to the FDA. In May 2014, under a CBE-30 supplement, the Company submitted additional data to the FDA with respect to manufacturing procedures of the product and achieved final approval in June 2014. As of June 30, 2014, the Company has recognized the $3,500,000 purchase price as revenue in Other income in the current period as it had received FDA approval and subsequently complied with all FDA requirements. Pursuant to the in-license agreement for diclofenac/misoprostol, the Company estimated amounts due to the licensor.

During fiscal year 2010 and 2011, the Company divested another non-core product and received proceeds of $6,500,000, comprised of $5,500,000 as a signing milestone which is recorded in deferred revenues and $500,000 for the initiation of Tech Transfer of which $250,000 remains in deferred revenues and a second payment of $500,000 for the completion of the Tech Transfer of which $250,000 remains in deferred revenues. Under the terms of this agreement, the licensor must obtain all of the following milestones in order for the Company to earn the revenues. These milestones are a) the receipt of an approvable letter from the FDA, b) acknowledgment from the FDA that no further clinical studies will be needed and c) an approval letter from the FDA. If these milestones are not met, then the $6,000,000 in total included in deferred revenue on the balance sheet at June 30, 2014 and September 30, 2013 must be refunded and the product rights are returned to the Company. In addition, the Company may receive additional milestones of up to $3,000,000 in the future, dependent on the licensor's actively selling the product in an exclusive market position.

See Note 5 for a summary of Deferred Revenue related to the Asset Sales.

11. Commitments

At June 30, 2014, the Company has purchase obligations in the amount of $751,000 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 expires on May 31, 2015. Rental expense was $68,104, $63,873, $208,457 and $270,482 for the three and nine months ended June 30, 2014 and 2013, respectively. The remaining future lease payments under the operating lease are $249,714 as of June 30, 2014, payable monthly through May 31, 2015.

12. Arbitration

On October 26, 2011, the Company filed a Demand for Arbitration with the American Arbitration Association against a commercial partner that licensed one of its products. Eagle's claims include breach of contract relating to the development of a new formulation of the product and lack of effort to seek and obtain regulatory approval, ultimately impacting the marketing and sale of that new formulation. As a result, Eagle alleged that it had been significantly damaged. A three person arbitration panel was appointed. The trial was completed on January 25, 2013.

In April 2013, the Company successfully renegotiated the terms of our legal fees to a contingent settlement as opposed to an hourly billing rate. As a result of the renegotiated terms, the Company recognized a $1,993,099 benefit.

On July 19, 2013, the American Arbitration Association panel awarded the Company $5,000,000 for damages plus $23,900 for apportioned costs related to the arbitration for breach of contract. The Company received the funds in September 2013 and the amount was recorded in the results of operations, net of expenses of $973,649 in the fourth quarter of fiscal year 2013.

13. 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.

See Notes 10 and 14 for a summary of legal proceedings with Hikma.

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NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)
(Financial information as of June 30, 2014 and for the three and nine months ended June 30, 2014 and 2013 is unaudited)

In September 2013, the Company filed a New Drug Application under Section 505(b)(2) for EP-3101 (bendamustine RTD) and notified Teva Pharmaceuticals, the holder of Treanda, the referenced approved drug in our application, of the Company's 505(b)(2) filing and paragraph IV certification. Teva 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. Teva's filing of the lawsuit invoked a 30-month stay of FDA approval of the Company's bendamustine product, which will delay FDA approval until the earlier of the March 2016 expiration of the 30-month stay imposed by the Hatch-Waxman Act, or such time as the district court enters judgment in the Company's favor or otherwise acts to shorten the stay. Moreover, regardless of when the 30-month stay is resolved or expires, the FDA may still be prohibited from approving the Company's 505(b)(2) NDA due to Teva's unexpired orphan drug and pediatric exclusivities for Treanda. Specifically, Teva has received orphan drug and related pediatric exclusivity expiring in September 2015 and May 2016 for the Chronic Lymphocytic Leukemia ("CLL") and indolent B-cell non-Hodgkin's Lymphoma ("NHL") indications, respectively. When a drug, such as Treanda, has orphan drug exclusivity, the FDA may not approve any other application to market the same drug for the same indication for a period of up to seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. In the United States, pediatric exclusivity adds six months to any existing exclusivity period. If the Company cannot demonstrate that EP-3101 is clinically superior to Treanda, or qualify under certain other limited exceptions, the Company will not be able to enter the market for the CLL indication until September 2015 (assuming the 30-month stay is resolved by that time) or the NHL indication until May 2016.
In July 2014, the FDA had granted tentative approval and orphan drug designation to the Company’s New Drug Application (the "NDA") for patented Bendamustine Hydrochloride Injection, a ready-to-dilute concentrate solution (“bendamustine RTD”) for the treatment of NHL.

14. Subsequent Events
On August 8, 2014, the Company settled the lawsuit with Hikma related to the APA (See Note 10 “Asset Sales”). Pursuant to the terms of the settlement the Company will retain ownership of diclofenac/misoprostol including the rights to launch and commercialize the Product, and the Company will pay to Hikma a percentage of Net Profits after recovery of certain of the Company's expenses.

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 the Prospectus that forms a part of our Registration Statement on Form S-1 (File No. 333-192984), which was filed with the Securities and Exchange Commission (the “SEC”) pursuant to Rule 424(b)(4) on February 13, 2014 (the “Prospectus”).
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) for injectable suspension indicated for the treatment of malignant hyperthermia 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 currently under development as a shorter infusion product. Orphan drug designation was granted for the treatment of chronic lymphocytic leukemia (“CLL”) and indolent B-cell non-Hodgkin’s lymphoma (“NHL”). We currently have six advanced product candidates, one commercialized product, argatroban and are planning the launches of Ryanodex® (dantrolene sodium), and diclofenac/misoprostol.

We have two commercial partners, The Medicines Company and Sandoz Inc., 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 revenues from argatroban with our commercial partners.

We intend to commercialize our 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 this strategy, we intend to establish a small, specialty sales force that will target group purchasing organizations, hospital groups and key stakeholders in acute care settings, primarily hospitals and infusion centers. 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 and income from collaborative arrangement 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 February 18, 2014 the Company closed its initial public offering 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 $46.1 million. Included in this amount is $20.9 thousand received from the exercise of Series C preferred stock warrants for 1,788 shares of common stock.

On July 2, 2014 we received tentative approval for EP-3101 (bendamustine RTD) for which a New Drug Application (an "NDA") was filed with the FDA on September 6, 2013. This NDA is subject to on-going litigation with the application holder (Teva/Cephalon) and we expect to continue to incur legal expenses associated with defending our position.

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On July 22, 2014 we received FDA approval for Ryanodex® (dantrolene sodium) for injectable suspension indicated for the treatment of malignant hyperthermia ("MH"), along with the appropriate supportive measures, for which an NDA was filed with the FDA on January 17, 2014. We are preparing for product launch and incurring expenses associated with marketing and other launch efforts.

On March 14, 2014, we received FDA approval of our Abbreviated New Drug Application for diclofenac/misoprostol tablets. In May 2014, under a CBE-30 supplement, we submitted additional data to the FDA with respect to manufacturing procedures of the product and final approval was achieved in June 2014.

On August 8, 2014, we settled the lawsuit with Hikma related to the APA (See Note 10 “Asset Sales”). Pursuant to the terms of the settlement we will retain ownership of diclofenac/misoprostol including the rights to launch and commercialize the product and the we will pay to Hikma a percentage of Net Profits after recovery of certain expenses.

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 to our commercial partners. Such sales are typically made at little or no profit for resale by our commercial partners.

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.

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. We did not recognize revenue from collaborative arrangements for the three and nine months ended June 30, 2014 and 2013.

Currently, our product sales and royalty income are derived from the sale of argatroban to, and the resale by, two commercial partners, Sandoz Inc., or 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.

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 and providing research and development services to our collaboration partners. In particular, our cost of revenue includes production costs of argatroban 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 to prepare for the commercial manufacture of products including Ryanodex®

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(dantrolene sodium), EP-3101 (bendamustine RTD), EP-3102 (bendamustine short infusion time), EP-6101 (bivalirudin) 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 dantrolene in additional indications. 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. 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 us being a public company.

