Amphastar Pharmaceuticals, Inc.
Form 10-Q
November 13, 2014
Table of Contents

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

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 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 x No ¨

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 November 10, 2014 was 44,648,798.

Table of Contents

AMPHASTAR PHARMACEUTICALS, INC.
TABLE OF CONTENTS
FORM 10-Q FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2014

Note About Forward-Looking Statements

Part I. FINANCIAL INFORMATION

PAGE

Item 1. Financial Statements (unaudited):

Condensed Consolidated Balance Sheets as of September 30, 2014 and December 31, 2013 1

Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2014 and 2013 2

Consolidated Statements of Comprehensive Income (Loss) for the Three and Nine Months Ended September 30, 2014 and 2013 3

Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2014 and 2013 4

Notes to Condensed Consolidated Financial Statements 5

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations 22

Item 3. Quantitative and Qualitative Disclosure about Market Risk 26

Item 4. Controls and Procedures 27

Part II. OTHER INFORMATION

Item 1. Legal Proceedings 27

Item 1A. Risk Factors 27

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds 29

Item 3. Default Upon Senior Securities 29

Item 4. Mine Safety Disclosures 29

Item 5. Other Information 29

Item 6. Exhibits 29

Signatures 30

Table of Contents

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.

Table of Contents

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2014	December 31, 2013
ASSETS	(unaudited)	
Current Assets:		
Cash and cash equivalents	$ 72,881	$ 53,587
Restricted cash and restricted short-term investments	1,495	1,325
Accounts receivable, net	26,604	24,585
Inventories, net	88,052	69,916
Income tax refund and deposits	5,139	2,429
Prepaid expenses and other assets	4,913	5,033
Deferred tax assets	16,096	16,096
Total current assets	215,180	172,971
Property, plant, and equipment, net	134,112	116,619
Goodwill and intangible assets, net	43,221	40,163
Other assets	2,502	2,877
Deferred tax assets	6,118	6,118
Total assets	$ 401,133	$ 338,748
LIABILITIES AND EQUITY		
Current Liabilities:		
Accounts payable	$ 10,013	$ 20,380
Accrued liabilities	10,446	7,628
Income taxes payable	2,791	2,847
Accrued payroll and related benefits	11,863	9,161
Current portion of product return accrual	2,498	2,639
Current portion of deferred revenue	14,596	643
Current portion of long-term debt and capital leases	10,078	22,104
Deferred tax liability	797	—
Total current liabilities	63,082	65,402
Long-term product return accrual	791	1,953
Long-term deferred revenue	2,143	2,625
Long-term debt and capital leases, net of current portion	41,271	10,069
Long-term deferred tax liabilities	10,726	7,154
Total liabilities	118,013	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—44,645,437 and 38,765,940 at September 30, 2014 and December 31, 2013, respectively		
Additional paid-in capital	219,288	177,732
Retained earnings	65,631	73,809
Accumulated other comprehensive loss	(1,803)	—
Total stockholders' equity	283,120	251,545
Total liabilities and stockholders' equity	$ 401,133	$ 338,748

See Accompanying Notes to Condensed Consolidated Financial Statements.

Table of Contents

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Net revenues	$59,711	$59,318	$154,584	$174,805
Cost of revenue	47,920	39,038	115,288	107,478
Gross profit	11,791	20,280	39,296	67,327
Operating expenses:				
Selling, distribution, and marketing	1,454	1,462	4,066	4,059
General and administrative	9,556	9,545	25,040	22,966
Research and development	8,585	9,041	20,788	25,736
Impairment of long-lived assets	13	6	361	6
Total operating expenses	19,608	20,054	50,255	52,767
Income (loss) from operations	(7,817)	226	(10,959)	14,560
Non-operating income (expense):				
Interest income	94	49	154	145
Interest expense, net	(504)	(195)	(1,159)	(737)
Other income (expense), net	243	255	(367)	477
Total non-operating income (expense), net	(167)	109	(1,372)	(115)
Income (loss) before income taxes	(7,984)	335	(12,331)	14,445
Income tax expense (benefit)	(2,605)	494	(4,153)	4,412
Net income (loss)	$(5,379)	$(159)	$(8,178)	$10,033
Net income (loss) per common share:				
Basic	$(0.12)	$0.00	$(0.20)	$0.26
Diluted	$(0.12)	$0.00	$(0.20)	$0.26
Weighted-average shares used to compute net income (loss) per common share:				
Basic	44,644	38,709	41,060	38,708
Diluted	44,644	38,709	41,060	38,848

See Accompanying Notes to Condensed Consolidated Financial Statements.

Table of Contents

AMPHASTAR PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(Unaudited; in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Net income (loss)	$(5,379)	$(159)	$(8,178)	$10,033
Accumulated other comprehensive loss				
Foreign currency translation adjustment	(1,535)	—	(1,803)	—
Accumulated other comprehensive loss	(1,535)	—	(1,803)	—
Total comprehensive income (loss)	$(6,914)	$(159)	$(9,981)	$10,033

See Accompanying Notes to Condensed Consolidated Financial Statements.

