Amphastar Pharmaceuticals, Inc.
Form 10-Q
August 13, 2014
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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 001-36509

AMPHASTAR PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	33-0702205
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

11570 6th Street
Rancho Cucamonga, CA 91730
(Address of principal executive offices, including zip code)

(909) 980-9484
(Registrant's telephone number, including area code)

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 ¨ No x

Indicate by check mark whether the Registrant (1) 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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 ¨ Accelerated filer ¨

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

The number of shares outstanding of the Registrant’s only class of common stock as of August 8, 2014 was 44,644,159.

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AMPHASTAR PHARMACEUTICALS, INC.

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NOTE ABOUT FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or Quarterly Report, contains "forward-looking statements" that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the following words: "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "p "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements relate to future events or our future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. These forward-looking statements include, but are not limited to, statements about:

- our expectations regarding the sales and marketing of our products, including our enoxaparin product;
- our expectations regarding the integrity of our supply chain for our products, including the risks associated with our single source suppliers;
- the timing and likelihood of FDA approvals and regulatory actions on our product candidates, manufacturing activities and product marketing activities;
- our ability to advance product candidates in our platforms into successful and completed clinical trials and our subsequent ability to successfully commercialize our product candidates;
- our ability to compete in the development and marketing of our products and product candidates;
- the potential for adverse application of environmental, health and safety and other laws and regulations on our operations;
- our expectations for market acceptance of our new products and proprietary drug delivery technologies;
- the potential for our marketed products to be withdrawn due to patient adverse events or deaths, or if we fail to secure FDA approval for products subject to the Prescription Drug Wrap-Up program;
- our expectations in obtaining insurance coverage and adequate reimbursement for our products from third-party payers;
- the amount of price concessions or exclusion of suppliers adversely affecting our business;
- our ability to establish and maintain intellectual property on our products and our ability to successfully defend these in cases of alleged infringement;
- the implementations of our business strategies, product candidates and technology;
- the potential for exposure to product liability claims;
- our ability to expand internationally;
- our ability to remain in compliance with laws and regulations that currently apply or become applicable to our business both in the United States and internationally; and

- our financial performance expectations.

You should read this Quarterly Report and the documents that we reference elsewhere in this Quarterly Report completely and with the understanding that our actual results may differ materially from what we expect as expressed or implied by our forward-looking statements. In light of the significant risks and uncertainties to which our forward-looking statements are subject, you should not place undue reliance on or regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all. We discuss many of these risks and uncertainties in greater detail in this Quarterly Report, particularly in Part II. Item 1A. “Risk Factors.” These forward-looking statements represent our estimates and assumptions only as of the date of this Quarterly Report regardless of the time of delivery of this Quarterly Report. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this Quarterly Report.

Unless expressly indicated or the context requires otherwise, references in this Quarterly Report on Form 10-Q to “Amphastar,” “Company,” “we,” “our,” and “us” refer to Amphastar Pharmaceuticals, Inc. and our subsidiaries, unless the context indicates otherwise.

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PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

AMPHASTAR PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited; in thousands, except share data)

	June 30, 2014	December 31, 2013
ASSETS		
Current Assets:		
Cash and cash equivalents	$64,081	$ 53,587
Restricted cash and restricted short-term investments	1,495	1,325
Accounts receivable, net	18,598	24,585
Inventories, net	106,017	69,916
Income tax refund and deposits	4,241	2,429
Prepaid expenses and other assets	3,699	5,033
Deferred tax assets	16,096	16,096
Total current assets	214,227	172,971
Property, plant, and equipment, net	133,991	116,619
Goodwill and intangible assets, net	39,330	40,163
Other assets	3,602	2,877
Deferred tax assets	6,118	6,118
Total assets	$397,268	$ 338,748
LIABILITIES AND EQUITY		
Current Liabilities:		
Accounts payable	$17,764	$ 20,380
Accrued liabilities	10,491	7,628
Income taxes payable	2,773	2,847
Accrued payroll and related benefits	10,846	9,161
Current portion of product return accrual	3,100	2,639
Current portion of deferred revenue	643	643
Current portion of long-term debt and capital leases	10,665	22,104
Total current liabilities	56,282	65,402
Long-term product return accrual	938	1,953
Long-term deferred revenue	2,303	2,625
Long-term debt and capital leases, net of current portion	42,850	10,069
Deferred tax liabilities	7,154	7,154
Total liabilities	109,527	87,203
Commitments and Contingencies:		
Stockholders' equity:		
Preferred stock: par value $.0001; authorized shares—20,000,000; none issued	—	—
	4	4

Common stock; par value $.0001; authorized shares—300,000,000; issued and outstanding shares—44,635,940 and 38,765,940 at June 30, 2014 and December 31, 2013, respectively		
Additional paid-in capital	216,995	177,732
Retained earnings	71,010	73,809
Accumulated other comprehensive loss	(268)	—
Total stockholders' equity	287,741	251,545
Total liabilities and stockholders' equity	$397,268	$ 338,748

See Accompanying Notes to Condensed Consolidated Financial Statements.

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AMPHASTAR PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited; in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Net revenues	$49,003	$62,524	$94,873	$115,487
Cost of revenue	34,007	35,035	67,368	68,440
Gross profit	14,996	27,489	27,505	47,047
Operating expenses:				
Selling, distribution, and marketing	1,352	1,203	2,612	2,597
General and administrative	8,638	6,513	15,484	13,420
Research and development	5,994	7,791	12,203	16,695
Impairment of long-lived assets	184	—	348	—
Total operating expenses	16,168	15,507	30,647	32,712
Income (loss) from operations	(1,172)	11,982	(3,142)	14,335
Non-operating income (expense):				
Interest income	32	47	60	96
Interest expense, net	(476)	(237)	(655)	(542)
Other income (expense), net	(260)	127	(610)	222
Total other income (expense), net	(704)	(63)	(1,205)	(224)
Income (loss) before income taxes	(1,876)	11,919	(4,347)	14,111
Income tax expense (benefit)	(696)	4,109	(1,548)	3,919
Net income (loss)	$(1,180)	$7,810	$(2,799)	$10,192
Net income (loss) per common share:				
Basic	$(0.03)	$0.20	$(0.07)	$0.26
Diluted	$(0.03)	$0.20	$(0.07)	$0.26
Weighted-average shares used to compute net income (loss) per common share:				
Basic	39,767	38,708	39,268	38,708
Diluted	39,767	38,847	39,268	38,846

See Accompanying Notes to Condensed Consolidated Financial Statements.

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AMPHASTAR PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(Unaudited; in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Net income (loss)	$(1,180)	$7,810	$(2,799)	$10,192
Other comprehensive loss				
Foreign currency translation adjustment	(268)	—	(268)	—
Other comprehensive loss	(268)	—	(268)	—
Total comprehensive income (loss)	$(1,448)	$7,810	$(3,067)	$10,192

See Accompanying Notes to Condensed Consolidated Financial Statements.

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AMPHASTAR PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited; in thousands)

	Six Months Ended June 30,	
	2014	2013
Cash Flows From Operating Activities:		
Net income (loss)	$ (2,799)	$ 10,192
Reconciliation to net cash provided by (used in) operating activities:		
Impairment of long-lived assets	348	—
Loss on disposal of property, plant, and equipment	44	32
Depreciation and amortization of property, plant, and equipment	6,036	5,397
Amortization of product rights, trademarks, and patents	956	950
Employee share-based compensation expense	3,546	2,348
Non-employee share-based compensation expense	475	474
Reserve for income tax liabilities	—	62
Changes in operating assets and liabilities:		
Accounts receivable, net	5,987	4,327
Inventories, net	(14,788)	(3,256)
Income tax refund and deposits	(1,812)	(3)
Prepaid expenses and other assets	(93)	744
Income taxes payable	(74)	3,328
Accounts payable and accrued liabilities	(2,727)	(2,774)
Net cash provided by (used in) operating activities	(4,901)	21,821
Cash Flows From Investing Activities:		
Acquisition of business	(18,352)	—
Purchases of property, plant, and equipment	(7,090)	(9,545)
Capitalized labor, overhead, and interest on self-constructed assets	(364)	(330)
Purchase of trademarks and other intangible assets	—	(28)
Sales of short-term investments, net	—	513
Decrease (increase) in restricted cash	(170)	50
Deposits and other assets, net	(739)	(711)
Net cash used in investing activities	(26,715)	(10,051)
Cash Flows From Financing Activities:		
Net proceeds from issuance of common stock	38,018	—
Net proceeds from exercise of common stock options	571	13
Costs related to public offering	(1,920)	—
Deferred offering cost	—	(168)
Proceeds from borrowing under lines of credit	25,000	35,000
Repayments under lines of credit	(40,000)	(40,000)
Proceeds from issuance of long-term debt	26,505	—
Principal payments on long-term debt	(6,032)	(874)

Net cash provided by (used in) financing activities	42,142	(6,029)
Effect of exchange rate changes on cash	(32)	—
Net increase in cash and cash equivalents	10,494	5,741
Cash and cash equivalents at beginning of period	53,587	50,213
Cash and cash equivalents at end of period	$ 64,081	$ 55,954
Noncash Investing and Financing Activities:		
Equipment acquired under capital leases	$ —	$ 44
Supplemental Disclosures of Cash Flow Information:		
Interest paid	$ 573	$ 607
Income taxes paid	$ 84	$ 75

See Accompanying Notes to Condensed Consolidated Financial Statements.

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AMPHASTAR PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. General

Amphastar Pharmaceuticals, Inc., a California corporation, was incorporated on February 29, 1996 and merged with and into Amphastar Pharmaceuticals, Inc., a Delaware corporation, in July 2004 (hereinafter referred to as "the Company"). The Company is a specialty pharmaceutical company that primarily develops, manufactures, markets, and sells generic and proprietary injectable and inhalation products, including products with high technical barriers to market entry. Most of the Company's products are used in hospital or urgent care clinical settings and are primarily contracted and distributed through group purchasing organizations and drug wholesalers. The Company's inhalation products will be primarily distributed through drug retailers once they are brought to market.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements of the Company for the year ended December 31, 2013 and the notes thereto as filed with the Securities and Exchange Commission in the Company's final prospectus for its initial public offering, or IPO, filed with the SEC pursuant to Rule 424(b) on June 25, 2014. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with generally accepted accounting principles, or GAAP, have been condensed or omitted from the accompanying condensed consolidated financial statements. The accompanying year-end condensed consolidated balance sheet was derived from the audited financial statements. The accompanying interim financial statements are unaudited, but reflect all adjustments which are, in the opinion of management, necessary for a fair statement of the Company's consolidated financial position, results of operations, and cash flows for the periods presented. Unless otherwise noted, all such adjustments are of a normal, recurring nature. The Company's results of operations and cash flows for the interim periods are not necessarily indicative of the results of operations and cash flows that it may achieve in future periods.

2. Summary of Significant Accounting Policies

Basis of Presentation

All significant intercompany activity has been eliminated in the preparation of the condensed consolidated financial statements. The unaudited condensed consolidated financial statements have been prepared in accordance with the requirements of Form 10-Q and Rule 10-01 of Regulation S-X. Some information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles, or GAAP, have been condensed or omitted pursuant to those rules and regulations. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments (consisting only of normal recurring adjustments) necessary to present fairly the consolidated financial position, results of operations, and cash flows of the Company.

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries: International Medication Systems, Limited, or IMS; Amphastar Laboratories, Inc.; Armstrong Pharmaceuticals, Inc., or Armstrong; Amphastar Nanjing Pharmaceuticals Co., Ltd., or ANP; and Amphastar France Pharmaceuticals, SAS, or AFP.

Use of Estimates

The preparation of consolidated financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying

notes. Actual results could differ from those estimates. The principal accounting estimates include: determination of allowances for doubtful accounts and discounts, liabilities for product returns and chargebacks, reserves for excess or unsellable inventory, impairment of long-lived and intangible assets and goodwill, self-insured claims, workers' compensation liabilities, litigation reserves, stock price volatilities for share-based compensation expense, fair market values of the Company's common stock, valuation allowances for deferred tax assets, and liabilities for uncertain income tax positions.

Foreign Currency

The functional currency of the Company and its domestic and Chinese subsidiaries is the U.S. dollar, or USD. The Company's Chinese subsidiary, ANP, maintains its books of record in Chinese Yuan. These books are remeasured into the functional currency of USD using the current or historical exchange rates. The resulting currency remeasurement adjustments and other transactional foreign exchange gains and losses are reflected in the Company's statement of operations. The Company's French subsidiary, AFP, maintains its books of record in Euros, which is the local currency in France and has been determined to be its functional currency. These books are translated to USD at the average exchange rates during the period. Assets and liabilities are translated at the rate of exchange prevailing on the balance sheet date. Equity is translated at the prevailing rate of exchange at the date of the equity transactions. Translation adjustments are reflected in stockholders' equity and are included as a component of other comprehensive income (loss). Additionally, the Company does not undertake hedging transactions to cover its foreign currency exposure.

Comprehensive Income (Loss)

For the three and six months ended June 30, 2014, the Company includes its foreign currency translation adjustment as part of its comprehensive loss as a result of the acquisition of Merck, Sharpe & Dohme's, or Merck's, Active Pharmaceutical Ingredient, or API, manufacturing business in Éragny-sur-Epte, France in April 2014 (see Note 3). For the three and six months ended June 30, 2013, net income equaled comprehensive income.

Financial Instruments

The carrying amounts of cash and cash equivalents, short-term investments, accounts receivable, accounts payable, accrued expenses, and short-term borrowings approximate fair value due to the short maturity of these items. A majority of the Company's long-term obligations consist of variable rate debt and their carrying value approximates fair value. Their carrying value approximates fair value as the stated borrowing rates are comparable to rates currently offered to the Company for instruments with similar maturities. However, the Company has one fixed-rate, long-term mortgage for which the carrying value differs from the fair value and is not remeasured on a recurring basis (see Note 13).

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AMPHASTAR PHARMACEUTICALS, INC.
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(Unaudited)

Deferred Income Taxes

The Company utilizes the liability method of accounting for income taxes. Under the liability method, deferred taxes are determined based on the temporary differences between the financial statements and the tax basis of assets and liabilities using enacted tax rates. A valuation allowance is recorded when it is more likely than not that the deferred tax assets will not be realized. The Company has adopted the with-and-without methodology for determining when excess tax benefits from the exercise of share-based awards are realized. Under the with-and-without methodology, current year operating loss deductions and prior-year operating loss carryforwards are deemed to be utilized prior to the utilization of current-year excess tax benefits from share-based awards.

Business Combinations

Business combinations are accounted for in accordance with Accounting Standards Codification, or ASC 805, Business Combinations, using the acquisition method of accounting. The acquisition method of accounting requires an acquirer to recognize the assets acquired and the liabilities assumed at the acquisition date measured at their fair values as of that date. Fair value determinations are based on discounted cash flow analyses or other valuation techniques. In determining the fair value of the assets acquired and liabilities assumed in a material acquisition, the Company may utilize appraisals from third party valuation firms to determine fair values of some or all of the assets acquired and liabilities assumed, or may complete some or all of the valuations internally. In either case, the Company takes full responsibility for the determination of the fair value of the assets acquired and liabilities assumed. The value of goodwill reflects the excess of the fair value of the consideration conveyed to the seller over the fair value of the net assets received. Under the acquisition method of accounting, the Company will identify the acquirer and the closing date and apply applicable recognition principles and conditions.

Acquisition-related costs are costs the Company incurs to effect a business combination. The Company accounts for acquisition-related costs as expenses in the periods in which the costs are incurred.

Recent Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board, or FASB, issued an Accounting Standard Update to the accounting guidance to address the diversity in practice related to the financial statement presentation of unrecognized tax benefits as either a reduction of a deferred tax asset or a liability when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. This guidance is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013. The adoption of this guidance did not have a material impact on the Company’s consolidated financial statements.

In April 2014, the FASB issued an accounting standards update that raises the threshold for disposals to qualify as discontinued operations and allows companies to have significant continuing involvement with and continuing cash flows from or to the discontinued operation. It also requires additional disclosures for discontinued operations and new disclosures for individually material disposal transactions that do not meet the definition of a discontinued operation. This guidance will be effective for fiscal years beginning after December 15, 2014, which will be the Company's fiscal year 2015, with early adoption permitted. The Company does not expect the adoption of the guidance will have a material impact on the Company's consolidated financial statements.

In May 2014, the FASB issued an accounting standards update that creates a single source of revenue guidance for companies in all industries. The new standard provides guidance for all revenue arising from contracts with customers

and affects all entities that enter into contracts to provide goods or services to their customers, unless the contracts are within the scope of other accounting standards. It also provides a model for the measurement and recognition of gains and losses on the sale of certain nonfinancial assets. This guidance must be adopted using either a full retrospective approach for all periods presented or a modified retrospective approach and will be effective for fiscal years beginning after December 15, 2016, which will be the Company's fiscal year 2017. The Company has not yet evaluated the potential impact of adopting the guidance on the Company's consolidated financial statements.

In June 2014, the FASB issued an accounting standards update that requires a performance target that affects vesting of a share-based payment award and that could be achieved after the requisite service period to be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant-date fair value of the award. Compensation cost should be recognized over the required service period, if it is probable that the performance target will be achieved. This guidance will be effective for fiscal years beginning after December 15, 2015, which will be the Company's fiscal year 2016, with early adoption permitted. The Company does not expect the adoption of the guidance will have a material impact on the Company's consolidated financial statements.

3. Business Acquisition

Acquisition of Merck Sharpe & Dohme’s API Manufacturing Business

On April 30, 2014, the Company completed its acquisition of Merck Sharpe & Dohme’s, or Merck’s, API manufacturing business in Éragny-sur-Epte, France, which manufactures porcine insulin API and recombinant human insulin API. The purchase price of the transaction on April 30, 2014 totaled €24.8 million, or $34.4 million, subject to certain customary post-closing adjustments and currency exchange fluctuations. The terms of the purchase include multiple payments over four years as follows (see Note 13):

	Euros	U.S. Dollars
	(in thousands)	
At Closing, April 2014	€13,252	$18,352
December 2014	4,899	6,708
December 2015	3,186	4,363
December 2016	3,186	4,363
December 2017	500	685
	€25,023	$34,471

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In order to facilitate the acquisition, the Company established a subsidiary in France, Amphastar France Pharmaceuticals, SAS, or AFP. The Company will continue the current site manufacturing activities, which consist of the manufacturing of porcine insulin API and recombinant human insulin API. As part of the transaction, the Company has entered into various additional agreements, including various supply agreements, as well as the assignment and licensing of patents under which Merck was operating at this facility. In addition, certain existing customer agreements have been assigned to AFP.

Prior to the Company's purchase of Merck's facility in Éragny-sur-Epte, France, Merck notified the Company of several items it had identified as part of its own internal auditing that relate to potential minor environmental issues. The Company understands from Merck that it identified these items because the items were not in alignment with Merck's own internal policies and procedures, and not because any of the items are in violation of any French environmental law or regulation. Under a letter of understanding, or LOU, dated April 30, 2014, Merck has agreed to pay for the remediation costs up to certain dollar limits, and to date, all estimates suggest the cost of conducting the remediation will be less than those dollar limits. The LOU also includes an indemnification provision that would require the Company to indemnify Merck for liability that might arise from performance of the remediation work itself but not for other types of liability.

The transaction will be accounted for as a business combination in accordance to ASC 805. The following table summarizes the estimated fair values of the assets acquired and liabilities assumed as of the acquisition date:

	Fair Value	
	Euros	U.S. Dollars
	(in thousands)	
Inventory	€15,565	$21,554
Real property	4,800	6,647
Machinery & equipment	6,800	9,417
Intangibles	80	111
Total assets acquired	€27,245	$37,729
Accrued liabilities	€2,425	$3,358
Total fair value of consideration transferred	€24,820	$34,371

The Company's accounting for this acquisition is preliminary. The fair value estimates for the assets acquired and liabilities assumed were based upon preliminary calculations and valuations, and the Company's estimates and assumptions are subject to change as the Company obtains additional information for its estimates during the measurement period (up to one year from the acquisition date) including the completion of our analysis to determine the acquisition date fair values of certain tax-related items and residual impact on purchase accounting. The operations of the acquired business have been included in the Company's condensed consolidated financial statements commencing on the acquisition date. The results of operations for this acquisition have not been separately presented because this acquisition is not material to the Company's condensed consolidated results of operations.

The following unaudited pro forma financial information for the six months ended June 30, 2014 and 2013 gives effect to the transaction as if it had occurred on January 1, 2013. Such unaudited pro forma information is based on historical financial information with respect to the transaction and does not reflect operational and administrative cost savings, or synergies, that management of the combined company estimates may be achieved as a result of the transaction. The unaudited pro forma information primarily reflects the additional depreciation related to the fair value adjustment to property, plant and equipment acquired, valuation step up related to the fair value of inventory and additional interest expense associated with the financing obtained by the Company in connection with the acquisition.

	Six Months Ended June 30,	
	2014	2013
	(in thousands, except per share data)	
Net revenues	$97,157	$122,436
Net income (loss)	(4,028)	10,709
Diluted net income (loss) per share	$(0.10)	$0.28

Acquisition Loan with Cathay Bank

On April 22, 2014, in conjunction with the Company's acquisition of Merck's API manufacturing business in Éragny-sur-Epte, France, the Company entered into a secured term loan with Cathay Bank as lender. The principal amount of the loan is $21.9 million and bears a variable interest rate at the prime rate as published by The Wall Street Journal, with a minimum interest rate of 4.00%. Beginning on June 1, 2014 and through the maturity date, April 22, 2019, the Company must make monthly payments of principal and interest based on the then outstanding amount of the loan amortized over a 120-month period. On April 22, 2019, all amounts outstanding under the loan become due and payable, which would be approximately $12.0 million based upon an interest rate of 4.00%. The loan is secured by 65% of the issued and outstanding shares of stock in AFP and certain assets of the Company, including accounts receivable, inventory, certain investment property, goods, deposit accounts, and general intangibles but not including the Company's equipment and real property.

The loan includes customary restrictions on, among other things, the Company's ability to incur additional indebtedness, pay dividends in cash or make other distributions in cash, make certain investments, create liens, sell assets, and make loans. The loan also includes customary events of defaults, the occurrence and continuation of any of which provide Cathay Bank the right to exercise remedies against the Company and the collateral securing the loan. These events of default include, among other things, the Company's failure to pay any amounts due under the loan, the Company's insolvency, the occurrence of any default under certain other indebtedness or material agreements, and a final judgment against the Company that is not discharged in 30 days.

4. Revenue Recognition

Generally, revenue is recognized at the time of product delivery to the Company's customers. In some cases, revenue is recognized at the time of shipment when stipulated by the terms of the sale agreements. The Company also records profit-sharing revenue stemming from a distribution agreement with Actavis, Inc., or Actavis (see Note 16). Profit-sharing revenue is recognized at the time Actavis sells the products to its customers. Revenues derived from contract manufacturing services are recognized when third-party products are shipped to customers, after the customer has accepted test samples of the products to be shipped.

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AMPHASTAR PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

The Company does not recognize product revenue unless the following fundamental criteria are met: (i) persuasive evidence of an arrangement exists, (ii) transfer of title has occurred, (iii) the price to the customer is fixed or determinable, and (iv) collection is reasonably assured. Furthermore, the Company does not recognize revenue until all customer acceptance requirements have been met. The Company estimates and records reductions to revenue for discounts, product returns, and pricing adjustments, such as wholesaler chargebacks, in the same period that the related revenue is recorded.

The Company's accounting policy is to review each agreement involving contract development and manufacturing services to determine if there are multiple revenue-generating activities that constitute more than one unit of accounting. Revenues are recognized for each unit of accounting based on revenue recognition criteria relevant to that unit. The Company does not have any revenue arrangements with multiple deliverables.

Provision for Wholesaler Chargebacks

The provision for chargebacks is a significant estimate used in the recognition of revenue. As part of its sales terms with wholesale customers, the Company agrees to reimburse wholesalers for differences between the gross sales prices at which the Company sells its products to wholesalers and the actual prices of such products at the time wholesalers resell them under the Company's various contractual arrangements with third parties such as hospitals and group purchasing organizations. The Company estimates chargebacks at the time of sale to wholesalers based on wholesaler inventory stocking levels, historic chargeback rates, and current contract pricing.

