Amphastar Pharmaceuticals, Inc.
Form 10-Q
November 09, 2016
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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, 2016

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 2, 2016 was 46,023,798.

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AMPHASTAR PHARMACEUTICALS, INC.

FORM 10-Q FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2016

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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," "might", "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "pr "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these identifying words. Forward-looking statements relate to future events or future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by the 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 during and following termination of our profit sharing agreement with Actavis;

- 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, as well as those of our API customers;

- 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 protection from our products and our ability to successfully defend our intellectual property in cases of alleged infringement;

- the implementation of our business strategies, product development strategies and technology utilization;

- the potential for exposure to product liability claims;

- future acquisitions or investments, including the anticipated benefits of such 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;

- our remediation efforts for a material weakness in our internal control over financial reporting; 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, 2015, 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 and such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information.. 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.

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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, 2016 (unaudited)	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 66,598	$ 66,074
Short-term investments	856	—
Restricted short-term investments	1,390	1,285
Accounts receivable, net	26,550	33,233
Inventories, net	90,650	70,665
Income tax refund and deposits	159	238
Prepaid expenses and other assets	3,983	4,439
Total current assets	190,186	175,934
Property, plant, and equipment, net	151,952	142,161
Goodwill and intangible assets, net	51,732	39,901
Other assets	7,544	4,696
Deferred tax assets	27,423	27,444
Total assets	$ 428,837	$ 390,136
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 13,439	$ 13,872
Accrued liabilities	14,695	16,732
Income taxes payable	6,210	3,076
Accrued payroll and related benefits	15,553	12,840
Current portion of product return accrual	1,569	1,858
Current portion of deferred revenue	830	643
Current portion of long-term debt and capital leases	8,541	10,934
Total current liabilities	60,837	59,955
Long-term product return accrual	1,137	763

Long-term reserve for income tax liabilities	497	497
Long-term deferred revenue	168	1,339
Long-term debt and capital leases, net of current portion	34,163	30,165
Long-term deferred tax liabilities	1,616	—
Other long-term liabilities	1,966	1,907
Total liabilities	100,384	94,626
Commitments and contingencies:		
Stockholders' equity:		
Preferred stock: par value $0.0001; 20,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock: par value $0.0001; 300,000,000 shares authorized; 47,506,416 and 46,038,022 shares issued and outstanding as of September 30, 2016 and 45,960,206 and 45,198,491 shares issued and outstanding as of December 31, 2015, respectively	5	5
Additional paid-in capital	276,543	247,829
Retained earnings	73,597	60,323
Accumulated other comprehensive loss	(2,581)	(2,475)
Treasury stock	(19,111)	(10,172)
Total stockholders' equity	328,453	295,510
Total liabilities and stockholders' equity	$ 428,837	$ 390,136

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,	
	2016	2015	2016	2015
Net revenues	$ 64,223	$ 63,868	$ 191,622	$ 174,607
Cost of revenues	36,611	46,290	107,394	130,431
Gross profit	27,612	17,578	84,228	44,176
Operating expenses:				
Selling, distribution, and marketing	1,291	1,171	3,975	4,163
General and administrative	10,801	9,034	31,129	32,793
Research and development	9,723	11,117	28,591	28,411
Impairment of long-lived assets	—	4	331	78
Total operating expenses	21,815	21,326	64,026	65,445
Income (loss) from operations	5,797	(3,748)	20,202	(21,269)
Non-operating income (expense):				
Interest income	63	83	187	240
Interest expense	(281)	(232)	(970)	(783)
Other income (expense), net	422	(379)	150	1,110
Total non-operating income (expense), net	204	(528)	(633)	567
Income (loss) before income taxes	6,001	(4,276)	19,569	(20,702)
Income tax expense (benefit)	2,111	(1,268)	6,295	(10,382)
Net income (loss)	$ 3,890	$ (3,008)	$ 13,274	$ (10,320)
Net income (loss) per share:				
Basic	$ 0.09	$ (0.07)	$ 0.29	$ (0.23)
Diluted	$ 0.08	$ (0.07)	$ 0.29	$ (0.23)
Weighted-average shares used to compute net income (loss) per share:				
Basic	45,398	45,310	45,132	44,920
Diluted	47,953	45,310	46,365	44,920

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,	
	2016	2015	2016	2015
Net income (loss)	$ 3,890	$ (3,008)	$ 13,274	$ (10,320)
Accumulated other comprehensive income (loss)				
Foreign currency translation adjustment	109	374	(106)	(2,106)
Total accumulated other comprehensive income (loss)	109	374	(106)	(2,106)
Total comprehensive income (loss)	$ 3,999	$ (2,634)	$ 13,168	$ (12,426)

