Amphastar Pharmaceuticals, Inc.
Form 10-Q
November 13, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2015

or

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

For the transition period from to

Commission file number 001-36509

AMPHASTAR PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

11570 6th Street

Rancho Cucamonga, CA 91730

(Address of principal executive offices, including zip code)

(909) 980-9484

(Registrant's telephone number, including area code)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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 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	(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

The number of shares outstanding of the Registrant's only class of common stock as of November 9, 2015 was 45,019,525.

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FORM 10-Q FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2015

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SPECIAL 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 our manufacturing and production and 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 implementation of our business strategies, product candidates and technology;

- the potential for exposure to product liability claims;

- future acquisitions or investments;

- our ability to expand internationally;

- economic and industry trends and trend analysis;

- 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, including our expectations regarding our revenue, cost of revenue, gross profit or gross margin, operating expenses, including changes in research and development, sales and marketing and general and administrative expenses, and our ability to achieve and maintain future profitability.

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 and in our Annual Report on Form 10-K for the year ended December 31, 2014, particularly in 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 to “Amphastar,” “the Company,” “we,” “our,” and “us” refer to Amphastar Pharmaceuticals, Inc. and our subsidiaries, unless the context indicates otherwise.

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PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

AMPHASTAR PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share data)

	September 30, 2015 (unaudited)	December 31, 2014
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 70,681	$ 67,828
Restricted cash and restricted short-term investments	1,285	1,495
Accounts receivable, net	24,998	22,852
Inventories, net	72,422	82,332
Income tax refund and deposits	6,297	273
Prepaid expenses and other assets	4,200	3,683
Deferred tax assets	19,176	19,533
Total current assets	199,059	197,996
Property, plant, and equipment, net	141,181	138,289
Goodwill and intangible assets, net	40,485	42,565
Other assets	4,364	3,588
Deferred tax assets	9,938	6,932
Total assets	$ 395,027	$ 389,370
LIABILITIES AND EQUITY		
Current Liabilities:		
Accounts payable	$ 12,265	$ 10,161
Accrued liabilities	22,622	13,144
Income taxes payable	2,094	3,123
Accrued payroll and related benefits	15,711	11,449
Current portion of product return accrual	2,395	1,918
Current portion of deferred revenue	643	14,013
Current portion of long-term debt and capital leases	14,762	7,594
Current portion of deferred tax liabilities	161	1,193
Total current liabilities	70,653	62,595

Long-term product return accrual	751	490
Long-term reserve for income tax liabilities	514	499
Long-term deferred revenue	1,500	1,982
Long-term debt and capital leases, net of current portion	31,354	36,106
Long-term deferred tax liabilities	5,838	5,838
Other long-term liabilities	631	—
Total liabilities	111,241	107,510
Commitments and Contingencies:		
Stockholders' equity:		
Preferred stock: par value $.0001; authorized shares—20,000,000; no shares issued and outstanding	—	—
Common stock: par value $.0001; authorized shares—300,000,000; issued and outstanding shares—45,206,511 and 44,646,767 at September 30, 2015 and December 31, 2014, respectively	5	4
Additional paid-in capital	240,745	220,745
Retained earnings	52,790	63,110
Accumulated other comprehensive loss	(3,760)	(1,654)
Treasury stock	(5,994)	(345)
Total stockholders' equity	283,786	281,860
Total liabilities and stockholders' equity	$ 395,027	$ 389,370

See Accompanying Notes to Condensed Consolidated Financial Statements.

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AMPHASTAR PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited; in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net revenues	$ 63,868	$ 59,711	$ 174,607	$ 154,584
Cost of revenue	46,290	47,920	130,431	115,288
Gross profit	17,578	11,791	44,176	39,296
Operating expenses:				
Selling, distribution, and marketing	1,171	1,454	4,163	4,066
General and administrative	9,034	9,556	32,793	25,040
Research and development	11,117	8,585	28,411	20,788
Impairment of long-lived assets	4	13	78	361
Total operating expenses	21,326	19,608	65,445	50,255
Loss from operations	(3,748)	(7,817)	(21,269)	(10,959)
Non-operating income (expense):				
Interest income	83	94	240	154
Interest expense	(232)	(504)	(783)	(1,159)
Other income (expense), net	(379)	243	1,110	(367)
Total non-operating income (expense), net	(528)	(167)	567	(1,372)
Loss before income taxes	(4,276)	(7,984)	(20,702)	(12,331)
Income tax benefit	(1,268)	(2,605)	(10,382)	(4,153)
Net loss	$ (3,008)	$ (5,379)	$ (10,320)	$ (8,178)
Net loss per share:				
Basic	$ (0.07)	$ (0.12)	$ (0.23)	$ (0.20)
Diluted	$ (0.07)	$ (0.12)	$ (0.23)	$ (0.20)
Weighted-average shares used to compute net loss per share:				
Basic	45,310	44,644	44,920	41,060
Diluted	45,310	44,644	44,920	41,060

See Accompanying Notes to Condensed Consolidated Financial Statements.

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AMPHASTAR PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(Unaudited; in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net loss	$ (3,008)	$ (5,379)	$ (10,320)	$ (8,178)
Accumulated other comprehensive income (loss)				
Foreign currency translation adjustment	374	(1,535)	(2,106)	(1,803)
Total accumulated other comprehensive income (loss)	374	(1,535)	(2,106)	(1,803)
Total comprehensive loss	$ (2,634)	$ (6,914)	$ (12,426)	$ (9,981)

See Accompanying Notes to Condensed Consolidated Financial Statements.

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AMPHASTAR PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited; in thousands)

	Nine Months Ended September 30,	
	2015	2014
Cash Flows From Operating Activities:		
Net loss	$ (10,320)	$ (8,178)
Reconciliation to net cash provided by (used in) operating activities:		
Impairment of long-lived assets	78	361
Loss on disposal of property, plant, and equipment	19	44
Depreciation of property, plant, and equipment	8,516	9,235
Amortization of product rights, trademarks, and patents	1,458	1,437
Imputed interest accretion	83	66
Employee share-based compensation expense	8,687	5,952
Non-employee share-based compensation expense	670	728
Reserve for income tax liabilities	16	—
Changes in deferred taxes	(3,541)	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(2,706)	(2,019)
Inventories, net	8,549	1,609
Income tax refund and deposits	21	2,690
Prepaid expenses and other assets	(6,516)	(1,318)
Income taxes payable	(1,083)	(5,456)
Accounts payable and accrued liabilities	3,463	3,578
Net cash provided by operating activities	7,394	8,729
Cash Flows From Investing Activities:		
Acquisition of business	—	(18,352)
Purchases of property, plant, and equipment	(10,685)	(11,118)
Capitalized labor, overhead, and interest on self-constructed assets	(1,242)	(555)
Proceeds from the sale of property, plant and equipment	51	—
Decrease (increase) in restricted cash	210	(170)
Deposits and other assets, net	(800)	350
Net cash used in investing activities	(12,466)	(29,845)
Cash Flows From Financing Activities:		
Net proceeds from issuance of common stock	—	38,018
Net proceeds from equity plans	11,539	216
Cost related to public offering	—	(1,920)
Repurchase of common stock	(857)	—
Payments on treasury stock	(5,687)	—
Proceeds from borrowing under lines of credit	—	25,000

Repayments under lines of credit	—	(40,000)
Proceeds from issuance of long-term debt	6,786	26,505
Principal payments on long-term debt	(3,973)	(7,149)
Net cash provided by financing activities	7,808	40,670

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	Nine Months Ended September 30,	
	2015	2014
Effect of exchange rate changes on cash	117	(260)
Net increase in cash and cash equivalents	2,853	19,294
Cash and cash equivalents at beginning of period	67,828	53,587
Cash and cash equivalents at end of period	$ 70,681	$ 72,881
Noncash Investing and Financing Activities:		
Equipment acquired under capital leases	$ 150	$ 78
Supplemental Disclosures of Cash Flow Information:		
Interest paid	$ 1,345	$ 978
Income taxes paid	$ 45	$ 86

See Accompanying Notes to Condensed Consolidated Financial Statements.

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AMPHASTAR PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. General

Amphastar Pharmaceuticals, Inc., a California corporation, was incorporated on February 29, 1996 and merged with and into Amphastar Pharmaceuticals, Inc., a Delaware corporation, in July 2004 (hereinafter referred to as "the Company"). The Company is a specialty pharmaceutical company that primarily develops, manufactures, markets, and sells generic and proprietary injectable and inhalation products, including products with high technical barriers to market entry. Additionally, in 2014, the Company commenced sales of insulin active pharmaceutical ingredient, or API products. 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 insulin API products are primarily sold to other pharmaceutical companies for use in their own products. 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, 2014 and the notes thereto as filed with the Securities and Exchange Commission in the Company's Annual Report on Form 10-K for the year ended December 31, 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, comprehensive loss 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, comprehensive loss 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.