The provision for chargebacks is reflected in net revenues and a reduction to accounts receivables. The following table is an analysis of the chargeback provision:

	Six Months Ended June 30, 2014	Year Ended December 31, 2013
	(in thousands)	
Beginning balance	$ 18,104	$ 11,898
Provision related to sales made in the current period	78,890	213,075
Credits issued to third parties	(87,393)	(206,869)
Ending balance	$ 9,601	$ 18,104

Changes in chargeback provision from period to period are primarily dependent on the Company's sales to its wholesalers, the level of inventory held by the wholesalers, and on the wholesaler customer mix. The approach that the Company uses to estimate chargebacks has been consistently applied for all periods presented. Variations in estimates have been historically small. The Company continually monitors the provision for chargebacks and makes adjustments when it believes that the actual chargebacks may differ from the estimates. The settlement of chargebacks generally occurs within 30 days after the sale to wholesalers.

Accrual for Product Returns

The Company offers most customers the right to return qualified excess or expired inventory for partial credit; however, products sold to Actavis are non-returnable. The Company's product returns primarily consist of the returns

of expired products from sales made in prior periods. Returned products cannot be resold. At the time product revenue is recognized, the Company records an accrual for estimated returns. The accrual is based, in part, upon the historical relationship of product returns to sales and customer contract terms. The Company also assesses other factors that could affect product returns including market conditions, product obsolescence, and the introduction of new competition. Although these factors do not normally give the Company's customers the right to return products outside of the regular return policy, the Company realizes that such factors could ultimately lead to increased returns. The Company analyzes these situations on a case-by-case basis and makes adjustments to the product return reserve as appropriate.

The provision for product returns is reflected in net revenues. The following table is an analysis of product return liability:

	Six Months Ended June 30, 2014	Year Ended December 31, 2013
	(in thousands)	
Beginning balance	$4,592	$ 2,673
Provision for product returns	191	2,711
Credits issued to third parties	(745)	(792)
Ending balance	$4,038	$ 4,592

For the six months ended June 30, 2014 and for the year ended December 31, 2013, the Company's aggregate product return rate was 1.2% and 1.4% of qualified sales, respectively.

If the product return provision percentage were to increase by 0.1% of qualified sales, then an additional provision of $1.0 million and $0.9 million would result for the six months ended June 30, 2014 and the year ended December 31, 2013, respectively.

5. Income (Loss) per Share

Basic income (loss) per share is calculated based upon the weighted-average number of common shares outstanding during the period and contingently issuable shares such as fully vested deferred stock units, or DSUs, as of the date all necessary conditions for issuance have been met. Diluted income per share gives effect to all potential dilutive common shares outstanding during the period, such as stock options and nonvested DSUs.

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As the Company reported a net loss for the three and six months ended June 30, 2014, the diluted net loss per share, as reported, is equal to the basic net loss per share since the effect of the assumed exercise of stock options and conversion of nonvested DSUs is anti-dilutive. Total stock options and nonvested DSUs excluded from the three and six months ended June 30, 2014, net loss per share were 12,309,229 and 510,699, respectively.

For the three and six months ended June 30, 2013, options to purchase 6,934,338 and 7,182,004 shares of common stock with a weighted-average exercise price of $19.35 and $19.05 per share, respectively, were excluded in the computation of diluted net income per share because the effect from the assumed exercise of these options would be anti-dilutive.

The following table provides the calculation of basic and diluted net income (loss) per common share for each of the periods presented:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(in thousands, except per share data)			
Basic and dilutive numerator:				
Net income (loss)	$(1,180)	$7,810	$(2,799)	$10,192
Denominator:				
Common shares outstanding	39,764	38,706	39,265	38,696
Contingently issuable shares - vested DSUs	3	2	3	12
Weighted-average common shares outstanding—basic	39,767	38,708	39,268	38,708
Net effect of dilutive securities:				
Stock options	—	63	—	57
Contingently issuable shares – nonvested DSUs	—	76	—	81
Weighted-average common shares outstanding—diluted	39,767	38,847	39,268	38,846
Net income (loss) per common share—basic	$(0.03)	$0.20	$(0.07)	$0.26
Net income (loss) per common share—diluted	$(0.03)	$0.20	$(0.07)	$0.26

6. Segment Reporting

The Company’s business is the development, manufacture, and marketing of pharmaceutical products. The Company has determined that all of its product groups have similar economic characteristics and may be aggregated into a single operational segment for reporting purposes.

Net revenues and carrying values of long-lived assets of enterprises by geographic regions are as follows:

	Net Revenue	Net Revenue	Long-Lived Assets	
	Three Months Ended June 30,	Six Months Ended June 30,	June 30,	December 31,

	2014	2013	2014	2013	2014	2013
				(in thousands)		
U.S.	$48,901	$62,524	$94,771	$115,487	$98,262	$ 99,398
China	—	—	—	—	20,029	17,221
France	102	—	102	—	15,700	—
Total	$49,003	$62,524	$94,873	$115,487	$133,991	$ 116,619

7. Customer and Supplier Concentration

Customer Concentrations

Three large wholesale drug distributors, AmerisourceBergen Corporation, or AmerisourceBergen, Cardinal Health, Inc. or Cardinal, and McKesson Corporation, or McKesson, are all distributors of the Company's products, as well as suppliers of a broad range of health care products. Actavis, Inc., has exclusive marketing rights of the Company's enoxaparin product to the U.S. retail pharmacy market. These four customers individually and collectively represented a significant percentage of the Company's net revenue for the three and six months ended June 30, 2014 and 2013 and accounts receivable as of June 30, 2014 and December 31, 2013.

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The following table provides accounts receivable and net revenues information for the Company's major customers:

	% of Total Accounts Receivable		% of Net Revenue		% of Net Revenue	
			Three Months Ended June 30,		Six Months Ended June 30,	
	June 30, 2014	December 31, 2013	2014	2013	2014	2013
Actavis, Inc.	45 %	44 %	35 %	37 %	33 %	35 %
AmerisourceBergen	5 %	11 %	16 %	14 %	16 %	14 %
Cardinal Health	15 %	7 %	14 %	14 %	15 %	14 %
McKesson	13 %	13 %	22 %	25 %	25 %	25 %

The Company's products are primarily sold in U.S. domestic markets. For the three and six months ended June 30, 2014 and 2013, foreign sales were minimal, therefore, the Company has little exposure to foreign currency price fluctuations on its sales and accounts receivable.

Supplier Concentrations

The Company depends on suppliers for raw materials, active pharmaceutical ingredients, and other components that are subject to stringent U.S. Food and Drug Administration, or FDA, requirements. Some of these materials may only be available from one or a limited number of sources. Establishing additional or replacement suppliers for these materials may take a substantial period of time, as suppliers must be approved by the FDA. Furthermore, a significant portion of raw materials may only be available from foreign sources. If the Company is unable to secure, on a timely basis, sufficient quantities of the materials it depends on to manufacture and market its products, it could have a materially adverse effect on the Company's business, financial condition, and results of operations.

8. Fair Value Measurements

The accounting standards of the Financial Accounting Standards Board, or FASB, define fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the principal or most advantageous market for the asset or liability at the measurement date (an exit price). These standards also establish a hierarchy that prioritizes observable and unobservable inputs used in measuring fair value of an asset or liability, as described below:

- Level 1 – Inputs to measure fair value are based on quoted prices (unadjusted) in active markets on identical assets or liabilities;

- Level 2 – Inputs to measure fair value are based on the following: a) quoted prices in active markets on similar assets or liabilities, b) quoted prices for identical or similar instruments in inactive markets, or c) observable (other than quoted prices) or collaborated observable market data used in a pricing model from which the fair value is derived; and

- Level 3 – Inputs to measure fair value are unobservable and the assets or liabilities have little, if any, market activity;

these inputs reflect the Company's own assumptions about the assumptions that market participants would use in pricing the assets or liabilities based on best information available in the circumstances.

The Company measures fair value based on the prices that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value measurements are based on a three-tier hierarchy that prioritizes the inputs used to measure fair value. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs for which little or no market data exists, therefore requiring an entity to develop its own assumptions.

The Company classifies its cash equivalents and short-term investments as Level 1 assets, as they are valued on a recurring basis using quoted market prices with no valuation adjustments applied. The Company does not hold any Level 2 or Level 3 instruments that are measured for fair value on a recurring basis.

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The fair values of the Company's financial assets and liabilities measured on a recurring basis, as of June 30, 2014 and December 31, 2013, are as follows:

	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		(in thousands)		
Cash equivalents:				
Money market accounts	$44,100	$ 44,100	$ —	$ —
Restricted short-term investments:				
Certificates of deposit	1,495	1,495	—	—
Fair value measurement as of June 30, 2014	$45,595	$ 45,595	$ —	$ —
Cash equivalents:				
Money market accounts	$41,183	$ 41,183	$ —	$ —
Restricted short-term investments:				
Certificates of deposit	1,325	1,325	—	—
Fair value measurement as of December 31, 2013	$42,508	$ 42,508	$ —	$ —

The fair value of the Company's cash equivalents includes money market funds and certificates of deposit with maturities of one year or less. Short-term investments consist of certificate of deposit accounts that expire within 12 months for which market prices are readily available. The restrictions placed on the certificate of deposit accounts have a negligible effect on the fair value of these financial assets; these funds are restricted to meet the Company's obligation for workers' compensation claims.

The Company adopted the required fair value measurements and disclosures provisions related to nonfinancial assets and liabilities. These assets and liabilities are not measured at fair value on a recurring basis but are subject to fair value adjustments in certain circumstances. These items primarily include long-lived assets, goodwill, and intangible assets for which the fair value of assets is determined as part of the related impairment test. As of June 30, 2014 and December 31, 2013, there were no significant adjustments to fair value for nonfinancial assets or liabilities.

9. Goodwill and Intangible Assets

Intangible assets include product rights, trademarks, patents, land-use rights, and goodwill. The table below shows the weighted-average life, original cost, accumulated amortization, and net book value by major intangible asset classification:

	Weighted-Average Life (Years)	Original Cost	Accumulated Amortization	Net Book Value
			(in thousands)	
Definite-lived intangible assets				

Product rights	12	$ 27,134	$ 20,005	$ 7,129
Patents	10	293	63	230
Trademarks	11	17	13	4
Land-use rights	39	2,540	189	2,351
Other intangible assets	1	505	505	—
Subtotal	12	30,489	20,775	9,714
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill	*	280	—	280
AFP customers	*	111	—	111
Subtotal	*	29,616	—	29,616
As of June 30, 2014	*	$ 60,105	$ 20,775	$ 39,330

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	Weighted-Average Life (Years)	Original Cost	Accumulated Amortization (in thousands)	Net Book Value
Definite-lived intangible assets				
Product rights	12	$ 27,134	$ 19,114	$ 8,020
Patents	10	298	50	248
Trademarks	11	19	13	6
Land-use rights	39	2,540	156	2,384
Other intangible assets	1	505	505	—
Subtotal	11	30,496	19,838	10,658
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill	*	280	—	280
Subtotal	*	29,505	—	29,505
As of December 31, 2013	*	$ 60,001	$ 19,838	$ 40,163

* Intangible assets with indefinite lives have an undeterminable average life.

Primatene Mist Trademark

In January, 2009, the Company acquired the exclusive rights to the trademark, domain name, website and domestic marketing, distribution and selling rights related to Primatene Mist, an over-the-counter bronchodilator product, for a total consideration of $29.2 million, which is its carrying value as of June 30, 2014.

In determining the useful life of the trademark, the Company considered the following: the expected use of the intangible; the longevity of the brand; the legal, regulatory and contractual provisions that affect their maximum useful life; the Company's ability to renew or extend the asset's legal or contractual life without substantial costs; effects of the regulatory environment; expected changes in distribution channels; maintenance expenditures required to obtain the expected future cash flows from the asset; and considerations for obsolescence, demand, competition and other economic factors.

As a result of environmental concerns about Chlorofluorocarbons, or CFCs, the FDA issued a final ruling on January 16, 2009 that required the CFC formulation of its Primatene Mist product to be phased out by December 31, 2011. The former formulation of Primatene Mist contained CFCs as a propellant; however, the Company intends to use the trademark for a future version of Primatene Mist that utilizes hydrofluoroalkane, or HFA, as a propellant.

In 2013, the Company filed a new drug application, or NDA, for Primatene Mist HFA and received a Prescription Drug User Fee Act date set for May 2014.

In May 2014, the Company received a complete response letter, or CRL, from the FDA, which requires additional non-clinical information, label revisions and follow-up studies (label comprehension, behavioral and actual use) to assess consumers' ability to use the device correctly to support approval of the product in the over-the-counter setting. Additionally, in the CRL for Primatene Mist HFA, the FDA noted current Good Manufacturing Practices, or cGMP, deficiencies in a recent inspection of the Company's API supplier's manufacturing facility, which produces epinephrine, and indicated that the Company's NDA could not be approved until these issues were resolved.

Subsequent to the receipt of the CRL, the supplier notified the Company that the cGMP deficiencies were satisfactorily resolved. Accordingly, the Company believes this condition for approval has been satisfied. The Company is in the process of generating the remaining data required by the CRL and will submit an NDA Amendment that it believes will address the FDA's concerns. However, there can be no guarantee that any amendment to the Company's NDA will result in timely approval of the product or approval at all.

Based on the Company's filed version of Primatene Mist HFA, the Company's plan to submit an NDA amendment to address the FDA's concerns, the long history of the Primatene Mist trademark (marketed since 1963) and the Company's perpetual rights to the trademark, the Company has determined that the trademark has an indefinite useful life. If the HFA version is approved by the FDA, it will be marketed under the same trade name; therefore, an impairment charge would not be required.

10. Inventories

Inventories are stated at the lower of cost or market, using the first-in, first-out method. Provisions are made for slow-moving, unsellable or obsolete items. Inventories consist of currently marketed products and products manufactured under contract. Inventories consist of the following:

	June 30, 2014	December 31, 2013
	(in thousands)	
Raw materials and supplies	$51,162	$ 34,470
Work in process	22,770	14,698
Finished goods	34,184	26,501
Total inventory	108,116	75,669
Less reserve for excess and obsolete inventories	(2,099)	(5,753)
Total inventory, net	$106,017	$ 69,916

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11. Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

	June 30, 2014	December 31, 2013
	(in thousands)	
Building	$64,156	$ 58,898
Leasehold improvements	23,935	23,834
Land	7,174	5,805
Machinery and equipment	104,140	93,617
Furniture, fixtures, and automobiles	10,947	9,355
Construction in progress	19,800	15,685
Total property, plant, and equipment	230,152	207,194
Less accumulated depreciation and amortization	(96,161)	(90,575)
Total property, plant, and equipment, net	$133,991	$ 116,619

As of June 30, 2014 and December 31, 2013, the Company had $3.2 million and $3.4 million in capitalized manufacturing equipment that is intended to be used specifically for the manufacture of Primatene Mist HFA, respectively. The Company will continue to monitor developments with the FDA as it relates to its Primatene Mist HFA indefinite lived intangible asset in determining if there is an impairment for these related fixed assets (see Note 9).

12. Impairment of Long-Lived Assets

All of the Company's impairments relate primarily to the write-off of certain manufacturing equipment related to abandoned projects. For the three months and six months ended June 30, 2014, the Company recorded an impairment loss of $0.2 million and $0.3 million, respectively. For the three and six months ended June 30, 2013, the Company did not record an impairment loss.

13. Debt

Debt consists of the following:

	June 30, 2014	December 31, 2013
	(in thousands)	
Loans with East West Bank		
Mortgage payable due January 2016	$3,965	$ 4,041
Mortgage payable due September 2016	2,327	2,364
Equipment loan due November 2014	360	783
Line of credit facility due March 2016	—	—
Equipment loan due April 2017	3,518	4,103
Line of credit facility due January 2019	—	—

Loans with Cathay Bank		
Mortgage payable due April 2021	4,591	4,624
Revolving line of credit due May 2016	—	15,000
Acquisition loan due April 2019	21,770	—
Payment obligation to Merck Sharpe & Dohme	15,869	—
Equipment Under Capital Leases	1,115	1,258
Total debt and capital leases	53,515	32,173
Less current portion of long-term debt and capital leases	10,665	22,104
Long-term debt, net of current portion and capital leases	$42,850	$ 10,069

Loans with East West Bank

Mortgage Payable—Due January 2016

In December 2010, the Company refinanced an existing mortgage term loan, which had a principal balance outstanding of $4.5 million at December 31, 2010. The loan is payable in monthly installments with a final balloon payment of $3.8 million. The loan is secured by one of the buildings at the Company's Rancho Cucamonga, California, headquarters complex, as well as one of its buildings at its Chino, California, complex. The loan bears a variable interest rate at the prime rate as published by The Wall Street Journal, with a minimum interest rate of 5.00%, and matures in January 2016.

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Mortgage Payable—Due September 2016

In September 2006, the Company entered into a mortgage term loan in the principal amount of $2.8 million, which matures in September 2016. The loan is payable in monthly installments with a final balloon payment of $2.2 million plus interest. The loan is secured by one of the buildings at the Company's Rancho Cucamonga, California, headquarters complex. The variable interest rate is equal to the three-month LIBOR plus 2.50%.

Equipment Loan—Due November 2014

In May 2009, the Company entered into an $8.0 million revolving credit facility that converted the outstanding principal balance of $3.2 million in November 2010 into an equipment loan. Borrowings under the facility are secured by equipment purchased with debt proceeds. The facility bears interest at the prime rate as published by The Wall Street Journal, with a minimum interest rate of 5.00%, and matures in November 2014.

Line of Credit Facility—Due March 2016

In March 2012, the Company entered into a $10.0 million line of credit facility. Borrowings under the facility are secured by inventory and accounts receivable. Borrowings under the facility bear interest at the prime rate as published by The Wall Street Journal. This facility was to mature in July 2014. In April 2014, the Company extended the maturity date to March 2016. As of June 30, 2014, the Company did not have any amounts outstanding under this facility.

Equipment Loan—Due April 2017

In March 2012, the Company entered into an $8.0 million revolving credit facility that converted the outstanding principal balance of $4.9 million in March 2013 into an equipment loan. Borrowings under the facility are secured by equipment purchased with debt proceeds. Borrowings under the facility bear interest at the prime rate as published by The Wall Street Journal, with a minimum interest rate of 3.50%. This facility matures in April 2017.

Line of Credit Facility—Due January 2019

In July 2013, the Company entered into an $8.0 million line of credit facility. Borrowings under the facility are secured by equipment. The facility bears interest at the prime rate as published in The Wall Street Journal plus 0.25% and matures in January 2019. As of June 30, 2014, the Company did not have any amounts outstanding under this facility.

Loans with Cathay Bank

Mortgage Payable—Due April 2021

In March 2007, the Company entered into a mortgage term loan in the principal amount of $5.3 million, which matured in March 2014. In April 2014, the Company refinanced the mortgage term loan, which had a principle balance outstanding of $4.6 million. The loan is payable in monthly installments of $28.1 thousand with a final balloon payment of $3.9 million. The loan is secured by the building at the Company's Canton, Massachusetts, location and bears interest at a fixed rate of 5.42% and matures in April 2021. As of June 30, 2014, the loan had a fair

value of $4.9 million, compared to a book value of $4.6 million. The fair value of the loan was determined by using the interest rate associated with the Company's mortgage loans with similar terms and collateral that has variable interest rates. The fair value of debt obligations is not measured on a recurring basis and the variable interest rate is deemed to be a Level 2 input for measuring fair value.

Revolving Line of Credit—Due May 2016

In April 2012, the Company entered into a $20.0 million revolving line of credit facility. Borrowings under the facility are secured by inventory, accounts receivables, and intangibles held by the Company. The facility bears interest at the prime rate as published by The Wall Street Journal with a minimum interest rate of 4.00%. This revolving line of credit was to mature in May 2014. In April 2014, the Company modified the facility to extend the maturity date to May 2016. As of June 30, 2014, the Company did not have any amounts outstanding under this facility.

Acquisition Loan with Cathay Bank—Due April 2019

On April 22, 2014, in conjunction with the Company's acquisition of Merck's API manufacturing business in Éragny-sur-Epte, France, the Company entered into a secured term loan with Cathay Bank as lender. The principal amount of the loan is $21.9 million and bears a variable interest rate at the prime rate as published by The Wall Street Journal, with a minimum interest rate of 4.00%. Beginning on June 1, 2014 and through the maturity date, April 22, 2019, the Company must make monthly payments of principal and interest based on the then outstanding amount of the loan amortized over a 120-month period. On April 22, 2019, all amounts outstanding under the loan become due and payable, which would be approximately $12.0 million based upon an interest rate of 4.00%. The loan is secured by 65% of the issued and outstanding shares of stock in AFP and certain assets of the Company, including accounts receivable, inventory, certain investment property, goods, deposit accounts, and general intangibles but not including the Company's equipment and real property.

The loan includes customary restrictions on, among other things, the Company's ability to incur additional indebtedness, pay dividends in cash or make other distributions in cash, make certain investments, create liens, sell assets, and make loans. The loan also includes customary events of defaults, the occurrence and continuation of any of which provide Cathay Bank the right to exercise remedies against the Company and the collateral securing the loan. These events of default include, among other things, the Company's failure to pay any amounts due under the loan, the Company's insolvency, the occurrence of any default under certain other indebtedness or material agreements, and a final judgment against the Company that is not discharged in 30 days.

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Payment obligation

Merck Sharpe & Dohme—Due December 2017

On April 30, 2014, in conjunction with the Company's acquisition of Merck's API manufacturing business in Éragny-sur-Epte, France, the Company entered into a commitment obligation with Merck, in the principal amount of €11.6 million, or $16.0 million, subject to currency exchange fluctuations. The terms of the purchase price include annual payments over four years and bear a fixed interest rate of 3.00%. The final payment to Merck relating to this obligation is due December 2017.

As of June 30, 2014, the payment obligation had a book value of $15.9 million, which approximates fair value. The fair value of the payment obligation was determined by using the interest rate associated with the Company's acquisition loan with Cathay Bank that bears a variable interest rate at the prime rate as published by the Wall Street Journal, with a minimum interest rate of 4.00%. The fair value of the debt obligation is not measured on a recurring basis and the variable interest rate is deemed to be a Level 2 input for measuring fair value.

Covenants

At June 30, 2014 and December 31, 2013, the Company was in compliance with its debt covenants, which include a minimum current ratio, minimum debt service coverage, minimum tangible net worth, and maximum debt-to-effective-tangible-net-worth ratio, computed on a consolidated basis in some instances and on a separate-company basis in others.

Equipment under Capital Leases

The Company entered into leases for certain equipment under capital leasing arrangements, which will expire at various times through 2018. The cost of equipment under capital leases was $1.5 million and $1.5 million at June 30, 2014 and December 31, 2013, respectively.

The accumulated amortization of equipment under capital leases was $0.3 million and $0.2 million at June 30, 2014 and December 31, 2013, respectively. Amortization of assets recorded under capital leases is included in depreciation and amortization expense in the accompanying consolidated financial statements.

14. Income Taxes

The following table sets forth the Company's income tax provision for the periods indicated:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(in thousands)			
Income (loss) before taxes	$(1,876)	$11,919	$(4,347)	$14,111
Income tax provision (benefit)	(696)	4,109	(1,548)	3,919
Net income (loss)	$(1,180)	$7,810	$(2,799)	$10,192

Income tax provision (benefit) as a percentage of income before income taxes	(37.1 %)	34.5 %	(35.6 %)	27.8 %

The Company's income tax benefit for the three and six months ended June 30, 2014 was (37.1%) and (35.6%) of income before income taxes, respectively. The blended effective income tax rate expected for the year ended December 31, 2014 is 36.2%. This tax provision rate factors in various domestic deductions and the impact of foreign operations on the Company's overall tax rate. The Company's income tax provision rate of 34.5% and 27.8% during the three and six months ended June 30, 2013, respectively factored in similar deductions as well as the impact of foreign operations.

Undistributed Earnings (Losses) from Foreign Operations

Deferred income taxes have not been provided on the accumulated undistributed losses of the Company's foreign subsidiaries of approximately $5.8 million and $5.0 million as of June 30, 2014 and December 31, 2013, respectively. The Company does not have plans to repatriate its foreign earnings to the U.S. as dividends.