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,	
	2016	2015
Cash Flows From Operating Activities:		
Net income (loss)	$ 13,274	$ (10,320)
Reconciliation to net cash provided by operating activities:		
Impairment of long-lived assets	331	78
Loss on disposal of property, plant, and equipment	663	19
Depreciation of property, plant, and equipment	9,009	8,516
Amortization of product rights, trademarks, and patents	1,751	1,458
Imputed interest accretion	55	83
Employee share-based compensation expense	10,482	8,687
Non-employee share-based compensation expense	1,122	670
Reserve for income tax liabilities	—	16
Changes in deferred taxes	—	(3,541)
Changes in operating assets and liabilities:		
Accounts receivable, net	6,756	(2,706)
Inventories, net	(19,477)	8,549
Income tax refund and deposits	3,112	21
Prepaid expenses and other assets	173	(6,516)
Income taxes payable	103	(1,083)
Accounts payable and accrued liabilities	(2,800)	3,463
Net cash provided by operating activities	24,554	7,394
Cash Flows From Investing Activities:		
Acquisition of business	(12,461)	—
Purchases of property, plant, and equipment	(14,457)	(10,685)
Capitalized labor, overhead, and interest on self-constructed assets	(1,588)	(1,242)
Proceeds from the sale of property, plant and equipment	—	51
Purchase of short-term investments	(2,270)	—
Maturity of short-term investments	1,414	—
Decrease (increase) in restricted cash	(105)	210
Payment of deposits and other assets	(2,921)	(800)
Net cash used in investing activities	(32,388)	(12,466)
Cash Flows From Financing Activities:		
Repurchase of common stock	(1,342)	(857)
Net proceeds from equity plans	18,499	11,539
Purchase of treasury stock	(8,986)	(5,687)
Proceeds from issuance of long-term debt	10,198	6,786

Principal payments on long-term debt	(9,968)	(3,973)
Net cash provided by financing activities	8,401	7,808
Effect of exchange rate changes on cash	(43)	117
Net increase in cash and cash equivalents	524	2,853
Cash and cash equivalents at beginning of period	66,074	67,828
Cash and cash equivalents at end of period	$ 66,598	$ 70,681

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	Nine Months Ended September 30,	
	2016	2015
Noncash Investing and Financing Activities:		
Equipment acquired under capital leases	$ 1,263	$ 150
Supplemental Disclosures of Cash Flow Information:		
Interest paid	$ 1,381	$ 1,345
Income taxes paid	$ 3,263	$ 45

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 (together with its subsidiaries, hereinafter referred to as "the Company"). The Company is a specialty pharmaceutical company that primarily develops, manufactures, markets, and sells generic and proprietary injectable, inhalation, and intranasal products including products with high technical barriers to market entry. Additionally, the Company sells 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 sold to other pharmaceutical companies for use in their own products and are being used by the Company in the development of injectable finished pharmaceutical 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, 2015, and the notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the Securities and Exchange Commission, or the SEC. 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 condensed consolidated financial position, results of operations, comprehensive income (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 income (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 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 condensed 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; Armstrong Pharmaceuticals, Inc., or Armstrong; Amphastar Nanjing Pharmaceuticals Co., Ltd., or ANP; Nanjing Letop Fine Chemistry Co., Ltd., or Letop, Amphastar France Pharmaceuticals, S.A.S., or AFP, Amphastar UK Ltd., or AUK, and International Medication Systems (UK) Limited, or IMS UK.

Use of Estimates

The preparation of the condensed consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed 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,

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

reserves for excess or unsellable inventory, impairment of long-lived and intangible assets and goodwill, self-insured claims, workers' compensation liabilities, litigation reserves, stock price volatilities for share-based compensation expense, valuation allowances for deferred tax assets, and liabilities for uncertain income tax positions.

Foreign Currency

The functional currency of the Company, its Chinese subsidiary, ANP, and its U.K. subsidiary, AUK, is the U.S. dollar, or USD. 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 currency exchange gains and losses are reflected in the Company's statements of operations.

The Company's French subsidiary, AFP, Chinese subsidiary, Letop, and U.K. subsidiary, IMS UK, maintain their books of record in Euros, Chinese Yuan, and Great Britain Pounds, respectively, which are the local currencies and have been determined to be their respective functional currencies. 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 income (loss). The gains or losses of intercompany foreign currency transactions that are of a long-term investment nature are reported in other comprehensive income (loss). The gains and losses of intercompany foreign currency transactions for the three and nine months ended September 30, 2016 were a $0.3 million gain and a $0.6 million gain, respectively, and for the three and nine months ended September 30, 2015 were a $0.3 million gain and a $1.6 million loss, respectively.

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

Comprehensive Income (Loss)

For the three and nine months ended September 30, 2016 and 2015, the Company included its foreign currency translation adjustment as part of its comprehensive income (loss).