Other Income and Expense

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

Income Tax Benefit

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

Results of Operations

Comparison of Three Months Ended June 30, 2014 and 2013

Revenues

	Three Months Ended June 30,		Increase/ (Decrease)
	2014	2013	
Product sales	$350,350	$2,489,310	$(2,138,960)
Royalty income	1,941,526	2,585,719	(644,193)
Other income	3,500,000	—	3,500,000
Total revenue	$5,791,876	$5,075,029	$716,847

Total revenue increased $0.7 million in the three months ended June 30, 2014 to $5.8 million as compared to $5.1 million in the three months ended June 30, 2013.

The net increase in total revenue was offset by a decrease in product sales of $(2.1) million in the three months ended June 30, 2014 to $0.4 million as compared to $2.5 million in the three months ended June 30, 2013. This decrease in product sales was due to longer lead times in procuring materials for manufacturing.

Royalty income decreased $(0.6) million in the three months ended June 30, 2014 to $1.9 million as compared to $2.6 million in the three months ended June 30, 2013, as a result of decreased end use sales of argatroban by our commercial partners that may be related to increased market competition.

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Other income increased by $3.5 million due to the FDA approval of diclofenac/misoprostol related to the asset sale agreement with Hikma Pharmaceutical. There were no revenues from collaborative arrangements in the periods presented.

Cost of Revenue

	Three Months Ended June 30,		Increase/ (Decrease)
	2014	2013	
Cost of revenue	$1,555,711	$2,925,046	$(1,369,335)

Cost of net revenues decreased by $(1.4) million to $1.6 million in the three months ended June 30, 2014 from $2.9 million in the three months ended June 30, 2013 as a result of the decrease in product sales of argatroban and royalty expense associated with our commercial and development partners. This $(1.4) million net decrease in cost of revenues was mainly attributable to a decrease in product sales and royalty income. This was offset by an increase in royalty expense to SciDose and under the terms of our revenue sharing arrangement with SciDose, we retained all revenue from the sale of a product commercialized under a 505(b)(2) application until we had recouped our expenses related to the development of that product. Once our expenses were recouped, we are required to split the net proceeds from royalty income received equally with SciDose. Expenses related to the development of argatroban were recouped during the quarter ended September 30, 2013. As a result we recognized $0.8 million in royalty expense for the three months ended June 30, 2014 and royalty expense for SciDose was not recognized for the three months ended June 30, 2013. Additionally and also offsetting the net decrease, we incurred $.02 million in cost related to the asset sale agreement in Other income.

With respect to product sales, we experienced longer lead times in procuring materials for manufacturing and the volume of product delivered in the quarter ended June 30, 2014 decreased by approximately 90% from the quarter ended June 30, 2013.

We would expect that our cost of revenues as a percentage of product sales and royalty income should remain consistent with the quarter ended June 30, 2014.

Research and Development

	Three Months Ended June 30,		Increase/ (Decrease)
	2014	2013	
EP-6101 (bivalirudin)	$536,197	$—	$536,197
EP-3101 (bendamustine RTD)	372,862	394,495	(21,633)
EP-3102 (bendamustine short infusion time)	1,460,804	329,161	1,131,643
Ryanodex® (dantrolene sodium)	431,276	222,069	209,207
All other projects	252,461	(111,445)	363,906
Diclofenac/misoprostol	417,710	—	417,710
Salary and other personnel related expenses	1,073,848	798,000	275,848
Total Research and Development	$4,545,158	1,632,280	2,912,878

Research and development expenses increased $2.9 million in the three months ended June 30, 2014 to $4.5 million as compared to $1.6 million in the three months ended June 30, 2013. Expenses in the three months ended June 30, 2014 were higher than in the three months ended June 30, 2013 as a result of a net increase in project spending for EP-6101 (bivalirudin), EP-3102 (bendamustine short infusion time), Ryanodex® (dantrolene sodium), diclofenac/misoprostol, salaries and other personnel related and certain other projects.

Selling, General and Administrative

Selling, general and administrative expenses increased $1.4 million in the three months ended June 30, 2014 to $2.7 million as compared to $1.3 million in the three months ended June 30, 2013. This increase is related to a $0.6 million increase in marketing related to the launch of Ryanodex® (dantrolene sodium), increase of $0.4 million of professional fees, insurance and miscellaneous expenses and $0.4 million increase in general and administrative salary

and personnel related expenses.
Professional Fee Benefit

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In connection with arbitration proceedings with our counter-party, we successfully renegotiated the terms of our legal fee to a contingent settlement as opposed to an hourly billing rate. This resulted in a $1.9 million benefit that was realized in the quarter ended June 30, 2013.

Other Income (Expense)

	Three Months Ended June 30,		Increase/ (Decrease)
	2014	2013	
Interest income	$17,826	$1,036	$16,790
Interest expense	(4,812)	(16,018)	11,206
Deferred financing costs	—	(38,567)	38,567
Amortization of debt discount	—	(436,350)	436,350
Change in value of warrant liability	—	(15,608)	15,608
Other income/(expense), net	35,305	332	34,973
Total other income/(expense), net	$48,319	$(505,175)	$553,494

Other income and (expense) decreased by $0.6 million in the three months ended June 30, 2014 to income of $48.3 thousand as compared to an expense of $0.5 million in the three months ended June 30, 2013. The decrease in Total Other income and expense for the three months ended June 30, 2014 was due to the recognition of the change in value of the warrant liability, and interest expense and the amortization and write-off of deferred financing costs and debt discount related to the convertible notes. These convertible notes and warrants converted to common stock in connection with the initial public offering in February 2014.

Income Tax Benefit

There was no Income tax benefit in the three months ended June 30, 2014 or the three months ended June 30, 2013 due to the timing of sales of our New Jersey State net operating losses.

Net Loss

Net loss for the three months ended June 30, 2014 was $(2.9) million as compared to net income of $0.8 million in the three months ended June 30, 2013, as a result of the factors discussed above.

Comparison of Nine Months Ended June 30, 2014 and 2013

Revenues

	Nine Months Ended June 30,		Increase/ (Decrease)
	2014	2013	
Product sales	$3,748,800	$3,689,640	$59,160
Royalty income	8,774,407	5,349,289	3,425,118
Other income	3,765,000	—	3,765,000
Total revenue	$16,288,207	$9,038,929	$7,249,278

Total revenues increased $7.2 million in the nine months ended June 30, 2014 to $16.3 million as compared with $9.0 million in the nine months ended June 30, 2013.

Product sales were approximately $3.7 million in both the nine months ended June 30, 2014 and nine months ended June 30, 2013. The volume of product shipped was approximately equal over both periods. There were fewer shipments in the October-December 2012 period due to a recall and fewer shipments in the April through June 2014 period due to longer lead times in procuring materials for manufacturing.

Royalty income increased $3.4 million in the nine months ended June 30, 2014 to $8.8 million as compared to $5.3 million in the nine months ended June 30, 2013, as a result of higher royalty income from the end use sales of argatroban by our commercial partners earlier in the period offset by decreased end use sales of argatroban by our commercial partners that may be related to increased market competition.

Other income increased by $3.8 million, which is primarily due to $3.5 million from the FDA approval of diclofenac/ misoprostol related to the asset sale agreement with Hikma Pharmaceutical and a final milestone of $0.3 million. There were no revenues from collaborative arrangements in the periods presented.

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Cost of Revenue

	Nine Months Ended June 30,		Increase/
	2014	2013	(Decrease)
Cost of revenue	$9,539,436	$4,449,337	$5,090,099

Cost of net revenues increased by $5.1 million to $9.5 million in the nine months ended June 30, 2014 from $4.4 million in the nine months ended June 30, 2013 mainly as a result of the increased royalty expense associated with our commercial and development partners. Of the $5.1 million increase in cost of revenues, $2.2 million is as a direct result of the increase in Royalty income and $2.7 million was due to an increase in royalty expense to both SciDose and the Medicines Company. Under the terms of our revenue sharing arrangement with SciDose, we retain all revenue from the sale of a product commercialized under a 505(b)(2) application until we have recouped our expenses related to the development of that product. Once our expenses are recouped, we are required to split the net proceeds from royalty income received equally with SciDose. Expenses related to the development of argatroban were recouped during the quarter ended September 30, 2013. As a result we recognized an increase of $2.7 million in royalty expense for the nine months ended June 30, 2014 that was not recognized for the nine months ended June 30, 2013.