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15. Stockholders' Equity

A summary of the changes in stockholders' equity for the six months ended June 30, 2014 consisted of the following:

	Six Months Ended June 30, 2014 (in thousands)
Stockholders' equity as of December 31, 2013	$ 251,545
Net loss	(2,799)
Other comprehensive loss	(268)
Common stock issued through initial public offering	38,018
Cost related to public offering	(3,347)
Exercise of stock options	571
Nonemployee share-based compensation expense	475
Employee share-based compensation expense	3,546
Stockholders' equity as of June 30, 2014	$ 287,741

Accumulated Other Comprehensive Loss

For the Company's recently acquired subsidiary in France, the Euro, which is the local currency in France, has been determined to be the functional currency. The results of the Company's French subsidiary's operations are translated to U.S. dollars at the average exchange rates during the period. Assets and liabilities are translated at the rate of exchange prevailing on the balance sheet date. Equity is translated at the prevailing rate of exchange at the date of the equity transaction. Translation adjustments are reflected in stockholders' equity and are included as a component of other comprehensive loss for the three and six months ended June 30, 2014.

Common Stock

In June 2014, the Company completed an Initial Public Offering in which the Company sold 5,840,000 shares of its common stock, which included 1,200,000 shares of the Company's common stock pursuant to the underwriters' exercise of their over-allotment option, at a price to the public of $7.00 per share, resulting in gross proceeds of $40.9 million. In connection with the offering, the Company paid $6.2 million in underwriting discounts, commissions, and offering costs, resulting in net proceeds of $34.7 million.

Share-Based Award Activity and Balances

The Company accounts for share-based compensation payments in accordance with FASB-issued accounting standards, which require measurement and recognition of compensation expense at fair value for all share-based payment awards made to employees, directors, and nonemployees. Under these standards, the fair value of share-based payment awards is estimated at the grant date using an option-pricing model and the portion that is ultimately expected to vest is recognized as compensation cost over the requisite service period. The Company uses the Black-Scholes option-pricing model to estimate the fair value of share-based awards and recognizes share-based

compensation cost over the vesting period using the straight-line single option method. Non-vested stock options held by non-employees are revalued using the Company's estimate of fair value at each balance sheet date.

The weighted-averages for key assumptions used in determining the fair value of options granted during the three and six months ended June 30, 2014 and 2013 are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Average volatility	33.3 %	31.7 %	29.9 %	31.7 %
Risk-free interest rate	2.2 %	1.5 %	1.7 %	1.5 %
Weighted-average expected life in years	6.3	6.3	5.0	6.3
Dividend yield rate	0.0 %	0.0 %	0.0 %	0.0 %

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Stock Options

A summary of option activity under all plans for the six months ended June 30, 2014 is presented below:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value(1) (in thousands)
Outstanding as of December 31, 2013	10,771,755	$ 15.39		
Options granted	1,661,862	15.04		
Options exercised	(30,000)	19.03		
Options cancelled	(42,600)	12.01		
Options expired	(51,788)	20.00		
Outstanding as of June 30, 2014	12,309,229	$ 15.32	4.82	$ 224
Exercisable as of June 30, 2014	5,244,799	$ 18.64	3.03	$ 224

(1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the estimated fair value of the Company's common stock for those awards that have an exercise price below the estimated fair value at June 30, 2014.

For the three and six months ended June 30, 2014, the Company recorded stock option expense related to employees under all plans of $1.8 million and $3.1 million, respectively. For the three and six months ended June 30, 2013, the Company recorded stock option expense related to employees under all plans of $1.0 million and $2.3 million, respectively.

Information relating to option grants and exercises is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(in thousands, except per share data)			
Weighted-average grant date fair value	$5.33	$3.66	$4.02	$3.66
Intrinsic value of options exercised	(139)	(4)	(139)	(4)
Cash received	571	13	571	13
Total fair value of the options vested during the year	290	301	816	855

A summary of the status of the Company's nonvested options as of June 30, 2014, and changes during the six months ended June 30, 2014, are presented below:

	Options	Weighted-Average Grant Date Fair Value

Nonvested as of December 31, 2013	5,617,554	$ 3.12
Options granted	1,661,862	4.02
Options vested	(172,386)	4.73
Options forfeited	(42,600)	4.31
Nonvested as of June 30, 2014	7,064,430	3.29

As of June 30, 2014, there was $15.6 million of total unrecognized compensation cost, net of forfeitures, related to nonvested stock option based compensation arrangements granted under the Company's 2005 Equity Incentive Award Plan, or the 2005 Plan. The cost is expected to be recognized over a weighted-average period of 2.6 years and will be adjusted for future changes in estimated forfeitures.

Deferred Stock Units

From 2007 through 2014, the Company granted restricted stock awards in the form of deferred stock units, or DSUs, to certain officers, consultants, and employees, either as compensation or in exchange for expiring stock options. The grantee receives one share of common stock at a specified future date for each DSU awarded. The DSUs may not be sold or otherwise transferred until certificates of common stock have been issued, recorded, and delivered to the participant. The DSUs do not have any voting or dividend rights prior to the issuance of certificates of the underlying common stock.

The Company issued DSUs that were treated as an accounting exchange for expiring stock options, whereby the fair value of the expiring stock options equaled the fair value of the DSUs at the date of the exchange. As such, the Company did not record any expense related to these award modifications.

Additionally, the Company issued DSUs to its Board of Directors and employees as compensation with a vesting period of up to five years. The share-based expense associated with these grants was based on the Company's common stock fair value at the time of grant and is amortized over the requisite service period, which generally is the vesting period. The Company recorded a total expense of $0.5 million and $0.7 million for the three and six months ended June 30, 2014, respectively, for these DSU awards, compared to the prior year expense for the three and six months ended June 30, 2013 of $0.1 million and $0.3 million, respectively.

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As of June 30, 2014, there was $6.0 million of total unrecognized compensation cost, net of forfeitures, related to nonvested DSU-based compensation arrangements granted under the 2005 Plan. The cost is expected to be recognized over a weighted-average period of 3.5 years and will be adjusted for future changes in estimated forfeitures.

Information relating to DSU grants and deliveries is as follows:

	Total DSUs Issued	Total Fair Market Value of DSUs Issued as Compensation(1) (in thousands)
DSUs outstanding at December 31, 2013	98,495	
DSUs granted	414,868	$ 5,974
DSUs outstanding at June 30, 2014	513,363	

(1) The total FMV is derived from the number of DSUs granted times the current stock price on the date of grant.

16. Commitments and Contingencies

Distribution Agreement with Actavis, Inc.

In May 2005, the Company entered into an agreement to grant certain exclusive marketing rights for its enoxaparin product to Andrx Pharmaceuticals, Inc., or Andrx, which generally extends to the U.S. retail pharmacy market. To obtain such rights, Andrx made a non-refundable, upfront payment of $4.5 million to the Company upon execution of the agreement. Under the agreement, the Company is paid a fixed cost per unit sold to Andrx and also shares in the gross profits (as defined) from Andrx's sales of the product in the U.S. retail pharmacy market. In November 2006, Watson Pharmaceuticals, Inc., or Watson, acquired Andrx and all of the rights and obligations associated with the agreement. The $4.5 million upfront payment was classified as deferred revenue on the accompanying consolidated balance sheets, as there had been no amortization through December 31, 2011.

In January 2012, the Federal Circuit Court issued a stay on the Preliminary Injunction (see Note 17) that had previously barred the Company from selling its generic enoxaparin product. This event, in addition to the Company's product launch, establishes the beginning of the seven-year period in which Watson has the exclusive marketing rights for the Company's enoxaparin product in the U.S. retail pharmacy market and the start of the Company's recognition of the $4.5 million deferred revenue over this period on a straight-line basis. Watson has an option to renew the agreement for an additional three years. As of June 30, 2014 and December 31, 2013, the balance of the deferred revenue was $2.9 million and $3.3 million, respectively.

In January 2013, Watson adopted Actavis, Inc. as its new global name. The agreement has a term that expires in January 2019 and can be extended by Actavis for an additional three years. The agreement may only be terminated prior to the end of the term by either party in the case of a breach of contract or insolvency of the other party, by the Company if Actavis fails to purchase a minimum number of units and by Actavis if an infringement claim is made against Actavis.

The Company manufactures its enoxaparin product for the retail market according to demand specifications of Actavis. Upon shipment of enoxaparin to Actavis, the Company recognizes product sales at an agreed transfer price and records the related cost of products sold. Based on the terms of the Company's distribution agreement with Actavis, the Company is entitled to a share of the ultimate profits based on the eventual net revenue from enoxaparin sales by Actavis to the end user less the agreed transfer price originally paid by Actavis to the Company. Actavis provides the Company with a quarterly sales report that calculates the Company's share of Actavis' enoxaparin gross profit. The Company records its share of Actavis' gross profit as a component of net revenue.

Operating Lease Agreements

The Company leases real and personal property, in the normal course of business, under various non-cancelable operating leases. The Company, at its option, can renew a substantial portion of its leases, at the market rate, for various renewal periods ranging from one to six years. Rental expense under these leases for the three and six months ended June 30, 2014 was approximately $1.4 million and $2.2 million, respectively, compared to the prior year three and six months ended June 30, 2013 when the expense was approximately $0.8 million and $1.6 million, respectively.

Purchase Commitments

As of June 30, 2014, the Company has entered into commitments to purchase equipment and raw materials for an aggregate of $8.7 million. The Company anticipates that most of these commitments will be fulfilled by 2015.

The Company has entered into agreements with a Chinese governmental entity to acquire land-use rights to real property in Nanjing, China. Under the terms of these agreements, the Company has committed to invest capital in its wholly-owned subsidiary, ANP, and to develop these properties as an API manufacturing facility for the Company's pipeline. In conjunction with these agreements, ANP modified its business license on July 3, 2012 to increase its authorized capital. As of June 30, 2014, the Company had invested approximately $37.8 million in ANP of its registered capital commitment of $61.0 million. The Company has committed to invest an additional $23.2 million in ANP, which is currently due by December 2014. This requirement to invest in ANP will result in cash being transferred from the U.S. parent company to ANP.

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Per these agreements, in January 2010, the Company acquired certain land-use rights with a carrying value of $1.2 million. In addition, the Company purchased additional land-use rights in November 2012 for $1.3 million. The Company is committed to spend approximately $15.0 million in land development. The agreements require the construction of fixed assets on the property and specified a timetable for the construction of these fixed assets. The current pace of development of the property is behind the schedules described in the purchase agreements and, per the purchase agreement, potential monetary penalties could result if the development is delayed or not completed in accordance with the guidelines stated in the purchase agreements. The Company is currently engaged in ongoing discussions with the Chinese governmental entity regarding the investment and the development of the properties. The Company believes that the Chinese governmental entity will accept its development plans for ANP.

Government Regulation

The Company’s products and facilities are subject to regulation by a number of federal and state governmental agencies. The Food and Drug Administration, or FDA, in particular, maintains oversight of the formulation, manufacture, distribution, packaging, and labeling of all of the Company’s products. The Drug Enforcement Administration, or DEA, maintains oversight over the Company’s products that are considered controlled substances.

On March 31, 2014 through April 4, 2014, the Company’s facility in Nanjing, China was subject to an inspection by the FDA. The inspection resulted in multiple observations on Form 483, an FDA form on which deficiencies are noted after an FDA inspection. The Company responded to those observations on April 25, 2014 and is in the process of implementing the required corrective actions.

On March 31, 2014 through April 3, 2014, the Company’s facility in Canton, MA was subject to a preapproval inspection by the FDA relating to the Company’s NDA for Primatene. The inspection did not result in any observations on Form 483.

From July 9, 2014 through August 8, 2014, the Company was subject to an inspection by the FDA. The inspection included a review of current Good Manufacturing Practices, preapproval inspections for two ANDAs currently being reviewed by the FDA, and a review of post-market adverse drug events. The inspections resulted in multiple observations on Form 483. The Company plans to respond to those observations by August 25, 2014.

AFP Environmental Indemnification

Prior to the Company’s purchase of Merck’s facility in Éragny-sur-Epte, France, Merck notified the Company of several items it had identified as part of its own internal auditing that relate to potential minor environmental issues. The Company understands from Merck that it identified these items because the items were not in alignment with Merck’s own internal policies and procedures, and not because any of the items are in violation of any French environmental law or regulation. Under a letter of understanding, or LOU, dated April 30, 2014, Merck has agreed to pay for the remediation costs up to certain dollar limits, and to date, all estimates suggest the cost of conducting the remediation will be less than those dollar limits. The LOU also includes an indemnification provision that would require the Company to indemnify Merck for liability that might arise from performance of the remediation work itself but not for other types of liability.

17. Litigation

Enoxaparin Patent Litigation

In September 2011, Momenta Pharmaceuticals, Inc, or Momenta, a Boston-based pharmaceutical company, and Sandoz Inc, or Sandoz, the generic division of Novartis, initiated litigation against the Company for alleged patent infringement of two patents related to testing methods for batch release of enoxaparin, which the Company refers to as the "'886 patent" and the "'466 patent." The lawsuit was filed in the United States District Court for the District of Massachusetts, or the District Court. In October 2011, the District Court issued a preliminary injunction barring the Company from selling its generic enoxaparin product and also requiring Momenta and Sandoz to post a $100.1 million bond. The preliminary injunction was stayed by the United States Court of Appeals for the Federal Circuit, or Federal Circuit, in January 2012 and reversed by the Federal Circuit in August 2012.

In January 2013, the Company moved for summary judgment of non-infringement of both patents. Momenta and Sandoz withdrew their allegations as to the '466 patent, and in July 2013, the District Court granted the Company's motion for summary judgment of non-infringement of the '886 patent and denied Momenta and Sandoz's motion for leave to amend infringement contentions. On January 24, 2014, the District Court judge entered final judgment in Amphastar's favor on both patents. Momenta and Sandoz also filed a motion to collect attorney's fees and costs relating to a discovery motion which the District Court granted. The parties have briefed the amount of attorney's fees that should be imposed, which the Company believes should not exceed an amount of approximately $40.0 thousand. On January 30, 2014, Momenta and Sandoz filed a notice of appeal to the Federal Circuit appealing the court's final judgment including summary judgment denying Momenta and Sandoz's motion for leave to amend their infringement contentions. The Company intends to attempt to collect the $100.1 million bond posted by Momenta and Sandoz following the appeal Momenta filed its opening appeal brief on June 27, 2014. Under the current briefing schedule for the appeal, the Company's brief is due by September 25, 2014, and Momenta's reply brief is due by October 13, 2014. A date for oral argument has not yet been set by the court of appeal.

False Claims Act Litigation

In January 2009, the Company filed a qui tam complaint in the U.S. District Court for the Central District of California alleging that Aventis Pharma S.A., or Aventis, through its acquisition of a patent through false and misleading statements to the U.S. Patent and Trademark Office, as well as through false and misleading statements to the FDA, overcharged the federal and state governments for its Lovenox product. If the Company is successful in this litigation, it could be entitled to a portion of any damage award that the government ultimately may recover from Aventis. In October 2011, the District Court unsealed the Company's complaint. Since the complaint was unsealed, this case has steadily progressed and remains pending with discovery underway. On February 28, 2014, Aventis filed a motion for summary judgment on the issue of the adequacy of the Company's notice letter to the government, and the District Court denied Aventis' motion for summary judgment in a final order it issued on May 12, 2014. On June 9, 2014, at Aventis' request, the District Court issued an order certifying for appeal its order denying Aventis' motion for summary judgment. On June 9, 2014, Aventis filed with the United States Court of Appeals for the Ninth Circuit a petition for permission to appeal the District Court's denial of Aventis' motion for summary judgment, and the Company filed an opposition to Aventis' petition on June 19, 2014. The District Court set an evidentiary hearing for July 7, 2014 on the "original source" issue, a key element under the False Claims Act. The evidentiary hearing was conducted as scheduled, from July 7, 2014 through July 10, 2014, and the parties are expected to file post-hearing briefs. The Company filed its post-hearing brief on August 11, 2014, and Aventis' post-hearing brief is due by September 10, 2014. The District Court set a hearing for closing argument on the original source issue for October 10, 2014.

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Other Litigation

The Company is also subject to various other claims and lawsuits arising in the ordinary course of business. In the opinion of management, the ultimate resolution of these matters is not expected to have a materially adverse effect on its financial position, results of operations, or cash flows; however, the results of litigation and claims are inherently unpredictable. Regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources, and other factors.

18. Subsequent Event

Supply Agreement with MannKind Corporation

Subsequent to the quarter end, on July 31, 2014, the Company's French subsidiary, Amphastar France Pharmaceuticals SAS, or AFP, entered in a supply agreement with MannKind Corporation, or MannKind, pursuant to which AFP will manufacture for and supply to MannKind certain quantities of recombinant human insulin, or Insulin, for use in MannKind's product AFREZZA®. Under the terms of the supply agreement, AFP will be responsible for manufacturing the Insulin in accordance with MannKind's specifications and agreed-upon quality standards. MannKind has agreed to purchase annual minimum quantities of Insulin under the supply agreement of an aggregate of approximately €120.1 million, or approximately $160.7 million, in calendar years 2015 through 2019. MannKind may request to purchase additional quantities of Insulin over such annual minimum quantities.

Within five business days of executing of the agreement, MannKind made a non-refundable reservation fee to AFP in the amount of €11.0 million, or approximately $14.7 million. Under the agreement, the non-refundable reservation fee is considered as partial payment for the purchase commitment quantity for 2015. The Company classified the amount as deferred revenue.

Unless earlier terminated, the term of the supply agreement expires on December 31, 2019 and can be renewed for additional, successive two-year terms upon 12 months' written notice given prior to the end of the initial term or any additional two-year term. MannKind and AFP each have normal and customary termination rights, including termination for material breach that is not cured within a specific time frame or in the event of liquidation, bankruptcy, or insolvency of the other party. In addition, MannKind may terminate the supply agreement upon two years' prior written notice to AFP without cause or upon 30 days prior written notice to AFP if a controlling regulatory authority withdraws approval for AFREZZA®; provided, however, in the event of a termination pursuant to either of these scenarios, the provisions of the supply agreement require MannKind to pay the full amount of all unpaid purchase commitments due over the initial term within 60 calendar days of the effective date of such termination.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward looking statements

The following discussion of our financial condition and the results of operations should be read in conjunction with the "Condensed Consolidated Financial Statements" and notes thereto included elsewhere in this Quarterly Report on Form 10-Q, or Quarterly Report. This discussion contains forward-looking statements that are subject to known and unknown risks, uncertainties, and other factors that may cause the Company's actual results to differ materially from those expressed or implied by such forward-looking statements. These risks, uncertainties, and other factors include, among others, those identified under the "Note Regarding Forward-Looking Statements," above, and elsewhere in this Quarterly Report, particularly in Part II. Item 1A. "Risk Factors," below.

Overview of Amphastar

Amphastar Pharmaceuticals, Inc., together with its wholly-owned subsidiaries, International Medication Systems, Limited, or IMS; Amphastar Laboratories, Inc.; Armstrong Pharmaceuticals, Inc., or Armstrong; Amphastar Nanjing Pharmaceuticals Co., Ltd., or ANP; and Amphastar France Pharmaceuticals, SAS, or AFP, (collectively, "Amphastar," " the Company," or "we"), is a specialty pharmaceutical company that primarily develops, manufactures, markets, and sells generic and proprietary injectable and inhalation products, including a portfolio of generic and proprietary products with high technical barriers to market entry. Most of the Company's products are used in hospital or urgent care clinical settings and are primarily contracted and distributed through group purchasing organizations and drug wholesalers. The Company's inhalation products will be primarily distributed through drug retailers when they are brought to the market.

2014 Significant Business Developments

During 2014, the Company announced the following transactions that impacted its results of operations and will continue to have an impact on its future operations.

Acquisition of Merck Sharpe & Dohme's API Manufacturing Business

On April 30, 2014, the Company completed its acquisition of Merck Sharpe & Dohme's, or Merck's, active pharmaceutical ingredient, or API, manufacturing business in Éragny-sur-Epte, France, which manufactures porcine insulin API and recombinant human insulin API. The purchase price of the transaction on April 30, 2014 totaled €24.8 million, or $34.4 million, subject to certain customary post-closing adjustments and currency exchange fluctuations. The terms of the purchase include multiple payments over four years as follows:

	Euros	U.S. Dollars
	(in thousands)	
At Closing, April 2014	€13,252	$18,352
December 2014	4,899	6,708
December 2015	3,186	4,363
December 2016	3,186	4,363
December 2017	500	685
	€25,023	$34,471

In order to facilitate the acquisition, the Company established a subsidiary in France, AFP. The Company will continue the current site manufacturing activities, which consist of the manufacturing of porcine insulin API and recombinant human insulin API. As part of the transaction, the Company has entered into various additional agreements, including various supply agreements, as well as the assignment and licensing of patents under which Merck was operating at this facility. In addition, certain existing customer agreements have been assigned to AFP.

Prior to the Company's purchase of Merck's facility in Éragny-sur-Epte, France, Merck notified the Company of several items it had identified as part of its own internal auditing that relate to potential minor environmental issues. The Company understands from Merck that it identified these items because the items were not in alignment with Merck's own internal policies and procedures, and not because any of the items are in violation of any French environmental law or regulation. Under a letter of understanding, or LOU, dated April 30, 2014, Merck has agreed to pay for the remediation costs up to certain dollar limits, and to date, all estimates suggest the cost of conducting the remediation will be less than those dollar limits. The LOU also includes an indemnification provision that would require the Company to indemnify Merck for liability that might arise from performance of the remediation work itself but not for other types of liability.

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The transaction will be accounted for as a business combination in accordance to Accounting Standard Codification, or ASC 805. The following table summarizes the estimated fair values of the assets acquired and liabilities assumed as of the acquisition date:

	Fair Value	
	Euros	U.S. Dollars
	(in thousands)	
Inventory	€15,565	$21,554
Real property	4,800	6,647
Machinery & equipment	6,800	9,417
Intangibles	80	111
Total assets acquired	€27,245	$37,729
Accrued liabilities	€2,425	$3,358
Total fair value of consideration transferred	€24,820	$34,371

The Company's accounting for this acquisition is preliminary. The fair value estimates for the assets acquired and liabilities assumed were based upon preliminary calculations and valuations, and the Company's estimates and assumptions are subject to change as the Company obtains additional information for its estimates during the measurement period (up to one year from the acquisition date) including the completion of our analysis to determine the acquisition date fair values of certain tax-related items and residual impact on purchase accounting. The operations of the acquired business have been included in the Company's condensed consolidated financial statements commencing on the acquisition date. The results of operations for this acquisition have not been separately presented because this acquisition is not material to the Company's condensed consolidated results of operations.

The following unaudited pro forma financial information for the six months ended June 30, 2014 and 2013 gives effect to the transaction as if it had occurred on January 1, 2013. Such unaudited pro forma information is based on historical financial information with respect to the transaction and does not reflect operational and administrative cost savings, or synergies, that management of the combined company estimates may be achieved as a result of the transaction. The unaudited pro forma information primarily reflects the additional depreciation related to the fair value adjustment to property, plant and equipment acquired, valuation step up related to the fair value of inventory and additional interest expense associated with the financing obtained by the Company in connection with the acquisition.

	Six Months Ended June 30,	
	2014	2013
	(in thousands, except per share data)	
Net revenues	$97,157	$122,436
Net income (loss)	(4,028)	10,709
Diluted net income (loss) per share	$(0.10)	$0.28

Initial Public Offering

In June 2014, the Company completed an initial public offering, or IPO in which the Company sold 5,840,000 shares of its common stock, which included 1,200,000 shares of the Company's common stock pursuant to the underwriters' exercise of their over-allotment option, at a price to the public of $7.00 per share, resulting in gross proceeds of $40.9

million. In connection with the offering, the Company paid $6.2 million in underwriting discounts, commissions, and offering costs, resulting in net proceeds of $34.7 million.

Results of Operations

Segment Reporting

The Company's business is the development, manufacture, and marketing of pharmaceutical products. The Company has determined that all of its product groups have similar economic characteristics and may be aggregated into a single operational segment for reporting purposes.