Financial Instruments

The carrying amounts of cash and cash equivalents, short-term investments, restricted 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.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

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 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 that the Company incurs to effect a business combination are expensed in the periods in which the costs are incurred.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or 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 2018. The Company has not yet evaluated the potential impact of adopting the guidance on the Company’s condensed 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 reporting 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 condensed 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 or 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 or 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 reporting periods therein. The standard will be effective for the Company for the first quarter of the Company's fiscal 2017. 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 condensed consolidated financial statements and related disclosures.

In November 2015, the FASB issued an accounting standards update to the balance sheet classification of deferred taxes. Under existing standards, deferred taxes for each tax-paying jurisdiction are presented as a net current asset or liability and net long-term asset or liability. To simplify presentation, the new guidance will require that all deferred tax assets and liabilities, along with related valuation allowances, be classified as long-term on the balance sheet. As a result, each tax-paying jurisdiction will now only have one net long-term deferred tax asset or liability. The new guidance does not change

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the existing requirement that prohibits offsetting deferred tax liabilities from one jurisdiction against deferred tax assets of another jurisdiction. The guidance is effective for annual periods beginning after December 15, 2016, and interim reporting periods therein. Early adoption is permitted. The new guidance may be applied prospectively or retrospectively. The Company has elected to adopt the guidance early and apply the guidance prospectively. Therefore, prior periods were not retrospectively adjusted. The reclassification of the Company's deferred tax assets and liabilities does not have any impact on the Company's net income or cash flow; thus, the adoption of the guidance does not have a material impact on the Company's condensed consolidated financial statements.

In February 2016, the FASB issued an accounting standards update that is aimed at making leasing activities more transparent and comparable, and which requires substantially all leases to be recognized by lessees on their balance sheets as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. This guidance will become effective for the Company's interim and annual reporting periods during the year ending December 31, 2019, and all annual and interim reporting periods thereafter. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of this guidance will have on its condensed consolidated financial statements and related disclosures.

In March 2016, the FASB issued an accounting standards update that is aimed at improving the employee share-based payment accounting. The standard update simplifies the accounting for employee share-based payments and involves several aspects of the accounting for share-based transactions, including the potential timing of expenses, the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. The guidance is effective for annual periods beginning after December 15, 2016, and interim reporting periods therein. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of this guidance will have on its condensed consolidated financial statements and related disclosures.

In June 2016, the FASB issued an accounting standards update that is aimed at providing financial statement users with more useful information about the expected credit losses on financial instruments and other commitments to extend credit. The standard update changes the impairment model for financial assets measured at amortized cost, requiring presentation at the net amount expected to be collected. The measurement of expected credit losses requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. Available-for-sale debt securities with unrealized losses will be recorded through an allowance for credit losses. The guidance is effective for the Company's interim and annual reporting periods during the year ending December 31, 2020. The Company is currently evaluating the impact that the adoption of this guidance will have on its condensed consolidated financial statements and related disclosures.

In August 2016, the FASB issued an accounting standards update that is aimed at addressing certain issues regarding classifications of certain cash receipt and cash payment on the statement of cash flows where diversity in practice was identified. The guidance is effective for the Company's interim and annual reporting periods during the year ending December 31, 2018. Early adoption is permitted. The Company does not believe that the adoption of this accounting guidance will have a material impact on the Company's condensed consolidated financial statements and related disclosures.

3. Business Acquisitions

Acquisition of International Medication Systems (UK) Limited from UCB PHARMA GmbH

In August 2016, the Company's newly established UK subsidiary, AUK, acquired IMS UK, a UK-based subsidiary of UCB PHARMA GmbH, including its trademarks, assets related to the products, as well as marketing authorizations for 33 products in the UK, Ireland, Australia, and New Zealand, representing 11 different injectable chemical entities. The Company paid $7.7 million in cash as consideration for the transaction. The Company plans to transfer the manufacturing

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AMPHASTAR PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

of the purchased products to its facilities in California. The transfer will require approval of the UK Medicines and Healthcare products Regulatory Agency and other related regulatory agencies before the products can be sold by the Company. The transaction is accounted for as a business combination in accordance with ASC 805.

The Company's accounting for this acquisition is preliminary specifically related to the fair value estimation of identified intangible assets. The fair values of the assets acquired and liabilities assumed include marketing authorizations of $9.2 million, manufacturing equipment of $0.1 million, and deferred tax liability of $1.6 million. The acquired marketing authorizations intangible assets are subject to a straight-line amortization over a useful life of approximately 10 years. The Company's estimates and assumptions are subject to change as the Company obtains additional information for its estimates during the measurement period (up to one year from the acquisition date).