With respect to product sales in the nine months ended June 30, 2014 we experienced a decrease in the cost of revenue of approximately $0.2 million over the nine months ended June 30, 2013. The volume of product shipped was approximately equal over both periods. There were fewer shipments in the October-December 2012 period due to a recall and fewer shipments in the April through June 2014 period due to longer lead times in procuring materials for manufacturing.

We would expect our cost of revenues as a percentage of product sales and royalty income to remain consistent with the quarter ended June 30, 2014.

Research and Development

	Nine Months Ended June 30,		Increase/
	2014	2013	(Decrease)
EP-6101 (bivalirudin)	$1,681,409	$119,278	$1,562,131
EP-3102 (bendamustine short infusion time)	2,677,825	411,383	2,266,442
EP-3101 (bendamustine RTD)	1,587,936	767,575	820,361
Ryanodex® (dantrolene sodium)	1,378,120	1,415,887	(37,767)
EP-4104 (dantrolene for EHS)	61,788	146,494	(84,706)
diclofenac/misoprostol	681,283	—	681,283
All other projects	255,365	1,026,444	(771,079)
Salary and other personnel related expenses	2,604,186	2,488,835	115,351
Total Research and Development	$10,927,912	$6,375,896	$4,552,016

Research and development expenses increased $4.6 million in the nine months ended June 30, 2014 to $10.9 million as compared to $6.4 million in the nine months ended June 30, 2013. Expenses in the nine months ended June 30, 2014 were higher than in the nine months ended June 30, 2013 as a result of increased project spending for EP-6101 (bivalirudin) related to registration batches, and technical transfer and manufacturing services, EP-3102 (bendamustine short infusion time) related to increased spending on the PK (pharmacokinetic) study and EP-3101 (bendamustine RTD) related to support of product approval and certain legal and professional expenses. Spending increase on diclofenac/misoprostol was related to legal costs and development costs to support FDA commitments and product approval. These increases were offset by a reduction in spending on other projects that have been delayed or will no longer be pursued. Salary and other personnel related expenses increased due to increased staffing.

Selling, General and Administrative

Selling general and administrative expenses decreased $0.7 million in the nine months ended June 30, 2014 to $5.5 million from $6.1 million in the nine months ended June 30, 2013. The decreased costs in the nine months ended June 30, 2014 over 2013 are primarily due to $2.1 million decrease in costs related to professional fees and the Hikma lawsuit as well as The Medicines Company arbitration (See Professional Fee Benefit) offset by an increase of $0.6 million in general and administrative salary and personnel related expenses, sales and marketing expenses increased by $0.6 million related to the Ryanodex® (dantrolene sodium) launch efforts and $0.3 million increase in

insurance and miscellaneous expenses.
Professional Fee Benefit

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In connection with legal proceedings with our counter-party, we successfully renegotiated the terms of our legal fees to a contingent settlement as opposed to an hourly billing rate. This resulted in a $1.9 million benefit that was realized in the quarter ended June 30, 2013.

Other Income and Expense

	Nine Months Ended June 30,		Increase/
	2014	2013	(Decrease)
Interest income	$26,647	$2,156	$24,491
Interest expense	(6,244)	(309,121)	302,877
Deferred financing costs	—	(96,417)	96,417
Amortization of debt discount	—	(1,090,878)	1,090,878
Change in value of warrant liability	(573,582)	(15,608)	(557,974)
Other income, net	35,590	3,202	32,388
Total other income/(expense), net	$(517,589)	$(1,506,666)	$989,077

Other income and (expense) decreased $1.0 million in the nine months ended June 30, 2014 to an expense of $0.5 million as compared to an expense of $1.5 million in the nine months ended June 30, 2013. The decrease in total other income and expense for the nine months ended June 30, 2014 was due to the recognition of the change in value of the warrant liability, and interest expense and the amortization and write-off of deferred financing costs and debt discount related to the convertible notes. These convertible notes and warrants converted to common stock in connection with the initial public offering in February 2014.

State Income Tax Benefit

Income tax benefit increased $0.4 million in the nine months ended June 30, 2014 to a benefit of $1.3 million as compared to a benefit of $0.9 million for the nine months ended June 30, 2013. Income tax benefit increased due to the higher sales of our New Jersey State net operating losses.

Net Loss

Net loss for the nine months ended June 30, 2014 was $8.9 million as compared to net loss of $6.5 million in the nine months ended June 30, 2013, as a result of the factors discussed above.

Liquidity and Capital Resources

On February 18, 2014, the Company closed its initial public offering 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 $46.1 million. Included in this amount is $20.9 thousand received from the exercise of Series C preferred stock warrants for 1,788 shares of common stock.

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 $49.8 million and $10.8 million as of June 30, 2014 and June 30, 2013, respectively.

For the nine months ended June 30, 2014, we incurred a net loss of $8.9 million. As of June 30, 2014, we had a working capital surplus of $41.5 million. For the nine months ended June 30, 2013, we incurred a net loss of $6.5 million. We have sustained significant losses since our inception on January 2, 2007 and had accumulated a deficit of $95.1 million million as of June 30, 2014.

We believe that future cash flows from operations, together with proceeds from the initial public offering will be sufficient to fund our currently anticipated working capital requirements through mid-calendar year 2016. 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 used in operating activities for the nine months ended June 30, 2014 was $6.7 million. Net loss for the period was $8.9 million offset by non-cash adjustments of approximately $1.0 million from the change in the value of the

warrant liability,

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depreciation and stock-based compensation expense. Net changes in working capital increased cash from operating activities by approximately $1.1 million, due to a decrease in prepaid expenses of $1.0 million related to prepaid insurance, and a decrease in deferred revenue of $3.8 million. We experienced an increase in accounts receivable of $1.6 million and an increase in accounts payable and accrued expenses of $5.8 million. Accounts payable and accrued expenses increased primarily due to accrued royalties . The total amount of accounts receivable at June 30, 2014 was approximately $6.7 million, which included approximately $0.5 million of product sales and approximately $5.9 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.
At June 30, 2014, our cumulative receivables related to royalty income consist of approximately $5.0 million in receivables from The Medicines Company and $0.9 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. Notwithstanding this, 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 June 30, 2014 , we recorded a receivable of approximately $5.0 million and a payable of $4.3 million to The Medicines Company (based upon a 50% revenue split on Sandoz sales). The net receivable The Medicines Company for the quarter ended June 30, 2014 therefore is $ 0.7 million. The receivable of $0.7 million from The Medicines Company as of June 30, 2014 therefore represents the net cumulative receivable of the Company.
We believe that our accounts receivable as of June 30, 2014, 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 the ordinary course in the fourth fiscal quarter, and thus would not have a material effect on our liquidity.
Net cash used in operating activities for the nine months ended June 30, 2013 was $5.6 million and resulted primarily from $6.5 million of net loss for the period. Non-cash adjustments amounted to approximately $1.9 million in depreciation, amortization, interest and stock-based compensation expense. Net changes in working capital decreased cash from operating activities by approximately $1.0 million, primarily due to an increase in prepaid expenses of $3.3 million ($1.0 million for prepaid product costs, $1.5 million in royalties due to The Medicines Company and $0.8 million for FDA user fees) offset by a decrease in accounts receivable of $1.3 million and an increase in deferred revenue of $0.9 million.

Investing Activities:
In the nine months ended June 30, 2014 and 2013, we invested $38.8 thousand and $30.7 thousand, respectively, for the purchase of property and equipment.
In the nine months ended June 30, 2014 and 2013, we redeemed $0 and $1.5 million, respectively, of short term investments.
Financing Activities:
Net cash provided by financing activities for the nine months ended June 30, 2014 was $46.0 million, primarily resulting from the issuance of Common Stock from the initial public offering and the exercise of warrants of $20.9 thousand.
Net cash provided by financing activities in the nine months ended June 30, 2013 was $9.8 million resulting from the issuance of Series C Preferred Stock.

Recent Accounting Pronouncements

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.

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Impact of Inflation

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

Critical Accounting Policies and Estimates

We have based our management's discussion and analysis of our financial condition and results of operations on our condensed financial statements that have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"). The preparation of these condensed financial statements requires us to make estimates that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the condensed financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to clinical trial expenses and stock-based compensation. We base our estimates on historical experience and on various other factors we believe to be appropriate under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. There have been no material changes to our critical accounting policies discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in the Prospectus filed with the SEC on February 13, 2014.