Three Months Ended June 30, 2014 Compared to Three Months Ended June 30, 2013

Net revenues

	Three Months Ended June 30,		Change	
	2014	2013	Dollars	%
	(in thousands)			
Net revenues				
Enoxaparin	$27,225	$41,339	$(14,114)	(34%)
Other products	21,778	21,185	593	3%
Total net revenues	49,003	62,524	(13,521)	(22%)
Cost of revenues	34,007	35,035	(1,028)	(3%)
Gross profit	$14,996	$27,489	$(12,493)	(45%)
as % of net revenues	31%	44%		

Net revenues were $49.0 million and $62.5 million for the three months ended June 30, 2014 and 2013, respectively, representing a decrease of $13.5 million, or 22%. The decrease was primarily due to a decrease in units sold and average selling price of enoxaparin. Other product revenue increased due to increased unit sales of naloxone, which were partially offset by lower unit sales of other injectable products.

Cost of revenues

Cost of revenues were $34.0 million and $35.0 million for the three months ended June 30, 2014 and 2013, respectively, representing a decrease of $1.0 million, or 3%, primarily due to a decrease in sales unit volume.

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Gross profit as a percentage of net revenues was 31% and 44% for the three months ended June 30, 2014 and 2013, respectively. The decrease is primarily related to a decrease in average net sales price of enoxaparin during 2014.

Operating Expenses

	Three Months Ended June 30,		Change	
	2014	2013	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	$1,352	$1,203	$149	12 %
General and administrative	8,638	6,513	2,125	33 %
Research and development	5,994	7,791	(1,797)	(23 %)
Impairment of long-lived assets	184	—	184	100 %

General and administrative expenses were $8.6 million and $6.5 million for the three months ended June 30, 2014 and 2013, respectively, representing an increase of $2.1 million, or 33%. The increase was primarily due to an increase in compensation expenses including an increase in stock-based compensation.

Research and development expenses were $6.0 million and $7.8 million for the three months ended June 30, 2014 and 2013, respectively, representing a decrease of $1.8 million, or 23%. The decrease is primarily related to a decrease in pre-launch inventory expense during the second quarter of 2014.

Impairment of long-lived assets was $0.2 million for the three months ended June 30, 2014. For the three months ended June 30, 2013, the Company did not have any impairment of long-lived asset expense.

Provision for income tax expense (benefit)

	Three Months Ended June 30,		Change	
	2014	2013	Dollars	%
	(in thousands)			
Income tax expense (benefit)	$(696)	$4,109	$(4,805)	(117 %)
Effective tax rate	(37 %)	34 %		

Income tax benefit was $0.7 million for the three months ended June 30, 2014 compared to an income tax expense of $4.1 million for the three months ended June 30, 2013, representing a decrease in income tax expense of $4.8 million, or 117%. The decrease in income tax expense is primarily related to the pre-tax loss that occurred during the second quarter of 2014.

Six Months Ended June 30, 2014 Compared to Six Months Ended June 30, 2013

Net revenues

	Six Months Ended June 30,		Change	
	2014	2013	Dollars	%
	(in thousands)			
Net revenues				
Enoxaparin	$53,297	$75,137	$(21,840)	(29 %)

Other products	41,576	40,350	1,226	3	%
Total net revenues	94,873	115,487	(20,614)	(18	%)
Cost of revenues	67,368	68,440	(1,072)	(2	%)
Gross profit	$27,505	$47,047	$(19,542)	(42	%)
as % of net revenues	29 %	41 %			

Net revenues were $94.9 million and $115.5 million for the six months ended June 30, 2014 and 2013, respectively, representing a decrease of $20.6 million, or 18%. The decrease was primarily due to a decrease in units sold and average selling price of enoxaparin. Other product revenue increased due to increased unit sales of naloxone, which were partially offset by lower sales of Cortrosyn and other injectable products.

Cost of revenues

Cost of revenues were $67.4 million and $68.4 million for the six months ended June 30, 2014 and 2013, respectively, representing a decrease of $1.0 million, or 2%, primarily due to a decrease in sales unit volume.

Gross profit as a percentage of net revenues was 29% and 41% for the six months ended June 30, 2014 and 2013, respectively. The decrease is primarily related to a decrease in average net sales price of enoxaparin.

Operating Expenses

	Six Months Ended June 30,		Change		
	2014	2013	Dollars	%	
	(in thousands)				
Selling, distribution, and marketing	$2,612	$2,597	$15	1	%
General and administrative	15,484	13,420	2,064	15	%
Research and development	12,203	16,695	(4,492)	(27	%)
Impairment of long-lived assets	348	—	348	100	%

General and administrative expenses were $15.5 million and $13.4 million for the six months ended June 30, 2014 and 2013, respectively, representing an increase of 2.1 million, or 15%. The increase was primarily due to an increase in compensation expenses including an increase in stock-based compensation expense.

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Research and development expenses were $12.2 million and $16.7 million for the six months ended June 30, 2014 and 2013, respectively, representing a decrease of $4.5 million, or 27%. The decrease is primarily related to a decrease in pre-launch inventory expense during 2014.

Impairment of long-lived assets was $0.3 million for the six months ended June 30, 2014. For the six months ended June 30, 2013, the Company did not have any impairment of long-lived asset expense.

Provision for income tax expense (benefit)

	Six Months Ended June 30,		Change	
	2014	2013	Dollars	%
	(in thousands)			
Income tax expense (benefit)	$(1,548)	$3,919	$(5,467)	(139%)
Effective tax rate	(36%)	28%		

Income tax benefit was $1.5 million for the six months ended June 30, 2014 compared to an income tax expense of $3.9 million for the six months ended June 30, 2013, representing a decrease in income tax expense of $5.4 million, or 139%. The decrease in income tax expense is primarily related to a pre-tax loss that occurred during the six months ended June 30, 2014.

Liquidity and Capital Resources

Cash Requirements and Sources

The Company's business requires capital resources in order to maintain and expand its business. The Company's future capital expenditures will include projects undertaken to upgrade, expand and improve its manufacturing facilities in the United States, China and France. The Company's cash obligations include the principal and interest payments due on its existing loans, as described below and throughout this report. The Company believes that its cash reserves, operating cash flows, and availability under its revolving credit facility will be sufficient to meet its cash needs for the foreseeable future.

Working capital increased $50.3 million to $157.9 million at June 30, 2014 compared to $107.6 million at December 31, 2013. The increase in working capital was primarily due to cash in-flows from operations and the proceeds from the Company's IPO partially offset by payments on debt ($6.0 million), payments pertaining to the acquisition of Merck's API manufacturing business in Éragny-sur-Epte, France ($18.4 million), and capital expenditures ($7.5 million).

Cash Flows from Operations

The following table summarizes the Company's cash flows used in operating, investing, and financing activities for the six months ended June 30, 2014.

	Six Months Ended June 30, 2014
	(in thousands)
Statement of Cash Flow Data:	
Net cash provided by (used in)	

Operating activities	$	(4,901)
Investing activities		(26,715)
Financing activities		42,142
Effect of exchange rate changes on cash		(32)
Net increase (decrease) in cash and cash equivalents	$	10,494

Sources and Use of Cash

Operating Activities

Net cash used in operating activities was $4.9 million for the six months ended June 30, 2014, which included a net loss of $2.8 million. Non-cash items is comprised of $7.0 million of depreciation and amortization and $4.0 million of share-based compensation expense. A net increase in working capital of $13.1 million was a significant use of cash. The largest component of the working capital change was an inventory increase, primarily for enoxaparin.

Investing Activities

Net cash used in investing activities of $26.7 million for the six months ended June 30, 2014 was primarily related to the purchase of an API facility in France from Merck with an initial payment of $18.4 million, and $7.5 million in purchases of property, machinery, and equipment, including the associated capitalized labor and interest on self-constructed assets. Additionally, $0.7 million in deposits were made for machinery and equipment.

Financing Activities

Net cash provided by financing activities of $42.1 million for the six months ended June 30, 2014 was primarily related to proceeds of the Company's IPO of $38.0 million, after deducting $2.9 million in underwriting discounts and commissions incurred in connection therewith. The Company also paid $3.3 million in offering expense incurred in connection with the IPO, resulting in net proceeds of $34.7 million. Additionally, net cash provided by financing activities related to $0.5 million relating to a stock option exercise, $21.9 million in borrowings related to the purchase of the API facility in France from Merck, and $4.6 million relating to the refinancing of an existing mortgage. This was offset by $1.9 million related to the cost associated with the IPO and $15.0 million in repayments related to the Company's line of credit and $6.0 million in principal payments on long-term debt.

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Debt and Borrowing Capacity

The Company's outstanding debt obligations are summarized as follows:

	June 30, 2014	December 31, 2013	change
	(in thousands)		
Short-term debt and current portion of long-term debt	$10,665	$ 22,104	$(11,439)
Long-term debt	42,850	10,069	32,781
Total debt	$53,515	$ 32,173	$21,342

The increase in long-term debt is primarily related to the debt associated with the acquisition of the Merck API facility in France and the refinancing of an existing mortgage which matured in March 2014 and will now mature in April 2021.

The Company has $38.0 million in unused borrowing capacity under revolving lines of credit with Cathay Bank and East West Bank.

Recent Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board, or FASB, issued an Accounting Standard Update to the accounting guidance to address the diversity in practice related to the financial statement presentation of unrecognized tax benefits as either a reduction of a deferred tax asset or a liability when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. This guidance is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In April 2014, the FASB issued an accounting standards update that raises the threshold for disposals to qualify as discontinued operations and allows companies to have significant continuing involvement with and continuing cash flows from or to the discontinued operation. It also requires additional disclosures for discontinued operations and new disclosures for individually material disposal transactions that do not meet the definition of a discontinued operation. This guidance will be effective for fiscal years beginning after December 15, 2014, which will be the Company's fiscal year 2015, with early adoption permitted. The Company does not expect the adoption of the guidance will have a material impact on the Company's consolidated financial statements.

In May 2014, the FASB issued an accounting standards update that creates a single source of revenue guidance for companies in all industries. The new standard provides guidance for all revenue arising from contracts with customers and affects all entities that enter into contracts to provide goods or services to their customers, unless the contracts are within the scope of other accounting standards. It also provides a model for the measurement and recognition of gains and losses on the sale of certain nonfinancial assets. This guidance must be adopted using either a full retrospective approach for all periods presented or a modified retrospective approach and will be effective for fiscal years beginning after December 15, 2016, which will be the Company's fiscal year 2017. The Company has not yet evaluated the potential impact of adopting the guidance on the Company's consolidated financial statements.

In June 2014, the FASB issued an accounting standards update that requires a performance target that affects vesting of a share-based payment award and that could be achieved after the requisite service period to be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant-date fair value of the award. Compensation cost should be recognized over the required service period, if it is probable that the

performance target will be achieved. This guidance will be effective for fiscal years beginning after December 15, 2015, which will be the Company's fiscal year 2016, with early adoption permitted. The Company does not expect the adoption of the guidance will have a material impact on the Company's consolidated financial statements.

Off-Balance Sheet Arrangements

The Company does not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, the Company does not engage in trading activities involving non-exchange traded contracts.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

The following discussion provides forward-looking quantitative and qualitative information about the Company's potential exposure to market risk. Market risk represents the potential loss arising from adverse changes in the value of financial instruments. The risk of loss is assessed based on the likelihood of adverse changes in fair values, cash flows or future earnings. The Company is exposed to market risk for changes in the market values of its investments (Investment Risk), the impact of interest rate changes (Interest Rate Risk), and the impact of foreign currency exchange changes (Foreign Currency Exchange Risk).

Cash and Cash Equivalents

As of June 30, 2014, the Company had $2.3 million deposited in three banks located in China and $1.8 million deposited in one bank located in France. The Company also maintained $44.1 million in Money Market, Money Market Insured Deposit Account Service, or MMIDAS, and Insured Cash Sweep, or ICS, accounts as of June 30, 2014. The remaining amounts of the Company's cash equivalent as of June 30, 2014 are in non-interest bearing accounts.

The MMIDAS accounts and ICS accounts allow the Company to distribute its funds among a network of depository institutions that are re-allocated such that each deposit account is below the $250.0 thousand Federal Deposit Insurance Corporation, or FDIC, limit, thus providing greater FDIC insurance coverage for the Company's overall cash balances. The Company has not experienced any losses in such accounts, nor does management believe it is exposed to any significant credit risk on its bank account balances.

Interest Rate Risk

The Company's primary exposure to market risk is interest-rate-sensitive investments and credit facilities, which are affected by changes in the general level of U.S. interest rates. Due to the nature of the Company's short-term investments, such as its certificates of deposit, the Company believes that it is not subject to any material interest rate risk.

As of June 30, 2014, the Company had $53.5 million in long-term debt and capital leases outstanding. Of this amount, $31.9 million had variable interest rates with a weighted-average interest rate of 4.0% at June 30, 2014. An increase in the index underlying these rates of 1% (100 basis points) would increase the Company's annual interest expense on the variable-rate debt by approximately $0.3 million per year.

Foreign Currency Rate Risk

Historically, less than 1% of the Company's sales come from outside the U.S. All foreign sales have been negotiated with payment terms in Canadian dollars. Therefore, the Company has limited exposure to foreign currency price fluctuation. Further, the Company has no derivative financial instruments.

The Company's Chinese subsidiary, Amphastar Nanjing Pharmaceuticals, Limited, or ANP, maintains its books of record in Chinese Yuan, or CNY. These books are remeasured into the functional currency of U.S. dollars, or USD, using the current or historical exchange rates. The resulting currency re-measurement adjustments and other transactional foreign exchange gains and losses are reflected in the Company's statement of operations.

The Company's French subsidiary, Amphastar France Pharmaceuticals, SAS, or AFP, maintains its books of record in Euros. These books are translated to USD at the average exchange rates during the period. Assets and liabilities are translated at the rate of exchange prevailing on the balance sheet date. Equity is translated at the prevailing rate of

exchange at the date of the equity transactions. Translation adjustments are reflected in stockholders' equity and are included as a component of other comprehensive income (loss). The Company does not undertake hedging transactions to cover its foreign currency exposure.

As of June 30, 2014, ANP had receivables denominated in CNY in the amount of $2.1 million and AFP had receivables denominated in Euros in the amount of $0.3 million.

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ITEM 4. CONTROLS AND PROCEDURES

The Company maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in the Company's reports pursuant to the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the U.S. Securities and Exchange Commission's, or SEC's rules and forms, and that such information is accumulated and communicated to the Company's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of the end of the quarter covered by this Quarterly Report. Based on the foregoing, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC and that such information is accumulated and communicated to the Company's management (including its Chief Executive Officer and Chief Financial Officer) to allow timely decisions regarding required disclosures.

There have been no changes in the Company's internal control over financial reporting during the three months ended June 30, 2014 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

For information regarding legal proceedings, refer to Litigation in Note 17 in the accompanying "Notes to Condensed Consolidated Financial Statements" in this Quarterly Report.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Quarterly Report, including our condensed consolidated financial statements and the related notes thereto. Our future operating results may vary substantially from anticipated results due to a number of risks and uncertainties, many of which are beyond our control. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. The following discussion highlights some of these risks and uncertainties and the possible impact of these risks on future results of operations. If any of the following risks occur, our business, financial condition or results of operations could be materially and adversely affected. In that case, the market value of our common stock could decline substantially and you could lose part or all of your investment.

Risks Relating to Our Business and Industry

Our enoxaparin product represents a significant portion of our net revenues. If the sales volume or pricing of this product continues to decline, or if we are unable to satisfy market demand for this product, it could have a material adverse effect on our business, financial position and results of operations.

Sales from our enoxaparin product, which is our largest selling product, represented 64% and 56% of our total net revenues for the year ended December 31, 2013 and the three months ended June 30, 2014, respectively. We are currently experiencing declining revenue from enoxaparin and some of our other existing products and anticipate that we may operate at a loss in the near term while continuing to invest in developing new products. If the sales volume or pricing of enoxaparin continues to decline, or if we are unable to satisfy market demand for this product, our business, financial position and results of operations could be materially and adversely affected, and the market value of our common stock could decline. For example, due to intense pricing competition in the pharmaceutical industry, we have experienced significant declines in the per unit pricing and gross margins attributable to our enoxaparin product since its commercial launch, even during periods where we have increased market share and net revenues. This product could be rendered obsolete or economically impractical by numerous factors, many of which are beyond our control, including:

- decreasing average sales prices;
- development by others of new pharmaceutical products that are more effective than ours;
- entrance of new competitors into our markets;
- loss of key relationships with suppliers, group purchasing organizations or end-user customers;
- manufacturing or supply interruptions;
- changes in the prescribing practices of physicians;
- changes in third-party reimbursement practices;
- product liability claims; and
- product recalls or safety alerts.

Any factor adversely affecting the sale of enoxaparin may cause our revenues to decline, and we may not be able to achieve and maintain profitability.

Our success depends on our ability to develop and/or acquire and commercialize additional pharmaceutical products.

Our financial results depend upon our ability to commercialize additional generic and proprietary pharmaceutical products that address unmet medical needs, are accepted by patients and physicians and are reimbursed by payers. Commercialization requires that we successfully and cost-effectively develop, test and manufacture or otherwise acquire both generic and proprietary products. All of our products must receive regulatory approval and meet (and continue to comply with) regulatory and safety standards. If health or safety concerns arise with respect to a product, we may be forced to withdraw it from the market. For example, as a result of environmental concerns over the use of chlorofluorocarbons, or CFCs, the U.S. Food and Drug Administration, or FDA, issued a final rule on January 16, 2009 that required the phase-out of the CFC formulation of our Primatene Mist product by December 31, 2011. As a result, in order to resume selling Primatene Mist we have developed a formulation of the product that will use hydrofluoroalkane, or HFA, as the propellant and we are now seeking FDA approval for the modified product. There can be no guarantee that our investment in research and development activities will result in FDA approval or produce a commercially viable new product. See the risk factor entitled “The FDA approval process is time-consuming and

complicated, and we may not obtain the FDA approval required for a product within the timeline we desire, or at all. Additionally, we may lose FDA approval and/or our products may become subject to foreign regulations."

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The development and commercialization process, particularly with respect to our proprietary products, is time-consuming, costly and involves a high degree of business risk. Our products currently under development, if and when fully developed and tested, may not perform as we expect. Necessary regulatory approvals may not be obtained in a timely manner, if at all, and we may not be able to produce and market such products successfully and profitably. For example, we filed an abbreviated new drug application, or ANDA, for our enoxaparin product in March 2003, but FDA approval was not granted until September 2011 due to delays caused largely by our inclusion in lengthy litigation with Sanofi S.A., or Sanofi, the FDA's requirement that we perform immunogenicity studies and the receipt of an FDA Warning Letter by the supplier of the starting material for our enoxaparin product, who also became the subject of an FDA Import Alert. Following FDA approval, we became involved in litigation with Momenta Pharmaceuticals, Inc. and Sandoz, Inc., which further delayed the commercial launch of our enoxaparin product until January 2012. Delays in any part of the process, or our inability to obtain regulatory approval of our products, could adversely affect our operating results by restricting or delaying our introduction of new products, which could cause the market value of our products to decline. To the extent that we expend significant resources on research and development efforts and are not able, ultimately, to introduce successful new products as a result of those efforts, our business, financial position and results of operations may be materially and adversely affected, and the market value of our common stock could decline.

Our ability to introduce new generic products also depends upon our success in challenging patent rights held by third parties or in developing non-infringing products. Due to the emergence and development of competing products over time, our overall profitability depends on, among other things, our ability to introduce new products in a timely manner, to continue to manufacture products cost-effectively and to manage the life cycle of our product portfolio. If we are unable to cost-effectively maintain an adequate flow of successful generic and proprietary products and new indications and/or delivery methods for existing products sufficient to cover our substantial research and development costs and the decline in sales of older products that either become subject to generic competition, or are displaced by competing products or therapies, this could have a material adverse effect on our business, financial condition or results of operations.

Our success depends on the integrity of our supply chain, including multiple single source suppliers, the disruption of which could negatively impact our business.

Some of our products are the result of complex manufacturing processes, and some require highly specialized raw materials. Because our business requires outsourcing in some instances, we are subject to inherent uncertainties related to product safety, availability and security. For some of our key raw materials, components and active pharmaceutical ingredient, or API, used in certain of our products, we have only a single, external source of supply, and alternate sources of supply may not be readily available. For example, we purchase heparin USP as the starting material for producing our enoxaparin product exclusively from a single source supplier and, in 2009, this supplier received a Warning Letter from the FDA and was the subject of an FDA Import Alert. The resulting shortage of heparin USP resulted in significant delays to the FDA approval process for our enoxaparin product. There are no guarantees our supplier will not receive Warning Letters in the future or that we will be able to replace this single source supplier with an alternate supplier on a commercially reasonable and timely basis, or at all, to prevent a shortage of heparin USP. Additionally, in 2013 our single source supplier of epinephrine API for our Primatene Mist HFA product candidate received a Warning Letter from the FDA, which our supplier has since addressed. In the future, it is possible that our suppliers will receive Warning Letters from the FDA and be unsuccessful in their efforts to address the issues raised in such Warning Letters on a timely basis, or at all, which would result in delays in commercialization and/or manufacturing of our products or product candidates, if FDA approval for such products or product candidates is received. Furthermore, we may be unable to replace such supplier with an alternate supplier on a commercially reasonable and timely basis, or at all.

If we fail to maintain relationships with our current suppliers, we may not be able to complete development, commercialization or marketing of our products, which would have a material and adverse effect on our business. Third-party suppliers may not perform as agreed or may terminate their agreements with us. For example, because these third parties provide materials to a number of other pharmaceutical companies, they may experience capacity constraints or choose to prioritize one or more of their other customers over us. Any significant problem that our suppliers experience could delay or interrupt our supply of materials until the supplier cures the problem or until we locate, negotiate for, validate and receive FDA approval for an alternative source of supply, if one is available. In the near term, we do not anticipate that the FDA will approve alternative sources to back up our primary suppliers. Therefore, if our primary suppliers become unable or unwilling to manufacture or deliver materials, we could experience protracted delays or interruptions in the supply of materials. This would ultimately delay our manufacture of products for commercial sale, which could materially and adversely affect our development programs, commercial activities, operating results and financial condition.

Additionally, any failure by us to forecast demand for, or to maintain an adequate supply of, the raw material and finished product could result in an interruption in the supply of certain products and a decline in sales of that product.

We face significant competition in the pharmaceutical industry with respect to both our proprietary and generic drugs, which may result in others developing or commercializing products before or more successfully than we do, which could significantly limit our growth and materially and adversely affect our financial results.

Our business operates in the pharmaceutical industry, which is an industry characterized by intense competition. Many of our competitors have longer operating histories and greater financial, research and development, marketing and other resources than we do. Consequently, many of our competitors may be able to develop products and/or processes competitive with, or superior to, our own. We are concentrating the majority of our efforts and resources on developing product candidates utilizing our proprietary technologies. The commercial success of products utilizing such technologies will depend, in large part, on the intensity of competition, labeling claims approved by the FDA for our products compared to claims approved for competitive products and the relative timing and sequence for commercial launch of new products by other companies that compete with our new products. If alternative technologies or other therapeutic approaches are adopted prior to our new product approvals, then the market for our new products may be substantially decreased, thus reducing our ability to generate future profits.

This intensely competitive environment requires an ongoing, extensive search for technological innovations and the ability to market products effectively, including the ability to communicate the effectiveness, safety and value of our products to healthcare professionals in private practice, group practices and managed care organizations. Our competitors vary depending upon product categories, and within each product category, upon dosage strengths and upon drug-delivery systems. Based on total assets, annual revenues and market capitalization, we are smaller than many of our national and international competitors with respect to both our generic and proprietary pharmaceutical products and product candidates. Many of our competitors have been in business for a longer period of time than us, have a greater number of products on the market and have greater financial and other resources than we do. Furthermore, recent trends in this industry are toward further market consolidation of large drug companies into a smaller number of very large entities, further concentrating financial, technical and market strength and increasing competitive pressure in the industry. If we directly compete with them for the same markets and/or products, their financial strength could prevent us from capturing a profitable share of those markets. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. It is possible that developments by our competitors will make our products or technologies noncompetitive or obsolete.

If we fail to obtain exclusive marketing rights for our generic pharmaceutical products or fail to introduce these generic products on a timely basis, our revenues, gross margin and operating results may decline significantly.