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, provision for chargebacks, liabilities for product returns, reserves for excess or unsellable inventory, impairment of long-lived and intangible assets and goodwill, self-insured claims,

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AMPHASTAR PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

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 into USD using 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 loss. Additionally, the Company does not undertake hedging transactions to cover its foreign currency exposure.

Comprehensive Loss

For the Company's French subsidiary, AFP, the Euro, which is the local currency, has been determined to be the functional currency. The results of AFP's operations are translated into USD using the average exchange rates during the period.

For the three and nine months ended September 30, 2015 and 2014, the Company included its foreign currency translation as part of its comprehensive 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 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 12).

Deferred Income Taxes

The Company utilizes the liability method of accounting for income taxes, under which 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, which 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

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AMPHASTAR PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

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.

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 April 2014, the FASB issued an accounting standards update that raised 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 is effective for fiscal years beginning after December 15, 2014, which is the Company's fiscal year 2015, with early adoption permitted. The adoption of the guidance did not 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, 2017, which will be the Company's fiscal year 2018. 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.

In July 2015, the FASB issued an accounting standards update which requires entities to measure most inventories at the lower of cost and net realizable value, or NRV, thereby simplifying the current guidance under which an entity must measure inventory at the lower of cost or market. Under the new guidance, inventory is measured at the lower of cost and net realizable value, which eliminates the need to determine replacement cost and evaluate whether it is above the ceiling (NRV) or below the floor (NRV less a normal profit margin). The guidance defines NRV as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance is effective for annual periods beginning after December 15, 2016, and interim periods therein. The

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AMPHASTAR PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

standard will be effective for the Company for the first quarter of the Company's fiscal year 2016. Early application is permitted. The new guidance must be applied prospectively. The Company does not believe the adoption of this accounting guidance will have a material impact on the Company's consolidated financial statements and related disclosures.

3. Business Acquisition

Acquisition of Merck's API Manufacturing Business

On April 30, 2014, the Company completed the acquisition of the Merck Sharpe & Dohme's API manufacturing business in Éragny-sur-Epte, France, or the Merck API Transaction, which manufactures porcine insulin API and recombinant human insulin API. The purchase price of the transaction totaled €24.8 million, or $34.4 million on April 30, 2014, 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 12):

	Euros	U.S. Dollars
	(in thousands)	
At Closing, April 2014	€ 13,252	$ 18,352
December 2014	4,899	5,989
December 2015	3,186	3,582
December 2016	3,186	3,582
December 2017	500	562
	€ 25,023	$ 32,067

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, or RHI API. As part of the transaction, the Company has entered into various additional agreements, including various supply agreements, as well as the assignment and/or licensing of patents under which Merck was operating at this facility. In addition, certain existing customer agreements have been assigned to AFP.

The transaction is accounted for as a business combination in accordance with 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 and 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

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(Unaudited)

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, 2015 and 2014 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,	
	2015	2014
	(in thousands, except per share data)	
Net revenues	$ 174,607	$ 156,868
Net loss	(10,320)	(9,407)
Diluted net loss per share	$ (0.23)	$ (0.23)

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.

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 Allergan plc, or Allergan (see Note 16). Profit-sharing revenue is recognized at the time Allergan sells the products to its customers. Revenues derived from contract manufacturing services are recognized when third-party products are shipped to customers, after the customer has accepted test samples of the products to be shipped.

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AMPHASTAR PHARMACEUTICALS, INC.

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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 receivable. The following table is an analysis of the chargeback provision:

	Nine Months Ended September 30,	
	2015	2014
	(in thousands)	
Beginning balance	$ 11,872	$ 18,104
Provision related to sales made in the current period	121,714	118,643

Credits issued to third parties	(121,914)	(124,449)
Ending balance	$ 11,672	$ 12,298

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's 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 Allergan 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.

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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,	
	2015	2014
	(in thousands)	
Beginning balance	$ 2,408	$ 4,592
Provision for product returns	1,971	(261)
Credits issued to third parties	(1,233)	(1,042)
Ending balance	$ 3,146	$ 3,289

For the nine months ended September 30, 2015 and 2014, the Company's aggregate product return rate was 1.1% and 1.2% of qualified sales, respectively.

5. Loss per Share

Basic loss per share is calculated based upon the weighted-average number of shares outstanding during the period and contingently issuable shares such as fully vested deferred stock units, or DSUs, and in 2015, such equity was issued as restricted stock units, or RSUs (such RSUs and DSUs are collectively referred to herein as RSUs), in addition to shares expected to be issued under the Company's employee stock purchase plan, or ESPP, as of the date all necessary conditions for issuance have been met. Diluted income per share gives effect to all potential dilutive shares outstanding during the period, such as stock options, nonvested RSUs and shares issuable under the Company's ESPP.

As the Company reported a net loss for the three and nine months ended September 30, 2015 and 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 vesting of nonvested RSUs and issuance of common shares under the Company's ESPP are anti-dilutive. Total stock options, nonvested RSUs, and shares issuable under the Company's ESPP, excluded from the three and nine months ended September 30, 2015, net loss per share were 12,471,789; 877,665, and 165,167, respectively. Additionally, as the Company reported a net loss for the three and nine months ended September 30,

2014, total stock options and nonvested RSUs excluded from the three and nine months ended September 30, 2014, net loss per share were 11,511,431 and 529,774, respectively.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(in thousands, except per share data)			
Basic and dilutive numerator:				
Net loss	$ (3,008)	$ (5,379)	$ (10,320)	$ (8,178)
Denominator:				
Shares outstanding	45,310	44,642	44,920	41,058
Contingently issuable shares – vested RSUs	—	2	—	2
Weighted-average shares outstanding — basic	45,310	44,644	44,920	41,060
Net effect of dilutive securities:				
Stock options	—	—	—	—
Contingently issuable shares – nonvested RSUs	—	—	—	—
Weighted-average shares outstanding — diluted	45,310	44,644	44,920	41,060
Net loss per share — basic	$ (0.07)	$ (0.12)	$ (0.23)	$ (0.20)
Net loss per share — diluted	$ (0.07)	$ (0.12)	$ (0.23)	$ (0.20)

6. Segment Reporting

The Company’s business is the development, manufacture, and marketing of pharmaceutical products. The Company has established two reporting segments that each report to the Chief Operating Decision Maker, or CODM, as defined in ASC 280, Segment Reporting. The Company’s performance is assessed and resources are 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.

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Selected financial information by reporting segment is presented below:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(in thousands)			
Net revenues:				
Finished pharmaceutical products	$ 57,902	$ 53,729	$ 158,849	$ 148,500
API	5,966	5,982	15,758	6,084
Total net revenues	63,868	59,711	174,607	154,584
Gross Profit:				
Finished pharmaceutical products	19,302	12,122	44,789	39,592
API	(1,724)	(331)	(613)	(296)
Total gross profit	17,578	11,791	44,176	39,296
Operating expenses	21,326	19,608	65,445	50,255
Loss from operations	(3,748)	(7,817)	(21,269)	(10,959)
Non-operating income (expenses)	(528)	(167)	567	(1,372)
Loss before income taxes	$ (4,276)	$ (7,984)	$ (20,702)	$ (12,331)

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		Long-Lived Assets	
Three Months Ended September 30,	Nine Months Ended September 30,	September 30,	December 31,

	2015	2014	2015	2014	2015	2014
	(in thousands)					
U.S.	$ 62,955	$ 53,729	$ 168,705	$ 148,500	$ 100,415	$ 102,313
China	—	—	—	—	27,535	22,170
France	913	5,982	5,902	6,084	13,231	13,806
Total	$ 63,868	$ 59,711	$ 174,607	$ 154,584	$ 141,181	$ 138,289

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. Allergan plc has exclusive marketing rights of the Company's enoxaparin product to the U.S. retail pharmacy market. MannKind Corporation began buying RHI API from the Company in December 2014. The Company considers these five customers to be its major customers, as each individually, and these customers collectively, represented a significant percentage of the Company's net revenue for the three and nine months ended September 30, 2015 and 2014 and accounts receivable as of September 30, 2015 and

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December 31, 2014. The following table provides accounts receivable and net revenues information for these major customers:

	% of Total Accounts Receivable		% of Net Revenue			
			Three Months Ended		Nine Months Ended	
	September 30, 2015	December 31, 2014	September 30, 2015	2014	2015	2014
Allergan plc(1)	17 %	18 %	22 %	35 %	22 %	33 %
AmerisourceBergen	13 %	5 %	17 %	14 %	17 %	15 %
Cardinal Health	17 %	15 %	14 %	13 %	16 %	14 %
MannKind Corporation	5 %	21 %	7 %	—	7 %	—
McKesson	25 %	13 %	25 %	19 %	22 %	23 %

(1) In June 2015, Actavis plc adopted Allergan plc as its new global name.