Acquisition of fourteen injectable products from Hikma Pharmaceuticals PLC

In March 2016, the Company acquired 14 abbreviated new drug applications, or ANDAs, representing 11 different injectable chemical entities from Hikma Pharmaceuticals PLC for $4.0 million. The Company plans to transfer the manufacturing of these products to its facilities in California, which will require U.S. Food & Drug Administration, or FDA approval before the products can be launched. The Company has concluded that this transaction will be accounted for as a business combination in accordance with ASC 805.

The Company's accounting for this acquisition is preliminary specifically related to the fair value estimation of identified intangible assets. The ANDA is estimated to have a fair value of $4.0 million, which is subject to a straight-line amortization over a useful life of approximately 15 years. The Company's estimates and assumptions are subject to change as the Company obtains additional information for its estimates during the measurement period (up to one year from the acquisition date).

Acquisition of Nanjing Letop Medical Technology Co. Ltd.

In January 2016, the Company's Chinese subsidiary, ANP, acquired Nanjing Letop Medical Technology Co. Ltd. for $1.7 million consisting of $0.8 million in cash and a deposit of $0.9 million that ANP had previously paid to Letop

and which was effectively eliminated upon the consummation of the transaction. The Company accounted for this transaction as a business combination in accordance with ASC 805. The Company recognized $1.4 million of acquired assets, $0.1 million of assumed liabilities, and $0.4 million of goodwill. Letop had previously supplied ANP with intermediates used in making various active pharmaceutical ingredients. In March 2016, the acquired subsidiary was renamed Nanjing Letop Fine Chemistry Co., Ltd.

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AMPHASTAR PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

Acquisition of Merck's API Manufacturing Business

On April 30, 2014, the Company completed its 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, or RHI 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 rate 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	3,483
December 2016	3,186	3,572
December 2017	500	561
	€ 25,023	$ 31,957

In order to facilitate the acquisition, the Company established AFP in France. The Company is continuing the current site manufacturing activities, which consist of the manufacturing of porcine insulin API and 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.

4. Revenue Recognition

Generally, revenue is recognized at the time of product delivery to the Company's customers. In some cases, revenue is recognized at the time of shipment when stipulated by the terms of the sale agreements. The Company also records profit-sharing revenue stemming from a distribution agreement with Actavis, Inc., or Actavis. This distribution agreement is in the process of being terminated (see Note 16). Profit-sharing revenue is recognized at the time Actavis sells the products to its customers. Revenues derived from contract manufacturing services are recognized when

third-party products are shipped to customers, after the customer has accepted test samples of the products to be shipped.

The Company does not recognize product revenue unless the following fundamental criteria are met: (i) persuasive evidence that 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

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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,	
	2016	2015
	(in thousands)	
Beginning balance	$ 15,217	$ 11,872
Provision related to sales made in the current period	105,772	121,714
Credits issued to third parties	(110,073)	(121,914)
Ending balance	$ 10,916	$ 11,672

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 Actavis are non-returnable. The Company's product returns primarily consist of the returns of expired products from sales made in prior periods. Returned products cannot be resold. At the time product revenue is recognized, the Company records an accrual for estimated returns. The accrual is based, in part, upon the historical relationship of product returns to sales and customer contract terms. The Company also assesses other factors that could affect product returns including market conditions, product obsolescence, and the introduction of new competition. Although these factors do not normally give the Company's customers the right to return products

outside of the regular return policy, the Company realizes that such factors could ultimately lead to increased returns. The Company analyzes these situations on a case-by-case basis and makes adjustments to the product return reserve as appropriate.

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

	Nine Months Ended September 30,	
	2016	2015
	(in thousands)	
Beginning balance	$ 2,621	$ 2,408
Provision for product returns	958	1,971
Credits issued to third parties	(873)	(1,233)
Ending balance	$ 2,706	$ 3,146

For the nine months ended September 30, 2016 and 2015, the Company's aggregate product return rate was 1.1% and 1.1% of qualified sales, respectively.

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5. Income (loss) per Share

Basic income (loss) per share is calculated based upon the weighted-average number of shares outstanding during the period. Diluted income per share gives effect to all potential dilutive shares outstanding during the period, such as stock options, nonvested deferred stock units and restricted stock units (collectively referred to herein as “RSUs”), and shares issuable under the Company’s Employee Stock Purchase Plan, or the ESPP.