The Hatch-Waxman amendments to the Federal Food, Drug, and Cosmetic Act, or FFDCA, provide for a period of 180 days of generic marketing exclusivity for any applicant that is first-to-file an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed with respect to the corresponding brand drug, which we refer to as a Paragraph IV certification. The holder of an approved ANDA containing a Paragraph IV certification that is successful in challenging the applicable brand drug patent(s) is often able to price the applicable generic drug to yield relatively high gross margins during this 180-day marketing exclusivity period. ANDAs that contain Paragraph IV certifications challenging patents, however, generally become the subject of patent litigation that can be both lengthy and costly. There is no certainty that we will prevail in any such litigation, that we will be the first-to-file and granted the 180-day marketing exclusivity period or, if we are granted the 180-day marketing exclusivity period, that we will not forfeit such period. Even where we are awarded marketing exclusivity, we may be required to share our exclusivity period with other ANDA applicants who submit Paragraph IV certifications. In addition, brand companies often authorize a generic version of the corresponding brand drug to be sold during any period of marketing exclusivity that is awarded, which reduces gross margins during the marketing exclusivity period. Brand companies may also reduce the price of their brand product to compete directly with generics entering the market, which similarly would have the effect of reducing gross margins. Furthermore, timely commencement of litigation by the patent owner imposes an automatic stay of ANDA approval by the FDA for 30 months, unless the case is decided in the ANDA applicant’s favor during that period. Finally, if the court’s decision is adverse to the ANDA applicant, the ANDA approval will be delayed until the challenged patent expires, and the applicant will not be granted the 180-day marketing exclusivity.

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Accordingly, our revenues and future profitability are dependent, in large part, upon our ability or the ability of our development partners to file ANDAs with the FDA timely and effectively or to enter into contractual relationships with other parties that have obtained marketing exclusivity. We may not be able to develop and introduce successful products in the future within the time constraints necessary to be successful. If we or our development partners are unable to continue to timely and effectively file ANDAs with the FDA or to partner with other parties that have obtained marketing exclusivity, our revenues, gross margin and operating results may decline significantly, and our prospects and business may be materially adversely affected.

Our generic products face and our generic product candidates will face additional competitive pressures that are specific to the generic pharmaceutical industry.

With respect to our generic pharmaceutical business, revenues and gross profit derived from the sales of generic pharmaceutical products tend to follow a pattern based on certain regulatory and competitive factors. As patents and exclusivities protecting a brand name product expire, the first manufacturer to receive regulatory approval for a generic version of the product is generally able to achieve significant market penetration. Therefore, our ability to increase or maintain revenues and profitability in our generics business is largely dependent on our success in challenging patents and developing non-infringing formulations of proprietary products. As competing manufacturers receive regulatory approvals on generic products or as brand manufacturers launch generic versions of their products (for which no separate regulatory approval is required), market share, revenues and gross profit typically decline, often significantly and rapidly. Accordingly, the level of market share, revenue and gross profit attributable to a particular generic product normally is related to the number of competitors in that product's market and the timing of that product's regulatory approval and launch, in relation to competing approvals and launches. For example, with respect to our enoxaparin product, Sandoz also markets the generic version of enoxaparin, Teva Pharmaceutical Industries Ltd. has received approval from the FDA of its ANDA for its generic enoxaparin product and Hospira, Inc. has filed an ANDA with the FDA for approval of its generic version. The presence of these current and prospective competitive products may have an adverse effect on our market share, revenue and gross profit from our enoxaparin product. Since the commercial launch of our enoxaparin product, we have experienced significant declines in the per unit pricing and gross margins attributable to this product, even as we have increased market share and net revenues. Consequently, we must continue to develop and introduce new generic products in a timely and cost-effective manner to maintain our revenues and gross margins. We may have fewer opportunities to launch significant generic products in the future, as the number and size of proprietary products that are subject to patent challenges is expected to decrease in the next several years compared to historical levels. Additionally, as new competitors enter the market, there may be increased pricing pressure on certain products, which may result in lower gross margins. In addition to our enoxaparin product, we have experienced significant pricing pressure on many of our other products, including Cortrosyn, and we expect this trend to continue in the future.

Competition in the generic drug industry has also increased due to the proliferation of authorized generic pharmaceutical products. "Authorized generics" are generic pharmaceutical products that are introduced by brand companies, either directly or through partnering arrangements with other generic companies. Authorized generics are equivalent to the brand companies' brand name drugs, but are sold at relatively lower prices than the brand name drugs. An authorized generic product can be marketed during the 180-day exclusivity granted to the first manufacturer or manufacturers to submit an ANDA with a Paragraph IV certification for a generic version of the brand product. The sale of authorized generics adversely impacts the market share of a generic product that has been granted 180-day exclusivity. For example, with respect to our enoxaparin product, Sanofi currently markets an authorized generic enoxaparin product through its subsidiary, Winthrop. This is a significant source of competition for us because brand companies do not face any regulatory barriers to introducing authorized generics of their products. Because authorized generics may be sold during our exclusivity periods, if any, they can materially decrease the profits that we could otherwise receive as an exclusive marketer of a generic alternative. Such actions have the effect of reducing the potential market share and profitability of our generic products and may inhibit us from developing and introducing

generic pharmaceutical products corresponding to certain brand name drugs.

Such competition can also result from the entry of generic versions of another product in the same therapeutic class as one of our drugs, or in another competing therapeutic class, or from the compulsory licensing of our products by governments, or from a general weakening of intellectual property laws in certain countries around the world.

If the market for a reference brand product, such as Lovenox, significantly declines, sales or potential sales of our generic and biosimilar products and product candidates may suffer and our business would be materially impacted.

Proprietary products face competition on numerous fronts as technological advances are made or new products are introduced. As new products are approved that compete with the reference proprietary product to our generic products and generic or biosimilar product candidates, such as Lovenox, which is the reference brand product for our enoxaparin product, sales of the reference brand products may be significantly and adversely impacted and may render the reference brand product obsolete. In addition, brand companies may pursue life cycle management strategies that also impact our generic products.

If the market for a reference brand product is impacted, we in turn may lose significant market share or market potential for our generic or biosimilar products and product candidates, and the value for our generic or biosimilar pipeline could be negatively impacted. As a result, our business, including our financial results and our ability to fund future discovery and development programs, would suffer.

Health care providers may not be receptive to our products, particularly those that incorporate our proprietary drug delivery platforms.

The commercial success of our products will depend on acceptance by health care providers and others that such products are clinically effective, affordable and safe. Our products utilizing our proprietary drug delivery technologies may not be accepted by health care providers and others. Factors that may materially affect market acceptance of our products include but are not limited to:

- the relative therapeutic advantages and disadvantages of our products compared to competitive products;
- the relative timing of commercial launch of our products compared to competitive products;
- the relative safety and efficacy of our products compared to competitive products;
- the product labeling approved by the FDA for our products and for competing products;
- the willingness of third party payers to reimburse for our prescription products;
- the willingness of pharmacy chains to stock our new products; and
- the willingness of consumers to pay for our products.

Our products, if successfully developed and commercially launched, will compete with both currently marketed products and new products launched in the future by other companies. Health care providers may not accept or utilize some of our products. Physicians and other prescribers may not be inclined to prescribe our prescription products unless our products demonstrate commercially viable advantages over other products currently marketed for the same indications. Pharmacy chains may not be willing to stock certain of our new products, and pharmacists may not recommend such products to consumers. Further, consumers may not be willing to purchase some of our products. If our products do not achieve market acceptance, we may not be able to generate significant revenues or become profitable.

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

Many of the existing and potential customers for our products have combined to form group purchasing organizations in an effort to lower costs. Group purchasing organizations negotiate pricing arrangements with medical supply manufacturers and distributors, and these negotiated prices are made available to a group purchasing organization's affiliated hospitals and other members. Group purchasing organizations provide 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 group purchasing organization of their choice for their purchasing needs. We currently derive, and expect to continue to derive, our revenue from end-user customers that are members of group purchasing organizations. Maintaining our strong relationships with these group purchasing organizations will require us to continue to be a reliable supplier, offer a broad product line, remain price competitive, comply with FDA regulations and provide high-quality products. Although our group purchasing organization pricing agreements are typically multi-year in duration, most of them may be terminated by either party with 60 or 90 days' notice. The group purchasing organizations with which we have relationships may have relationships with manufacturers that sell competing products, and such group purchasing organizations may earn higher margins from these competing products or combinations of competing products or may prefer products other than ours for other reasons. If we are unable to maintain our group purchasing organization relationships, sales of our products and revenue could decline.

Although we reported net income for fiscal 2012 and fiscal 2013, we have incurred losses in the first and second quarters of 2014.

We recorded net losses of $1.6 million and $1.2 million for the three months ended March 31, 2014 and June 30, 2014, respectively, compared with net income of $2.4 million and $7.8 million for the three months ended March 31, 2013 and June 30, 2013, respectively. This loss resulted principally from a decrease in profit sharing revenues under our profit sharing agreement with Actavis, Inc., or Actavis, under which Actavis markets and distributes our enoxaparin product to the retail market in the U.S. We may continue to incur operating and net losses and negative cash flow from operations. Our business may generate operating losses to the extent Actavis reports decreased profit levels on their determined sales volumes and product pricing for enoxaparin, if we are unable to maintain and expand our relationships with group purchasing organizations or if we do not successfully commercialize our product candidates and generate sufficient revenues to support our level of operating expenses. Because of the numerous risks and uncertainties associated with our profit sharing agreement, our commercialization efforts and future product development, we are unable to predict whether we will be able to achieve and maintain profitability.

Consolidation in the health care industry could lead to demands for price concessions or for the exclusion of some suppliers from certain of our markets, which could have an adverse effect on our business, financial condition or results of operations.

Because health care costs have risen significantly, numerous initiatives and reforms by legislatures, regulators and third-party payers to curb these cost increases have resulted in a trend in the health care industry to consolidate product suppliers and purchasers. As the health care industry consolidates, competition among suppliers to provide products to purchasers has become more intense. This in turn has resulted and will likely continue to result in greater pricing pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations and large single accounts continue to use their market power to influence product pricing and purchasing decisions. As the U.S. payer market concentrates further and as more drugs become available in generic form, biopharmaceutical companies may face greater pricing pressure from private third-party payers, who will continue to drive more of their patients to use lower cost generic alternatives. This drive towards generic alternatives could adversely affect sales of our proprietary products and increase competition among generic manufacturers.

Sales of our products may be adversely affected by the continuing consolidation of our customer base.

A significant proportion of our sales are made to relatively few U.S. wholesalers and group purchasing organizations. These customers are continuing to undergo significant consolidation. Sales to three of these customers for the year ended December 31, 2013 and the three months ended June 30, 2014, respectively, accounted for approximately 54% and 52% of our total net revenues, respectively. Such consolidation has provided and may continue to provide them with additional purchasing leverage, and consequently may increase the pricing pressures that we face. Additionally, the emergence of large buying groups representing independent retail pharmacies, and the prevalence and influence of managed care organizations and similar institutions, enable those groups to extract price discounts on our products.

Moreover, we are exposed to a concentration of credit risk as a result of this concentration among our customers. If one or more of our major customers experienced financial difficulties, the effect on us would be substantial. This could have a material adverse effect on our business, financial condition and results of operations.

Our net sales and quarterly growth comparisons may also be affected by fluctuations in the buying patterns of retail chains, major distributors and other trade buyers, whether resulting from seasonality, pricing, wholesaler buying decisions or other factors. In addition, because a significant portion of our U.S. revenues is derived from relatively few customers, any financial difficulties experienced by a single customer, or any delay in receiving payments from a single customer, could have a material adverse effect on our business, financial condition and results of operations.

If our business partners do not fulfill their obligations with respect to our distribution or collaboration agreements our revenues and our business will suffer.

Pursuant to certain distribution or collaboration agreements, the success of some of our products or product candidates also depends on the success of the collaboration with our business partners, who are responsible for certain aspects of researching, developing, marketing, distributing or commercializing our products or product candidates. If such an agreement were to be terminated in accordance with its terms, including due to a party’s failure to perform its obligations or responsibilities under the agreement, revenues could be delayed or diminished from these products and our revenues and/or profit share for these products could be adversely impacted.

For example, we have a profit sharing agreement with Actavis to market and distribute our enoxaparin product to the retail market in the U.S. If Actavis fails to commit sufficient resources to market and distribute our products to the retail market, our profit sharing revenue from retail sales of enoxaparin could be severely impacted.

The revenues we earn and report from our profit sharing agreement with Actavis are subject to their marketing, pricing and reporting practices.

Under the terms of our profit sharing agreement, Actavis markets and distributes our enoxaparin product to the retail market in the U.S., we share in the profits from these activities as reported to us by Actavis. Accordingly, the amounts of profit sharing revenues we recognize each period are subject to Actavis’ marketing, pricing and reporting practices. To the extent Actavis reports varying profit levels on their determined sales volumes and product pricing, our profit sharing revenue from retail sales of enoxaparin, financial position, results of operations and cash flows could be materially impacted.

We depend upon our key personnel, the loss of whom could adversely affect our operations. If we fail to attract and retain the talent required for our business, our business could be materially harmed.

We depend to a significant degree on our key management employees, including our Chief Executive Officer and Chief Science Officer, Jack Y. Zhang; Chief Operating Officer and Chief Scientist, Mary Z. Luo; President, Jason B. Shandell; Chief Financial Officer and Senior Vice President, William J. Peters; and Corporate Executive Vice

President of Operations and President, International Medication Systems, Ltd., Marilyn J. Purchase. The loss of services from any of these persons may significantly delay or prevent the achievement of our product development or business objectives. Our officers all serve “at will” and we or they can terminate their employment with us at any time. We do not carry key man life insurance on any key personnel. Competition among pharmaceutical companies for qualified employees is intense, and the ability to attract and retain qualified individuals is critical to our success. We have experienced attrition among our executive officers in the past, although we do not believe that the departures of executive officers have had a materially adverse effect on our business. However, any future loss of key members of our organization, or any inability to continue to attract high-quality employees, may delay or prevent the achievement of major business objectives. Our productivity may be adversely affected if we do not integrate or train our new employees quickly and effectively.

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Competition for highly-skilled personnel is often intense, especially in Southern California, where we have a substantial presence and need for highly-skilled personnel. We may not be successful in attracting, integrating or retaining qualified personnel to fulfill our current or future needs. Also, to the extent we hire personnel from competitors, we may be subject to allegations that we have improperly solicited, or that they have divulged proprietary or other confidential information, or that their former employers own their inventions or work product.

Because a portion of our future manufacturing is expected to take place in China, a significant disruption in the construction or operation of our manufacturing facility in China or political unrest in China could materially and adversely affect our business, financial condition and results of operations.

We intend to invest in the expansion of our manufacturing facility in China. Any disruption in construction of the facility or the inability of our manufacturing facility in China to produce adequate quantities of raw materials or APIs to meet our needs, whether as a result of a natural disaster or other causes, could impair our ability to operate our business. Furthermore, since this facility is located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the Chinese government, political unrest or unstable economic conditions in China. The nationalization or other expropriation of private enterprises by the Chinese government could result in the total loss of our investment in China. Any of these matters could materially and adversely affect our business and results of operations. These interruptions or failures could also impede commercialization of our product candidates and impair our competitive position.

We are exposed to risks related to our international operations and failure to manage these risks may adversely affect our operating results and financial condition.

We have operations both inside and outside the U.S. For example, we have suppliers in Asia and Europe, and we own manufacturing facilities in Nanjing, China and Éragny-sur-Epte, France. As a result, a significant portion of our operations are conducted by and/or rely on entities outside the markets in which our products are sold, and, accordingly, we import a substantial number of products into such markets. We may, therefore, be denied access to our customers or suppliers or denied the ability to ship products from any of our sites as a result of a closing of the borders of the countries in which we sell our products, or in which our operations are located, due to economic, legislative, political and military conditions in such countries.

International operations are subject to a number of other inherent risks, and our future results could be adversely affected by a number of factors, including:

- requirements or preferences for domestic products or solutions, which could reduce demand for our products;
- differing existing or future regulatory and certification requirements;
- management communication and integration problems resulting from cultural and geographic dispersion;
- greater difficulty in collecting accounts receivable and longer collection periods;
- difficulties in enforcing contracts;
- difficulties and costs of staffing and managing non-U.S. operations;
- the uncertainty of protection for intellectual property rights in some countries;
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tariffs and trade barriers, export regulations and other regulatory and contractual limitations on our ability to sell our products;

•greater risk of a failure of foreign employees to comply with both U.S. and foreign laws, including export and antitrust regulations, the U.S. Foreign Corrupt Practices Act and any trade regulations ensuring fair trade practices;

•uneven electricity supply that can negatively impact manufacturing;

•heightened risk of unfair or corrupt business practices in certain geographies and of improper or fraudulent sales arrangements that may impact financial results and result in restatements of, or irregularities in, financial statements;

•potentially adverse tax consequences, including multiple and possibly overlapping tax structures; and

•political and economic instability, political unrest and terrorism.

In addition, the expansion of our existing international operations, including our facility expansion in Nanjing, China, and entry into additional international markets, including our recent acquisition of a manufacturing business in Éragny-sur-Epte, France, have required and will continue to require significant management attention and financial resources. These and other factors could harm our ability to gain future revenues and, consequently, materially impact our business, operations results and financial condition.

The Chinese government may exert substantial influence over the manner in which we conduct our business operations in China.

The Chinese government has exercised, and continues to exercise, substantial control over virtually every sector of the Chinese economy through regulation and state ownership. Our ability to conduct our proposed manufacturing operations in China may be harmed by changes in its laws and regulations, including those relating to taxation, import and export tariffs, environmental regulations, land use rights, property ownership and other matters. We believe that our operations in China are in material compliance with all applicable legal and regulatory requirements. However, the central or local governments of the jurisdictions in which we operate may impose new, stricter regulations or interpretations of existing regulations that would require additional expenditures and efforts on our part to ensure our compliance with such regulations or interpretations. Accordingly, government actions in the future, including any decision not to continue to support recent economic reforms and to return to a more centrally planned economy or regional or local variations in the implementation of economic policies, could have a significant effect on economic conditions in China or particular regions thereof and could require us to divest ourselves of any interest we then hold in Chinese properties or entities, including our Chinese operating subsidiary, Amphastar Nanjing Pharmaceuticals Co., Ltd., or ANP.

The Chinese legal system can be uncertain and could limit the legal protections available to us.

Unlike common law systems, such as the United States, the Chinese legal system is based on written statutes and decided legal cases have little precedential value. Our Chinese operating subsidiary, ANP, is subject to laws and regulations applicable to foreign investment in China in general and laws and regulations applicable to foreign invested enterprises in particular. ANP is also subject to laws and regulations governing the formation and conduct of domestic Chinese companies. Relevant Chinese laws, regulations and legal requirements may change frequently, and their interpretation and enforcement involve uncertainties. For example, we may have to resort to administrative and court proceedings to enforce the legal protections under law or contract. However, since Chinese administrative and court authorities have significant discretion in interpreting and implementing statutory and contract terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and our level of legal protection in China compared to other legal systems. Such uncertainties, including the inability to enforce our contracts and intellectual property rights, could materially and adversely affect our business and operations. In addition,

confidentiality protections in China may not be as effective as in the U.S. or other countries. Accordingly, future developments in the Chinese legal system, including the promulgation of new laws, changes to existing laws or the interpretation or enforcement thereof, or the preemption of local requirements by national laws, could limit the legal protections available to us.

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We could be materially and adversely affected by violations of the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws.

The U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Our policies mandate compliance with these anti-bribery laws, which often carry substantial penalties. We are currently expanding our operation abroad, including expanding our facilities in China, a country which has experienced governmental and private sector corruption to some degree, and in certain circumstances, strict compliance with anti-bribery laws may conflict with certain local customs and practices. Our internal control policies and procedures may not always protect us from reckless or other inappropriate acts committed by our affiliates, employees or agents. Violations of these laws, or allegations of such violations, 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.

Movements in foreign currency exchange rates 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.

A portion of our revenues, indebtedness and other liabilities and our costs are denominated in foreign currencies, including the Chinese Yuan and the Euro. We report our financial results in U.S. dollars. Our results of operations and, in some cases, cash flows may in the future be adversely affected by certain movements in exchange rates. From time to time, we may implement currency hedges intended to reduce our exposure to changes in foreign currency exchange rates. However, our hedging strategies may not be successful, and any of our unhedged foreign exchange exposures will continue to be subject to market fluctuations. These risks could cause 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.

We may be exposed to product liability claims and may not be able to obtain or maintain adequate product liability insurance.

Our business exposes us to potential product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. Product liability claims might be made by patients, health care providers or others who sell or consume our products. These claims may be made even with respect to those products that possess regulatory approval for commercial sale.

Our reputation is the foundation of our relationships with physicians, patients, group purchasing organizations and other customers. If we are unable to effectively manage real or perceived issues that could negatively impact sentiments toward us, our business could suffer. Our customers may have a number of concerns about the safety of our products whether or not such concerns have a basis in generally accepted science or peer-reviewed scientific research. These concerns may be increased by negative publicity, even if the publicity is inaccurate. Any negative publicity, whether accurate or inaccurate, about the efficacy, safety or side effects of our products or product categories, whether involving us, a competitor or a reference drug, could materially reduce market acceptance of our products, cause consumers to seek alternatives to our products, result in product withdrawals and cause our stock price to decline. Negative publicity could also result in an increased number of product liability claims, whether or not these claims have a basis in scientific fact.

We currently maintain a $10.0 million product liability insurance policy, which covers both Amphastar and International Medication Systems, Ltd., or IMS, products, but our insurance coverage may not reimburse us or may not be sufficient to reimburse us for all expenses or losses we may suffer from any product liability claims. 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. Large judgments have been awarded in class action lawsuits based on drug products that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

If serious adverse events or deaths are identified relating to any of our products once they are on the market, we may be required to withdraw our products from the market, which would hinder or preclude our ability to generate revenues.

We are required to report to relevant regulatory authorities adverse events or deaths associated with our product candidates or approved products. Based on such events, regulatory authorities may withdraw their approvals of such products or take enforcement actions. We may be required to reformulate our products, and/or we may have to recall the affected products from the market and may not be able to reintroduce them into the market. Furthermore, our reputation in the marketplace may suffer and we may become the target of lawsuits, including class actions suits. Any of these events could harm or prevent sales of the affected products and could have a material adverse effect upon our business and financial condition.

Any acquisitions of technologies, products and businesses may be difficult to integrate, could adversely affect our relationships with key customers and/or could result in significant charges to earnings.

We plan to regularly review potential acquisitions of technologies, products and businesses complementary to our business. Acquisitions typically entail many risks and could result in difficulties in integrating operations, personnel, technologies and products. If we are not able to successfully integrate our acquisitions, we may not obtain the advantages and synergies that the acquisitions were intended to create, which may have a material adverse effect on our business, results of operations, financial condition and cash flows, our ability to develop and introduce new products and the market price of our stock. In addition, in connection with acquisitions, we could experience disruption in our business, technology and information systems, customer or employee base, including diversion of management's attention from our continuing operations. There is also a risk that key employees of companies that we acquire or key employees necessary to successfully commercialize technologies and products that we acquire may seek employment elsewhere, including with our competitors. Furthermore, there may be overlap between our products or customers and the companies that we acquire that may create conflicts in relationships or other commitments detrimental to the integrated businesses. If we are unable to successfully integrate technologies, products, businesses or personnel that we acquire, we could incur significant impairment charges or other adverse financial consequences.

Identifying, executing and realizing attractive returns on acquisitions is highly competitive and involves a high degree of uncertainty. We expect to encounter competition for potential target businesses from both strategic and financial buyers. Some of these competitors may be well established and have extensive experience in identifying and consummating business combinations. Some of these competitors may possess greater technical, human and other resources than us, and our financial resources may be relatively limited when contrasted with those of our competitors. We may lose acquisition opportunities if we do not match our competitors' pricing, terms and structure criteria for such acquisitions. If we are forced to match these criteria to make acquisitions, we may not be able to achieve acceptable returns on our acquisitions or may bear substantial risk of capital loss. In addition, target companies may not be willing to sell assets at valuations which are attractive to us. Furthermore, the terms of our existing or future indebtedness may hinder or prevent us from making additional acquisitions of technologies, products or businesses. Because of these factors, we may not be able to consummate an acquisition on attractive terms, if at all.