Supplier Concentrations

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

8. Fair Value Measurements

The accounting standards of the Financial Accounting Standards Board, or FASB, define fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in

the principal or most advantageous market for the asset or liability at the measurement date (an exit price). These standards also establish a hierarchy that prioritizes observable and unobservable inputs used in measuring fair value of an asset or liability, as described below:

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

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

- Level 3 – Inputs to measure fair value are unobservable and the assets or liabilities have little, if any, market activity; these inputs reflect the Company's own assumptions about the assumptions that market participants would use in pricing the assets or liabilities based on best information available in the circumstances.

The Company measures fair value based on the prices that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

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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, 2015 and December 31, 2014, are as follows:

	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
	(in thousands)			
Cash equivalents:				
Money market accounts	$ 47,920	$ 47,920	$ —	$ —
Restricted short-term investments:				
Certificates of deposit	1,285	1,285	—	—
Fair value measurement as of September 30, 2015	$ 49,205	$ 49,205	$ —	$ —
Cash equivalents:				
Money market accounts	$ 42,994	$ 42,994	$ —	$ —
Restricted short-term investments:				
Certificates of deposit	1,495	1,495	—	—
Fair value measurement as of December 31, 2014	$ 44,489	$ 44,489	$ —	$ —

The fair value of the Company's cash equivalents includes money market funds and certificates of deposit with original maturities of three months 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, 2015 and December 31, 2014, there were no significant adjustments to fair value for nonfinancial assets or liabilities.

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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 (in thousands)	Accumulated Amortization	Net Book Value
Definite-lived intangible assets				
Product rights	12	$ 27,134	$ 22,233	$ 4,901
Patents	10	293	100	193
Trademarks	11	15	15	—
Land-use rights	39	2,540	271	2,269
Other intangible assets	1	595	530	65
Subtotal	12	30,577	23,149	7,428
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill				
Finished pharmaceutical products	*	280	—	280
API	*	3,552	—	3,552
Subtotal	*	33,057	—	33,057
As of September 30, 2015	*	$ 63,634	$ 23,149	$ 40,485

	Weighted-Average Life (Years)	Original Cost	Accumulated Amortization	Net Book Value

		(in thousands)		
Definite-lived intangible assets				
Product rights	12	$ 27,134	$ 20,896	$ 6,238
Patents	10	293	78	215
Trademarks	11	19	15	4
Land-use rights	39	2,540	221	2,319
Other intangible assets	1	602	505	97
Subtotal	12	30,588	21,715	8,873
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill				
Finished pharmaceutical products	*	280	—	280
API	*	4,187	—	4,187
Subtotal	*	33,692	—	33,692
As of December 31, 2014	*	$ 64,280	$ 21,715	$ 42,565

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

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Goodwill

The Changes in the carrying amounts of goodwill were as follows:

	September 30, 2015	December 31, 2014
	(in thousands)	
Beginning balance	$ 4,467	$ 280
Goodwill related to acquisition of business	—	4,369
Currency translation and other adjustments	(635)	(182)
Ending balance	$ 3,832	$ 4,467

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, 2015.

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

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

In 2013, the Company filed a new drug application, or NDA, for Primatene® Mist HFA and received a Prescription Drug User Fee Act date set for May 2014. In May 2014, the Company received a complete response letter, or CRL, from the FDA, which requires additional non-clinical information, label revisions and follow-up studies (label comprehension, behavioral and actual use) to assess consumers' ability to use the device correctly to support approval of the product in the over-the-counter setting. Additionally 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.

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.

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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 the following:

	September 30, 2015	December 31, 2014
	(in thousands)	
Raw materials and supplies	$ 32,555	$ 41,996
Work in process	21,537	16,221
Finished goods	19,351	24,755
Total inventory	73,443	82,972
Less reserve for excess and obsolete inventories	(1,021)	(640)
Total inventory, net	$ 72,422	$ 82,332

11. Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

	September 30, 2015	December 31, 2014
	(in thousands)	
Building	$ 69,050	$ 67,760
Leasehold improvements	23,320	23,960
Land	6,929	7,020
Machinery and equipment	107,030	104,819

Furniture, fixtures, and automobiles	12,910	12,213
Construction in progress	31,679	25,068
Total property, plant, and equipment	250,918	240,840
Less accumulated depreciation	(109,737)	(102,551)
Total property, plant, and equipment, net	$ 141,181	$ 138,289

As of September 30, 2015, the Company had $2.9 million in capitalized manufacturing equipment that is intended to be used specifically for the manufacture of Primatene® Mist HFA. 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).

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12. Debt

Debt consists of the following:

	September 30, 2015	December 31, 2014
	(in thousands)	
Loans with East West Bank		
Mortgage payable due January 2016	$ 3,766	$ 3,887
Mortgage payable due September 2016	2,231	2,289
Line of credit facility due March 2016	—	—
Equipment loan due April 2017	2,010	2,923
Equipment loan due January 2019	5,133	—
Loans with Cathay Bank		
Mortgage payable due April 2021	4,483	4,549
Revolving line of credit due May 2016	—	—
Acquisition loan due April 2019	19,484	20,870
Loans with Seine-Normandie Water Agency		
French government loan 1 due March 2018	47	—
French government loan 2 due June 2020	131	—
French government loan 3 due July 2021	333	—
Payment obligation to Merck	7,621	8,160
Equipment under Capital Leases	877	1,022
Total debt and capital leases	46,116	43,700
Less current portion of long-term debt and capital leases	14,762	7,594
Long-term debt and capital leases, net of current portion	$ 31,354	$ 36,106

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%.

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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, 2015, 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. In March 2013, the Company converted the outstanding principal balance of $4.9 million 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.

Equipment Loan—Due January 2019

In July 2013, the Company entered into an $8.0 million line of credit facility. Borrowings under the facility were secured by equipment. The facility bore interest at the prime rate as published in The Wall Street Journal plus 0.25% and was to mature in January 2019.

In January 2015, the Company drew down $6.2 million from the line of credit facility. Subsequently, the facility was then converted into an equipment loan with an outstanding principal balance of $6.2 million. Borrowings under the facility are secured by equipment purchased with the debt proceeds. The Company entered into a fixed interest rate swap contract on this facility to exchange the floating rate for a fixed interest payment over the life of the facility without the exchange of the underlying notional debt amount. The fair value of the derivative and unrealized loss was immaterial to the Company’s consolidated financial statement at September 30, 2015. The facility bears interest at a

fixed rate of 4.48% and matures in January 2019. As of September 30, 2015, the loan had a book value of $5.1 million, which approximates fair value. The variable interest rate is deemed to be a Level 2 input for measuring fair value.

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 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, 2015, the loan had a fair value of $4.7 million, compared to a book value of $4.5 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 receivable, 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

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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, 2015, 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.

Loans with Seine-Normandie Water Agency

In January 2015, the Company entered into three French government loans with the Seine-Normandie water agency in the aggregate amount of €0.6 million, or $0.7 million, subject to currency exchange fluctuations. The life of the loans range between three to six years, and includes annual equal payments and bears no interest over the life of the loans.

As of September 30, 2015, the payment obligation had an aggregate book value of €0.5 million, or $0.5 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.

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. In December 2014, the Company made a principal payment of €4.9 million, or $6.0 million.

As of September 30, 2015, the payment obligation had a book value of €6.8 million, or $7.6 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.

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Covenants

At September 30, 2015, 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. At December 31, 2014, the Company was not in compliance with two of its financial covenants with Cathay Bank. The first one requiring a fixed charge coverage ratio of 1.2 to 1.0, or greater, and the second one required a minimum debt service coverage ratio of 1.5 to 1.0, or greater. On March 13, 2015, the Company obtained waivers of the debt covenants for the period ending December 31, 2014.

Equipment under Capital Leases

The Company entered into leases for certain equipment under capital leasing arrangements, which will expire at various times through 2020. The cost of equipment under capital leases was $1.5 million at September 30, 2015 and December 31, 2014.

The accumulated depreciation of equipment under capital leases was $0.6 million and $0.4 million at September 30, 2015 and December 31, 2014, respectively. Depreciation of assets recorded under capital leases is included in depreciation expense in the accompanying consolidated financial statements.

13. 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,	
	2015	2014	2015	2014
	(in thousands)			
Loss before taxes	$ (4,276)	$ (7,984)	$ (20,702)	$ (12,331)
Income tax benefit	(1,268)	(2,605)	(10,382)	(4,153)
Net loss	$ (3,008)	$ (5,379)	$ (10,320)	$ (8,178)
Income tax benefit as a percentage of income before income taxes	(29.7) %	(32.6) %	(50.1) %	(33.7) %

The Company's income tax benefit for the three and nine months ended September 30, 2015 was 29.7% and 50.1% of income before income taxes, respectively. The blended effective income tax rate expected for the year ended December 31, 2015 is 51.5%. 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 benefit of 32.6% and 33.7% during the three and nine months ended September 30, 2014, respectively, factored in similar deductions as well as the impact of foreign operations.