For the three months ended September 30, 2016, options to purchase 1,357,154 shares of stock with a weighted-average exercise price of $29.31 per share, were excluded in the computation of diluted net income per share because the effect from the assumed exercise of these options would be anti-dilutive. For the nine months ended September 30, 2016, options to purchase 4,510,729 shares of stock with a weighted-average exercise price of $19.84 per share, were excluded in the computation of diluted net income per share because the effect from the assumed exercise of these options would be anti-dilutive.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(in thousands, except per share data)			
Basic and dilutive numerator:				

Net income (loss)	$ 3,890	$ (3,008)	$ 13,274	$ (10,320)
Denominator:				
Weighted-average shares outstanding — basic	45,398	45,310	45,132	44,920
Net effect of dilutive securities:				
Incremental shares from equity awards	2,555	—	1,233	—
Weighted-average shares outstanding — diluted	47,953	45,310	46,365	44,920
Net income (loss) per share — basic	$ 0.09	$ (0.07)	$ 0.29	$ (0.23)
Net income (loss) per share — diluted	$ 0.08	$ (0.07)	$ 0.29	$ (0.23)

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®, Amphadase®, naloxone, lidocaine jelly, as well as various other critical and non-critical care drugs. The API segment manufactures and distributes RHI and porcine insulin. The Company also uses RHI for internal product development.

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Selected financial information by reporting segment is presented below:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(in thousands)			
Net revenues:				
Finished pharmaceutical products	$ 59,058	$ 57,902	$ 181,368	$ 158,849
API	5,165	5,966	10,254	15,758
Total net revenues	64,223	63,868	191,622	174,607
Gross profit:				
Finished pharmaceutical products	28,621	19,302	85,042	44,789
API	(1,009)	(1,724)	(814)	(613)
Total gross profit	27,612	17,578	84,228	44,176
Operating expenses	21,815	21,326	64,026	65,445
Income (loss) from operations	5,797	(3,748)	20,202	(21,269)
Non-operating income (expenses)	204	(528)	(633)	567
Income (loss) before income taxes	$ 6,001	$ (4,276)	$ 19,569	$ (20,702)

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.

Prior to the Merck API Transaction on April 30, 2014, Merck notified the Company of several environmental items that were not in alignment with Merck's internal policies and procedures. None of these items were in violation of any French environmental law or regulation. The Company has assessed the nature of the remedial actions to be undertaken and since April 30, 2014, recorded the related expenses of €0.6 million as incurred in cost of sales within the API segment. Based on the letter of understanding signed in conjunction with the acquisition on April 30, 2014, the Company and Merck further entered into an agreement on May 11, 2016, pursuant to which Merck shall reimburse the Company for the costs to complete the remedial actions up to €6.0 million. Accordingly, in the nine months ended September 30, 2016, the Company recorded the reimbursement of €0.6 million for the expenses already incurred as a

reduction of cost of sales within the API segment.

The amount of net revenues in the finished pharmaceutical products segment is presented below:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(in thousands)			
Finished pharmaceutical products net revenues:				
Enoxaparin	$ 15,363	$ 21,264	$ 51,049	$ 64,647
Naloxone	12,407	10,519	38,222	27,944
Lidocaine	8,279	6,176	26,378	20,662
Phytonadione	8,667	5,935	23,555	10,301
Epinephrine	5,303	5,032	14,921	9,958
Other finished pharmaceutical products	9,039	8,976	27,243	25,337
Total finished pharmaceutical products net revenues	$ 59,058	$ 57,902	$ 181,368	$ 158,849

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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,
	2016	2015	2016	2015	2016	2015
	(in thousands)					
United States	$ 62,691	$ 62,955	$ 188,865	$ 168,705	$ 103,179	$ 100,404
China	—	—	—	—	34,541	28,547
France	1,532	913	2,757	5,902	14,135	13,210
United Kingdom	—	—	—	—	97	—
Total	$ 64,223	$ 63,868	$ 191,622	$ 174,607	$ 151,952	$ 142,161

7. Customer and Supplier Concentration

Customer Concentrations

Three large wholesale drug distributors, AmerisourceBergen Corporation, or AmerisourceBergen, Cardinal Health, Inc. or Cardinal Health, and McKesson Corporation, or McKesson, are all distributors of the Company’s products, as well as suppliers of a broad range of health care products. Actavis had exclusive marketing rights of the Company’s enoxaparin product to the U.S. retail pharmacy market (see Note 16). 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, 2016 and 2015, and accounts receivable as of September 30, 2016 and December 31, 2015. 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, 2016	December 31, 2015	September 30, 2016	2015	2016	2015
Actavis(1)	10 %	12 %	16 %	22 %	19 %	22 %
AmerisourceBergen	13 %	12 %	19 %	17 %	19 %	17 %
Cardinal Health	23 %	20 %	19 %	14 %	20 %	16 %
MannKind Corporation	12 %	13 %	5 %	7 %	4 %	7 %
McKesson	20 %	21 %	21 %	25 %	20 %	22 %

(1) Effective June 30, 2016, the Company and Actavis agreed to terminate the agreement upon the earlier of (i) January 1, 2017, and (ii) such earlier date that is 30 days after Actavis notifies the Company in writing that Actavis has less than 30 days inventory of the enoxaparin product remaining in its possession or scheduled to be delivered pursuant to the pending purchase orders (see Note 16).