Table of Contents

AMPHASTAR PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited; in thousands)

	Nine Months Ended September 30,	
	2014	2013
Cash Flows From Operating Activities:		
Net income (loss)	$(8,178)	$10,033
Reconciliation to net cash provided by (used in) operating activities:		
Impairment of long-lived assets	361	6
Loss on disposal of property, plant, and equipment	44	116
Depreciation and amortization of property, plant, and equipment	9,235	8,187
Amortization of product rights, trademarks, and patents	1,437	1,430
Amortization of imputed interest and debt discount	66	—
Employee share-based compensation expense	5,952	4,569
Non-employee share-based compensation expense	728	715
Reserve for income tax liabilities	—	89
Changes in operating assets and liabilities:		
Accounts receivable, net	(2,019)	5,430
Inventories, net	1,609	(8,694)
Income tax refund and deposits	2,690	(92)
Prepaid expenses and other assets	(1,318)	(468)
Income taxes payable	(5,456)	(133)
Accounts payable and accrued liabilities	3,578	1,342
Net cash provided by operating activities	8,729	22,530
Cash Flows From Investing Activities:		
Acquisition of business	(18,352)	—
Purchases of property, plant, and equipment	(11,118)	(13,896)
Capitalized labor, overhead, and interest on self-constructed assets	(555)	(507)
Purchase of trademarks and other intangible assets	—	(43)
Sales of short-term investments, net	—	513
Decrease (increase) in restricted cash	(170)	50
Deposits and other assets, net	350	(1,246)
Net cash used in investing activities	(29,845)	(15,129)
Cash Flows From Financing Activities:		
Net proceeds from issuance of common stock	38,018	—
Payments on repurchase of common stock	(485)	(15)
Net proceeds from exercise of common stock options	701	51
Costs related to public offering	(1,920)	—
Deferred offering cost	—	(255)
Proceeds from borrowing under lines of credit	25,000	51,000
Repayments under lines of credit	(40,000)	(55,000)
Proceeds from issuance of long-term debt	26,505	—
Principal payments on long-term debt	(7,149)	(1,451)

Net cash provided by (used in) financing activities	40,670	(5,670)
Effect of exchange rate changes on cash	(260)	—
Net increase in cash and cash equivalents	19,294	1,731
Cash and cash equivalents at beginning of period	53,587	50,213
Cash and cash equivalents at end of period	$72,881	$51,944
Noncash Investing and Financing Activities:		
Equipment acquired under capital leases	$78	$712
Supplemental Disclosures of Cash Flow Information:		
Interest paid	$978	$845
Income taxes paid	$86	$4,017

See Accompanying Notes to Condensed Consolidated Financial Statements.

Table of Contents

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, S.A.S., or AFP.

Amounts reclassified

Certain amounts in the prior years' financial statements have been reclassified to conform to the current year presentation. These reclassifications relate to the Company's accounting for accrued chargebacks, which was originally included on the Company's consolidated balance sheets as a liability and is now reflected as a reduction to accounts

receivable. These reclassifications have no impact on net income or cash flows.

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 nine months ended September 30, 2014, the Company includes its foreign currency translation adjustment as part of its comprehensive loss as a result of establishing the Company's subsidiary, AFP, in France. For the three and nine months ended September 30, 2013, net income (loss) equaled total comprehensive income (loss).

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).

Table of Contents

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

In August 2014, the FASB issued an accounting standards update that will require management to evaluate if there is substantial doubt about the Company’s ability to continue as a going concern and, if so, to disclose this in both interim and annual reporting periods. This guidance will become effective for the Company’s annual filing for the period ending December 31, 2016 and interim periods thereafter, and allows for early adoption. 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’s API Manufacturing Business

On April 30, 2014, the Company completed the Merck API Transaction, 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	6,214
December 2015	3,186	4,041
December 2016	3,186	4,041
December 2017	500	634
	€25,023	$33,282

Table of Contents

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

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 Merck API Transaction, 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
Goodwill	3,155	4,369
Total assets acquired	€30,400	$42,098
Accrued liabilities	€2,425	$3,358
Deferred tax liabilities	3,155	4,369
Total liabilities assumed	5,580	7,727
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. During the nine months ended September 30, 2014, the Company received updated information regarding its deferred tax liability and related goodwill recorded as of the acquisition date. While finalizing acquisition accounting, the Company recorded a measurement period adjustment which impacted goodwill and deferred tax liability by $4.4 million and $4.4 million, respectively during the nine months ended September 30, 2014. 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 nine months ended September 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 prior to the transaction as well as actual results subsequent to the acquisition with respect to the transaction and does not reflect estimated operational and administrative cost savings, or synergies for periods prior to the transaction, 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.