Valuation Allowance

In assessing the need for a valuation allowance, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized. Ultimately, the realization of deferred tax assets depends on the existence of future taxable income. Management considers sources of taxable income such as income in prior carryback periods, future reversal of existing deferred taxable temporary differences, projected future taxable income, and tax-planning strategies. Based on all available evidence, management believes that the Company's deferred tax assets will more likely than not be realized in future years.

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In connection with the AFP purchase accounting, the Company recorded a valuation allowance against an intangible deferred tax asset of €3.2 million, or $4.4 million with an offsetting entry to goodwill, since management did not believe that it was more likely than not that the deferred tax asset would be realized. In March 2015, the Company reversed the €3.2 million, or $3.3 million deferred tax valuation allowance in conjunction with the transfer of AFPs intangible assets from France to the U.S. The difference in U.S. dollars relates to the currency exchange fluctuation, which is recorded in the Company's accumulated other comprehensive loss as a foreign currency translation adjustment.

14. Stockholders' Equity

A summary of the changes in stockholders' equity for the nine months ended September 30, 2015 consisted of the following:

	Nine Months Ended September 30, 2015 (in thousands)
Stockholders' equity as of December 31, 2014	$ 281,860
Net loss	(10,320)
Accumulated other comprehensive loss	(2,106)
Exercise of stock options	11,539
Nonemployee share-based compensation expense	670
Employee share-based compensation expense	8,687
Repurchase of common stock(1)	(857)
Purchase of treasury stock	(5,687)
Stockholders' equity as of September 30, 2015	$ 283,786

(1) Repurchase of common stock relating to the tax withholding of equity award settlements.

2014 Employee Stock Purchase Plan

In June 2014, the Company adopted the Employee Stock Purchase Plan, or ESPP, in connection with its initial public offering. A total of 2,000,000 shares of common stock are reserved for issuance under this plan. The Company's ESPP permits eligible employees to purchase common stock at a discount through payroll deductions during defined offering periods. Under the ESPP, the Company may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of its common stock will be purchased for employees participating in the offering. An offering may be terminated under certain circumstances. The price at which the stock is purchased is equal to the lower of 85% of the fair market value of the common stock at the beginning of an offering period or on the date of purchase.

The first offering period commenced on February 1, 2015 and ends on November 30, 2015. As of September 30, 2015, the Company has not issued any shares of common stock under the ESPP and 2,000,000 shares of its common stock remained available for issuance.

For the three and nine months ended September 30, 2015, the Company recorded ESPP expense of $0.1 million and $0.4 million, respectively.

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Share Buyback Program

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 are being 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. These repurchased shares are accounted for under the cost method and are included as a component of treasury stock in the Company's Consolidated Balance Sheets.

Pursuant to the Company's share repurchase program, the Company purchased 208,000 and 403,700 shares of its common stock during the three and nine months ended September 30, 2015 totaling $3.0 million and $5.7 million, respectively.

The 2015 Equity Incentive Plan

In March 2015, the Board of Directors adopted the Company's 2015 Equity Incentive Plan, or the 2015 Plan, which was approved by the Company's stockholders in May 2015 and is set to expire in March 2025. The 2015 Plan is designed to meet the needs of a publicly traded company, including the requirements for granting "performance based compensation" under Section 162(m) of the Internal Revenue Code. The 2015 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units, performance shares, and other stock or cash awards to employees of the Company and its subsidiaries, members of the Board of Directors and consultants.

The Company initially reserved 5,000,000 shares of common stock for issuance under the 2015 Plan. This number will be increased by the number of shares available for issuance under the Company's prior equity incentive plans or

arrangements that are not subject to options or other awards, plus the number of shares of common stock related to options or other awards granted under the Company's prior equity incentive plans or arrangements that are repurchased, forfeited, expired, or cancelled on or after the effective date of the 2015 Plan. The 2015 Plan also contains an "evergreen provision" that allows for an annual increase in the number of shares available for issuance on January 1 of each year during the 10 year term of the 2015 Plan, beginning January 1, 2016. The annual increase in the number of shares shall be the lessor of (i) 3,000,000 shares, (ii) two and one-half percent (2.5%) of the outstanding shares on the last day of the immediately preceding fiscal year, or (iii) such number of shares as determined by the Board of Directors. As of the effective date, there were 5,300,296 shares available for grant under the 2015 Plan.

Share-Based Award Activity and Balances

The Company accounts for share based compensation payments in accordance with ASC 718, which requires 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.

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The weighted-averages for key assumptions used in determining the fair value of options granted during the three and nine months ended September 30, 2015 and 2014 are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014(1)	2015	2014
Average volatility	27.5 %	— %	27.1 %	29.9 %
Risk-free interest rate	2.0 %	— %	1.3 %	1.7 %
Weighted-average expected life in years	6.3	—	4.5	5.0
Dividend yield rate	— %	— %	— %	— %

(1) The Company did not grant any stock options during the three months ended September 30, 2014.

A summary of option activity under all plans for the nine months ended September 30, 2015 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, 2014	11,371,891	$ 15.12		
Options granted	2,270,661	15.71		
Options exercised	(1,070,843)	13.32		
Options cancelled	(30,590)	13.76		
Options expired	(69,330)	21.63		
Outstanding as of September 30, 2015	12,471,789	$ 15.35	4.57	$ 1,953
Exercisable as of September 30, 2015	6,964,360	$ 16.33	3.49	$ 1,185

(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, 2015.

For the three and nine months ended September 30, 2015, the Company recorded stock option expense related to employees under all plans of $1.9 million and $5.8 million, respectively. 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.

Information relating to option grants and exercises is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(in thousands, except per share data)			
Weighted-average grant date fair value	$ 4.54	$ —	$ 3.44	$ 4.02
Intrinsic value of options exercised	268	283	2,721	144
Cash received	816	130	11,257	701
Total fair value of the options vested during the year	2,888	3,510	5,423	4,324

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A summary of the status of the Company's nonvested options as of September 30, 2015, and changes during the nine months ended September 30, 2015, are presented below:

	Options	Weighted-Average Grant Date Fair Value
Nonvested as of December 31, 2014	5,090,591	$ 3.34
Options granted	2,270,661	3.44
Options vested	(1,823,233)	2.97
Options forfeited	(30,590)	4.95
Nonvested as of September 30, 2015	5,507,429	3.49

As of September 30, 2015, there was $13.5 million of total unrecognized compensation cost, net of forfeitures, related to nonvested stock option based compensation arrangements granted under all plans. The cost is expected to be recognized over a weighted-average period of 2.1 years and will be adjusted for future changes in estimated forfeitures.

Deferred Stock Units/Restricted Stock Units

Beginning in 2007, the Company granted deferred stock units, or DSUs, to certain employees and members of the Board of Directors with a vesting period of up to five years, and commencing in 2015, such equity was issued as restricted stock units, or RSUs (such RSUs and DSUs are collectively referred to herein as RSUs). The grantee receives one share of common stock at a specified future date for each RSU awarded. The RSUs may not be sold or otherwise transferred until certificates of common stock have been issued, recorded, and delivered to the participant. The RSUs do not have any voting or dividend rights prior to the issuance of certificates of the underlying common stock. 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 $1.1 million and $2.8 million for the three and nine months ended September 30, 2015, respectively, for these RSU awards, compared to the prior year expense of $0.5 million and $1.2 million for the three and nine months ended September 30, 2014, respectively.

As of September 30, 2015, there was $9.3 million of total unrecognized compensation cost, net of forfeitures, related to nonvested RSU-based compensation arrangements granted under 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.

Additionally, prior to the Company’s initial public offering, the Company issued RSUs 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 RSUs at the date of the exchange. As such, the Company did not record any expense related to these award modifications.

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Information relating to RSU grants and deliveries is as follows:

	Total RSUs Issued	Total Fair Market Value of RSUs Issued as Compensation(1) (in thousands)
RSUs outstanding at December 31, 2014	503,010	
RSUs granted	523,203	$ 7,838
RSUs forfeited	(3,938)	
Common stock delivered	(55,426)	
RSUs surrendered for taxes	(89,184)	
RSUs outstanding at September 30, 2015	877,665	

(1) The total fair market value is derived from the number of RSUs granted times the current stock price on the date of grant.