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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 June 30, 2014 we had cash and cash equivalents of $49.8 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 June 30, 2014, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective.

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PART II-OTHER INFORMATION

Item 1. Legal Proceedings

On March 28, 2012, the Company entered into an Asset Purchase Agreement (“APA”) with Hikma Pharmaceutical Co. LTD, or Hikma. Under the terms of the agreement, Hikma acquired exclusive U.S. rights to market diclofenac/misoprostol following regulatory approval. The Company received $3,500,000 upon signing the APA. This amount was included in deferred revenue until FDA approval, since it was otherwise refundable. In addition, the Company was entitled to receive another $1,000,000 upon regulatory approval, validation batch manufacturing with inventory released for launch, and sufficient launch inventory. Before approval, this approval milestone was to be reduced for each generic competitor that received regulatory approval (excluding an "authorized generic" version of the Brand Product); however, the milestone was not to be reduced to an amount less than $500,000. The Company was to receive a royalty on Net Profits of the product for a period of ten years from the date of the first commercial sale of the product, with the royalty percentage varying depending upon certain events and competition.

On June 24, 2013, Hikma filed a lawsuit against the Company in the United States District Court for the Southern District of New York alleging that the Company (a) breached the Hikma, APA by failing to refund the purchase price following Hikma's purported termination of the Hikma APA as a result of the Company failing to receive timely ANDA approval, and (b) intentionally failed to disclose alleged manufacturing product defects to Hikma. The Company believed that it did not fail to receive timely ANDA approval and therefore that Hikma was not entitled to (a) terminate the Hikma APA or (b) receive a refund of the purchase price. The Company also believed that it did not intentionally fail to disclose alleged manufacturing product defects to Hikma. If Hikma had prevailed on its claims, the Company could have been required to return the $3,500,000 purchase price plus interest, as well as other damages. The Company could not estimate the possible loss or range of loss related to the Hikma litigation beyond the $3,500,000 purchase price.

On March 14, 2014, the Company received ANDA approval and had not yet recognized the $3,500,000 as revenue since it was required to submit additional data to the FDA. In May 2014, under a CBE-30 supplement, the Company submitted additional data to the FDA with respect to manufacturing procedures of the product and achieved final approval in June 2014.

As of June 30, 2014, the Company has recognized the $3,500,000 purchase price as revenue in Other income in the current period as it had received FDA approval and subsequently complied with all FDA requirements. Pursuant to the in-license agreement for diclofenac/misoprostol, the Company estimated amounts due to the licensor.

On August 8, 2014, the Company settled the lawsuit with Hikma related to the APA (See Note 10 “Asset Sales”). Pursuant to the terms of the settlement the Company will retain ownership of diclofenac/misoprostol including the rights to launch and commercialize the Product, and the Company will pay to Hikma a percentage of Net Profits after recovery of certain of the Company's expenses.

In addition to the matter described above, from time to time, third parties may assert patent infringement claims against us in the form of letters, litigation, or other forms of communication; we may be subject to other legal proceedings and claims in the ordinary course of business, including claims of alleged infringement of trademarks, copyrights and other intellectual property rights; employment claims; and general contract or other claims. We may, from time to time, also be subject to various legal or government claims, disputes, or investigations. Such matters may include, but not be limited to, claims, disputes, or investigations related to breach of contract, employment, intellectual property, government regulation, or compliance or other matters.

In September 2013, the Company filed a New Drug Application under Section 505(b)(2) for EP-3101 (bendamustine RTD) and notified Teva Pharmaceuticals, the holder of Treanda, the referenced approved drug in our application, of the Company's 505(b)(2) filing and paragraph IV certification. Teva 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. Teva's filing of the lawsuit invoked a 30-month stay of FDA approval of the Company's bendamustine product, which will delay FDA approval until the earlier of the March 2016 expiration of the 30-month stay imposed by the Hatch-Waxman Act, or such time as the district court enters judgment in the Company's favor or

otherwise acts to shorten the stay. Moreover, regardless of when the 30-month stay is resolved or expires, the FDA may still be prohibited from approving the Company's 505(b)(2) NDA due to Teva's unexpired orphan drug and pediatric exclusivities for Treanda. Specifically, Teva has received orphan drug and related pediatric exclusivity expiring in September 2015 and May 2016 for the CLL and NHL indications, respectively. When a drug, such as Treanda, has orphan drug exclusivity, the FDA may not approve any other application to market the same drug for the same indication for a period of up to seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. In the United States, pediatric exclusivity adds six months to any existing exclusivity period. If the Company cannot demonstrate that EP-3101 is clinically superior to Treanda, or qualify under certain other limited exceptions, the Company will not be able to enter the market for the CLL indication until September 2015 (assuming the 30-month stay is resolved by that time) or the NHL indication until May 2016.

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On July 2, 2014 the FDA granted the Company tentative approval for EP-3101 (bendamustine RTD). On July 8, 2014, the FDA granted orphan drug designation to bendamustine hydrochloride ("HCl"),

Item 1a. Risk Factors

You should carefully consider the following risk factors, as well as the other information in this report, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business. We have marked with an asterisk (*) those risk factors that reflect changes from the risk factors included in our Form 10-Q for the period ended March 31, 2014.

Risks Related to Our Financial Condition and Need for Additional Capital

We have incurred significant losses since our inception and we will 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 two 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 may not generate significant revenue from sales of our product candidates in the near-term, if ever. We have incurred significant net losses of $8.9 million for the nine months ended June 30, 2014. As of June 30, 2014, we had an accumulated deficit of $95.1 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 has 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 through the third quarter of fiscal year 2015.

If we fail to obtain additional financing, we would be forced to delay, reduce or eliminate our product development programs.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect our development expenses to substantially increase in connection with our ongoing activities, particularly as we advance our clinical programs.

The net proceeds from our initial public offering were approximately $46.1 million. Regardless of our expectations as to how long our net proceeds from will fund our operations, changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, our product development efforts could encounter technical or other difficulties that could increase our development costs more than we expect. In any event, we may require additional capital prior to obtaining regulatory approval for, or commercializing, any of our product candidates.

In addition, attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. We cannot guarantee

that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back or discontinue the development or commercialization of our product candidates;
- seek corporate partners for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- relinquish or license on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves; or
- significantly curtail, or cease, operations.

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

We may sell additional equity or incur debt to fund our operations, which may result in dilution to our stockholders and impose restrictions on our business.

In order to raise additional funds to support our operations, we may sell additional equity or incur debt, which could adversely impact our stockholders, as well as our business. The sale of additional equity or convertible debt securities would result in the issuance of additional shares of our capital stock and dilution to all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

We may not have enough available cash or be able to raise additional funds on satisfactory terms, if at all, through equity or debt financings to repay our indebtedness at the time any such repayment is required (causing a default under such indebtedness), which could have a material adverse effect on our business, financial condition and results of operations.

Our short operating history makes it difficult to evaluate our business and prospects.

We were incorporated in and have only been conducting operations since 2007. Our operations to date have been limited to developing and bringing to market a limited number of products and developing our other product candidates. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing a significant number of pharmaceutical products.

Risks Related to Regulatory Approval

We are heavily dependent on the success of our lead product candidates EP-3101 (bendamustine RTD), EP-3102 (bendamustine short infusion time), 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 short infusion time), 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) in the United States.

If the FDA does not conclude that our product candidates satisfy the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of any of our product candidates under Section 505(b)(2) are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.

We intend to seek FDA approval through the 505(b)(2) regulatory pathway for each of our product candidates described in this Form 10Q. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act, or FDCA.

Section 505(b)(2) permits the filing 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.

If the FDA does not allow us to pursue the 505(b)(2) regulatory pathway for our product candidates as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates would likely substantially increase. Moreover, the inability to pursue the 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than our product candidates, which could materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the 505(b)(2) regulatory pathway for a product candidate, we cannot assure you that we will receive the requisite or timely approvals for commercialization of such product candidate.

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In addition, we expect that our competitors will file citizens' petitions with the FDA in an attempt to persuade the FDA that our product candidates, 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).

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development.