We intend to conduct an extensive due diligence investigation for any business we consider acquiring. Intensive due diligence is often time consuming and expensive due to the operations, finance and legal professionals who may be involved in the due diligence process. Even if we conduct extensive due diligence on a target business which we acquire, we may not identify all material issues that are present inside a particular target business. If our due diligence fails to discover or identify material issues relating to a target business, industry or the environment in which the

target business operates, we may be forced to later write-down or write-off assets, restructure the target business's operations or incur impairment or other charges that could result in losses to us.

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Charges to earnings resulting from acquisitions 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.

Under U.S. generally accepted accounting principles, or GAAP, business combination accounting standards, we recognize the identifiable assets acquired, the liabilities assumed and any non-controlling interests in acquired companies generally at their acquisition date fair values and, in each case, separately from goodwill. Goodwill as of the acquisition date is measured as the excess amount of consideration transferred, which is also generally measured at fair value, and the net of the acquisition date amounts of the identifiable assets acquired and the liabilities assumed. Our estimates of fair value are based upon assumptions believed to be reasonable but which are inherently uncertain. After we complete an acquisition, the following factors could result in material charges and adversely affect our operating results and may adversely affect our cash flows:

- costs incurred to combine the operations of companies we acquire, such as transitional employee expenses and employee retention, redeployment or relocation expenses;
- impairment of goodwill or intangible assets, including acquired in-process research and development;
- amortization of intangible assets acquired;
- a reduction in the useful lives of intangible assets acquired;
- identification of or changes to assumed contingent liabilities, including, but not limited to, contingent purchase price consideration, income tax contingencies and other non-income tax contingencies, after our final determination of the amounts for these contingencies or the conclusion of the measurement period (generally up to one year from the acquisition date), whichever comes first;
- charges to our operating results to eliminate certain duplicative pre-acquisition activities, to restructure our operations or to reduce our cost structure;
- charges to our operating results resulting from expenses incurred to effect the acquisition; and
- changes to contingent consideration liabilities, including accretion and fair value adjustments.

A significant portion of these adjustments could be accounted for as expenses that will decrease our net income and earnings per share for the periods in which those costs are incurred. Such charges could cause a material adverse effect on our business, financial position and results of operations and could cause the market value of the common stock to decline.

The Affordable Care Act and certain new legislation and regulatory proposals may increase our costs of compliance and negatively impact our profitability over time.

In March 2010, President Barack Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, which we refer to collectively as “the Affordable Care Act.” The Affordable Care Act makes extensive changes to the delivery of health care in the U.S. We expect that the rebates, discounts, taxes and other costs resulting from the Affordable Care Act over time will have a negative effect on our expenses and profitability in the future. Furthermore, the Independent Payment Advisory Board created by the Affordable Care Act to reduce the per capita rate of growth in Medicare spending could potentially limit access to certain treatments or mandate price controls for our products. Moreover, expanded government investigative authority and increased disclosure obligations may increase the cost of compliance with new regulations and programs.

Congress has also proposed a number of legislative initiatives, including possible repeal of the Affordable Care Act. At this time, it remains unclear whether there will be any changes made to the Affordable Care Act, whether to certain provisions or its entirety. In addition, some details regarding the implementation of the Affordable Care Act are yet to be determined, and, at this time, the full effect that the Affordable Care Act would have on our business remains unclear.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, on August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. As a result of the failure of the Joint Select Committee to propose, and of Congress to enact, deficit reduction measures of at least $1.2 trillion for the years 2013 through 2021, the Budget Control Act provides for automatic cuts to be made to most federal government programs, which, with respect to Medicare, would include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. Pursuant to the American Taxpayer Relief Act of 2012, which was enacted by Congress on January 1, 2013, the imposition of these automatic cuts began April 1, 2013. In addition, the new law, among other things, reduces Medicare inpatient payment amounts to hospitals and increases the statute of limitations for recovering overpayments from three years to five years. The full impact on our business of this new law, assuming it is implemented, is uncertain. Nor is it clear whether other legislative changes will be adopted or how such changes would affect the demand for our products.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the pharmaceutical industry. In particular, California has enacted legislation that requires development of an electronic pedigree to track and trace each prescription drug at the saleable unit level through the distribution system. California’s electronic pedigree requirement is scheduled to take effect in January 2015. Compliance with California and future federal or state electronic pedigree requirements may increase our operational expenses and impose significant administrative burdens. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition and results of operations.

President Barack Obama also signed into law the Food and Drug Administration Safety and Innovation Act. The new law and related agreements make several significant changes to the FFDCA and FDA’s processes for reviewing marketing applications that could have a significant impact on the pharmaceutical industry, including, among other things, the following:

- reauthorizes the Prescription Drug User Fee Act, which increases the amount of associated user fees, and, for certain types of applications, increases the expected time frame for FDA review of new drug applications, or NDAs;

- permanently reauthorizes and makes some revisions to the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, which provide for pediatric exclusivity and mandated pediatric assessments for certain types of applications, respectively;

- revises certain standards and requirements for FDA inspections of manufacturing facilities and the importation of drug products from foreign countries;

- creates incentives for the development of certain antibiotic drug products;

- modifies the standards for accelerated approval of certain new medical treatments;

- expands the reporting requirements for potential and actual drug shortages;

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- requires the FDA to issue a report on, among other things, ensuring the safety of prescription drugs that have the potential for abuse;

- requires the FDA to hold a public meeting regarding the potential rescheduling of drug products containing hydrocodone, which was held in October 2012; and

- requires electronic submission of certain marketing applications following the issuance of final FDA regulations.

The full impact on our business of the new laws is uncertain; however, we anticipate that it will have an adverse effect on our results of operations.

Additionally, we encounter similar regulatory and legislative issues in most other countries. In the European Union, or EU, and some other international markets, the government provides health care at low cost to consumers and regulates pharmaceutical prices, patient eligibility or reimbursement levels to control costs for the government-sponsored health care system. This international system of price regulations may lead to inconsistent prices.

If significant additional reforms are made to the U.S. health care system, or to the health care systems of other markets in which we operate, those reforms 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.

Global macroeconomic conditions may negatively affect us and may magnify certain risks that affect our business.

Our business is sensitive to general economic conditions, both inside and outside the U.S. Slower global economic growth, credit market crises, high levels of unemployment, reduced levels of capital expenditures, government deficit reduction, sequestration and other austerity measures and other challenges affecting the global economy adversely affect us and our distributors, customers and suppliers. It is uncertain how long these effects will last, or whether economic and financial trends will worsen or improve. Such uncertain economic times may have a material adverse effect on our revenues, results of operations, financial condition and, if circumstances worsen, our ability to raise capital at reasonable rates. If slower growth in the global economy or in any of the markets we serve continues for a significant period, if there is significant deterioration in the global economy or such markets or if improvements in the global economy don’t benefit the markets we serve, our business and financial statements could be adversely affected.

Additionally, as a result of the current or a future global economic downturn, our third-party payers may delay or be unable to satisfy their reimbursement obligations. Sales of our principal products are dependent, in part, on the availability and extent of reimbursement from third-party payers, including government programs such as Medicare and Medicaid and private payer healthcare and insurance programs. A reduction in the availability or extent of reimbursement from government and/or private payer healthcare programs could have a material adverse effect on the sales of our products, our business and results of operations.

Current economic conditions may adversely affect the ability of our distributors, customers, suppliers and service providers to obtain the liquidity required to pay for our products, or otherwise to buy necessary inventory or raw materials, and to perform their obligations under agreements with us, which could disrupt our operations, and could negatively impact our business and cash flow. Although we make efforts to monitor these third parties’ financial condition and their liquidity, our ability to do so is limited, and some of them may become unable to pay their bills in a timely manner, or may even become insolvent, which could negatively impact our business and results of operations. These risks may be elevated with respect to our interactions with third parties with substantial operations in countries where current economic conditions are the most severe, particularly where such third parties are themselves exposed to sovereign risk from business interactions directly with fiscally-challenged government payers.

At the same time, significant changes and volatility in the financial markets, in the consumer and business environment, in the competitive landscape and in the global political and security landscape make it increasingly difficult for us to predict our revenues and earnings into the future. As a result, any revenue or earnings guidance or outlook which we have given or might give may be overtaken by events, or may otherwise turn out to be inaccurate. Though we endeavor to give reasonable estimates of future revenues and earnings at the time we give such guidance, based on then-current conditions, there is a significant risk that such guidance or outlook will turn out to be, or to have been, incorrect.

Significant balances of intangible assets, including goodwill, are subject to impairment testing and may result in impairment charges, which may materially and adversely affect our results of operations and financial condition.

A significant amount of our total assets is related to goodwill and intangible assets. As of June 30, 2014 the value of our goodwill and intangible assets net of accumulated amortization was $39.3 million. Goodwill and other intangible assets are tested for impairment annually when events occur or circumstances change that could potentially reduce the fair value of the reporting unit or intangible asset. Impairment testing compares the fair value of the reporting unit or intangible asset to its carrying amount. For example, for the year ended December 31, 2012 we had an impairment charge of $2.1 million primarily related to equipment for a production project that was suspended. Any future goodwill or other intangible asset impairment, if any, would be recorded in operating income and could have a material adverse effect on our results of operations and financial condition.

Our outstanding loan agreements contain restrictive covenants that may limit our operating flexibility.

Our loan agreements are collateralized by substantially all of our presently existing and subsequently acquired personal property assets, and subject us to certain affirmative and negative covenants, including limitations on our ability to transfer or dispose of assets, merge with or acquire other companies, make investments, pay dividends, incur additional indebtedness and liens and conduct transactions with affiliates. We are also subject to certain covenants that require us to maintain certain financial ratios and are required under certain conditions to make mandatory prepayments of outstanding principal. As a result of these covenants and ratios, we have certain limitations on the manner in which we can conduct our business, and we may be restricted from engaging in favorable business activities or financing future operations or capital needs until our current debt obligations are paid in full or we obtain the consent of our lenders, which we may not be able to obtain. We may not be able to generate sufficient cash flow or revenue to meet the financial covenants or pay the principal and interest on our debt. In addition, upon the occurrence of an event of default, our lenders, among other things, can declare all indebtedness due and payable immediately, which would adversely impact our liquidity and reduce the availability of our cash flows to fund working capital needs, capital expenditures and other general corporate purposes. An event of default includes our failure to pay any amount due and payable under the loan agreements, the occurrence of a material adverse change in our business as defined in the loan agreements, our breach of any covenant in the loan agreements, subject to a grace period in some cases, or an involuntary insolvency proceeding. Additionally, a lender could exercise its lien on substantially all of our assets and our future working capital, borrowings or equity financing may not be available to repay or refinance any such debt.

As a public company, we are obligated to develop and maintain adequate internal controls and be able, on an annual basis, to provide an assertion as to the effectiveness of such controls. Failure to maintain adequate internal controls or to implement new or improved controls 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.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. We are in the very early stages of the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation

needed to comply with Section 404 of the Sarbanes-Oxley Act of 2002. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective.

If we are unable to assert that our internal control over financial reporting is effective, we could lose investor confidence in the accuracy and completeness of our financial reports, which would cause the price of our common stock to decline, and we may be subject to investigation or sanctions by the Securities and Exchange Commission, or SEC.

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We are required, pursuant to Section 404 of the Sarbanes-Oxley Act to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting as of the end of our fiscal year 2014. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting.

We are required to disclose changes made in our internal control and procedures on a quarterly basis. However, our independent registered public accounting firm will not be required to report on the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act until the later of the year following our first annual report required to be filed with the SEC, or the date we are no longer an “emerging growth company” as defined in the JOBS Act if we take advantage of the exemptions contained in the JOBS Act. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. Our remediation efforts may not enable us to avoid a material weakness in the future.

Additionally, to comply with the requirements of being a public company, we may need to undertake various actions, such as implementing new internal controls and procedures and hiring accounting or internal audit staff, which may adversely affect our operating results and financial condition.

There are inherent uncertainties involved in estimates, judgments and assumptions used in the preparation of financial statements in accordance with GAAP. Any future changes in estimates, judgments and assumptions used or necessary revisions to prior estimates, judgments or assumptions or changes in accounting standards could lead to a restatement or revision to previously consolidated financial statements, which 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 preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, as discussed in greater detail in the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our operating results may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our operating results to fall below the expectations of securities analysts and investors, resulting in a decline in our stock price. Significant assumptions and estimates used in preparing our consolidated financial statements include those related to revenue recognition, provision for wholesaler chargebacks, accruals for product returns, valuation of inventory, impairment of intangibles and long-lived assets, accounting for income taxes and share-based compensation. Furthermore, although we have recorded reserves for litigation related contingencies based on estimates of probable future costs, such litigation related contingencies could result in substantial further costs. Also, any new or revised accounting standards may require adjustments to previously issued financial statements. Any such changes could result in corresponding changes to the amounts of liabilities, revenues, expenses and income. Any such changes 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.

Changes in financial accounting standards or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and varying interpretations of accounting pronouncements have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our business and financial results.

Changes in income tax laws, tax rulings and other factors may have a significantly adverse impact on our effective tax rate and tax expense, which 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.

Potential changes to income tax laws in the U.S. include measures which would defer the deduction of interest expense related to deferred income; determine the foreign tax credit on a pooling basis; tax currently excess returns associated with transfers of intangibles offshore; and limit earnings stripping by expatriated entities. In addition, proposals were made to encourage manufacturing in the U.S., including reduced rates of tax and increased deductions related to manufacturing. We cannot determine whether these proposals will be modified or enacted, whether other proposals unknown at this time will be made or the extent to which the corporate tax rate might be reduced and ameliorate the adverse impact of some of these proposals. If enacted, and depending on its precise terms, such legislation could materially increase our overall effective income tax rate and income tax expense. This 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.

In addition to income taxes in the U.S. we are subject to income taxes in many foreign jurisdictions. Significant judgment is required in determining our worldwide provision for income taxes. In the ordinary course of business, there are many transactions and calculations where the ultimate tax determination is uncertain. The final determination of any tax audits or related litigation could be materially different from our historical income tax provisions and accruals.

Additionally, increases in our effective tax rate as a result of a change in the mix of earnings in countries with differing statutory tax rates, changes in our overall profitability, changes in the valuation of deferred tax assets and liabilities, the results of audits and the examination of previously filed tax returns by various taxing authorities and continuing assessments of our tax exposures could impact our tax liabilities and affect our income tax expense, which 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.

Counterfeit versions of our products could harm our patients and reputation.

Our industry has been increasingly challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. Counterfeit products are frequently unsafe or ineffective, and can be potentially life-threatening. To distributors and patients, counterfeit products may be visually indistinguishable from the authentic version. Reports of adverse reactions to counterfeit drugs or increased levels of counterfeiting could materially affect patient confidence in the authentic product, and harm the business of companies such as ours. Additionally, it is possible that adverse events caused by unsafe counterfeit products would mistakenly be attributed to the authentic product. If a product of ours was the subject of counterfeits, we could incur substantial reputational and financial harm in the longer term.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed clinical trials 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 results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of our product candidates may be delayed.

In addition, we rely on complex information technology systems, including Internet-based systems, to support our supply chain processes as well as internal and external communications. The size and complexity of our systems make them potentially vulnerable to breakdown or interruption, whether due to computer viruses or other causes that may result in the loss of key information or the impairment of production and other supply chain processes. Such disruptions and breaches of security could adversely affect our business.

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We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

The facilities we use for our headquarters, laboratory and research and development activities are located in earthquake-prone areas of California. A significant percentage of the facilities we use for our manufacturing, packaging, warehousing, distribution and administration offices are also located in these areas. Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our facilities, that damaged critical infrastructure, such as our manufacturing facilities, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans.

Risks Relating to Regulatory Matters

The FDA approval process is time-consuming and complicated, and we may not obtain the FDA approval required for a product within the timeline we desire, or at all. Additionally, we may lose FDA approval and/or our products may become subject to foreign regulations.

The development, testing, manufacturing, marketing and sale of generic and proprietary pharmaceutical products and biological products are subject to extensive federal, state and local regulation in the U.S. and other countries. Satisfaction of all regulatory requirements, which typically takes years for drugs that have to be approved in ANDAs, NDAs, biological license applications, or BLAs, or biosimilar applications is dependent upon the type, complexity and novelty of the product candidate and requires the expenditure of substantial resources for research (including qualification of suppliers and their supplied materials), development, in vitro and in vivo (including nonclinical and clinical trials) studies, manufacturing process development and commercial scale up. All of our products are subject to compliance with the FFDCA and/or the Public Health Service Act, or PHSA, and with the FDA's implementing regulations. Failure to adhere to applicable statutory or regulatory requirements by us or our business partners would have a material adverse effect on our operations and financial condition. In addition, in the event we are successful in developing product candidates for distribution and sale in other countries, we would become subject to regulation in such countries. Such foreign regulations and product approval requirements are expected to be time consuming and expensive as well.

We may encounter delays or agency rejections during any stage of the regulatory review and approval process based upon a variety of factors, including without limitation the failure to provide clinical data demonstrating compliance with the FDA's requirements for safety, efficacy and quality. Those requirements may become more stringent prior to submission of our applications for approval or during the review of our applications due to changes in the law or changes in FDA policy or the adoption of new regulations. After submission of an application, the FDA may refuse to file the application, deny approval of the application or require additional testing or data. The FDA can convene an Advisory Committee to assist the FDA in examining specific issues related to the application. In February 2014, the FDA held a joint meeting of its Nonprescription Drugs Advisory Committee and its Pulmonary Allergy Drugs Advisory Committee, which we refer to as the Committee, to discuss the NDA for Primatene Mist HFA. The Committee voted 14 to 10 that the data in the NDA supported efficacy, but voted 17 to 7 that safety had not been established for the intended over-the-counter use. The Committee also voted 18 to 6 that the product did not have a favorable risk-benefit profile for the intended over-the-counter use, and individual Committee members provided recommendations for resolving their concerns. Although the FDA is not required to follow the recommendations of its advisory committees, it usually does. On May 22, 2014, we received a CRL from the FDA, which requires additional

non-clinical information, label revisions and follow-up studies (label comprehension, behavioral and actual use) to assess consumers' ability to use the device correctly to support approval of the product in the over-the-counter setting. Additionally, in the CRL for Primatene Mist HFA, the FDA noted current Good Manufacturing Practices, or cGMP, deficiencies in a recent inspection of our API supplier's manufacturing facility, which produces epinephrine, and indicated that our NDA could not be approved until these issues were resolved. Subsequent to the receipt of the CRL, the supplier notified us that the cGMP deficiencies were satisfactorily resolved. Accordingly, we believe this condition for approval has been satisfied. We intend to generate the remaining data required by the CRL and submit an NDA Amendment that we believe will address the FDA's concerns. However, there can be no guarantee that any amendment to our NDA will result in timely approval of the product or approval at all.

Under various user fee enactments, the FDA has committed to timelines for its review of NDAs, ANDAs, BLAs and biosimilar applications. However, the FDA's timelines described in its guidance on these statutes are flexible and subject to changes based on workload and other potential review issues that may delay the FDA's review of an application. Further, the terms of approval of any applications may be more restrictive than our expectations and could affect the marketability of our products.

The FDA also has the authority to revoke or suspend approvals of previously approved products for cause, to debar companies and individuals from participating in the approval process for ANDAs, to request recalls of allegedly violative products, to seize allegedly violative products, to obtain injunctions that may, among other things, close manufacturing plants that are not operating in conformity with cGMP and stop shipments of potentially violative products and to prosecute companies and individuals for violations of the FFDCA. In the event that the FDA takes any such action relating to our products or product candidates, such actions would have a material adverse effect on our operations and financial condition.

Clinical failure can occur at any stage of clinical development. The results of earlier clinical trials are not necessarily predictive of future results and any product candidate we advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Clinical failure can occur at any stage of our clinical development. Clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to 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. Success in preclinical studies and early clinical trials does not ensure that subsequent clinical trials will generate the same or similar results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in Phase 3 clinical trials, even after seeing promising results in earlier clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well-advanced. Further, clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts. If any of our product candidates are found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for them and our business would be harmed.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Our clinical trials may not demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If we are unable to bring any of our current or future product candidates to market, or to acquire any marketed, previously approved products, our ability to create long-term stockholder value will be limited.

If clinical studies for our product candidates are unsuccessful or significantly delayed, we will be unable to meet our anticipated development and commercialization timelines, which would have an adverse impact our business.

Some of our new drug candidates must be approved in NDAs based on clinical studies demonstrating safety and/or effectiveness. For these types of studies, we rely on our investigational teams, who mainly are medical experts working in multicenter hospitals, to execute our study protocols with our product candidates. As a result, we have less control over our development program than if we were to perform the studies entirely on our own. Third parties may not perform their responsibilities according to our anticipated schedule. Delays in our development programs could significantly increase our product development costs and delay product commercialization.

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The commencement of clinical trials on our product candidates may be delayed for several reasons, including but not limited to delays in demonstrating sufficient pre-clinical safety required to obtain regulatory clearance to commence a clinical trial, reaching agreements on acceptable terms with prospective contract research organizations, clinical trial sites and licensees, manufacturing and quality assurance release of a sufficient supply of a product candidate for use in our clinical trials, delays in recruiting sufficient subjects for a clinical trial and/or obtaining institutional review board approval to conduct a clinical trial at a prospective clinical site. Once a clinical trial has begun, it may be delayed, suspended or terminated by us or by regulatory authorities for a variety of reasons, including without limitation ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials, a determination by us or regulatory authorities that continuing a trial presents an unreasonable health risk to participants, failure to conduct clinical trials in accordance with regulatory requirements, lower than anticipated recruitment or retention rate of patients in clinical trials, inspection of the clinical trial operations or trial sites by regulatory authorities, the imposition of a clinical hold by the FDA, lack of adequate funding to continue clinical trials and/or negative or unanticipated results of clinical trials.

Patient enrollment, a significant factor in the time required to complete a clinical study, is affected by many factors, including the size and nature of the study subject population, the proximity of patients to clinical sites, the eligibility criteria for the study, the design of the clinical study, competing clinical studies and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to available alternatives, including without limitation therapies being investigated by other companies. Further, completion of a clinical study and/or the results of a clinical study may be adversely affected by failure to retain subjects who enroll in a study but withdraw due to, among other things, adverse side effects, lack of efficacy, improvement in condition before treatment has been completed or for personal issues or who fail to return for or complete post-treatment follow-up.

Changes in governmental regulations and guidance relating to clinical studies may occur and we may need to amend study protocols to reflect these changes. Protocol amendments may require us to resubmit protocols to institutional review boards for reexamination or renegotiate terms with contract research organizations and study sites and investigators, all of which may adversely impact the costs or timing of or our ability to successfully complete a trial.

Clinical trials required by the FDA for approval of our products may not produce the results we need to move forward in product development or to submit or obtain approval of an NDA. Success in pre-clinical testing and early phase clinical trials does not assure that late phase clinical trials will be successful. Even if the results of any future Phase 3 clinical trials are positive, we may have to commit substantial time and additional resources to conduct further pre-clinical and clinical studies before we can submit NDAs or obtain FDA approval for our product candidates.

Clinical trials are expensive and at times difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Further, if participating subjects or patients in clinical studies suffer drug-related adverse reactions during the course of such trials, or if we or the FDA believes that participating patients are being exposed to unacceptable health risks, we may suspend the clinical trials. Failure can occur at any stage of the trials, and we could encounter problems that would cause us to abandon clinical trials and/or require additional clinical studies relating to a product candidate.

Even if our clinical trials and laboratory testing are completed as planned, their results may fail to provide support for approval of our products or for label claims that will make our products commercially viable.

Positive results in nonclinical testing and early phase clinical studies do not ensure that late phase clinical studies will be successful or that our product candidates will be approved by the FDA. To obtain FDA approval of our proprietary product candidates, we must demonstrate through nonclinical testing and clinical studies that each product is safe and effective for each proposed indication. Further, clinical study results frequently are susceptible to varying interpretations. Medical professionals, investors and/or regulatory authorities may analyze or weigh study data

differently than we do. In addition, determining the value of clinical data typically requires application of assumptions and extrapolations to raw data. Alternative methodologies may lead to differing conclusions, including with respect to the safety or efficacy of our product candidates.