The Company recorded share-based compensation expense under all plans and is included in the Company's consolidated statement of operations as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(in thousands)			
Cost of revenues	$ 638	$ 477	$ 1,856	$ 1,164
Operating expenses:				
Selling, distribution and marketing	49	46	148	96
General and administrative	2,536	1,923	6,676	4,935
Research and development	204	214	677	485
Total share-based compensation	$ 3,427	$ 2,660	$ 9,357	$ 6,680

15. Employee Benefits

401(k) Plan

The Company has a defined contribution 401(k) plan, or the Plan, whereby eligible employees voluntarily contribute up to a defined percentage of their annual compensation. The Company matches contributions at a rate of 50% on the first 4% of employee contributions, or up to 2% of their annual compensation, and pays the administrative costs of the Plan. Employer contributions vest over four years. Total employer contributions for the three and nine months ended September 30, 2015 were approximately $0.2 million and $0.5 million, respectively, compared to the prior year expense of $0.2 million and $0.5 million for the three and nine months ended September 30, 2014, respectively.

Defined Benefit Pension Plan

In connection with the Merck API Transaction, the Company assumed an obligation associated with a defined-benefit plan for eligible employees of AFP. This plan provides benefits to the employees from the date of retirement and is based on the employee's length of time with the Company. The calculation is based on a statistical calculation combining a number of factors that include the employee's age, length of service, and AFPs turnover rate.

The liability under the plan is based on a discount rate of 1.75% as of September 30, 2015 and December 31, 2014. The liability is included in accrued liabilities in the accompanying consolidated balance sheets. The plan is currently unfunded, and the benefit obligation under the plan was $1.7 million and $1.1 million at September 30, 2015 and December 31, 2014, respectively. The Company recorded an immaterial amount of expense under the plan for the three

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months ended September 30, 2015, and $0.1 million for the nine months ended September 30, 2015.

16. Commitments and Contingencies

Distribution Agreement with Allergan plc

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 which was classified as deferred revenues. 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. In January 2013, Watson adopted Actavis, Inc. as its new global name. In March 2015, Actavis acquired Allergan plc and adopted Allergan plc as its new global name in June 2015. The agreement has a term that expires in January 2019 and can be extended by Allergan 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 Allergan fails to purchase a minimum number of units and by Allergan if an infringement claim is made against Allergan.

In January 2012, the Company launched enoxaparin, beginning the seven-year period in which Allergan 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. Allergan has an option to renew the agreement for an additional three years. As of September 30, 2015 and December 31, 2014, the balance of the deferred revenue was $2.1 million and $2.6 million, respectively.

The Company manufactures its enoxaparin product for the retail market according to demand specifications of Allergan. Upon shipment of enoxaparin to Allergan, 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 Allergan, the Company is entitled to a share of the ultimate profits based on the eventual net revenue from enoxaparin sales by Allergan to the end user less the agreed transfer price originally paid by Allergan to the Company. Allergan provides the Company with a quarterly sales report that calculates the Company's share of Allergan enoxaparin gross

profit. The Company records its share of Allergan gross profit as a component of net revenue.

Supply Agreement with MannKind Corporation

On July 31, 2014, the Company entered in a supply agreement with MannKind Corporation, or MannKind, pursuant to which the Company will manufacture for and supply to MannKind certain quantities of recombinant human insulin, or RHI, for use in MannKind's product Afrezza®. Under the terms of the supply agreement, the Company will be responsible for manufacturing the RHI in accordance with MannKind's specifications and agreed-upon quality standards. MannKind has agreed to purchase annual minimum quantities of RHI under the supply agreement of an aggregate amount of approximately €120.1 million, or approximately $146.0 million, in calendar years 2015 through 2019.

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. As of September 30, 2015, the full amount of the deferred revenue has been recognized.

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 month's written notice given prior to the end of the initial term or any

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additional two-year term. MannKind and the Company each have 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.

In January 2015, the Company entered into a supply option agreement with MannKind, pursuant to which MannKind will have the option to purchase RHI, for use in MannKind's product Afrezza®, in addition to the amounts specified in the July 2014 supply agreement. Under the agreement, MannKind has the option to purchase additional RHI in calendar years 2016 through 2019. In the event MannKind elects not to exercise its minimum annual purchase option for any year, MannKind shall pay the Company a capacity cancellation fee.

Collaboration agreement with a medical device manufacturer

The Company has entered into a collaboration agreement with a medical device manufacturer to develop a drug delivery system to be used by the Company for one of its pipeline products. As of September 30, 2015 the Company has paid an upfront payment of $0.5 million and a $0.1 million milestone payment under this agreement, which was classified as research and development expense. The Company is obligated to pay up to an additional $1.9 million if certain milestones are met. If the medical device manufacturer is successful in the development of this drug delivery system and the Company's pipeline products receives appropriate regulatory approval, the Company intends to enter into a commercial supply agreement with such medical device manufacturer for a minimum purchase of 1.0 million units during the first 12 months.

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, 2015 was approximately $0.8 million and $2.5 million, respectively, compared to $0.8 million and $2.3 million for the three and nine months ended September 30, 2014, respectively.

Purchase Commitments

As of September 30, 2015, the Company has entered into commitments to purchase equipment and raw materials for an aggregate of $7.3 million. The Company anticipates that most of these commitments will be fulfilled by 2016.

The Company 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 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 products. In conjunction with these agreements, ANP modified its business license on July 3, 2012 to increase its authorized capital. As of September 30, 2015, the Company had invested approximately $49.0 million in ANP of its registered capital commitment of $61.0 million. The Company has committed to invest an additional $12.0 million in ANP by December 2017. This investment 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 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

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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.

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 the 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. 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 a decision on the merits in the event the Company prevails.

Following appeal briefing filed by the parties, the Federal Circuit held oral argument on May 4, 2015. On November 10, 2015, the Federal Circuit panel affirmed-in-part and vacated-in-part the decision of the District Court granting summary judgment of non-infringement as to the Company, and it remanded the case to the District Court for further

proceedings consistent with its opinion. The Federal Circuit panel affirmed the District Court's holding in the Company's favor that the Company does not infringe under 35 U.S.C. 271(g), and the panel vacated the grant of summary judgment to the extent it was based on the determination that the Company's activities fall within the 35 U.S.C. 271(e)(1) safe harbor. The Federal Circuit panel also left to the District Court's discretion whether to reconsider on remand its denial of leave for Momenta and Sandoz to amend their infringement contentions. The Company intends to consider all appeal options, and to vigorously defend this case on further appeal and/or in the District Court.

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, or the District Court, 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.

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

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Appeals for the Ninth Circuit, or 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 Ninth Circuit granted Aventis' petition. The parties have completed and filed their respective appeal briefs with the Ninth Circuit. A date for oral argument has not been set by the Ninth Circuit.

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. On July 13, 2015, the District Court issued a ruling concluding that the Company is not an original source under the False Claims Act, and the District Court entered final judgment dismissing the case for lack of subject matter jurisdiction. On July 27, 2015, Aventis filed a request for attorneys' fees with the District Court, and on August 3, 2015, the Company filed objections to Aventis's request. On July 20, 2015, the Company filed with the Ninth Circuit a notice of appeal of the District Court's dismissal of the case, and Aventis filed a notice of cross-appeal on August 5, 2015. The Company's opening appeal brief is due to be filed with the Ninth Circuit by December 28, 2015, and Aventis's answering appeal brief is due to be filed by January 27, 2016. On November 12, 2015, Aventis filed a pleading asking that the District Court impose various monetary penalties and fines against the Company, including disgorgement of enoxaparin revenues and attorneys' fees expended by Aventis in this action, based on Aventis's allegations that the Company engaged in sanctionable conduct. While the outcome of litigation is inherently uncertain, the Company believes Aventis's request is without merit, and it intends to vigorously defend against it.

California Employment Litigation

On January 6, 2015, the Company received a formal demand from Plaintiff's counsel in an employment related lawsuit captioned Eva Hernandez v. International Medication Systems Limited, in connection with a complaint originally filed on February 4, 2013 in the Superior Court of California County of Los Angeles, or the Court, by plaintiff Eva Hernandez on behalf of herself and others similarly situated. Plaintiff's complaint included alleged violations of the California Labor Code stemming from the Company's alleged timekeeping practices, as well as other similar and related claims brought under California law. In the complaint, Plaintiff sought damages and related remedies under California law, as well as various penalty payments under the California Labor Code, on behalf of herself and others similarly situated. On April 7, 2015, solely to resolve the dispute, minimize disruption to the Company due to ongoing litigation, and other similar and related factors (but unrelated to the alleged merits of Plaintiff's claims), the Company reached an agreement in principle to settle this matter on a class wide basis for a total amount of $3.2 million, plus applicable payroll taxes. The Joint Stipulation of Settlement as executed by the parties was filed with the Court on June 2, 2015. On July 1, 2015, the Court preliminarily approved the settlement, and on November 5, 2015, the Court entered an order granting final approval of the settlement.

Momenta/Sandoz Antitrust Litigation

On September 17, 2015, the Company initiated a lawsuit by filing a Complaint in the Central District of California against Momenta and Sandoz. The Company's Complaint generally asserts that Momenta and Sandoz have engaged in certain types of illegal, monopolistic, and anticompetitive conduct giving rise to various causes of action against them.