Clinical testing, even when utilizing the 505(b)(2) pathway, is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process, even with active ingredients that have previously been approved by the FDA as safe and effective. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later stage clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

Our product candidates are in various stages of development, from early stage to late stage. Clinical trial failures may occur at any stage and may result from a multitude of factors both within and outside our control, including flaws in formulation, adverse safety or efficacy profile and flaws in trial design, among others. If the trials result in negative or inconclusive results, we or our collaborators may decide, or regulators may require us, to discontinue trials of the product candidates or conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. For these reasons, our future clinical trials may not be successful.

We do not know whether any future clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If any product candidate for which we are conducting clinical trials is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it. If we are unable to bring any of our current or future product candidates to market, our business would be materially harmed and our ability to create long-term stockholder value will be limited.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and could jeopardize or delay our ability to obtain regulatory approval and commence product sales. We may also find it difficult to enroll patients in our clinical trials, which could delay or prevent development of our product candidates.

We may experience delays in clinical trials of our product candidates. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including:

- inability to raise or delays in raising funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, or failure by such CROs to carry out the clinical trial at each site in accordance with the terms of our agreements with them;
- delays in obtaining required institutional review board, or IRB, approval at each site;
- difficulties or delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites electing to terminate their participation in one of our clinical trials, which would likely have a detrimental effect on subject enrollment;
- time required to add new clinical sites; or
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

If initiation or completion of our planned clinical trials is delayed for any of the above reasons or other reasons, our development costs may increase, our regulatory approval process could be delayed and our ability to commercialize and commence sales of our product candidates could be materially harmed, which could have a material adverse effect on our business.

In addition, identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates as well as completion of required follow-up periods. We may not be able to identify, recruit and enroll a sufficient number of

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patients, or those with required or desired characteristics or to complete our clinical trials in a timely manner. Patient enrollment is and completion of the trials is affected by factors including:

- severity of the disease under investigation;
- design of the trial protocol;
- size of the patient population;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under trial;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

Our products or product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance, or result in significant negative consequences following marketing approval, if any.

As with many pharmaceutical and biological products, treatment with our products or product candidates may produce undesirable side effects or adverse reactions or events. Although the nature of our products or product candidates as containing active ingredients that have already been approved means that the side effects arising from the use of the active ingredient or class of drug in our products or product candidates is generally known, our products or product candidates may still cause undesirable side effects. These could be attributed to the active ingredient or class of drug or to our unique formulation of such products or product candidates, or other potentially harmful characteristics. Such characteristics could cause us, our IRBs, clinical trial sites, the FDA or other regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay, denial or withdrawal of regulatory approval, which may harm our business, financial condition and prospects significantly.

Further, if any of our products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution;
- the FDA may require implementation of a Risk Evaluation and Mitigation Strategy, or REMS;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical studies;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or product candidate and could substantially increase the costs of commercializing our products and product candidates.

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

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. To date we have obtained regulatory approval for one product in the United States and one product in Europe, but it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval in the United States or other jurisdictions.

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

- the FDA or comparable foreign regulatory authorities may disagree that our changes to branded reference drugs meet the criteria for the 505(b)(2) regulatory pathway or foreign regulatory pathways;

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

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

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

We have limited experience using the 505(b)(2) regulatory pathway to submit an NDA or any similar drug approval filing to the FDA, and we cannot be certain that any of our product candidates will receive regulatory approval. For example, we obtained FDA approval for our product argatroban using the 505(b)(2) regulatory pathway, but, after discussions with the FDA, we decided not to continue pursuing FDA approval of our product EP-2101 (topotecan). 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) in the United States. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such products, if approved.

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

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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. We filed an application with the FDA for our EP-3101 (bendamustine RTD) product candidate through the 505(b)(2) regulatory pathway on September 6, 2013, referencing Teva's Treanda product, including a paragraph IV certification stating our belief that our bendamustine product will not infringe Teva's patents on Treanda. We notified Teva of our 505(b)(2) filing and paragraph IV certification, and Teva filed a patent infringement lawsuit against us in the United States District Court for the District of Delaware on October 21, 2013. Teva's filing of the lawsuit invoked a 30-month stay of FDA approval of our bendamustine product, which will delay the FDA from granting final approval for EP-3101 (bendamustine RTD) until the earlier of the March 2016 expiration of the 30-month stay imposed by the Hatch-Waxman Act, or such time as the district court enters judgment in our favor or otherwise acts to shorten the stay. Moreover, regardless of when the 30-month stay is resolved or expires, the FDA may still be prohibited from approving our 505(b)(2) NDA due to Teva's unexpired orphan drug and related pediatric exclusivities for Treanda. Specifically, Teva has received orphan drug and pediatric exclusivity expiring in September 2015 and May 2016 for the CLL and NHL indications (as defined in "Business—Our Products and Product Portfolio"), respectively. When a drug, such as Treanda, has orphan drug exclusivity, the FDA may not approve any other application to market the same drug for the same indication for a period of up to seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. In the United States, pediatric exclusivity adds six months to any existing exclusivity period. If we cannot demonstrate that EP-3101 is clinically superior to Treanda, or qualify under certain other limited exceptions, we will not be able to enter the market for the CLL indication until September 2015 (assuming the 30-month stay is resolved by that time) or the NHL indication until May 2016.

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.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If we are found to have improperly promoted off-label uses of our products or product candidates, if approved, we may become subject to significant liability. Such enforcement has become more common in the industry. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for our product candidates for our proposed indications, physicians may nevertheless use our

products for their patients in a manner that is inconsistent with the approved label, if the physicians personally believe in their professional medical judgment it could be used in such manner. However, if we are found to have promoted our products for any off-label uses, the federal government could levy civil, criminal and/or administrative penalties, and seek fines against us. The FDA or other regulatory authorities could also request that we enter into a consent decree or a corporate integrity agreement, or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Our business is subject to extensive regulatory requirements and our approved product and product candidates that obtain regulatory approval will be subject to ongoing and continued regulatory review, which may result in significant expense and limit our ability to commercialize such products.

Even after a product is approved, we will remain subject to ongoing FDA and other regulatory requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, import, export, record-keeping and reporting of safety

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and other post-market information. The holder of an approved NDA is obligated to monitor and report adverse events, or AEs, and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. In addition, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. For example, a product's approval may contain requirements for potentially costly post-approval studies and surveillance to monitor the safety and efficacy of the product, or the imposition of a REMS program.

Manufacturers of drug products and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, and adherence to commitments made in the NDA. If we or a regulatory agency discovers previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring product recall, notice to physicians, withdrawal of the product from the market or suspension of manufacturing.

If we or our products or product candidates or our manufacturing facilities fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters asserting that we are in violation of the law;
- impose restrictions on the marketing or manufacturing of the product;
- seek an injunction or impose civil, criminal and/or administrative penalties, damages, assess monetary fines, require disgorgement, consider exclusion from participation in Medicare, Medicaid and other federal health care programs and require curtailment or restructuring of our operations;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA submitted by us;
- seize product; or
- refuse to allow us to enter into government contracts.

Similar post-market requirements may apply in foreign jurisdictions in which we may seek approval of our products. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenues.

In addition, the FDA's regulations, policies or guidance may change and new or additional statutes or government regulations in the United States and other jurisdictions may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. For example, the Food and Drug Administration Safety and Innovation Act, or FDASIA, requires the FDA to issue new guidance on permissible forms of Internet and social media promotion of regulated medical products, and the FDA may soon specify new restrictions on this type of promotion. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our products and/or product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct that violates (1) the laws of the United States FDA and similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulatory bodies; (2) health care fraud and abuse laws of the United States and similar foreign

fraudulent misconduct laws; and (3) laws requiring the reporting of financial information or data accurately. Specifically, the promotion, sales and marketing of health care items and services, as well as certain business arrangements in the health care industry are subject to extensive laws designed to prevent misconduct, including fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing, structuring and commission(s), certain customer incentive programs and other business arrangements generally.

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Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. It is not always possible to identify and deter employee and other third-party misconduct. The precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws. If any such actions are instituted against us, and we are not successful in defending ourselves, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Any relationships with health care professionals, principal investigators, consultants, customers (actual and potential) and third party payors are and will continue to be subject, directly or indirectly, to federal and state health care fraud and abuse laws, false claims laws, marketing expenditure tracking and disclosure, or sunshine laws, government price reporting and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face penalties, including, without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations.