In addition, if we license to third parties rights to develop our product candidates in other geographic areas or for other indications, we may have limited control over nonclinical testing or clinical studies that may be conducted by such third-party licensees in those territories or for those indications. If data from third-party testing identifies a safety or efficacy concern, such data could adversely affect our or another licensee's development of such product.

There is significant risk that our products could fail to show anticipated results in nonclinical testing and/or clinical studies and, as a result, we may elect to discontinue the development of a product for a particular indication or altogether. A failure to obtain requisite regulatory approvals or to obtain approvals of the scope requested may delay or preclude us from marketing our products or limit the commercial use of the products, and would have a material adverse effect on our business, financial condition and results of operations.

The novel use of HFA for any of our product candidates, or any of our other product candidates requiring novel particle engineering, may not receive regulatory approval, and without regulatory approval we will not be able to market our product candidates.

We are engaging in particle engineering for certain product candidates, including and especially the use of HFA for our Primatene Mist HFA product candidate. With respect to Primatene Mist HFA, we have chosen to develop a formulation of the product candidate that will use HFAs as a propellant because of an FDA-mandated phase-out of drugs utilizing CFCs as propellants. Although HFAs have been used in other settings, using HFAs as a propellant in an epinephrine inhalation product is a novel use, and there is no guarantee that we will obtain regulatory approval or, upon commercialization, market acceptance of this product. In addition to Primatene Mist HFA, we are similarly engaging in particle engineering for additional product candidates and, similarly, there is no guarantee that we will obtain regulatory approval or, upon commercialization, market acceptance of these products.

The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulations by the FDA in the U.S. and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market our product candidates in the U.S. until we receive approval of an NDA from the FDA. NDA approvals may require extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. NDAs must include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. If we submit an NDA to the FDA, the FDA must decide whether to accept or reject the submission for filing. Any submissions may not be accepted for filing and review by the FDA. Even if a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require additional expensive and time-consuming post-approval clinical trials or reporting as conditions of approval. Regulators of other countries and jurisdictions have their own procedures for approval of product candidates with which we must comply prior to marketing in those countries or jurisdictions. Obtaining regulatory approval for marketing of a product candidate in one country does not necessarily ensure that we will be able to obtain regulatory approval in any other country.

In addition, delays in approvals or rejections of marketing applications in the U.S. or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding our product candidates or other products. Also, regulatory approval for any of our product candidates may be withdrawn.

We also have plans to develop synthetic APIs. Our ongoing trials and studies may not be successful or regulators may not agree with our conclusions regarding the preclinical studies and clinical trials we have conducted to date or approve the use of such synthetic APIs.

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If we are unable to obtain approval from the FDA or other regulatory agencies for our product candidates or synthetic APIs, we will not be able to market such product candidates and our ability to achieve profitability may be materially impaired.

The commercial success of our NDA product candidates will depend in significant measure on the label claims that the FDA approves for such products.

The scientific foundation of our NDA products will be based on our various proprietary technologies and the commercial success of these product candidates will depend in significant measure upon our ability to obtain FDA approval of labeling describing such products' expected features or benefits. Failure to achieve FDA approval of product labeling containing adequate information on features or benefits will prevent or substantially limit our advertising and promotion of such features in order to differentiate our proprietary technologies from those products that already exist in the market. This failure would have a material adverse impact on our business.

Our ANDA products are also subject to FDA approval of their labeling.

Even if we are able to obtain regulatory approval for our generic products, state pharmacy boards or state agencies may conclude that our products are not substitutable at the pharmacy level for the reference listed drug. If our generic products are not substitutable at the pharmacy level for their reference listed drugs, this could materially reduce sales of our products and our business would suffer.

Although the FDA may determine that a generic product is therapeutically equivalent to a brand product and indicate this therapeutic equivalence by providing it with an "A" rating in the FDA's Orange Book, this designation is not binding on state pharmacy boards or state agencies. As a result, in states that do not deem our product candidates substitutable at the pharmacy level, physicians may be required to specifically prescribe our product or a generic product alternative in order for our product to be dispensed. Should this occur with respect to one of our generic product candidates, it could materially reduce sales in those states, which would substantially harm our business.

Our investments in biosimilar products may not result in products that are approved by the FDA or other foreign regulatory authorities and, even if approved by such authorities, may not result in commercially successful products.

We plan to build on our existing platforms to produce biosimilar products in the future. In 2010, Congress amended the PHSA to create an abbreviated approval pathway for follow-on biologics. This approval pathway is available for "biosimilar" products, which are products that are highly similar to previously approved biologics notwithstanding minor differences in inactive components. The process for bringing a biosimilar product to market is uncertain and may be drawn out for an extended period of time. The FDA has not yet promulgated regulations governing this process and no biosimilar application has yet been approved. Approval of biosimilar applications may be delayed by exclusivity on the BLA for the reference product for up to twelve years. Biosimilar applicants are also subjected to a patent resolution process that will require biosimilar applicants to share the contents of their application and information concerning its manufacturing processes with counsel for the company holding the BLA for the reference drug and to engage in a patent litigation process that could delay or prevent the commercial launch of a product for many years.

Biosimilar products are not presumed to be substitutable for the reference drug under the Biologics Price Competition and Innovation Act, or BPCIA. Biosimilar applicants must seek a separate FDA determination that they are "interchangeable" with the reference drug, meaning that they can be expected to produce the same clinical result in any given patient without an increase in risk due to switching from the brand product. The statutory standards for determining biosimilarity and interchangeability are broad and uncertain, and the FDA has broad discretion to determine the nature and extent of product characterization, nonclinical testing and clinical testing on a product-by-product basis.

Products approved based on biosimilarity without an FDA determination of interchangeability may not be substitutable at the retail pharmacy level. Some states have passed laws limiting pharmacy substitution to biosimilar products that the FDA has determined to be interchangeable, as well as restrictions on the substitution of interchangeable biosimilar products. These restrictions include, among other things, requirements for informing the patient and the prescribing physician of the substitution or proposed substitution, authority for the prescribing physician and the patient to preclude substitution and recordkeeping requirements. There is no certainty that other states will not impose similar restrictions or that states will not impose further restrictions or preclude substitution of interchangeable biosimilar products entirely.

Our competitive advantage in this area will depend on our success in demonstrating to the FDA that platform technology provides a level of scientific assurance that facilitates determinations of interchangeability, reduces the need for expensive clinical or other testing and raises the scientific quality requirements for our competitors to demonstrate that their products are highly similar to a brand product. Our ability to succeed will depend in part on our ability to invest in new programs and develop data in a timeframe that enables the FDA to consider our approach as the FDA begins to implement the new law. BLA holders will develop strategies and precedents for delaying or impeding approvals of biosimilar products and determinations of interchangeability. For example, the lengthy 12-year exclusivity protection provides the BLA holder for the reference drug with an opportunity to develop and replace its original product with a modified product that may avoid a determination of interchangeability and that may qualify for an additional 12-year marketing exclusivity period, reducing the potential opportunity for substitution at the retail pharmacy level for interchangeable biosimilars. As brand and biosimilar companies gain greater understanding of and experience with the new regulatory pathway, we expect to see new and unexpected company strategies, FDA decisions and court decisions that will pose unexpected challenges that will prevent, delay or make more difficult biosimilar approvals. As an example, there is a currently pending Citizen Petition filed with the FDA that argues that approving a biosimilar that relies on a reference product approved under a BLA submitted prior to passage of the BPCIA would constitute a taking under the Fifth Amendment to the U.S. Constitution that requires just compensation. The Citizen Petition requests that the FDA not accept for filing, file, approve, discuss or otherwise take any action with regard to any investigational new drug application or BLA for a product for which the reference product BLA was submitted prior to passage of the BPCIA. Should this petition be granted, there would be far fewer approved biologics that could serve as reference products for biosimilar applications, which could have a significant adverse impact on our business.

In addition, the BPCIA was passed as part of the Affordable Care Act and there have been ongoing legislative proposals to repeal the Affordable Care Act. If the Affordable Care Act is amended or is repealed with respect to the biosimilar approval pathway, our opportunity to develop biosimilars (including interchangeable biologics) could be materially impaired and our business could be materially and adversely affected.

Some of our products are used with drug delivery or companion diagnostic devices which have their own regulatory, manufacturing, reimbursement and other risks.

Some of our products or product candidates may be used in combination with a drug delivery device, such as an injector or other delivery system. Our product candidates intended for use with such devices, or expanded indications that we may seek for our products used with such devices, may not be approved or may be substantially delayed in receiving approval if the devices do not gain and/or maintain their own regulatory approvals or clearances. Where approval of the drug product and device is sought under a single application, the increased complexity of the review process may delay approval. In addition, some of these drug delivery devices are provided by single source unaffiliated third-party companies. We are dependent on the sustained cooperation and effort of those third-party companies both to supply the devices and, in some cases, to conduct the studies required for approval or other regulatory clearance of the devices. We are also dependent on those third-party companies continuing to maintain such approvals or clearances once they have been received. Failure of third-party companies to supply the devices, to successfully complete studies on the devices in a timely manner, or to obtain or maintain required approvals or

clearances of the devices could result in increased development costs, delays in or failure to obtain regulatory approval and delays in product candidates reaching the market or in gaining approval or clearance for expanded labels for new indications. We filed a Field Alert Report for enoxaparin in June 2013, as required by the FDA for certain quality issues with safety implications, because the product did not meet functionality criteria. The needle-shielding component was breaking during shipping, preventing correct administration of the medication. While the specific issues related to this Field Alert Report were resolved, we may experience similar issues in the future. In addition, loss of regulatory approval or clearance of a device that is used with our product may result in the removal of our product from the market.

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The drug delivery devices used with our products are also subject to many of the same reimbursement risks and challenges to which our products are subject. A reduction in the availability of, or the coverage and/or reimbursement for, drug delivery devices used with our products could have a material adverse effect on our product sales, business and results of operations.

If pharmaceutical companies are successful in limiting the use of generics through their legislative, regulatory and/or other efforts, our sales of generic products may suffer.

Many pharmaceutical companies producing proprietary drugs have increasingly used state and federal legislative and regulatory means to delay, impede and/or prevent generic competition. These efforts have included but are not limited to the following:

- making changes to the formulation of their product and arguing that potential generic competitors must demonstrate bioequivalence and/or comparable abuse-resistance to the reformulated brand product;

- pursuing new patents for existing products which may be granted immediately prior to the expiration of earlier patents, which could extend patent protection for additional years or otherwise delay the launch of generics;

- selling the brand product as an authorized generic, either by the brand company directly, through an affiliate or by a marketing partner;

- using the FDA's Citizen Petition process to request amendments to FDA standards or otherwise delay generic drug approvals;

- challenging FDA denials of Citizen Petitions in court and seeking injunctive relief to reverse approval of generic drug applications;

- seeking changes to standards in the U.S. Pharmacopeia/National Formulary, which are compendial drug standards that are recognized by industry and, in some instances, are enforceable under the FFDCA;

- attempting to use the legislative and regulatory process to have drugs reclassified or rescheduled by the DEA;

- using the legislative and regulatory process to set standards and requirements for abuse deterrent formulations that are patented or that will otherwise impede or prevent generic competition;

- seeking special patent-term extensions through amendments to non-related federal legislation;

- engaging in initiatives to enact state legislation that would restrict the substitution of certain generic drugs, including products that we are developing;

- entering into agreements with pharmacy benefit management companies that block the dispensing of generic products;

- seeking patents on methods of manufacturing certain API;

- settling patent lawsuits with generic companies in a manner that leaves the patent as an obstacle for approval of other companies' generic drugs;

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settling patent litigation with generic companies in a manner that avoids forfeiture of or otherwise protects or extends the exclusivity period;

•providing medical education or other information to physicians, third-party payers and federal and state regulators that takes the position that certain generic products are inappropriate for approval or for substitution after approval;

•seeking state law restrictions on the substitution of generic and biosimilar products at the pharmacy level without the instruction or permission of a physician; and

•seeking federal or state regulatory restrictions on the use of the same non-proprietary name as the reference brand product for a biosimilar or interchangeable biologic.

If pharmaceutical companies or other third parties are successful in limiting the use of generic products through these or other means, our sales of generic products may decline. If we experience a material decline in generic product sales, our results of operations, financial condition and cash flows will suffer.

In the event that we are successful in bringing any products to market, our revenues may be adversely affected if we fail to obtain insurance coverage or adequate reimbursement for our products from third-party payers and administrators.

Our ability to successfully commercialize our products may depend in part on the availability of reimbursement for and insurance coverage of our prescription products from government health administration authorities, private health insurers and other third-party payers and administrators, including Medicaid and Medicare. Third-party payers and administrators, including state Medicaid programs and Medicare, have been recently challenging the prices charged for pharmaceutical products. Government and other third-party payers increasingly are limiting both coverage and the level of reimbursement for new drugs. Third-party insurance coverage may not be available to patients for some of our products candidates. The continuing efforts of government and third-party payers to contain or reduce the costs of health care may limit our commercial opportunity. If government and other third-party payers do not provide adequate coverage and reimbursement for certain of our products, health care providers may not prescribe them or patients may ask their health care providers to prescribe competing products with more favorable reimbursement.

Managed care organizations and other private insurers frequently adopt their own payment or reimbursement reductions. Consolidation among managed care organizations has increased the negotiating power of these entities. Private third-party payers, as well as governments, increasingly employ formularies to control costs by negotiating discounted prices in exchange for formulary inclusion. While these approaches generally favor generic products over brands, generic competition is stronger. Our existing products and our product candidates include proprietary products and generic products. Failure to obtain timely or adequate pricing or formulary placement for our products or obtaining such pricing or placement at unfavorable pricing could adversely impact revenue. In addition to formulary tier co-pay differentials, private health insurance companies and self-insured employers have been raising co-payments required from beneficiaries, particularly for proprietary pharmaceuticals and biotechnology products. Private health insurance companies also are increasingly imposing utilization management tools, such as requiring prior authorization for a proprietary product if a generic product is available or requiring the patient to first fail on one or more generic products before permitting access to a proprietary medicine. We do not currently have any managed care organization agreements and do not intend to have managed care organization agreements in the future.

We must manufacture our product at our facilities in conformity with cGMP regulations; failure to maintain compliance with cGMP regulations may prevent or delay the manufacture or marketing of our products or product candidates and may prevent us from gaining approval of our products.

All of our products and product candidates for use in clinical studies must be manufactured, packaged, labeled and stored in accordance with cGMP. For our approved products, modifications, enhancements, or changes in

manufacturing processes and sites may require supplemental FDA approval, which may be subject to a lengthy application process or which we may be unable to obtain.

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All facilities of Amphastar and our subsidiaries are periodically subject to inspection by the FDA and other governmental entities, and operations at these facilities could be interrupted or halted if the FDA or another governmental entity deems such inspections as unsatisfactory. In addition, our secondary heparin supplier in China has yet to be inspected by the FDA. Products manufactured in our facilities must be made in a manner consistent with cGMP or similar standards in each territory in which we manufacture. Compliance with such standards requires substantial expenditures of time, money and effort in such areas as production and quality control to ensure full technical compliance. Failure to comply with cGMP or with other state or federal requirements may result in unanticipated compliance expenditures, total or partial suspension of production or distribution, suspension of review of applications submitted for approval of our product candidates, termination of ongoing research, disqualification of data derived from studies on our products and/or enforcement actions such as recall or seizure of products, injunctions, civil penalties and criminal prosecutions of the company and company officials. Any suspension of production or distribution would require us to engage contract manufacturing organizations to manufacture our products or to accept a hiatus in marketing our products. Any contract manufacturing organization we engage will require time to learn our methods of production and to scale up to full production of our products. Any delays caused by the transfer of manufacturing to a contract manufacturing organization may have a material adverse effect on our results of operations. Additionally, any contract manufacturing organization that we engage will be subject to the same cGMP regulations as us, and any failure on their part to comply with FDA or other governmental regulations will result in similar consequences.

Our operations are subject to environmental, health and safety and other laws and regulations, with which compliance is costly and which exposes us to penalties for non-compliance.

Our business, products and product candidates are subject to federal, state and local laws and regulations relating to the protection of the environment, natural resources and worker health and safety and the use, management, storage and disposal of hazardous substances, waste and other regulated materials. Because we own and operate real property, various environmental laws also may impose liability on us for the costs of cleaning up and responding to hazardous substances that may have been released on our property, including releases unknown to us. These environmental laws and regulations also could require us to pay for environmental remediation and response costs at third-party locations where we dispose of or recycle hazardous substances. The costs of complying with these various environmental requirements, as they now exist or as may be altered in the future, could adversely affect our financial condition and results of operations. For example, as a result of environmental concerns about the use of CFCs, the FDA issued a final rule on January 16, 2009 that required the phase-out of the CFC version of our Primatene Mist product by December 31, 2011. This phase out caused us to halt sales of the CFC version of our Primatene Mist product subsequent to December 31, 2011 and write off our inventory for the product, which had an adverse effect on our financial results.

We also must comply with data protection and data privacy requirements. Compliance with these laws, rules and regulations regarding privacy, security and protection of employee data could result in higher compliance and technology costs for us, as well as significant fines, penalties and damage to our global reputation and our brand as a result of non-compliance.

Our products may be subject to federal and state laws and certain initiatives relating to cost control, which may decrease our profitability.

In the U.S., we expect there may be federal and state proposals for cost controls. We expect that increasing emphasis on managed care in the U.S. will continue to put pressure on the pricing of pharmaceutical products. In addition, we are required to pay rebates to states, which are generally calculated based on the prices for our products that are paid by state Medicaid programs. Cost control initiatives could decrease the price that we charge, and increase the rebate amounts that we must provide, for any of our products in the future. Further, cost control initiatives could impair our

ability to commercialize our products and our ability to earn significant revenues from commercialization. In the U.S., all of our pharmaceutical products are subject to increasing pricing pressures. Such pressures have increased as a result of the Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, due to the enhanced purchasing power of the private sector plans that negotiate on behalf of Medicare beneficiaries. To date, we do not believe that federal and state cost control initiatives have had a direct impact on the pricing of our products, but they could have such an impact in the future. Similarly, rebate obligations have been relatively stable, but if such obligations increase, our revenue could be adversely affected. In addition, if the MMA or the Affordable Care Act were amended to impose direct governmental price controls and access restrictions, it would have a significant adverse impact on our business. Furthermore, managed care organizations, as well as Medicaid and other government agencies, continue to seek price discounts. Some states have implemented, and other states are considering, price controls or patient access constraints under the Medicaid program, and some states are considering price-control regimes that would affect rebate levels and apply to broader segments of their populations that are not Medicaid-eligible. Further, there continue to be legislative proposals to amend U.S. laws to allow the importation into the U.S. of prescription drugs, which can be sold at prices that are regulated by the governments of various foreign countries. In addition to well-documented safety concerns, such as the increased risk of counterfeit products entering the supply chain, such importation could impact pharmaceutical prices in the U.S.

Some of our products are marketed without FDA approval and may be subject to enforcement actions by the FDA.

A number of our prescription products are marketed without FDA approval. These products, like many other unapproved prescription drugs on the market, contain active ingredients that were first marketed prior to the enactment of the FFDCA. The FDA has assessed these products in a program known as the “Prescription Drug Wrap-Up” and has stated that these drugs cannot be lawfully marketed unless they comply with certain “grandfather” exceptions to the definition of “new drug” in the FFDCA. These exceptions have been strictly construed by FDA and by the courts, and the FDA has stated that it is unlikely that any of the unapproved prescription drugs on the market, including certain of our drugs, qualify for the exceptions. At any time, the FDA may require that some or all of our unapproved prescription drugs be approved and may direct that we recall these products and/or cease marketing the products until they are approved. The FDA may also take enforcement actions based on our marketing of these unapproved products, including but not limited to the issuance of an untitled letter or a warning letter, and a judicial action seeking injunction, product seizure and civil or criminal penalties. While the FDA has not undertaken any such enforcement actions against our unapproved drugs, the enforcement posture could change at any time and our ability to market such drugs would terminate with little or no notice. Moreover, our competitors may market FDA approved prescription products that compete against our unapproved prescription products. Such competitors have brought, and in the future may bring, claims against us alleging unfair competition or related claims.

As a result of our meetings with the FDA in 2009, we decided to discontinue all of our products that were subject to the Prescription Drug Wrap-Up program, with the exception of epinephrine in vial form. These products were all produced at our subsidiary, IMS. During the third quarter of 2010, the FDA requested that IMS reintroduce several of the withdrawn products to cope with a drug shortage, while IMS prepared and filed applications for approval of the products. Between August and October, 2010, IMS reintroduced atropine, calcium chloride, morphine, dextrose, epinephrine, lidocaine and sodium bicarbonate injections, and continues to market these products without FDA approval. For the year ended December 31, 2013 and the three months ended June 30, 2014, we recorded net revenues of $29.6 million and $7.0 million, respectively, from these products. IMS has received approval for one ANDA, filed three ANDAs and is preparing two additional ANDAs and one NDA with respect to these products for submission under an expedited review process by the FDA. We may not obtain approval for any of these products.

Our reporting and payment obligations under the Medicare and/or Medicaid drug rebate programs and other governmental purchasing and rebate programs are complex and may involve subjective decisions that could change as a result of new business circumstances, new regulatory guidance or advice of legal counsel. Any determination of failure to comply with those obligations could subject us to penalties and sanctions which could have a material adverse effect on our business, financial position and results of operations and the market value of our common stock

could decline.

The regulations regarding reporting and payment obligations with respect to Medicare and/or Medicaid reimbursement and rebates and other governmental programs are complex. Because our processes for these calculations and the judgments involved in making these calculations involve, and will continue to involve, subjective decisions and complex methodologies, these calculations are subject to the risk of errors. In addition, they are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in material changes. The Affordable Care Act includes a provision requiring the Centers for Medicare and Medicaid Services, or CMS, to publish a weighted Average Manufacturer Price, or AMP, for all multi-source drugs. The provision was effective October 1, 2010; however, weighted average AMP's have not yet been published by CMS, except in draft form, and have not been implemented for use in the calculation of Federal Upper Limits. Although the weighted average AMP would not reveal our individual AMP, publishing a weighted average AMP available to customers and the public at large could negatively affect our leverage in commercial price negotiations.

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In addition, as also disclosed herein, a number of state and federal government agencies are conducting investigations of manufacturers' reporting practices with respect to Average Wholesale Prices, or AWP, in which they have suggested that reporting of inflated AWP has led to excessive payments for prescription drugs. Numerous pharmaceutical companies have been named as defendants in various actions relating to pharmaceutical pricing issues and whether allegedly improper actions by pharmaceutical manufacturers led to excessive payments by Medicare and/or Medicaid.

Any governmental agencies that have commenced, or may commence, an investigation of our business relating to the sales, marketing, pricing, quality or manufacturing of pharmaceutical products could seek to impose, based on a claim of violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs including Medicare and/or Medicaid. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with regard to how to properly calculate and report payments — and even in the absence of any such ambiguity — a governmental authority may take a position contrary to a position we have taken, and may impose civil and/or criminal sanctions. Any such penalties or sanctions 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.

Proposed FDA labeling rules could result in additional liability risks for our products.

The FDA has recently proposed allowing generic drug manufacturers to independently update product labeling to reflect newly discovered safety data, which could result in failure-to-warn suits. This could increase our labeling obligations and potentially increase our liability risk for our products.

We may be subject to enforcement action if we engage in the off-label promotion of our products.

Our promotional materials and training methods must comply with the FFDCA and other applicable laws and regulations, including restraints and prohibitions on the promotion of off-label, or unapproved, use. Physicians may prescribe our products for off-label use without regard to these prohibitions, as the FFDCA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including but not limited to the issuance of an untitled letter or warning letter, and a judicial action seeking injunction, product seizure and civil or criminal penalties. It is also possible that other federal, state or non-U.S. enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products could be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us and harm our reputation.

The pharmaceutical industry is highly regulated and pharmaceutical companies are subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act.

Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include:

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the federal healthcare programs' anti-kickback law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

•federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;

•the federal Health Insurance Portability and Accountability Act of 1996, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

•the FFDCA and similar laws regulating advertisement and labeling;

•the U.S. Foreign Corrupt Practices Act, which prohibits corrupt payments, gifts or transfers of value to non-U.S. officials; and

•non-U.S. and U.S. state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers.