	Nine Months Ended September 30,	
	2014	2013
	(in thousands, except per share data)	
Net revenues	$ 156,868	$ 185,293
Net income (loss)	(9,407)	10,827
Diluted net income (loss) per share	$ (0.23)	$ 0.28

Acquisition Loan with Cathay Bank

On April 22, 2014, in conjunction with the Merck API Transaction, 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.

Table of Contents

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

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.

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:

	Nine Months Ended September 30, 2014	Year Ended December 31, 2013
	(in thousands)	
Beginning balance	$18,104	$ 11,898
Provision related to sales made in the current period	118,643	213,075
Credits issued to third parties	(124,449)	(206,869)
Ending balance	$12,298	$ 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:

	Nine Months Ended September 30, 2014	Year Ended December 31, 2013
	(in thousands)	
Beginning balance	$4,592	$ 2,673
Provision for product returns	(261)	2,711
Credits issued to third parties	(1,042)	(792)
Ending balance	$3,289	$ 4,592

For the nine months ended September 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. The reduced product return rate resulted from a $1.3 million decrease in the 2014 provisions for product returns related to sales in prior periods.

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 nine months ended September 30, 2014 and the year ended December 31, 2013, respectively.

Table of Contents

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

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.

As the Company reported a net loss for the three and nine months ended September 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 nine months ended September 30, 2014, net loss per share were 11,511,431 and 529,774, respectively. Additionally, as the Company reported a net loss for the three months ended September 30, 2013, total stock options and nonvested DSUs excluded from the three months ended September 30, 2013 were 10,305,452 and 131,184, respectively.

For the nine months ended September 30, 2013, options to purchase 8,391,236 shares of common stock with a weighted-average exercise price of $16.54 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 September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(in thousands, except per share data)			
Basic and dilutive numerator:				
Net income (loss)	$(5,379)	$(159)	$(8,178)	$10,033
Denominator:				
Common shares outstanding	44,642	38,707	41,058	38,699
Contingently issuable shares - vested DSUs	2	2	2	9
Weighted-average common shares outstanding—basic	44,644	38,709	41,060	38,708
Net effect of dilutive securities:				
Stock options	—	—	—	63
Contingently issuable shares – nonvested DSUs	—	—	—	77
Weighted-average common shares outstanding—diluted	44,644	38,709	41,060	38,848
Net income (loss) per common share—basic	$(0.12)	$0.00	$(0.20)	$0.26
Net income (loss) per common share—diluted	$(0.12)	$0.00	$(0.20)	$0.26

Table of Contents

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

6. Segment Reporting

The Company's business is the development, manufacture, and marketing of pharmaceutical products. On April 30, 2014, the Company established AFP and as a result, during the quarter ended September 30, 2014, the Company changed the structure of its reportable segments, establishing two reporting segments that each report to the Chief Operating Decision Maker, or CODM, as defined in ASC Topic 280, Segment Reporting. The Company's performance will be assessed and resources will be allocated by the CODM based on the following two reportable segments:

- Finished pharmaceutical products
- Active pharmaceutical ingredients, or API

The finished pharmaceutical products segment manufactures, markets and distributes enoxaparin, Cortrosyn®, naloxone, lidocaine jelly, as well as, various other critical and non-critical care drugs. The API segment manufactures and distributes recombinant human insulin and porcine insulin.

Selected financial information by reporting segment is presented below:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(in thousands)			
Net revenues:				
Finished pharmaceutical products	$ 53,729	$ 59,318	$ 148,500	$ 174,805
API	5,982	—	6,084	—
Total net revenues	59,711	59,318	154,584	174,805
Gross Profit:				
Finished pharmaceutical products	12,122	20,280	39,592	67,327
API	(331)	—	(296)	—
Total gross profit	11,791	20,280	39,296	67,327
Operating expenses	19,608	20,054	50,255	52,767
Income (loss) from operations	(7,817)	226	(10,959)	14,560
Non-operating income (expenses)	(167)	109	(1,372)	(115)
Income (loss) before income taxes	$ (7,984)	$ 335	$ (12,331)	$ 14,445

The Company manages its business segments to the gross profit level and manages its operating and other costs on a company-wide basis. The Company does not identify total assets by segment for internal purposes, as the Company's CODM does not assess performance, make strategic decisions, or allocate resources based on assets.

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 September 30,		Nine Months Ended September 30,		September 30,	December 31,
	2014	2013	2014	2013	2014	2013
	(in thousands)					
U.S.	$ 53,729	$ 59,318	$ 148,500	$ 174,805	$ 98,744	$ 99,398
China	—	—	—	—	21,011	17,221
France	5,982	—	6,084	—	14,357	—
Total	$ 59,711	$ 59,318	$ 154,584	$ 174,805	$ 134,112	$ 116,619

Table of Contents

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

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. The Company considers these four customers to be its major customers, as each individually, and they collectively, represented a significant percentage of the Company's net revenue for the three and nine months ended September 30, 2014 and 2013 and accounts receivable as of September 30, 2014 and December 31, 2013. The following table provides accounts receivable and net revenues information for these major customers:

	% of Total Accounts Receivable				% of Net Revenue				% of Net Revenue			
					Three Months Ended September 30,				Nine Months Ended September 30,			
	September 30, 2014		December 31, 2013		2014		2013		2014		2013	
Actavis, Inc.	31	%	44	%	35	%	32	%	33	%	34	%
AmerisourceBergen	10	%	11	%	14	%	15	%	15	%	15	%
Cardinal Health	10	%	7	%	13	%	13	%	14	%	14	%
McKesson	16	%	13	%	19	%	29	%	23	%	26	%

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.