Other Litigation

The Company is also subject to various other claims and lawsuits from time-to-time arising in the ordinary course of business. The Company records a provision for contingent losses when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. In the opinion of management, the ultimate resolution of any such 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 and the Company's view of these matters may change in the future. 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.

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AMPHASTAR PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

18. Subsequent Events

On November 10, 2015, the Company's Board of Directors authorized an increase of $10.0 million to the Company's 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.

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

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 our 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 "Special Note About Forward-Looking Statements," above.

Overview of Amphastar

Amphastar Pharmaceuticals, Inc., together with our 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, is a specialty pharmaceutical company that focuses primarily on developing, manufacturing, marketing and selling technically-challenging generic and proprietary injectable and inhalation products. In 2014, we commenced sales of insulin API products. We currently manufacture and sell 18 products including Amphadase®, which we re-launched in the fourth quarter of 2015. Additionally, we are developing a portfolio of 15 generic and six proprietary injectable and inhalation product candidates.

Our largest product by net revenues is currently enoxaparin sodium injection, the generic equivalent of Sanofi S.A.'s Lovenox®. Enoxaparin is a difficult to manufacture injectable form of low molecular weight heparin that is used as an anticoagulant and is indicated for multiple indications, including the prevention and treatment of deep vein thrombosis.

We have agreements with established group purchasing organizations and wholesaler networks to distribute enoxaparin, which is marketed under our own label for the hospital and clinic market. For the U.S. retail market, we have an agreement with Allergan plc, or Allergan, to distribute enoxaparin, which is marketed under their subsidiary Actavis' label.

In June 2015, we received approval of our new drug application, or NDA supplement for Amphadase®. This marks the first approved starting material from ANP and signifies that our facility located in Nanjing, China has been qualified by the U.S. Food and Drug Administration, or FDA. We re-launched Amphadase® in the fourth quarter of 2015. Amphadase® is competing in the hyaluronidase market and is used to improve the resorption of radiopaque agents.

Our pipeline of 21 generic and proprietary product candidates is in various stages of development and targets a variety of indications. With respect to these product candidates, we have filed three abbreviated new drug applications and one NDA with the FDA.

To complement our internal growth and expertise, we have made several strategic acquisitions of companies, products and technologies. These acquisitions collectively have strengthened our core injectable and inhalation product technology infrastructure by providing additional manufacturing, marketing, and research and development capabilities including the ability to manufacture raw materials, APIs and other components for our products.

Business Segments

Our performance will be assessed and resources will be allocated based on the following two reportable segments: (1) finished pharmaceutical products and (2) active pharmaceutical ingredients, or API products. The finished pharmaceutical products segment currently manufactures, markets and distributes enoxaparin, Cortrosyn®, naloxone, lidocaine jelly, as well as, various other critical and non-critical care drugs. The API segment currently manufactures and distributes recombinant human insulin and porcine insulin. Information reported herein is consistent with how it is reviewed and evaluated by our Chief Operating Decision Maker. Factors used to identify our segments include markets, customers and products.

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For more information regarding our segments, see "Part I – Item 1. Financial Statements – Notes to Consolidated Financial Statements – Segment Reporting."

Results of Operations

Three Months Ended September 30, 2015 Compared to Three Months Ended September 30, 2014

Net revenues

	Three Months Ended September 30,		Change	
	2015	2014	Dollars	%
	(in thousands)			
Net revenues				
Finished pharmaceutical products				
Enoxaparin	$ 21,264	$ 32,040	$ (10,776)	(34)%
Other products	36,638	21,689	14,949	69 %
Total finished pharmaceutical products	$ 57,902	$ 53,729	$ 4,173	8 %
API	5,966	5,982	(16)	(0) %
Total net revenues	$ 63,868	$ 59,711	$ 4,157	7 %
Cost of revenues				
Finished pharmaceutical products	$ 38,601	$ 41,607	$ (3,006)	(7) %
API	7,689	6,313	1,376	22 %
Total cost of revenues	$ 46,290	$ 47,920	$ (1,630)	(3) %
Gross profit	$ 17,578	$ 11,791	$ 5,787	49 %
as % of net revenues	28 %	20 %		

Net revenues were $63.9 million and $59.7 million for the three months ended September 30, 2015 and 2014, respectively, representing an increase of $4.2 million, or 7%. Sales of enoxaparin decreased $10.8 million to $21.3 million primarily due to lower average selling prices. Sales of other finished pharmaceutical products increased $14.9 million to $36.6 million, which was primarily due to an increase in sales of naloxone to $10.5 million from $3.7 million, as a result of increased unit volumes at higher average prices.

We expect that the declines in the average selling price of enoxaparin will continue and that unit volume will decline in the near term as an additional competitor, Teva, launched a competing enoxaparin product in February 2015. We believe this trend will be partially offset by pricing increases on several other finished pharmaceutical products. Net revenues would also be impacted if sales of our products were affected by any manufacturing or production issues,

supply chain interruptions or unexpected regulatory issues.

Although quarterly sales may fluctuate, we anticipate that sales of insulin API will increase due to sales under our supply agreement with MannKind. Most of our API sales are denominated in Euros, and the decline in the value of the Euro versus the dollar compared to 2014 has had and will continue to have a negative impact on API sales revenues in the near term.

Cost of revenues

Cost of revenues was $46.3 million and $47.9 million for the three months ended September 30, 2015 and 2014, respectively, representing a decrease of $1.6 million, or 3%. The cost of revenues as a percentage of revenues decreased to 72% from 80% primarily due to higher average prices of naloxone and our other finished pharmaceutical products. Cost of revenues for the API business increased as a percentage of revenues due to increased cost and lower production in the quarter. The decline in margins due to enoxaparin pricing was partially offset by a lower cost per unit.

The declining prices and unit volume of enoxaparin will put additional downward pressure on gross margins, but we believe this trend will be partially offset by increases in prices of several other finished pharmaceutical products.

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Selling, distribution and marketing, general and administrative, and impairment of long-lived assets

	Three Months Ended September 30,		Change	
	2015	2014	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	$ 1,171	$ 1,454	$ (283)	(19)%
General and administrative	9,034	9,556	(522)	(5) %
Impairment of long-lived assets	4	13	(9)	(69)%

General and administrative expenses were $9.0 million and $9.6 million for the three months ended September 30, 2015 and 2014, respectively, representing a decrease of $0.6 million, or 5%. The decrease was primarily due to a decrease in legal expenses during the third quarter of 2015.

We expect that general and administrative expenses will increase on an annual basis due to the costs associated with compliance with Sarbanes-Oxley section 404, and the full year impact of corporate public company expenses.

Research and development

	Three Months Ended September 30,		Change	
	2015	2014	Dollars	%
	(in thousands)			
Research and development	$ 11,117	$ 8,585	$ 2,532	29 %

Research and development expenses were $11.1 million and $8.6 million for the three months ended September 30, 2015 and 2014, respectively, representing an increase of $2.5 million, or 29%. This increase was primarily due to an increase of $1.1 million in clinical trial expense, as well as, an increase of $1.1 million in pre-launch inventory and purchases of materials and other research and development supplies, relating to the approval of Amphadase® which we re-launched in October 2015 as well as the development of our intranasal naloxone product candidate.

Research and development costs consist primarily of costs associated with the research and development of our product candidates, such as salaries and other personnel related expenses for employees involved with research and development activities, manufacturing pre launch inventory, clinical trials, FDA fees, testing, operating and lab supplies, depreciation and other related expenses. We expense research and development costs as incurred.

We have made, and expect to continue to make, substantial investments in research and development to expand our product portfolio and grow our business. These costs will fluctuate significantly from quarter to quarter based on the timing of various clinical trials, the pre-launch costs associated with new products, and FDA filing fees. As we undertake new and challenging research and development projects, we anticipate that the associated annual costs will increase significantly over the next several years.

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The following table sets forth our research and development expenses for the three months ended September 30, 2015 and 2014:

	Three Months Ended September 30,		Change	
	2015	2014	Dollars	%
	(in thousands)			
Salaries and personnel-related expenses	$ 3,777	$ 3,267	$ 510	16 %
Pre-launch inventory	933	4	929	23,225%
Clinical trials	1,963	878	1,085	124 %
FDA fees	41	—	41	N/A
Testing, operating and lab supplies	2,765	2,632	133	5 %
Depreciation	893	946	(53)	(6) %
Other expenses	745	858	(113)	(13) %
Total research and development expenses	$ 11,117	$ 8,585	$ 2,532	29 %

Provision for income tax benefit

	Three Months Ended September 30,		Change	
	2015	2014	Dollars	%
	(in thousands)			
Income tax benefit	$ 1,268	$ 2,605	$ (1,337)	(51)%
Effective tax rate	30 %	33 %		

Income tax benefit was $1.3 million and $2.6 million for the three months ended September 30, 2015 and 2014, respectively, representing a decrease in income tax benefit of $1.3 million, or 51%. The decrease in income tax benefit was primarily related to a smaller pre-tax loss that occurred during the three months ended September 30, 2015.