The federal false claims laws have been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers or formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Most states also have statutes or regulations similar to the federal anti-kickback law and federal false claims laws, which apply to items and services covered by Medicaid and other state programs, or, in several states, apply regardless of the payer. Administrative, civil and criminal sanctions may be imposed under these federal and state laws.

Further, the Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity can now be found guilty under the Affordable Care Act without actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare and Medicaid programs and forfeiture of amounts collected in violation of such prohibitions. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

To enforce compliance with the federal laws, the U.S. Department of Justice, or DOJ, has recently increased its scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, if a healthcare provider settles an investigation with the DOJ or other law enforcement agencies, we may be forced to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

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Over the past few years, a number of pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing. Some states, such as California, Massachusetts and Vermont, mandate implementation of commercial compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may run afoul of one or more of the requirements.

If the activities of any of our business partners are found to be in violation of these laws or any other federal and state fraud and abuse laws, they may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of its activities with regard to the commercialization of our products, which could harm the commercial success of our products and materially affect our business, financial condition and results of operations. While we have implemented numerous risk mitigation measures to comply with such regulations in this complex operating environment, we cannot guarantee that we will be able to effectively mitigate all operational risks. While we have developed and instituted a corporate compliance program, we cannot guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all potentially applicable U.S. federal and state regulations and/or laws, all potentially applicable foreign regulations and/or laws and/or all requirements of the corporate integrity agreement. Because of the far-reaching nature of these laws, we may be required to alter or discontinue one or more of our business practices to be in compliance with these laws. If we fail to adequately mitigate our operational risks or if we or our agents fail to comply with any of those regulations, laws and/or requirements, a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of our products from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation. Such occurrences could have a material and adverse effect on our product sales, business and results of operations.

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal or state regulatory authorities might challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. In addition, efforts to ensure that our business arrangements with third parties will comply with these laws and regulations will involve substantial costs. Any state or federal regulatory review of us or the third parties with whom we contract, regardless of the outcome, would be costly and time-consuming.

Risks Relating to our Intellectual Property

Our success depends on our ability to protect our intellectual property.

In addition to obtaining FDA approval for our generic and proprietary drug candidates, our success also depends on our ability to obtain and maintain patent protection for new products developed utilizing our technologies, in the U.S. and in other countries, and to enforce these patents. The patent positions of pharmaceutical firms, including us, are generally uncertain and involve complex legal and factual issues. Any of our patent claims in our approved and pending non-provisional and provisional patent applications relating to our technologies may not be issued or, if issued, any of our existing and future patent claims may not be held valid and enforceable against third-party infringement. Moreover, any patent claims relating to our technologies may not be sufficiently broad to protect our

products. In addition, issued patent claims may be challenged, potentially invalidated, or potentially circumvented. Our patent claims may not afford us protection against our competitors. We currently have a number of U.S. and foreign patents issued. However, issuance of a patent is not conclusive evidence of its validity or enforceability. We may not receive patents for any of our pending patent applications or any patent applications that we may file in the future and our issued patents may not be upheld if challenged.

In March 2013, the U.S. transitioned to a first inventor to file system in which, assuming the other requirements for patentability are met, the first inventor to file a patent application is entitled to receive a patent (rather than the first to invent as was the case under prior U.S. law). Accordingly, it is possible that potentially invalidating prior art may become available in between the time that we develop an invention and file a patent application that covers the invention. In addition, we may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, reexamination, inter parties review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights.

Past enforcement of intellectual property rights in countries outside the U.S., including China in particular, has been limited or non-existent. Future enforcement of patents and proprietary rights in many other countries will likely be problematic or unpredictable. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions.

We also rely on, or intend to rely on, our trademarks, trade names and brand names to distinguish our products from the products of our competitors and have registered or applied to register our own trademarks. However, our trademark applications may not be approved. Third parties may also oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our product, which could result in loss of brand recognition and could require us to devote significant resources to advertising and marketing these new brands. Further, our competitors may infringe our trademarks or we may not have adequate resources to enforce our trademarks.

With respect to our proprietary products, if we fail to adequately protect or enforce our intellectual property rights, we could lose sales to generic versions of our proprietary products which could cause 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 success of our proprietary products depends in part on our ability to obtain, maintain and enforce patents and trademarks, and to protect trade secrets, know-how and other proprietary information. Our ability to commercialize any proprietary product successfully will largely depend upon our ability to obtain and maintain patents of sufficient scope to prevent third parties from developing substantially equivalent products. In the absence of patent and trade secret protection, competitors may adversely affect our proprietary products business by independently developing and marketing substantially equivalent products. It is also possible that we could incur substantial costs if we are required to initiate litigation against others to protect or enforce our intellectual property rights.

We have filed patent applications covering compositions of, methods of making and/or methods of using, our proprietary products and proprietary product candidates. We may not be issued patents based on patent applications already filed or that we may file in the future, and if patents are issued, they may be insufficient in scope to cover our proprietary products. The issuance of a patent in one country does not ensure the issuance of a similar patent in any other country, or that we will even seek patent protection in all countries worldwide. Furthermore, the patent position of companies in the pharmaceutical industry generally involves complex legal and factual questions and has been and remains the subject of much litigation. Legal standards relating to scope and validity of patent claims are evolving and

may differ in various countries. Any patents we have obtained, or will obtain in the future, may be challenged, invalidated or circumvented. Moreover, the USPTO or any other governmental agency, as well as third parties, may commence interference, opposition or other related third party proceedings involving our patents or patent applications. Any challenge to, or invalidation or circumvention of, our patents or patent applications would be costly, would require significant time and attention of our management, could cause 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.

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Our unpatented trade secrets, know-how, confidential and proprietary information and technology may be inadequately protected.

We rely on unpatented trade secrets, know-how and technology. This intellectual property is difficult to protect, especially in the pharmaceutical industry, where much of the information about a product must be submitted to regulatory authorities during the regulatory approval process. We seek to protect trade secrets, confidential information and proprietary information, in part, by entering into confidentiality and invention assignment agreements with employees, consultants and others. These parties may breach or terminate these agreements, and we may not have adequate remedies for such breaches. Furthermore, these agreements may not provide meaningful protection for our trade secrets or other confidential or proprietary information or result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized use or disclosure of confidential information or other breaches of the agreements. Despite our efforts to protect our trade secrets and our other confidential and proprietary information, we or our collaboration partners, board members, employees, consultants, contractors, or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors.

There is a risk that our trade secrets and other confidential and proprietary information could have been, or could, in the future, be shared by any of our former employees with, and be used to the benefit of, any company that competes with us.

If we fail to maintain trade secret protection or fail to protect the confidentiality of our other confidential and proprietary information, our competitive position may be adversely affected. Competitors may also independently discover our trade secrets. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secret protections against them, which could have a material adverse effect on our business.

There can be no assurance of timely patent review and approval to minimize competition and generate sufficient revenues.

There can be no assurance that the USPTO will have sufficient resources to review and grant our patent applications in a timely manner. Consequently, our patent applications may be delayed for many years (if they issue as patents at all), which would prevent intellectual property protection for our products. If we fail to successfully commercialize our products due to the lack of intellectual property protection, we may be unable to generate sufficient revenues to meet or grow our business according to our expected goals and this may have a materially adverse effect on our profitability, financial condition and operations.

We may become involved in patent litigations or other intellectual property proceedings relating to our future product approvals, which could result in liability for damages or delay or stop our development and commercialization efforts.

The pharmaceutical industry has been characterized by significant litigation and other proceedings regarding patents, patent applications and other intellectual property rights. The situations in which we may become parties to such litigation or proceedings may include any third parties initiating litigation claiming that our products infringe their patent or other intellectual property rights; in such case, we will need to defend against such proceedings. For example, the field of generic pharmaceuticals is characterized by frequent litigation that occurs in connection with generic pharmaceutical companies filing ANDAs, Paragraph IV certifications and attempting to invalidate the patents of the proprietary reference drug. Any non-generic products that we successfully develop may be subject to such challenge by third parties. As a generic pharmaceutical company, we also expect to file ANDAs, Paragraph IV certifications and to attempt to invalidate patents of third party reference drugs for which we seek to develop generic

versions.

The costs of resolving any patent litigation or other intellectual property proceeding, even if resolved in our favor, could be substantial. Many of our potential competitors will be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other intellectual property proceedings may also consume significant management time.

In the event that a competitor infringes upon our patent or other intellectual property rights, enforcing those rights may be costly, difficult and time-consuming. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive and time-consuming and could divert our management's attention. We may not have sufficient resources to enforce our intellectual property rights or to defend our patent or other intellectual property rights against a challenge. If we are unsuccessful in enforcing and protecting our intellectual property rights and protecting our products, it could materially harm our business.

For example, we have been involved in litigation related to our sales of enoxaparin. A preliminary injunction was issued on October 28, 2011 that barred us from selling our generic enoxaparin until the injunction was stayed on January 25, 2012. After appeal, the U.S. Supreme Court denied certiorari and on July 19, 2013, the District Court granted our motion for summary judgment in accordance with the Federal Circuit opinion and denied Momenta and Sandoz's motion for leave to amend infringement contentions. For further details, see the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Litigation in Note 17 in the accompanying "Notes to Condensed Consolidated Financial Statements" in this Quarterly Report. Despite the ultimately favorable ruling in the litigation, the protracted litigation involved large legal expenses and the diversion of management's time and effort away from the business. Any future adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could result in substantial monetary damage awards and could prevent us from manufacturing and selling our products, which could have a material and adverse effect on our financial condition.

There may also be situations where we use our business judgment and decide to market and sell products, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts, which is commonly referred to 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 as well as injunctive relief, which would halt our ability to market and sell such products altogether. 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 generic products, patented proprietary products generally realize a substantially higher profit margin than generic products. An adverse decision in a case such as this or in other similar 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.

We may be subject to claims that we, our board members, employees or consultants have used or disclosed alleged trade secrets or other proprietary information belonging to third parties and any such individuals who are currently affiliated with one of our competitors may disclose our proprietary technology or information.

As is commonplace in the biotechnology and pharmaceutical industries, some of our board members, employees and consultants are or have been employed at, or associated with, other biotechnology or pharmaceutical companies that compete with us. While employed at or associated with these companies, these individuals may become exposed to or involved in research and technology similar to the areas of research and technology in which we are engaged. We may be subject to claims that we, or our employees, board members or consultants have inadvertently, willfully or otherwise used or disclosed alleged trade secrets or other proprietary information of those companies. Litigation may

be necessary to defend against such claims.

We have entered into confidentiality agreements with our executives and key consultants. However, we do not have, and are not planning to enter into, any confidentiality agreements with our non-executive directors because they have a fiduciary duty of confidentiality as directors. Our former board members, employees or consultants who are currently employed at, or associated with, one of our competitors may unintentionally or willfully disclose our proprietary technology or information.

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Risks Related to Ownership of Our Common Stock

Our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

Our operating results may be subject to quarterly and annual fluctuations as a result of a number of factors, including the following:

- the commercial success of our key products;
- results of clinical trials of our product candidates or those of our competitors;
- pricing actions by competitors;
- the timing of orders from our customers;
- manufacturing or supply interruptions;
- actions by regulatory bodies, such as the FDA, that have the effect of delaying or rejecting approvals of our product candidates;
- changes in the prescription practices of physicians;
- changes or developments in laws or regulations applicable to our product candidates;
- introduction of competitive products or technologies;
- failure to meet or exceed financial projections we provide to the public;
- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed the estimates and projections of securities analysts or investors;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- general economic and market conditions and overall fluctuations in U.S. equity markets;
- developments concerning our sources of manufacturing supply;
- disputes or other developments relating to patents or other proprietary rights;
- litigation or investigations involving us, our industry, or both;
- additions or departures of key scientific or management personnel;
- issuances of debt, equity or convertible securities;
- changes in the market valuations of similar companies;

- major catastrophic events;
- major changes in our board of directors or management or departures of key personnel; or
- the other factors described in this "Item 1.A Risk Factors" section.

Any one of the factors above, or the cumulative effect of some of the factors referred to above, may result in significant fluctuations in our quarterly or annual operating results. This variability and unpredictability could result in our failing to meet our revenue, billings or operating results expectations or those of securities analysts or investors for any period. In addition, a significant percentage of our operating expenses are fixed in nature and based on forecasted revenue trends. Accordingly, in the event of revenue shortfalls, we are generally unable to mitigate the negative impact on operating results in the short term. If we fail to meet or exceed such expectations for these or any other reasons, our business could be materially adversely affected and our stock price could fluctuate or decline substantially.

In addition, if the market for pharmaceutical company stocks or the stock market in general experience a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, operating results or financial condition. The trading price of our common stock might also decline in reaction to events that affect other companies in our industry even if these events do not directly affect us. Our stock price may also be affected by the expiration of market stand-offs or contractual lock-up agreements or sales of large blocks of our stock.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. If our stock price is volatile, we may become the target of securities litigation. Securities litigation could result in substantial costs and divert our management's attention and resources from our business, and this could have a material adverse effect on our business, operating results and financial condition.

Future sales of our common stock may cause our stock price to decline.

If our existing stockholders sell, or indicate an intent to sell, substantial amounts of our common stock in the public market after the contractual lock-up agreements executed as part of our initial public offering and other legal restrictions on resale lapse, the trading price of our common stock could decline.

Our directors, officers and holders of substantially all of our capital stock and securities convertible into capital stock are subject to a 180-day market stand-off or a contractual lock-up agreement that prevents them from selling their securities prior to the expiration of the 180-day period beginning June 24, 2014, the date of the prospectus to our initial public offering,. The underwriters may, in their sole discretion, permit securities subject to the lock-up to be sold prior to its expiration. Stockholders holding approximately 49% of our outstanding shares have executed an additional lock-up agreement pursuant to which such stockholders are prohibited from selling (i) 100% of their securities for 180 days, (ii) 95% of their securities for the period of 181 to 270 days, (iii) 75% of their securities for the period of 271 to 360 days, (iv) 50% of their securities for the period of 361 days to 450 days and (v) 25% of their securities for the period of 451 to 540 days, with each period being measured from June 24, 2014, the date of the prospectus to our initial public offering. Jefferies LLC and BMO Capital Markets Corp. may, in their joint discretion, permit securities subject to this additional lock-up to be sold prior to its expiration.

After the market stand-offs and lock-up agreements pertaining to our initial public offering expire, up to an additional 35,708,329 shares will be eligible for sale in the public market, of which 12,523,882 are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act and various vesting agreements.

In addition, we have registered approximately 16.3 million shares subject to options outstanding or reserved for future issuance under our equity compensation plans. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

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Jack Y. Zhang and Mary Z. Luo, each of whom serves as a director and an executive officer, own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of August 4, 2014, Jack Y. Zhang and Mary Z. Luo, each of whom serves as one of our directors and executive officers, and their affiliates beneficially own approximately 23.4% of our outstanding common stock, including shares of common stock subject to options exercisable within 60 days of August 4, 2014. Our directors, executive officers and each of our stockholders who own greater than 5% of our outstanding common stock and their affiliates, in the aggregate, own approximately 25.8% of the outstanding, including shares of our common stock, based on the number of shares outstanding and shares of our common stock subject to options exercisable within 60 days of August 4, 2014. As a result, these stockholders, if acting together, will be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may also have interests that differ from yours and may vote in a way with which you disagree and which may be adverse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and might ultimately affect the market price of our common stock.

We do not intend to pay dividends for the foreseeable future.

The continued operation and expansion of our business will require substantial funding. Accordingly, we do not anticipate that we will pay any cash dividends on shares of our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant. Our existing loan agreements restrict, and any future indebtedness may restrict, our ability to pay dividends. Investors seeking cash dividends should not purchase our common stock. Accordingly, realization of a gain on your investment will depend on the appreciation of the price of our common stock, which may never occur.

The requirements of being a public company may strain our resources, divert management’s attention and affect our ability to attract and retain executive management and qualified board members.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Act, the listing requirements of the NASDAQ Stock Market LLC and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources, particularly after we are no longer an “emerging growth company,” as defined in the JOBS Act. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management’s attention may be diverted from other business concerns, which could adversely affect our business and operating results. Although we have already hired additional employees to comply with these requirements, we may need to hire more employees in the future or engage outside consultants, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is

provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

We also believe that being a public company and these new rules and regulations will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors and qualified executive officers.

As a result of disclosure of information in this Quarterly report and in filings required of a public company, our business and financial condition are more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and operating results could be adversely affected. Even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and adversely affect our business and operating results.

We may become involved in securities class action litigation that could divert management's attention from our business and adversely affect our business and could subject us to significant liabilities.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical companies. These broad market fluctuations as well as a broad range of other factors, including the realization of any of the risks described in this "Item 1.A Risk Factors" section, may cause the market price of our common stock to decline. 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 generally experience significant stock price volatility. We may become involved in this type of litigation in the future. Litigation is often expensive and could divert management's attention and resources from our primary business, which could adversely affect our business. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments.

We are an emerging growth company and the reduced reporting requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of 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 nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Investors may 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.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we chose to "opt out" of such

extended transition period, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

As an emerging growth company, we have also chosen to take advantage of certain provisions of the JOBS Act that allow us to provide you with less information in our public reports than would otherwise be required if we are not an emerging growth company. As a result, this Quarterly Report includes less information about us than would otherwise be required if we were not an emerging growth company within the meaning of the JOBS Act, which may make it more difficult for you to evaluate an investment in our company.

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We would cease to be an emerging growth company upon the earliest of: (i) the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering, which occurred on June 30, 2014, (ii) the last day of the fiscal year during which we have annual gross revenue of at least $1.0 billion, (iii) the date on which we are deemed to be a "large accelerated filer" under the Exchange Act (we will qualify as a large accelerated filer as of the first day of the first fiscal year after we have (a) more than $700.0 million in outstanding common equity held by our non-affiliates and (b) been public for at least 12 months; the value of our outstanding common equity will be measured each year on the last business day of our second fiscal quarter); or (iv) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt securities.

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.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws, as well as provisions of the Delaware General Corporation Law, or the DGCL, could depress the trading price of our common stock by making 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, including transactions in which stockholders might otherwise receive a premium for their shares. 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;

- 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;

- 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; and

- establishing a classified board of directors, whereby only one-third of the members of our board of directors are elected at one time.

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 DGCL, 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 delay or prevent a change of control, whether or not it is desired by or beneficial to our stockholders, which could also affect the price that some investors are willing to pay for our common stock.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(a) Recent Sales of Unregistered Securities

From April 1, 2014 through June 30, 2014, we granted to employees options to purchase an aggregate of 640,502 shares of common stock under our 2005 Equity Incentive Award Plan, (the "2005 Plan"), at a weighted-average exercise price of $14.40 per share.

From April 1, 2014 through June 30, 2014, we granted an aggregate of 107,108 Deferred Stock Units to employees under our 2005 Plan. Each award entitles the grantee to receive his or her vested portion of shares of common stock on each vesting anniversary date.

From April 1, 2014 through June 30, 2014, we issued and sold to a consultant an aggregate of 30,000 shares of common stock upon the exercise of options under the 2005 Plan at an exercise price ranging from $19.03 per share, for an aggregate purchase price of approximately $0.6 million.

The issuances described above were made pursuant to written compensatory plans or agreements in reliance on the exemption provided by Rule 701 promulgated under Section 3(b) of the Securities Act or in reliance on Section 4(a)(2) promulgated under the Securities Act as transactions by an issuer not involving a public offering, to the extent an exemption from such registration was required.

(b) Use of Proceeds

On June 24, 2014, our registration statement on Form S-1 (File No. 333-196097), as amended, filed in connection with the initial public offering of our common stock, was declared effective. Pursuant to the registration statement, we registered the offering and sale of 4,640,000 shares of our common stock by the Company, 3,360,000 shares of our common stock by a selling stockholder, and the sale pursuant to the underwriters' over-allotment option of an additional 1,200,000 shares of our common stock by the Company, at a price of $7.00 per share. The offering, which closed on June 30, 2014, did not terminate until after the sale of all of the shares registered on the registration statement, including the shares issued upon exercise of the underwriters' overallotment option, which was exercised in full on June 26, 2014. Jefferies LLC, BMO Capital Markets Corp. and Piper Jaffray & Co. acted as joint book-running managers. Needham & Company, LLC acted as co-manager.

As a result of the offering, on June 30, 2014, we received net proceeds of approximately $34.7 million, which is comprised of gross proceeds of approximately $40.9 million, offset by underwriting discounts and commissions of approximately $2.9 million and other offering expenses of approximately $3.3 million. We did not receive any proceeds from the sale of the shares by the selling stockholder. No payments for the foregoing expenses were made by us to any of our officers, directors or persons owning ten percent or more of our common stock, or to the associates of any of the foregoing, or to our affiliates.

The net proceeds have been invested in cash and cash equivalents. There has been no material change in the expected use of the net proceeds from our initial public offering as described in our final prospectus filed with the SEC on June 25, 2014 relating to our registration statement on Form S-1.

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(c) Issuer Purchases of Equity Securities

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

A list of exhibits is set forth on the Exhibit Index immediately following the signature page of this Quarterly Report on Form 10-Q, and is incorporated herein by reference.

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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.

AMPHASTAR
PHARMACEUTICALS, INC.
(Registrant)

By: /s/ JACK Y. ZHANG
Jack Y. Zhang
Chief Executive Officer
(Principal Executive Officer)

Date: August 13, 2014

AMPHASTAR
PHARMACEUTICALS, INC.
(Registrant)

By: /s/ WILLIAM J. PETERS
William J. Peters
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: August 13, 2014

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AMPHASTAR PHARMACEUTICALS, INC.

EXHIBIT INDEX TO FORM 10-Q

For the Quarterly Period Ended JUNE 30, 2014

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.3 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.4 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
4.1	Specimen common stock certificate (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on June 5, 2014)
10.1	Asset Purchase Agreement, dated April 30, 2014, among Diosynth France, Amphastar France Pharmaceuticals SAS and Schering-Plough (incorporated by reference to Exhibit 10.18 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.2	Loan Agreement, dated April 22, 2014, between Amphastar Pharmaceuticals, Inc. and Cathay Bank (incorporated by reference to Exhibit 10.19 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.3	Promissory Note, dated April 22, 2014, by Amphastar Pharmaceuticals, Inc. payable to Cathay Bank in the original principal sum of $21,900,000 (incorporated by reference to Exhibit 10.20 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.4	Employment Agreement, dated May 19, 2014, between Amphastar Pharmaceuticals, Inc. and Jack Zhang (incorporated by reference to Exhibit 10.21 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.5	Employment Agreement, dated May 19, 2014, between Amphastar Pharmaceuticals, Inc. and Mary Luo (incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.6	Employment Agreement, dated May 19, 2014, between Amphastar Pharmaceuticals, Inc. and Jason Shandell (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)

10.7	Employment Agreement, dated May 19, 2014, between Amphastar Pharmaceuticals, Inc. and Marilyn Purchase (incorporated by reference to Exhibit 10.24 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.8	Employment Agreement, dated March 11, 2014, between Amphastar Pharmaceuticals, Inc. and William Peters (incorporated by reference to Exhibit 10.25 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
31.1	Certification of Chief Executive Officer Pursuant to Rules 13a-14(a) and 15d-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 Chief Financial Officer Pursuant to Rules 13a-14(a) and 15d-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 Chief Executive Officer Pursuant to Rules 13a-14(b) and 15d-14(b) of the Securities Exchange Act of 1394 and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2#	Certification of Chief Financial Officer Pursuant to Rules 13a-14(b) and 15d-14(b) of the Securities Exchange Act of 1394 and 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.LAB	XBRL Taxonomy Extension Label Linkbase Document.*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.*
101.DEF	XBRL Taxonomy Extension Definitions Linkbase Document.*

The information in Exhibits 32.1 and 32.2 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act (including this Report), unless the Registrant specifically incorporates the foregoing information into those documents by reference.

* These interactive data files are being furnished as part of this Quarterly Report, and, in accordance with Rule 402 of Regulation S-T, shall not be deemed filed for purposes of Section 11 or 12 of the Securities Act of 1933, as amended, or Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability under those sections.