Table of Contents

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

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.

The fair values of the Company's financial assets and liabilities measured on a recurring basis, as of September 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	$40,013	$ 40,013	$ —	$ —
Restricted short-term investments:				
Certificates of deposit	1,495	1,495	—	—
Fair value measurement as of September 30, 2014	$41,508	$ 41,508	$ —	$ —
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 September 30, 2014 and December 31, 2013, there were no significant adjustments to fair value for nonfinancial assets or liabilities.

Table of Contents

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

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 (in thousands)	Net Book Value
Definite-lived intangible assets				
Product rights	12	$27,134	$ 20,451	$6,683
Patents	10	293	71	222
Trademarks	11	19	13	6
Land-use rights	39	2,540	206	2,334
Other intangible assets	1	505	505	—
Subtotal	12	30,491	21,246	9,245
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill	*	4,649	—	4,649
AFP customers	*	102	—	102
Subtotal	*	33,976	—	33,976
As of September 30, 2014	*	$64,467	$ 21,246	$43,221

	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.

Goodwill acquired during the nine months ended September 30, 2014 is wholly related to the Merck API Transaction (see Note 3).

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 September 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. 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, the CRL 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 met with the FDA in October 2014 to discuss preliminary data results and to clarify the FDA requirements for further studies. 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.

Table of Contents

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

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:

	September 30, 2014	December 31, 2013
	(in thousands)	
Raw materials and supplies	$42,049	$ 34,470
Work in process	23,558	14,698
Finished goods	23,430	26,501
Total inventory	89,037	75,669
Less reserve for excess and obsolete inventories	(985)	(5,753)
Total inventory, net	$88,052	$ 69,916

11. Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

	September 30, 2014	December 31, 2013
	(in thousands)	
Building	$66,764	$ 58,898
Leasehold improvements	23,942	23,834
Land	7,073	5,805
Machinery and equipment	104,176	93,617
Furniture, fixtures, and automobiles	11,171	9,355
Construction in progress	20,319	15,685
Total property, plant, and equipment	233,445	207,194
Less accumulated depreciation and amortization	(99,333)	(90,575)
Total property, plant, and equipment, net	$134,112	$ 116,619

As of September 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 of 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 ended September 30, 2014, the Company recorded an immaterial amount of impairment loss. For the nine months ended September 30, 2014, the Company recorded an impairment loss of $0.4 million. For the three and nine months ended September 30, 2013, the Company recorded an immaterial amount of impairment loss.

Table of Contents

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

13. Debt

Debt consists of the following:

	September 30, 2014	December 31, 2013
	(in thousands)	
Loans with East West Bank		
Mortgage payable due January 2016	$3,927	$ 4,041
Mortgage payable due September 2016	2,308	2,364
Equipment loan due November 2014	145	783
Line of credit facility due March 2016	—	—
Equipment loan due April 2017	3,222	4,103
Line of credit facility due January 2019	—	—
Loans with Cathay Bank		
Mortgage payable due April 2021	4,571	4,624
Revolving line of credit due May 2016	—	15,000
Acquisition loan due April 2019	21,323	—
Payment obligation to Merck	14,740	—
Equipment under Capital Leases	1,113	1,258
Total debt and capital leases	51,349	32,173
Less current portion of long-term debt and capital leases	10,078	22,104
Long-term debt, net of current portion and capital leases	$41,271	$ 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.

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 September 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 September 30, 2014, the Company did not have any amounts outstanding under this facility.

Table of Contents

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

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 principal 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 September 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 September 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 Merck API Transaction, 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.

Payment Obligation

Merck—Due December 2017

On April 30, 2014, in conjunction with the Merck API Transaction, 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 September 30, 2014, the payment obligation had a book value of $14.7 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 September 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 $1.6 million and $1.5 million at September 30, 2014 and December 31, 2013, respectively.

The accumulated amortization of equipment under capital leases was $0.4 million and $0.2 million at September 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.