Our business operations and activities may be directly, or indirectly, subject to various federal, state and local fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as proposed and future sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by the federal government, state governments and foreign jurisdictions in which we conduct our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal health care program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other third party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, health care benefits, items or services relating to health care matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered health care providers, health plans and health care clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal Physician Payment Sunshine Act, created under Section 6002 of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, ACA, and its implementing regulations requires manufacturers of drugs, devices, biologicals and medical supplies for which

payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members, with data collection required beginning August 1, 2013 and reporting to the Centers for Medicare & Medicaid Services was required by March 31, 2014 and by the 90th day of each subsequent calendar year;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

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- federal government price reporting laws, changed by ACA to, among other things, increase the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program and offer such rebates to additional populations, that require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on our marketed drugs. Participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs and potentially limit our ability to offer certain marketplace discounts;
- the Foreign Corrupt Practices Act, a United States law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals); and
- state law equivalents of each of the above federal laws, such as anti-kickback, false claims, consumer protection and unfair competition laws which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving health care items or services reimbursed by any third party payors, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to health care providers;
- state laws that require drug manufacturers to file reports with states regarding marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to health care professionals and entities (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative effect on our business and/or increase enforcement scrutiny of our activities); and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, with differing effects.

In addition, any sales of our products or product candidates once commercialized outside the United States will also likely subject us to foreign equivalents of the health care laws mentioned above, among other foreign laws.

Efforts to ensure that our business arrangements will comply with applicable health care laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other health care laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to, without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

We are required to obtain regulatory approval for each of our products in each jurisdiction in which we intend to market such products, and the inability to obtain such approvals would limit our ability to realize their full market potential.

In order to market products outside of the United States, we must comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. However, the failure to obtain regulatory approval in one jurisdiction may adversely impact our ability to obtain regulatory approval in another jurisdiction. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional non-clinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

If we fail to develop, acquire or in-license other product candidates or products, our business and prospects will be limited.

Our long-term growth strategy is to develop and commercialize a portfolio of product candidates in addition to our existing product candidates. We may also acquire or in-license such product candidates. Although we have internal research and development capacity that we believe will enable us to make improvements to existing compounds or active ingredients, we do not have internal drug discovery capabilities to identify and develop entirely new chemical entities or compounds. As a result, our primary means of expanding our pipeline of product candidates is to develop improved formulations and delivery methods for existing FDA-approved products and/or select and acquire or in-license product candidates for the treatment of therapeutic indications that complement or augment our current targets, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Developing new formulations of existing products or identifying, selecting and acquiring or in-licensing promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual

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development, acquisition or in-license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. If we are unable to add additional product candidates to our pipeline, our long-term business and prospects will be limited.

Risks Related to Commercialization of Our Products and Product Candidates

Our commercial success depends upon attaining significant market acceptance of our products and product candidates, if approved, among physicians, nurses, pharmacists, patients and the medical community.

Even if we obtain regulatory approval for our product candidates, our product candidates may not gain market acceptance among physicians, nurses, pharmacists, patients, the medical community or third party payors, which is critical to commercial success.

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Market acceptance of our products and any product candidate for which we receive approval depends on a number of factors, including:

- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- the convenience and ease of administration to patients of the product candidate;
- the potential and perceived advantages of such product candidate over alternative treatments;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- the availability of coverage and adequate reimbursement and pricing by third party payors and government authorities;
- relative convenience and ease of administration;
- any negative publicity related to our or our competitors' products that include the same active ingredient;
- the prevalence and severity of adverse side effects, including limitations or warnings contained in a product's FDA-approved labeling; and
- the effectiveness of sales and marketing efforts.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be known until after it is launched. If our products or product candidates, if approved, fail to achieve an adequate level of acceptance by physicians, nurses, pharmacists, patients and the medical community, we will be unable to generate significant revenues, and we may not become or remain profitable.

Guidelines and recommendations published by government agencies can reduce the use of our product candidates.

Government agencies promulgate regulations and guidelines applicable to certain drug classes which may include our products and product candidates that we are developing. Recommendations of government agencies may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Regulations or guidelines suggesting the reduced use of certain drug classes which may include our products and product candidates that we are developing or the use of competitive or alternative products as the standard of care to be followed by patients and health care providers could result in decreased use of our product candidates or negatively impact our ability to gain market acceptance and market share.

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.

Although we intend to establish a small, focused, specialty sales and marketing organization to promote any approved products 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. Eagle has no 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 outside of the United States. We may have difficulty establishing 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.

If any of our product candidates are approved for commercialization, we may enter into agreements with third parties to market these 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;

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- 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.

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

Our strategy is to have our drugs enter the market no later than the first generic to the applicable branded reference drug. We expect to compete against branded reference drugs and to compete with their generic counterparts that will be sold for a lower price. Although we believe that our product candidates will be clinically differentiated from branded reference drugs and their generic counterparts, if any, it is possible that such differentiation will not impact our market position. If we are unable to achieve significant differentiation for our product candidates against other drugs, the opportunity for our product candidates to achieve premium pricing and be commercialized successfully would be adversely affected.

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

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, and West-Ward Pharmaceuticals, or West-Ward, under the brand name Argatroban and bendamustine is marketed in the United States by Teva Pharmaceuticals 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. Teva has obtained approval for a ready to dilute, or RTD, version of Treanda which will compete with our EP-3101 (bendamustine RTD) product. We filed a submission for our EP-3101 (bendamustine RTD) product with the FDA on September 6, 2013, including a paragraph IV certification of non-infringement of Teva's patents covering its Treanda product and received tentative approval on July 2, 2014. We notified Teva of our 505(b)(2) filing and paragraph IV certification, and Teva

filed a patent infringement lawsuit against us in the United States District Court for the District of Delaware on October 21, 2013. Teva's filing of the lawsuit invoked a 30-month stay of FDA approval of our bendamustine product, which will delay the FDA from approving EP-3101 (bendamustine RTD) until the earlier of the March 2016 expiration of the 30-month stay imposed by the Hatch-Waxman Act, or such time as the district court enters judgment in our favor or otherwise acts to shorten the stay. Moreover, regardless of when the 30-month stay is resolved or expires, the FDA may still be prohibited from granting final product approval of our 505(b)(2) NDA due to Teva's unexpired orphan drug and related pediatric exclusivities for Treanda. Specifically, Teva has received orphan drug and pediatric exclusivity expiring in September 2015 and May 2016 for the CLL and NHL indications (as defined in "Business—Our Products and Product Portfolio"), respectively. When a drug, such as Treanda, has orphan drug exclusivity, the FDA may not approve any other application to market the same drug for the same indication for a period of up to seven years,

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except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. In the United States, pediatric exclusivity adds six months to any existing exclusivity period. If we cannot demonstrate that EP-3101 is clinically superior to Treanda, or qualify under certain other limited exceptions, we will not be able to enter the market for the CLL indication until September 2015 (assuming the 30-month stay is resolved by that time) or the NHL indication until May 2016.

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 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 could incur substantial costs and disruption to our business and delays in the launch of our product candidates if our competitors and/or collaborators bring legal actions against us, which could harm our business and operating results.

We cannot predict whether our competitors or potential competitors, some of whom we collaborate with, may bring legal actions against us based on our research, development and commercialization activities, as well as any product candidates or products resulting from these activities, claiming, among other things, infringement of their intellectual property rights, breach of contract or other legal theories. If we are forced to defend any such lawsuits, whether they are with or without merit or are ultimately determined in our favor, we may face costly litigation and diversion of technical and management personnel. These lawsuits could hinder our ability to enter the market early with our

product candidates and thereby hinder our ability to influence usage patterns when fewer, if any, of our potential competitors have entered such market, which could adversely impact our potential revenue from such product candidates. Some of our competitors have substantially greater resources than we do and could be able to sustain the cost of litigation to a greater extent and for longer periods of time than we could. Furthermore, an adverse outcome of a dispute may require us: to pay damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed a party's patent or other intellectual property rights; to cease making, licensing or using products that are alleged to incorporate or make use of the intellectual property of others; to expend additional development resources to reformulate our products or prevent us from marketing a certain drug; and to enter into potentially unfavorable royalty or license agreements in order to obtain the

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rights to use necessary technologies. Royalty or licensing agreements, if required, may be unavailable on terms acceptable to us, or at all.

If we are unable to achieve and maintain adequate levels of coverage and reimbursement for our products or product candidates, if approved, their commercial success may be severely hindered.