Supplier Concentrations

The Company depends on suppliers for raw materials, active pharmaceutical ingredients, and other components that are subject to stringent 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 amount 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 that it depends on to manufacture and market its products, it could have a material adverse effect on the Company’s business, financial condition, and results of operations.

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8. Fair Value Measurements

The accounting standards of the 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 the 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.

The Company classifies its cash equivalents and restricted 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, 2016 and December 31, 2015, 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	$ 44,695	$ 44,695	$ —	$ —
Restricted short-term investments	1,390	1,390	—	—
Fair value measurement as of September 30, 2016	$ 46,085	$ 46,085	$ —	$ —
Cash equivalents	$ 42,486	$ 42,486	$ —	$ —
Restricted short-term investments	1,285	1,285	—	—
Fair value measurement as of December 31, 2015	$ 43,771	$ 43,771	$ —	$ —

The fair value of the Company's cash equivalents includes money market accounts, money market funds, Money Market Insured Deposit Account Service and Insured Cash Sweep accounts. Restricted 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.

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Short-term investments primarily consist of held-to-maturity municipal bonds with original maturities greater than three months. The municipal bonds are carried at amortized cost in the Company's consolidated balance sheet, which approximates their fair value determined based on Level 2 inputs. The Company does not intend to and will not be required to sell the investments before recovery of their amortized cost basis.

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, 2016 and December 31, 2015, there were no significant adjustments to fair value for nonfinancial assets or liabilities.

9. Goodwill and Intangible Assets

The table below shows the weighted-average life, original cost, accumulated amortization, and net book value by major intangible asset classification as of the dates set forth below:

	Weighted-Average Life (Years) (in thousands)	Original Cost	Accumulated Amortization	Net Book Value
Definite-lived intangible assets				
Product rights	12	$ 27,134	$ 24,015	$ 3,119
Acquired international product rights(1)	10	9,075	151	8,924
Acquired ANDAs(2)	15	4,000	156	3,844
Patents	10	293	129	164
Land-use rights	39	2,540	337	2,203
Other intangible assets	1	574	531	43
Subtotal	12	43,616	25,319	18,297
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill				

Finished pharmaceutical products	*	4,210	—	4,210
Subtotal	*	33,435	—	33,435
As of September 30, 2016	*	$ 77,051	$ 25,319	$ 51,732

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

(1)In August 2016, the Company acquired International Medication Systems (UK) Limited from UCB PHARMA GmbH for $7.7 million. The fair value of the marketing authorization was $9.2 million as of the acquisition date. The accounting for this transaction is preliminary (see Note 3).

(2)In March 2016, the Company acquired 14 ANDAs representing 11 different injectable chemical entities from Hikma Pharmaceuticals PLC for $4.0 million. The accounting for this transaction is preliminary (see Note 3).

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	Weighted-Average Life (Years) (in thousands)	Original Cost	Accumulated Amortization	Net Book Value
Definite-lived intangible assets				
Product rights	12	$ 27,134	$ 22,679	$ 4,455
Patents	10	293	107	186
Land-use rights	39	2,540	288	2,252
Other intangible assets	1	590	533	57
Subtotal	12	30,557	23,607	6,950
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill				
Finished pharmaceutical products	*	3,726	—	3,726
Subtotal	*	32,951	—	32,951
As of December 31, 2015	*	$ 63,508	$ 23,607	$ 39,901

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

Goodwill

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

	September 30, 2016	December 31, 2015
	(in thousands)	
Beginning balance	$ 3,726	$ 4,467
Goodwill related to acquisition of business	391	—
Currency translation and other adjustments	93	(741)
Ending balance	$ 4,210	$ 3,726

Primatene® 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, 2016.

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® that utilizes hydrofluoroalkane, or HFA, as a propellant.

In 2013, the Company filed a new drug application, or NDA, for Primatene® Mist 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 required additional non-clinical information, label revisions and follow-up studies (label comprehension,

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behavioral/human factors and actual use) to assess consumers' ability to use the device correctly to support approval of the product in the over-the-counter setting. 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 received further advice regarding its ongoing studies from the FDA in January 2016, and subsequently completed the human factor studies accordingly. The Company submitted the NDA amendment on June 28, 2016 and received a target response date of December 28, 2016. However, there can be no guarantee that any amendment to the Company's NDA will result in timely approval of Primatene® Mist, or approval at all.