Nine Months Ended September 30, 2015 Compared to Nine Months Ended September 30, 2014

Net revenues

	Nine Months Ended September 30,		Change	
	2015	2014	Dollars	%
	(in thousands)			
Net revenues				
Finished pharmaceutical products				
Enoxaparin	$ 64,647	$ 85,337	$ (20,690)	(24)%
Other products	94,202	63,163	31,039	49 %
Total finished pharmaceutical products	$ 158,849	$ 148,500	$ 10,349	7 %
API	15,758	6,084	9,674	159 %
Total net revenues	$ 174,607	$ 154,584	$ 20,023	13 %
Cost of revenues				
Finished pharmaceutical products	$ 114,061	$ 108,908	$ 5,153	5 %
API	16,370	6,380	9,990	157 %
Total cost of revenues	$ 130,431	$ 115,288	$ 15,143	13 %
Gross profit	$ 44,176	$ 39,296	$ 4,880	12 %
as % of net revenues	25 %	25 %		

Net revenues were $174.6 million and $154.6 million for the nine months ended September 30, 2015 and 2014, respectively, representing an increase of $20.0 million, or 13%. Sales of enoxaparin decreased $20.7 million to $64.6 million on higher unit volumes at lower average selling prices. The increase in sales of other finished pharmaceutical products was largely due to an increase in sales of naloxone to $27.9 million from $11.6 million, as a result of increased

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unit volumes at higher average prices. Additionally, we had an increase of $9.7 million in sales of recombinant human insulin and porcine insulin from our insulin business, which we acquired from Merck in April 2014.

We expect that the declines in the average selling price of enoxaparin will continue and that unit volume will decline in the near term as an additional competitor, Teva, launched a competing enoxaparin product in February 2015. We believe this trend will be partially offset by pricing increases on several other finished pharmaceutical products. Net revenues would also be impacted if sales of our products were affected by any manufacturing or production issues, supply chain interruptions or unexpected regulatory issues.

Although quarterly sales may fluctuate, we anticipate that sales of insulin API will increase due to sales under our supply agreement with MannKind. Most of our API sales are denominated in Euros, and the decline in the value of the Euro versus the dollar compared to 2014 has had and will continue to have a negative impact on API sales revenues in the near term.

Cost of revenues

Cost of revenues was $130.4 million and $115.3 million for the nine months ended September 30, 2015 and 2014, respectively, representing an increase of $15.1 million, or 13%. The increase was primarily due to the overall cost of revenue for the API business. This was partially offset by a decrease in average cost per unit of enoxaparin. The cost of revenues as a percentage of revenues remained stable at 75%.

The declining prices and unit volume of enoxaparin will put additional downward pressure on gross margins, but we believe this trend will be partially offset by increases in prices of several other finished pharmaceutical products.

Selling, distribution and marketing, general and administrative, and impairment of long-lived assets

	Nine Months Ended September 30,		Change	
	2015	2014	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	$ 4,163	$ 4,066	$ 97	2 %
General and administrative	32,793	25,040	7,753	31 %
Impairment of long-lived assets	78	361	(283)	(78)%

General and administrative expenses were $32.8 million and $25.0 million for the nine months ended September 30, 2015 and 2014, respectively, representing an increase of $7.8 million, or 31%. The increase was primarily due to an accrual of $3.2 million, plus applicable payroll taxes relating to a settlement of our California employment litigation. We had an increase of $1.3 million, primarily related to the cost associated with our compliance with Sarbanes-Oxley section 404, as well as, the inclusion of expenses generated at our French subsidiary, AFP, which we acquired in April 2014.

We expect general and administrative expenses will increase on an annual basis due to the costs associated with compliance with Sarbanes-Oxley section 404, and the full year impact of corporate public company expenses.

Research and development

	Nine Months Ended September 30,		Change	
	2015	2014	Dollars	%
	(in thousands)			
Research and development	$ 28,411	$ 20,788	$ 7,623	37 %

Research and development expenses were $28.4 million and $20.8 million for the nine months ended September 30, 2015 and 2014, respectively, representing an increase of $7.6 million, or 37%. This increase was primarily due to an increase of $3.0 million in clinical trial expense, related to our naloxone nasal product candidate and external studies related to our generic pipeline, as well as, to an increase in expense of $3.2 million in pre-launch inventory and

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purchases of materials and other research and development supplies, relating to the approval of Amphadase® which we re-launched in October 2015 as well as the development of intranasal naloxone product candidate.

Research and development costs consist primarily of costs associated with the research and development of our product candidates, such as salaries and other personnel related expenses for employees involved with research and development activities, manufacturing pre launch inventory, clinical trials, FDA fees, testing, operating and lab supplies, depreciation and other related expenses. We expense research and development costs as incurred.

We have made, and expect to continue to make, substantial investments in research and development to expand our product portfolio and grow our business. These costs will fluctuate significantly from quarter to quarter based on the timing of various clinical trials, the pre-launch costs associated with new products, and FDA filing fees. As we undertake new and challenging research and development projects, we anticipate that the associated annual costs will increase significantly over the next several years.

The following table sets forth our research and development expenses for the nine months ended September 30, 2015 and 2014:

	Nine Months Ended September 30,		Change	
	2015	2014	Dollars	%
	(in thousands)			
Salaries and personnel-related expenses	$ 10,464	$ 8,854	$ 1,610	18 %
Pre-launch inventory	933	1,018	(85)	(8) %
Clinical trials	3,833	817	3,016	369 %
FDA fees	215	—	215	N/A
Testing, operating and lab supplies	7,933	4,814	3,119	65 %
Depreciation	2,894	2,749	145	5 %
Other expenses	2,139	2,536	(397)	(16) %
Total research and development expenses	$ 28,411	$ 20,788	$ 7,623	37 %

Provision for income tax benefit

	Nine Months Ended September 30,		Change	
	2015	2014	Dollars	%
	(in thousands)			

Income tax benefit	$ 10,382	$ 4,153	$ 6,229	150%
Effective tax rate	50 %	34 %		

Income tax benefit was $10.4 million and $4.2 million for the nine months ended September 30, 2015 and 2014, respectively, representing an increase in income tax benefit of $6.2 million, or 150%. The increase in income tax benefit was primarily related to the pre-tax loss that occurred during the nine months ended September 30, 2015 and the reversal of a deferred tax valuation allowance during the first quarter of 2015, which had previously been reserved.

Liquidity and Capital Resources

Cash Requirements and Sources

We need capital resources to maintain and expand our business. Our future capital expenditures will include projects to upgrade, expand and improve our manufacturing facilities in the United States, China and France. Our cash obligations include the principal and interest payments due on our existing loans, as described below and throughout this Quarterly Report. We believe that our cash reserves, operating cash flows, and availability under our revolving credit facility will be sufficient to fund our operations for the next 12 months. If we require or elect to seek additional capital through debt or equity financing in the future, we may not be able to raise capital on terms acceptable to us or at all. If we are required

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and unable to raise additional capital when desired, our business, operating results and financial condition may be adversely affected.

Working capital decreased $7.0 million to $128.4 million at September 30, 2015 compared to $135.4 million at December 31, 2014. The decrease in working capital was primarily due to payments on long-term debt of $4.0 million and capital expenditures of $11.9 million, which was partially offset by cash in-flows from operations of $7.4 million and cash provided by option exercises of $11.5 million.

Cash Flows from Operations

The following table summarizes our cash flows used in operating, investing, and financing activities for the nine months ended September 30, 2015:

	Nine Months Ended September 30, 2015 (in thousands)
Statement of Cash Flow Data:	
Net cash provided by (used in)	
Operating activities	$ 7,394
Investing activities	(12,466)
Financing activities	7,808
Effect of exchange rate changes on cash	117
Net increase in cash and cash equivalents	$ 2,853

Sources and Use of Cash

Operating Activities

Net cash provided by operating activities was $7.4 million for the nine months ended September 30, 2015, which included a net loss of $10.3 million. Non-cash items are comprised of $10.0 million of depreciation and amortization, and $9.4 million of share-based compensation expense. This was partially offset by an increase of $2.6 million in operating assets and liabilities and a $4.6 million change in deferred taxes and other tax related items.

Investing Activities

Net cash used in investing activities of $12.5 million for the nine months ended September 30, 2015 was primarily related to $11.9 million in purchases of property, machinery, and equipment, including the associated capitalized labor and interest on self-constructed assets. Additionally, $0.8 million in deposits were made for machinery and equipment.

Financing Activities

Net cash provided by financing activities of $7.8 million for the nine months ended September 30, 2015 was primarily related to $6.8 million in additional borrowings and $11.5 million from proceeds of stock options exercised. This was partially offset by $6.5 million relating to the repurchase of our common stock and $4.0 million in principal payments on our long-term debt.