Successful sales of our products and any other approved product candidates depend on the availability of adequate coverage and reimbursement from third party payors. Patients who are prescribed medications for the treatment of their conditions generally rely on third party payors to reimburse all or part of the costs associated with their prescription drugs. Adequate coverage and reimbursement from governmental health care programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Assuming we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for argatroban and our product candidates will depend significantly on access to third party payors' drug formularies, or lists of medications for which third party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access through formulary controls or otherwise to a branded drug when a less costly generic equivalent or other alternative is available.

Third party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling health care costs. In addition, in the United States, no uniform policy requirement for coverage and reimbursement for drug products exists among third party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third party coverage and reimbursement for our product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Recently enacted and future legislation may increase the difficulty and cost for us to commercialize our product candidates and affect the prices we may obtain.

The United States and some foreign jurisdictions are considering, or have enacted, a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products and our product candidates profitably, once they are approved for sale. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in health care systems with the stated goals of containing health care costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

In March 2010, the ACA was enacted, which includes measures that have or will significantly change the way health care is financed by both governmental and private insurers. Among the ACA provisions of importance to the pharmaceutical industry are the following:

- an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government health care programs that began in 2011;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;
-

extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- methodologies by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and for drugs that are line extensions;
- changes to the Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;

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- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing manufacturers' Medicaid rebate liability;
- requirements under the federal Physician Payment Sunshine Act for reporting by manufacturers of drugs, devices, biologicals and medical supplies of information related to payments or other transfers of value made or distributed to physicians and teaching hospitals, as well as certain investment interests;
- the requirement to annually report drug samples that manufacturers and distributors provide to licensed practitioners or to pharmacies of hospitals or other health care entities, effective April 1, 2012;
- expansion of health care fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute changes, new government investigative powers and enhanced penalties for noncompliance;
- a licensure framework for follow-on biologic products;
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- creation of the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs.

In addition, other legislative changes have been proposed and adopted since ACA was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals for spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The full impact of these new laws, as well as laws and other reform measures that may be proposed and adopted in the future remains uncertain, but may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and, accordingly, our financial operations.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third party CROs to monitor and manage data for our preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with FDA laws and regulations regarding current good clinical practice, or GCP, which are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Conference on Harmonization, or ICH, guidelines for all of our products in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. While we have agreements governing activities of our CROs, we have limited influence over their actual performance. In addition, portions of the clinical trials for our product candidates are expected to be conducted outside

of the United States, which will make it more difficult for us to monitor CROs and perform visits of our clinical trial sites and will force us to rely heavily on CROs to ensure the proper and timely conduct of our clinical trials and compliance with applicable regulations, including GCP. Failure to comply with applicable regulations in the conduct of the clinical trials for our product candidates may require us to repeat clinical trials, which would delay the regulatory approval process.

Some of our CROs have an ability to terminate their respective agreements with us if, among other reasons, it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general

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assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely on third parties to manufacture commercial supplies of argatroban 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 for the manufacture of 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

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clinical trials and development purposes or to further commercialize argatroban 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, 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 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 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

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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.

We may not be successful in establishing development and commercialization collaborations which could adversely affect, and potentially prohibit, our ability to develop our product candidates.

Because developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products are expensive, we are exploring collaborations with third parties outside of the United States that have more resources and experience. For example, we are exploring selective partnerships with third parties for development and commercialization of our product candidates outside of the United States. We may, however, be unable to advance the development of our product candidates in territories outside of the United States, which may limit the market potential for this product candidate.

In situations where we enter into a development and commercial collaboration arrangement for a product candidate, we may also seek to establish additional collaborations for development and commercialization in territories outside of those addressed by the first collaboration arrangement for such product candidate. There are a limited number of potential partners, and we expect to face competition in seeking appropriate partners. If we are unable to enter into any development and commercial collaborations and/or sales and marketing arrangements on acceptable terms, if at all, we may be unable to successfully develop and seek regulatory approval for our product candidates and/or effectively market and sell future approved products, if any, in all of the territories outside of the United States where it may otherwise be valuable to do so.

We may not be successful in maintaining development and commercialization collaborations, and any partner may not devote sufficient resources to the development or commercialization of our product candidates or may otherwise fail in development or commercialization efforts, which could adversely affect our ability to develop certain of our product candidates and our financial condition and operating results.

Even if we are able to establish collaboration arrangements, any such collaboration may not ultimately be successful, which could have a negative impact on our business, results of operations, financial condition and prospects. If we partner with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. It is possible that a partner may not devote sufficient resources to the development or commercialization of our product candidate or may otherwise fail in development or commercialization efforts, in which event the development and commercialization of such product candidate could be delayed or terminated and our business could be substantially harmed. In addition, the terms of any collaboration or other arrangement that we establish may not prove to be favorable to us or may not be perceived as favorable, which may negatively impact the trading price of our common stock. In some cases, we may be responsible for continuing development of a product candidate or research program under a collaboration, and the payment we receive from our partner may be insufficient to cover the cost of this development. Moreover,

collaborations and sales and marketing arrangements are complex and time consuming to negotiate, document and implement, and they may require substantial resources to maintain.

We are subject to a number of additional risks associated with our dependence on collaborations with third parties, the occurrence of which could cause our collaboration arrangements to fail. Conflicts may arise between us and our partners, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. If any such conflicts arise, a partner could act in its own self-interest, which may be adverse to our interests. Any such disagreement between us and a partner could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates and harm our business:

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- reductions in the payment of royalties or other payments we believe are due pursuant to the applicable collaboration arrangement;
- actions taken by a partner inside or outside our collaboration which could negatively impact our rights or benefits under our collaboration; and
- unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities.

If we are unable to maintain our group purchasing organization, or GPO, relationships, our revenues could decline and future profitability could be jeopardized.

Most of the end-users of injectable pharmaceutical products have relationships with GPOs whereby such GPOs provide such end-users access to a broad range of pharmaceutical products from multiple suppliers at competitive prices and, in certain cases, exercise considerable influence over the drug purchasing decisions of such end-users. Hospitals and other end-users contract with the GPO of their choice for their purchasing needs. We currently derive, and expect to continue to derive, a large percentage of our revenue from end-user customers that are members of a small number of GPOs. Maintaining strong relationships with these GPOs will require us to continue to be a reliable supplier, remain price competitive and comply with FDA regulations. The GPOs with whom we have relationships may have relationships with companies that sell competing products, and such GPOs may earn higher margins from these products or combinations of competing products or may prefer products other than ours for other reasons. If we are unable to maintain our GPO relationships, sales of our products and revenue could decline.

We rely on a limited number of pharmaceutical wholesalers to distribute our products.

As is typical in the pharmaceutical industry, we rely upon pharmaceutical wholesalers in connection with the distribution of our products. A significant amount of our products are sold to end-users under GPO pricing arrangements through a limited number of pharmaceutical wholesalers. If we are unable to maintain our business relationships with these pharmaceutical wholesalers on commercially acceptable terms, it could have a material adverse effect on our sales and may prevent us from achieving profitability.

Risks Related to Our Business Operations and Industry

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the principal members of our executive team, which includes Scott Tarriff, our Chief Executive Officer, David E. Riggs, our Chief Financial Officer, Paul Bruinenberg, M.D., our Chief Medical Officer and Steven Krill, Ph.D., our Chief Scientific Officer. The loss of these executives' services may adversely impact the achievement of our objectives. Any of our executive officers could leave our employment at any time, as all of our employees are "at will" employees. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit key executives or the loss of the services of any executive or key employee might impede the progress of our development and commercialization objectives.

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

As of June 30, 2014 we had a total of 28 full-time and two 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 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.

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The use of our product candidates in clinical trials (if any), and the sale of argatroban 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, 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 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.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our product development and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of product development or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs and the development of our product candidates could be delayed.

Business interruptions could delay us in the process of developing our product candidates and could disrupt our sales of EP-1101(argatroban) and any other products we may sell.*

Our headquarters are located in Woodcliff Lake, New Jersey. If we encounter any disruptions to our operations at this building or if it were to shut down for any reason, including by fire, natural disaster, such as a hurricane, tornado or severe storm, power outage, systems failure, labor dispute or other unforeseen disruption, then we may be prevented from effectively operating our business. We do not carry insurance for natural disasters and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to any of our product candidates, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and our product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover the products in the United States or in foreign countries or territories. If this were to occur, early generic competition could be expected against our

products and our product candidates in development. There may be relevant prior art relating to our patents and patent applications which could invalidate a patent or prevent a patent from issuing based on a pending patent application. In particular, because the active pharmaceutical ingredients in many of our product candidates have been on the market as separate products for many years, it is possible that these products have previously been used off-label in such a manner that such prior usage would affect the validity of our patents or our ability to obtain patents based on our patent applications.

Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Any adverse outcome in these types of matters could result in one or more generic versions of our products being launched before the expiration of the listed patents, which could adversely affect our ability to successfully execute our business strategy to increase sales of our products and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the patent applications we hold with respect to our products or product candidates fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop them and threaten our ability to commercialize our product candidates. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will be found not invalid and not unenforceable or will go unthreatened by third parties. Further, if we encounter delays in regulatory approvals, the period of time during which we could market our product candidates under patent protection could be reduced. If third parties have filed such patent applications, an interference proceeding in the United States can be provoked by a third party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug development and reformulation processes that involve proprietary know-how, information or technology that is not covered by patents. For example, we maintain trade secrets with respect to certain of the formulation and manufacturing techniques related to argatroban and our product candidates. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information.

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For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all.

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office, or USPTO, has developed new and untested regulations and procedures to govern the full implementation of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in March 2013. The Leahy-Smith Act has also introduced procedures making it easier for third-parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy-Smith Act contains new statutory provisions that still require the USPTO to issue new regulations for their implementation and it may take the courts years to interpret the provisions of the new statute. Accordingly, it is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. An inability to obtain, enforce and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance to us, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims in, or the written description or enablement in, a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Our drug development strategy relies heavily upon the 505(b)(2) regulatory pathway, which requires us to certify that we do not infringe upon third-party patents covering approved drugs. Such certifications typically result in third-party claims of intellectual property infringement, the defense of which will be costly and time consuming, and an unfavorable outcome in any litigation may prevent or delay our development and commercialization efforts which would harm our business.

Litigation or other proceedings to enforce or defend intellectual property rights are often complex in nature, may be very expensive and time-consuming, may divert our management's attention from other aspects of our business and may result in unfavorable outcomes that could adversely impact our ability to launch and market our product candidates, or to prevent third parties from competing with our products and product candidates.

There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party reexamination proceedings before the USPTO. Numerous United States and

foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

In particular, our commercial success depends in large part on our avoiding infringement of the patents and proprietary rights of third parties for existing approved drug products. Because we utilize the 505(b)(2) regulatory pathway for the approval of our products and product candidates, we rely in whole or in part on studies conducted by third parties related to those approved drug products. As a result, upon filing with the FDA for approval of our product candidates, we will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of our proposed drug product. When we submit a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be

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sent to the patent owner once our 505(b)(2) NDA is accepted for filing by the FDA. The third party may then initiate a lawsuit against us to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving our NDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in our favor. If the third party does not file a patent infringement lawsuit within the required 45-day period, our NDA will not be subject to the 30-month stay.

In addition to paragraph IV litigation noted above, third-party owners of patents may generally assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of argatroban and/or our product candidates. Because patent applications can take many years to issue, there may be currently pending or subsequently filed patent applications which may later result in issued patents that may be infringed by our products or product candidates. If any third-party patents were held by a court of competent jurisdiction to cover aspects of our product candidates, including the formulation, method of use, any method or process involved in the manufacture of any of our product candidates, any molecules or intermediates formed during such manufacturing process or any other attribute of the final product itself, the holders of any such patents may be able to block our ability to commercialize our product candidates unless we obtain a license under the applicable patents, or until such patents expire. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may request and/or obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates on a temporary or permanent basis. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products or manufacturing processes, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research, manufacture clinical trial supplies or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third party patents do not exist which might be enforced against our products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

If we fail to comply with our obligations in the agreements under which we license rights to technology from third parties, or if the license agreements are terminated for other reasons, we could lose license rights that are important to our business.

We are a party to a number of technology licenses that are important to our business and expect to enter into additional licenses in the future. Our existing license agreements impose, and we expect that future license agreements will impose, on us, various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. Additionally, one of our existing license agreements is a sublicense from a third party who is not the original licensor of the intellectual property at issue. Under these agreements, we must rely on our licensor to comply with their obligations under the primary license agreements under which such third party obtained rights in the applicable intellectual property, where we may have no relationship with the original licensor of such rights. If our licensors fail to comply with their obligations under these upstream license agreements, the original third-party licensor may have the right to terminate the original license, which may terminate our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do at a reasonable cost or on reasonable terms, which may impact our ability to continue to develop and commercialize our product candidates and companion diagnostic incorporating the relevant intellectual property. If we fail to comply with our obligations under

our license agreements, or we are subject to a bankruptcy or insolvency, the licensor may have the right to terminate the license. In the event that any of our important technology licenses were to be terminated by the licensor, we would likely cease further development of the related program or be required to spend significant time and resources to modify the program to not use the rights under the terminated license.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

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Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

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 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) and argatroban 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, 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) and argatroban 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

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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.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates and companion diagnostic. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

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Risks Related to Ownership of Our Common Stock

We expect that our stock price may fluctuate significantly.

Our initial public offering was completed in February 2014 at a public offering price of $15.00 per share. The trading price of our common stock 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 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 or any of our product candidates;
- adverse regulatory decisions;
- introduction of new products or technologies by our competitors;
- failure to meet or exceed product development or financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future; and
- trading volume of our common stock.

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

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

- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes on our growth rate relative to our competitors;
- competition from existing products or new products that may emerge;
- announcements of significant acquisitions, strategic partnerships, joint ventures, collaborations, or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;

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- additions or departures of key management or scientific personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- announcement or expectation of additional debt or equity financing efforts;
- sales of our common stock by us, our insiders or our other stockholders; and
- general economic and market conditions.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock.

In addition, the stock market in general, and NASDAQ and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

An active trading market for our common stock may not develop.

There has been a public market for our common stock for only a short period of time. If an active market for our common stock does not develop, you may not be able to sell your shares quickly or at an acceptable price.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.*

As of June 30, 2014, our executive officers, directors, 5% or greater stockholders and their affiliates beneficially own approximately 64% of our voting stock. These stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of the initial public offering, (b) in which we have total annual gross revenue of at least $1 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior March 31st, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this

exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

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Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our condensed financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We will incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company.

For example, as a public company, we are now subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition. We have incurred and will continue to incur costs associated with the preparation in filing of these reports. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC, and Nasdaq have imposed various other requirements on public companies and we have incurred and will continue to incur costs associated with compliance with such requirements. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that required the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to fall.*

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock.

As of August 8, 2014, we had 14,020,133 shares of common stock outstanding, all of which, other than shares held by our directors and certain officers, are eligible for sale in the public market, subject in some cases to compliance with the requirements of Rule 144, including volume limitations and manner of sale requirements. In addition

In addition, shares issued upon exercise of vested options are eligible for sale. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock.

Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended, or the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Future issuances of our common stock or rights to purchase our common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

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Pursuant to our 2014 Equity Incentive Plan, or the 2014 plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares available for future grant under the 2014 plan will automatically increase each year by 4% of all shares of our capital stock outstanding as of September 30 of the prior calendar year, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. Currently, we plan to register the increased number of shares available for issuance under the 2014 plan each year. If our board of directors elects to increase the number of shares available for future grant by the maximum amount each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

We have broad discretion in the use of the net proceeds from our recently completed initial public offering and may not use them effectively.*

Our management has broad discretion in the application of the net proceeds from our recently completed initial public offering. Because of the number and variability of factors that will determine our use of the net proceeds from our initial public offering, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from our initial public offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited. We believe that, with our initial public offering, our most recent private placement and other transactions that have occurred over the past three years, we may have triggered an "ownership change" limitation. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a classified board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;

- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

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These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

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

Item 3. Defaults Upon Senior Securities
Not applicable.

Item 4. Mine Safety Disclosures
Not applicable.

Item 5. Other Information
Not applicable.

Item 6. Exhibits
The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

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

EAGLE PHARMACEUTICALS, INC.

DATED: August 11, 2014

By: /s/ Scott Tarriff

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

DATED: August 11, 2014

By: /s/ David E. Riggs

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

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EXHIBIT INDEX

Exhibit Number	Description of Exhibit
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document