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

10. Inventories

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

	September 30, 2016	December 31, 2015
	(in thousands)	
Raw materials and supplies	$ 47,240	$ 31,878
Work in process	15,645	21,455
Finished goods	29,351	19,867
Total inventory	92,236	73,200
Less reserve for excess and obsolete inventories	(1,586)	(2,535)
Total inventory, net	$ 90,650	$ 70,665

11. Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

	September 30, 2016	December 31, 2015
	(in thousands)	
Buildings	$ 84,533	$ 82,309
Leasehold improvements	24,638	23,392
Land	6,926	6,895
Machinery and equipment	110,371	108,442
Furniture, fixtures, and automobiles	14,978	13,439
Construction in progress	29,955	19,942
Total property, plant, and equipment	271,401	254,419
Less accumulated depreciation	(119,449)	(112,258)
Total property, plant, and equipment, net	$ 151,952	$ 142,161

As of September 30, 2016, the Company had $2.6 million in capitalized manufacturing equipment that is intended to be used specifically for the manufacture of Primatene® Mist. The Company will continue to monitor developments with the FDA as it relates to its Primatene® 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, 2016	December 31, 2015
	(in thousands)	
Loans with East West Bank		
Mortgage payable matured January 2016	$ —	$ 3,725
Mortgage payable matured September 2016	—	2,211
Equipment loan due April 2017	754	1,700
Line of credit facility due September 2017	—	—
Equipment loan due January 2019	3,593	4,748
Mortgage payable due February 2021	3,679	—
Equipment credit line due September 2021	2,882	—
Mortgage payable due October 2026	3,591	—
Loans with Cathay Bank		
Line of credit facility due May 2018	—	—
Acquisition loan due April 2019	17,570	19,012
Mortgage payable due April 2021	4,391	4,460
Loans with Seine-Normandie Water Agency		
French government loan 1 due March 2018	31	46
French government loan 2 due June 2020	104	128
French government loan 3 due July 2021	277	325
Payment Obligation to Merck	4,097	3,942
Equipment under Capital Leases	1,735	802
Total debt and capital leases	42,704	41,099
Less current portion of long-term debt and capital leases	8,541	10,934
Long-term debt and capital leases, net of current portion	$ 34,163	$ 30,165

Loans with East West Bank

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, which matures in April 2017. Borrowings under the facility are secured by equipment purchased with debt proceeds. Borrowings under the facility bear a variable interest rate at the prime rate as published by The Wall Street Journal, plus 0.25%, with a minimum interest rate of 3.50%. As of September 30, 2016, the fair value of the loan approximates its book value. The interest rate used in the fair value estimation was determined to be a Level 2 input.

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Line of Credit Facility—Due September 2017

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 a variable interest rate at the prime rate as published by The Wall Street Journal. This facility matured in March 2016.

In March 2016, the Company amended the facility to increase the line of credit to $15.0 million and extended the maturity date to September 2017. As of September 30, 2016, the Company did not have any amounts outstanding under this facility.

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 a variable interest rate 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 converted into an equipment loan with an outstanding principal balance of $6.2 million and a maturity date of January 2019. Borrowings under the facility are secured by the equipment purchased with the debt proceeds. The Company entered into a fixed interest rate swap contract on this facility to exchange the variable interest rate for a fixed interest rate of 4.48% 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 condensed consolidated financial statement at September 30, 2016. As of September 30, 2016, the fair value of the loan approximates its book value. The interest rate used in the fair value estimation was determined to be a Level 2 input.

Mortgage Payable—Due February 2021

In December 2010, the Company refinanced an existing mortgage term loan, which had an outstanding principal balance of $4.5 million at December 31, 2010. The loan was payable in monthly installments with a final balloon payment of $3.8 million. The loan was 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 had a variable interest rate at the prime rate as published by The Wall Street Journal, with a minimum interest rate of 5.00%, and matured in January 2016.

The Company refinanced the existing mortgage term loan in January 2016, which had an outstanding principal balance of $3.7 million at December 31, 2015, and a maturity date of February 2021. The refinanced loan is payable in monthly installments with a final balloon payment of $3.3 million. The refinanced loan is secured by one of the buildings at the Company's Rancho Cucamonga, California, headquarters complex. The refinanced loan has a variable interest rate at the prime rate as published by The Wall Street Journal. Subsequently, the Company entered into a fixed interest rate swap contract on this loan to exchange the variable interest rate for a fixed interest rate of 4.39% over the life of the loan without the exchange of the underlying notional debt amount. The fair value of the derivative and unrealized loss was approximately $0.1 million at September 30, 2016. As of September 30, 2016, the fair value of the loan approximates its book value. The interest rate used in the fair value estimation was determined to be a Level 2 input.

Equipment Credit Line–Due September 2021

In March 2016, the Company entered into a $5.0 million equipment credit line with an 18-month draw down period and interest payments due monthly through September 2017 at the prime rate as published by The Wall Street Journal. After the draw down period, the outstanding principal balance converts into a 48-month loan with principal and interest payments due monthly. Borrowings under the facility are secured by the equipment purchased with the debt proceeds, and bear a variable interest rate at the prime rate as published by The Wall Street Journal. This facility matures in September

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2021. As of September 30, 2016, the fair value of the loan approximates its book value. The interest rate used in the fair value estimation was determined to be a Level 2 input. As of September 30, 2016, the Company has drawn $2.9 million from the equipment line of credit.