Table of Contents

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

14. Income Taxes

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(in thousands)			
Income (loss) before taxes	$ (7,984)	$ 335	$ (12,331)	$ 14,445
Income tax provision (benefit)	(2,605)	494	(4,153)	4,412
Net income (loss)	$ (5,379)	$ (159)	$ (8,178)	$ 10,033
Income tax provision (benefit) as a percentage of income before income taxes	(32.6%)	147.5%	(33.7%)	30.5%

The Company's income tax benefit for the three and nine months ended September 30, 2014 was (32.6%) and (33.7%) of income before income taxes, respectively. The blended effective income tax rate expected for the year ended December 31, 2014 is 33.8%. 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 147.5% and 30.5% during the three and nine months ended September 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 $9.8 million and $5.0 million as of September 30, 2014 and December 31, 2013, respectively. The Company does not have plans to repatriate its foreign earnings to the U.S. as dividends.

15. Stockholders' Equity

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

	Nine Months Ended September 30, 2014 (in thousands)
Stockholders' equity as of December 31, 2013	$ 251,545
Net loss	(8,178)
Accumulated other comprehensive loss	(1,803)
Common stock issued through initial public offering	38,018
Common stock issued to employees, net of shares withheld	(485)
Cost related to public offering	(3,358)
Exercise of stock options	701
Nonemployee share-based compensation expense	728

Employee share-based compensation expense		5,952
Stockholders' equity as of September 30, 2014	$	283,120

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 Accumulated other comprehensive loss for the three and nine months ended September 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.

Table of Contents

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

The Company did not grant any stock options during the three months ended September 30, 2014. The weighted-averages for key assumptions used in determining the fair value of options granted during the nine months ended September 30, 2014 and the three and nine months ended September 30, 2013 are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Average volatility	—	28.3 %	29.9 %	28.5 %
Risk-free interest rate	—	1.2 %	1.7 %	1.2 %
Weighted-average expected life in years	—	4.4	5.0	4.4
Dividend yield rate	—	0.0 %	0.0 %	0.0 %

Stock Options

A summary of option activity under all plans for the nine months ended September 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	(65,000)	10.79		
Options cancelled	(60,198)	12.11		
Options expired	(796,988)	18.86		
Outstanding as of September 30, 2014	11,511,431	$ 15.14	4.87	$ 1,975
Exercisable as of September 30, 2014	5,732,361	$ 17.27	3.60	$ 806

(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 September 30, 2014.

For the three and nine months ended September 30, 2014, the Company recorded stock option expense related to employees under all plans of $2.0 million and $5.1 million, respectively. For the three and nine months ended September 30, 2013, the Company recorded stock option expense related to employees under all plans of $2.2 million and $4.5 million, respectively.

Information relating to option grants and exercises is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013

	(in thousands, except per share data)			
Weighted-average grant date fair value	$—	$2.50	$4.02	$2.54
Intrinsic value of options exercised	283	4	144	(1)
Cash received	130	38	701	51
Total fair value of the options vested during the year	3,510	3,203	4,324	4,056

A summary of the status of the Company's nonvested options as of September 30, 2014, and changes during the nine months ended September 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	(1,440,148)	3.00
Options forfeited	(60,198)	4.35
Nonvested as of September 30, 2014	5,779,070	3.39

As of September 30, 2014, there was $13.8 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 2.5 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.

Table of Contents

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

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 $1.2 million for the three and nine months ended September 30, 2014, respectively, for these DSU awards, compared to the prior year expense for the three and nine months ended September 30, 2013 of $0.2 million and $0.4 million, respectively.

As of September 30, 2014, there was $5.8 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 3.4 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	449,544	$ 6,389
DSUs forfeited	(994)	
Common stock delivered	(9,497)	
DSUs surrendered for taxes	(7,774)	
DSUs outstanding at September 30, 2014	529,774	

(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 September 30, 2014 and December 31, 2013, the balance of the deferred revenue was $2.8 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.

Supply Agreement with MannKind Corporation

On July 31, 2014, the Company entered into 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 $152.3 million, in calendar years 2015 through 2019. MannKind may request to purchase additional quantities of Insulin over such annual minimum quantities.

Table of Contents

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

MannKind paid a non-refundable reservation fee to the Company in the amount of €11.0 million, or approximately $14.0 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 the Company 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 the Company without cause or upon 30 days prior written notice to the Company 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.

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 nine months ended September 30, 2014 was approximately $0.8 million and $2.3 million, respectively, compared to the prior year three and nine months ended September 30, 2013 when the expense was approximately $0.8 million and $2.4 million, respectively.

Purchase Commitments

As of September 30, 2014, the Company has entered into commitments to purchase equipment and raw materials for an aggregate of $7.7 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 September 30, 2014, the Company had invested approximately $41.0 million in ANP of its registered capital commitment of $61.0 million. The Company has committed to invest an additional $20.0 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.

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. During the three months ended September 30, 2014, the Company invested $3.2 million to fund the Company's research and development pipeline.

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 has implemented the required corrective actions. The Company believes that it addressed all of the observations, and the Company responded to the FDA with data supporting its actions in October 2014.

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's facility in Rancho Cucamonga, CA 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 responded to those observations on August 25, 2014. The Company believes that its responses to the Form 483 will satisfy the FDA and that no significant further actions will be necessary.