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Contractual Obligations

There have been no material changes outside the ordinary course of our business in the contractual obligations disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014, except that our outstanding debt obligations have changed as follows:

	September 30, 2015	December 31, 2014	Change
	(in thousands)		
Short-term debt and current portion of long-term debt	$ 14,762	$ 7,594	$ 7,168
Long-term debt	31,354	36,106	(4,752)
Total debt	$ 46,116	$ 43,700	$ 2,416

The increase in outstanding debt is primarily related to the debt associated with the $6.2 million draw down from our line of credit in January 2015, which was subsequently converted into an equipment loan that matures in January 2019.

As of September 30, 2015, we had $30.0 million in unused borrowing capacity under revolving lines of credit with Cathay Bank and East West Bank.

We have entered into a collaboration agreement with a medical device manufacturer to develop a drug delivery system to be used by us for one of our pipeline products. As of September 30, 2015 we have paid an upfront payment of $0.5 million and a $0.1 million milestone payment under this agreement, which was classified as research and development expense. We are obligated to pay up to an additional $1.9 million if certain milestones are met. If the medical device manufacturer is successful in the development of this drug delivery system and the Company’s pipeline products receives appropriate regulatory approval, we intend to enter into a commercial supply agreement with such medical device manufacturer for a minimum purchase of 1.0 million units during the first 12 months.

Recent Accounting Pronouncements

In April 2014, the FASB issued an accounting standards update that raised 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 is effective for fiscal years beginning after December 15, 2014, which is our fiscal year 2015,

with early adoption permitted. The adoption of the guidance did not have a material impact on our 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, 2017, which will be our fiscal year 2018. We have not yet evaluated the potential impact of adopting the guidance on our 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 our fiscal year 2016, with early adoption permitted. We do not expect the adoption of the guidance will have a material impact on our consolidated financial statements.

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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 our annual filing for the period ending December 31, 2016 and interim periods thereafter, and allows for early adoption. We do not expect the adoption of the guidance will have a material impact on our consolidated financial statements.

In July 2015, the FASB issued an accounting standards update which requires entities to measure most inventories at the lower of cost and net realizable value, or NRV, thereby simplifying the current guidance under which an entity must measure inventory at the lower of cost or market. Under the new guidance, inventory is measured at the lower of cost and net realizable value, which eliminates the need to determine replacement cost and evaluate whether it is above the ceiling (NRV) or below the floor (NRV less a normal profit margin). The guidance defines NRV as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance is effective for annual periods beginning after December 15, 2016, and interim periods therein. The standard will be effective for us for the first quarter of our fiscal year 2016. Early application is permitted. The new guidance must be applied prospectively. We do not believe the adoption of this accounting guidance will have a material impact on our consolidated financial statements and related disclosures.

Off-Balance Sheet Arrangements

We do 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, we do not engage in trading activities involving non-exchange traded contracts.

Government Regulation

Our 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 our products. The Drug Enforcement Administration, or DEA, maintains oversight over our products that are considered controlled substances.

From January 19 through January 22, 2015, our facility in Éragny-Sur-Epte, France was subject to an inspection by the French National Agency for Medicines and Health Products Safety (Agence nationale de sécurité du médicament et des produits de santé), or ANSM. The inspection included a review of current EU Good Manufacturing Practices for Medicinal Products for Human and Veterinary Use (EU-GMP Part II for Active Substances) and Manufacture of Biological Active Substances and Medicinal Products for Human Use (EU-GMP Annex 2). The inspections resulted in various observations issued formally to the facility. We responded to those observations on March 13, 2015, with a

minor follow up response on April 3, 2015. We received acknowledgment from ANSM that our responses to the observations were satisfactorily addressed and was issued a certificate of GMP compliance from the Agency dated April 9, 2015 that is valid until January 2018.

From July 22, 2015 through August 10, 2015, our IMS facility in South El Monte, CA was subject to an inspection by the FDA. The inspection included a review of cGMP and preapproval inspections for abbreviated new drug applications currently being reviewed by the FDA. The inspections resulted in multiple observations on Form 483, an FDA form on which deficiencies are noted after an FDA inspection. We responded to those observations on August 31, 2015.

No other FDA inspections of our facilities were undertaken during the third quarter of 2015.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

The following discussion provides forward-looking quantitative and qualitative information about our 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. We are exposed to market risk for changes in the market values of our investments (Investment Risk), the impact of interest rate changes (Interest Rate Risk), and the impact of foreign currency exchange changes (Foreign Currency Exchange Risk).

Investment Risk

We regularly review the carrying value of our investments and identify and recognize losses, for income statement purposes, when events and circumstances indicate that any declines in the fair values of such investments below our accounting basis are other than temporary. As of September 30, 2015, we did not have any such investments.

As of September 30, 2015, we had $7.2 million deposited in three banks located in China and $1.0 million deposited in one bank located in France. We also maintained $47.9 million in Money Market, Money Market Insured Deposit Account Service, or MMIDAS, and Insured Cash Sweep, or ICS, accounts as of September 30, 2015. The remaining amounts of our cash equivalent as of September 30, 2015 are in non-interest bearing accounts.

The MMIDAS accounts and ICS accounts allow us to distribute our funds among a network of depository institutions that are re allocated such that each deposit account is below the $250 thousand Federal Deposit Insurance Corporation, or FDIC, limit, thus providing greater FDIC insurance coverage for our overall cash balances. We have not experienced any losses in such accounts, nor does management believe we are exposed to any significant credit risk on our bank account balances.

Interest Rate Risk

Our 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 our short-term investments, such as our certificates of deposit, we believe that we are not subject to any material interest rate risk with respect to our short-term investments.

As of September 30, 2015, we had $46.1 million in long-term debt and capital leases outstanding. Of this amount, $32.6 million had variable interest rates with a weighted-average interest rate of 4.1% at September 30, 2015. An increase in the index underlying these rates of 1% (100 basis points) would increase our annual interest expense on the variable-rate debt by approximately $0.3 million per year.

Foreign Currency Rate Risk

Our products are primarily sold in U.S. domestic markets. For the three and nine months ended September 30, 2015 and 2014, foreign sales were minimal. Therefore, we had little exposure to foreign currency price fluctuations. However, as a result of our acquisition of API manufacturing business in Éragny-sur-Epte, France, we are exposed to market risk related to changes in foreign currency exchange rates. Specifically, our insulin sales contracts are primarily denominated in Euros, which are subject to fluctuations relative to the U.S. dollar, or USD. We do not currently hedge our foreign currency exchange rate risk. At this time, an immediate 10% change in currency exchange rates could have a material effect on our financial position, results of operations or cash flows.

Our 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 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 our statement of operations.

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Our French subsidiary, Amphastar France Pharmaceuticals, S.A.S., or AFP, maintains its books of record in Euros. These books are translated into USD using 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 loss. We do not undertake hedging transactions to cover its foreign currency exposure.

As of September 30, 2015, our foreign subsidiaries had receivables denominated in foreign currencies in the amount of $2.7 million.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, including our Chief Executive Officer and our Chief Financial Officer, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were effective to provide reasonable assurance that information that we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms.

Disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act, such as this Quarterly Report on Form 10-Q, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the three months ended September 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Internal control over financial reporting means a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP.

Inherent Limitations of Internal Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

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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

There were no material changes from the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014, filed with the Securities and Exchange Commission on March 26, 2015.

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

(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 (1)	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, 2015	24,300	$ 17.35	24,300	—
August 1 – August 31, 2015	61,500	14.33	61,500	—
September 1 – September 30, 2015	122,200	13.61	122,200	—

(1)

During the third quarter of 2015, we repurchased shares of our common stock as part of the $10.0 million share buyback program authorized by our Board of Directors in November 2014.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

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

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SIGNATURES

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

AMPHASTAR PHARMACEUTICALS, INC.
(Registrant)
By: /s/ JACK Y. ZHANG
Jack Y. Zhang
Chief Executive Officer
(Principal Executive Officer)

Date: November 13, 2015

AMPHASTAR PHARMACEUTICALS, INC.
(Registrant)
By: /s/ WILLIAM J. PETERS
William J. Peters
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: November 13, 2015

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AMPHASTAR PHARMACEUTICALS, INC.

EXHIBIT INDEX TO FORM 10-Q

For the Quarterly Period Ended September 30, 2015

Exhibit No.	Description
31.1	Certification of Chief Executive Officer Pursuant to Rules 13a-14(a) Under the Securities Exchange Act of 1934.
31.2	Certification of Chief Financial Officer Pursuant to Rules 13a-14(a) Under the Securities Exchange Act of 1934.
32.1#	Certification of Chief Executive Officer Pursuant to Rules 13a-14(b) and 15d-14(b) of the Securities Exchange Act of 1934 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 1934 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.