From August 27, 2014 through September 12, 2014, the Company's IMS facility in South El Monte, CA was subject to a current Good Manufacturing Practices inspection by the FDA. The inspections resulted in multiple observations on Form 483. The Company responded to those observations on October 3, 2014. The Company believes that its responses to the Form 483 will satisfy the FDA and that no significant further actions will be necessary.

AFP Environmental Indemnification

Prior to the Merck API Transaction, 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.

Table of Contents

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

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 the Company'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, and the Company filed its responding brief on September 25, 2014. Under the current briefing schedule for the appeal, Momenta's reply brief is due by November 13, 2014. A date for oral argument has not yet been set by the Federal Circuit.

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. On August 22, 2014, the Court of Appeals granted Aventis' petition. Under the current schedule, Aventis' opening appeal brief is due by December 1, 2014, and the Company's answering brief is due by January 2, 2015.

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. The Company filed its post-hearing brief on August 11, 2014, Aventis filed its post-hearing brief on September 10, 2014, and the Company filed its reply brief on September 24, 2014. The District Court conducted a hearing for closing argument on the original source issue on October 10, 2014. The original source issue currently is under submission with the District Court.

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 Events

On November 6, 2014, the Company’s Board of Directors authorized a $10.0 million share buyback program, which is expected to continue for an indefinite period of time. The primary goal of the program is to offset dilution created by the Company’s equity compensation programs.

Purchases may be made through the open market and private block transactions pursuant to Rule 10b5-1 plans, privately negotiated transactions or other means as determined by the Company’s management and in accordance with the requirements of the Securities and Exchange Commission.

The timing and actual number of shares repurchased will depend on a variety of factors including price, corporate and regulatory requirements, and other conditions.

Table of Contents

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, S.A.S., 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.

Results of Operations

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

Net revenues

	Three Months Ended September 30,		Change	
	2014	2013	Dollars	%
	(in thousands)			
Net revenues				
Enoxaparin	$32,040	$36,189	$(4,149)	(11%)
Insulin	5,982	—	5,982	100%
Other products	21,689	23,129	(1,440)	(6%)
Total net revenues	59,711	59,318	393	1%
Cost of revenues	47,920	39,038	8,882	23%
Gross profit	$11,791	$20,280	$(8,489)	(42%)
as % of net revenues	20%	34%		

Net revenues were $59.7 million and $59.3 million for the three months ended September 30, 2014 and 2013, respectively, representing an increase of $0.4 million, or 1%. The increase is primarily due to sales of recombinant human insulin and porcine insulin, or Insulin, at our recently established AFP subsidiary. This increase was offset by lower sales of enoxaparin and Cortrosyn®. Enoxaparin sales were down due to lower average prices, but unit sales of enoxaparin to Actavis increased due to the timing of shipments. Sales of naloxone increased in the current quarter,

which partially offset lower sales of other products.

Cost of revenues

Cost of revenues were $47.9 million and $39.0 million for the three months ended September 30, 2014 and 2013, respectively, representing an increase of $8.9 million, or 23%. The increase is primarily due to cost of sales of Insulin at AFP. Insulin inventory has been recorded at fair value due to purchase price accounting rules. Therefore shipments of insulin in the quarter were at a gross margin of approximately 0%. Additionally, reductions in production levels at AFP and the Company's Rancho Cucamonga facility during the three months ended September 30, 2014 resulted in higher manufacturing variances which caused a temporary increase in cost of revenues for the period.

Operating Expenses

	Three Months Ended September 30,		Change	
	2014	2013	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	$1,454	$1,462	$(8)	1%
General and administrative	9,556	9,545	11	0%
Research and development	8,585	9,041	(456)	(5%)
Impairment of long-lived assets	13	6	7	117%

General and administrative expenses were $9.6 million and $9.5 million for the three months ended September 30, 2014 and 2013, respectively. Expenses at AFP were offset by lower corporate expenses.

Research and development expenses were $8.6 million and $9.0 million for the three months ended September 30, 2014 and 2013, respectively, representing a decrease of $0.4 million, or 5%. The decrease is primarily due to decreased submission fees paid to the FDA during the three months ended September 30, 2014. This decrease was partially offset by increases in clinical trial expenses and expenses related to purchases of materials and other research and development supplies during the three months ended September 30, 2014. Research and development expenses are expected to increase in the next several quarters as we begin further clinical and pre-clinical trials.

Table of Contents

Provision for income tax expense (benefit)

	Three Months Ended September 30,		Change	
	2014	2013	Dollars	%
	(in thousands)			
Income tax expense (benefit)	$(2,605)	$494	$(3,099)	(627)%
Effective tax rate	(33)%	147%		

Income tax benefit was $2.6 million for the three months ended September 30, 2014 compared to an income tax expense of $0.5 million for the three months ended September 30, 2013, representing a decrease in income tax expense of $3.1 million. The decrease in income tax expense is primarily related to the pre-tax loss that occurred during the third quarter of 2014.

Nine Months Ended September 30, 2014 Compared to Nine Months Ended September 30, 2013

Net revenues

	Nine Months Ended September 30,		Change	
	2014	2013	Dollars	%
	(in thousands)			
Net revenues				
Enoxaparin	$85,337	$111,326	$(25,989)	(23)%
Insulin	6,084	—	6,084	100%
Other products	63,163	63,479	(316)	0%
Total net revenues	154,584	174,805	(20,221)	(12)%
Cost of revenues	115,288	107,478	7,810	7%
Gross profit	$39,296	$67,327	$(28,031)	(42)%
as % of net revenues	25%	39%		

Net revenues were $154.6 million and $174.8 million for the nine months ended September 30, 2014 and 2013, respectively, representing a decrease of $20.2 million, or 12%. The decrease is primarily due to decreases in overall sales of enoxaparin and Cortrosyn®. This decrease was partially offset by sales of Insulin from AFP and an increase in sales of naloxone.

Cost of revenues

Cost of revenues were $115.3 million and $107.5 million for the nine months ended September 30, 2014 and 2013, respectively, representing an increase of $7.8 million, or 7%. The increase is primarily related to the Company’s AFP business. The decrease in gross profit as a percentage of sales was due to lower pricing on enoxaparin and Cortrosyn® as well as negative gross margins in the AFP subsidiary.

Operating Expenses

	Nine Months Ended September 30,		Change	
	2014	2013	Dollars	%
	(in thousands)			

Selling, distribution, and marketing	$4,066	$4,059	$7	0	%
General and administrative	25,040	22,966	2,074	9	%
Research and development	20,788	25,736	(4,948)	(19	%)
Impairment of long-lived assets	361	6	355	5,917	%

General and administrative expenses were $25.0 million and $23.0 million for the nine months ended September 30, 2014 and 2013, respectively, representing an increase of $2.0 million, or 9%. The increase is due to an increase in compensation expense including stock based compensation expense as well as expenses related to AFP.

Research and development expenses were $20.8 million and $25.7 million for the nine months ended September 30, 2014 and 2013, respectively, representing a decrease of $4.9 million, or 19%. The decrease is primarily due to decreased submission fees paid to the FDA during the nine months ended September 30, 2014 and a decrease in spending on materials and other research and development supplies. This decrease was partially offset by an increase in payroll expense and clinical trials expense. Research and development expenses are expected to increase in the next several quarters as we begin further clinical and pre-clinical trials.

Impairment of long-lived assets was $0.4 million for the nine months ended September 30, 2014. For the nine months ended September 30, 2013, the Company recorded an immaterial amount of impairment of long-lived asset expense. The write-off during the nine months ended September 30, 2014 was primarily related to capitalized costs associated with a project that was suspended.

Provision for income tax expense (benefit)

	Nine Months Ended September 30,		Change	
	2014	2013	Dollars	%
	(in thousands)			
Income tax expense (benefit)	$(4,153)	$4,412	$(8,565)	(194 %)
Effective tax rate	(34 %)	31 %		

Income tax benefit was $4.2 million for the nine months ended September 30, 2014 compared to an income tax expense of $4.4 million for the nine months ended September 30, 2013, representing a decrease in income tax expense of $8.6 million. The decrease in income tax expense is primarily related to a pre-tax loss that occurred during the nine months ended September 30, 2014.

Table of Contents

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 Quarterly 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 $44.5 million to $152.1 million at September 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 ($8.7 million) and the proceeds from the Company's IPO ($34.7 million) partially offset by payments on debt ($7.1 million), payments pertaining to the acquisition of Merck's API manufacturing business in Éragny-sur-Epte, France, or the Merck API Transaction ($18.4 million), and capital expenditures ($11.7 million).

Cash Flows from Operations

The following table summarizes the Company's cash flows used in operating, investing, and financing activities for the nine months ended September 30, 2014:

	Nine Months Ended September 30, 2014 (in thousands)
Statement of Cash Flow Data:	
Net cash provided by (used in)	
Operating activities	$ 8,729
Investing activities	(29,845)
Financing activities	40,670
Effect of exchange rate changes on cash	(260)
Net increase (decrease) in cash and cash equivalents	$ 19,294

Sources and Use of Cash

Operating Activities

Net cash provided by operating activities was $8.7 million for the nine months ended September 30, 2014, which included a net loss of $8.2 million. Non-cash items are comprised of $10.7 million of depreciation and amortization and $6.7 million of share-based compensation expense. Additionally, the Company received a deposit of €11.0 million, or approximately $14.0 million, from MannKind Corporation for future deliveries of insulin. For the nine months ended September 30, 2014, inventory decreases were partially offset by increases in receivables.

Investing Activities

Net cash used in investing activities of $29.8 million for the nine months ended September 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 $11.7

million in purchases of property, machinery, and equipment, including the associated capitalized labor and interest on self-constructed assets. Additionally, $0.4 million in deposits were made for machinery and equipment.

Financing Activities

Net cash provided by financing activities of $40.7 million for the nine months ended September 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 was $0.2 million relating to various equity transactions, $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, $15.0 million in net repayments related to the Company's line of credit and $7.1 million in principal payments on long-term debt.

Table of Contents

Debt and Borrowing Capacity

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

	September 30, 2014	December 31, 2013	Change
		(in thousands)	
Short-term debt and current portion of long-term debt	$10,078	$ 22,104	$(12,026)
Long-term debt	41,271	10,069	31,202
Total debt	$51,349	$ 32,173	$19,176

The increase in long-term debt is primarily related to the debt associated with the Merck API Transaction 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.

In August 2014, the FASB issued an accounting standards update that will require management to evaluate if there is substantial doubt about the Company’s ability to continue as a going concern and, if so, to disclose this in both interim and annual reporting periods. This guidance will become effective for the Company’s annual filing for the period ending December 31, 2016 and interim periods thereafter, and allows for early adoption. 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.

Table of Contents

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 September 30, 2014, the Company had $5.9 million deposited in three banks located in China and $14.6 million deposited in one bank located in France. The Company also maintained $40.0 million in Money Market, Money Market Insured Deposit Account Service, or MMIDAS, and Insured Cash Sweep, or ICS, accounts as of September 30, 2014. The remaining amounts of the Company's cash equivalent as of September 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 with respect to its short-term investments.

As of September 30, 2014, the Company had $51.3 million in long-term debt and capital leases outstanding. Of this amount, $30.9 million had variable interest rates with a weighted-average interest rate of 4.0% at September 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

The Company's products are primarily sold in U.S. domestic market, and for the three and nine months ended September 30, 2014 and 2013, foreign sales were minimal. Therefore, the Company has little exposure to foreign currency price fluctuations. However, as a result of the Company's acquisition of the Insulin business in France, the Company is exposed to market risk related to changes in foreign currency exchange rates. Specifically, the Company's insulin sales contracts are primarily denominated in Euros, which are subject to fluctuations relative to the U.S. dollar. The Company does not currently hedge its foreign currency exchange rate risk. At this time, an immediate 10% change in currency exchange rates would not have a material effect on its financial position, results of operations or cash flows.

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, S.A.S., 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 September 30, 2014, ANP had receivables denominated in CNY in the amount of $2.2 million.

Table of Contents

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 September 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

Except as set forth below there were no material changes from the risk factors previously disclosed in the Company's IPO prospectus filed June 25, 2014 and our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2014, as filed with the SEC on August 13, 2014.

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 54% of our total net revenues for the year ended December 31, 2013 and the three months ended September 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.

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

We recorded net losses of $1.6 million, $1.2 million, and $5.4 million for the three months ended March 31, 2014, June 30, 2014, and September 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, and a net loss of $0.2 million for the three months ended September 30, 2013, respectively. The losses 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.

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 September 30, 2014, respectively, accounted for approximately 54% and 46% 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.

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 September 30, 2014 the value of our goodwill and intangible assets net of accumulated amortization was $43.2 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.

Risks Relating to Regulatory Matters

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 September 30, 2014, we recorded net revenues of $29.6 million and $8.3 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.

Risks Related to Ownership of Our Common Stock

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 November 10, 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 November 10, 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 26.2% 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 November 10, 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.

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

(a) Recent Sales of Unregistered Securities

None.

(b) Use of Proceeds

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 and our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2014, as filed with the SEC on August 13, 2014.

(c) Issuer Purchases of Equity Securities

The table below provides information with respect to repurchases of our common stock.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
July 1 – July 31, 2014	—	—	—	—
August 1 – August 31, 2014	—	—	—	—
September 1 – September 30, 2014	35,000 [1]	$11.81	—	—

[1] In September 2014, the Company issued and sold to former employees an aggregate of 35,000 shares of common stock upon exercise of options at exercise prices ranging from $1.75 to $10.73 per share. These former employees elected to take a net cash settlement upon exercise of their stock options. As a result, the Company repurchased the shares with an average price of $11.18 per share.

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.

Table of Contents

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: November 13, 2014

AMPHASTAR PHARMACEUTICALS, INC.
(Registrant)

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

Date: November 13, 2014

Table of Contents

AMPHASTAR PHARMACEUTICALS, INC.
EXHIBIT INDEX TO FORM 10-Q
For the Quarterly Period Ended September 30, 2014

Exhibit No.	Description
10.1†	Supply Agreement, dated July 31, 2014, between MannKind Corporation and Amphastar France Pharmaceuticals, S.A.S.
10.2	First Amendment to Supply Agreement, dated October 31, 2014, by and between MannKind Corporation, Amphastar France Pharmaceuticals, S.A.S., and Amphastar Pharmaceuticals, Inc.
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.

† Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the SEC.