Mortgage Payable—Due October 2026

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

The Company refinanced the existing mortgage term loan in September 2016, which increased the principal amount to $3.6 million and extended the maturity date to October 2026. The refinanced loan is payable in monthly installments with a final balloon payment of $2.9 million. The refinanced loan has a variable interest rate at the one-month LIBOR rate plus 2.75%. Subsequently, the Company entered into a fixed interest rate swap contract on this loan to exchange the variable interest rate for a fixed interest rate of 4.15% until October 2021 without the exchange of the underlying notional debt amount. The fair value of the derivative and the unrealized loss was approximately $0.1 million at September 30, 2016. As of September 30, 2016, the fair value of the loan approximates its book value. The interest rate used in the fair value estimation was determined to be a Level 2 input.

Loans with Cathay Bank

Line of Credit Facility—Due May 2018

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 a variable interest rate at the prime rate as published by The Wall Street Journal with a minimum interest rate of 4.00%. This revolving line of credit was to mature in May 2016. In June 2016, the Company modified the facility to extend the maturity date to May 2018. As of September 30, 2016, 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. As of September 30, 2016, the fair value of the loan approximates its book value. The interest rate used in the fair value estimation was determined to be a Level 2 input.

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

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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 an outstanding principal balance 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, bears interest at a fixed rate of 5.42%, and matures in April 2021. As of September 30, 2016, the fair value of the loan approximates its book value. The interest rate used in the fair value estimation was determined to be a Level 2 input.

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 rate fluctuations. The life of the loans ranges between three to six years, includes annual equal payments and bears no interest over the life of the loans.

As of September 30, 2016, the payment obligation had an aggregate book value of €0.4 million, or $0.4 million, subject to currency exchange rate fluctuations, 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%. Such interest rate is deemed to be a Level 2 input for measuring fair value.

Payment Obligation to Merck

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 rate 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 2015 and 2014, the Company made a principal payment of €3.2 million, or $3.5 million and €4.9 million, or $6.0 million, respectively.

As of September 30, 2016, the payment obligation had a book value of €3.6 million, or $4.1 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%. Such interest rate is deemed to be a Level 2 input for measuring fair value.

Covenants

At September 30, 2016 and December 31, 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.

Equipment under Capital Leases

The Company entered into leases for certain equipment under capital leasing arrangements, which will expire at various times through 2021. The cost of equipment under capital leases was $2.0 million and $1.5 million at September 30, 2016 and December 31, 2015, respectively.

The accumulated depreciation of equipment under capital leases was $0.1 million and $0.7 million at September 30, 2016

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and December 31, 2015, respectively. Depreciation of assets recorded under capital leases is included in depreciation expense in the accompanying condensed 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,	
	2016	2015	2016	2015
	(in thousands)			
Income (loss) before taxes	$ 6,001	$ (4,276)	$ 19,569	$ (20,702)
Income tax expense (benefit)	2,111	(1,268)	6,295	(10,382)
Net income (loss)	$ 3,890	$ (3,008)	$ 13,274	$ (10,320)
Income tax provision (benefit) as a percentage of income (loss) before income taxes	35.2 %	(29.7) %	32.2 %	(50.1) %

The Company's income tax provision for the three and nine months ended September 30, 2016, was 35.2% and 32.2% of income before taxes, respectively. The Company has a full valuation allowance against its French deferred tax assets; however, a tax benefit is included in the annual effective tax rate computation due to the French entity reporting a year-to-date foreign exchange gain in other comprehensive income. The blended effective income tax rate expected for the year ending December 31, 2016, is 32.4%. This effective tax rate factors in various permanent differences, including domestic deductions, the impact of foreign operations, and various credits. The Company's income tax benefit of 29.7% and 50.1% during the three and nine months ended September 30, 2015, respectively, factored in similar permanent items, as well as the impact of its 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, tax-planning strategies, and projected future taxable income.

In connection with the AFP purchase accounting in 2014, the Company recorded a valuation allowance against a deferred tax asset of €3.2 million, or $4.4 million, subject to currency exchange rate fluctuations, 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, subject to currency exchange rate fluctuations, deferred tax valuation allowance in conjunction with the transfer of AFP's intangible assets from France to the United States. The difference in U.S. dollars relates to the currency exchange rate fluctuation, which is recorded in the Company's accumulated other comprehensive loss as a foreign currency translation adjustment.

In 2015, the Company assessed the realizability of the deferred tax assets for AFP. Due to the potential impact of reduced revenues from the MannKind contract and other factors, the Company determined that it was not more likely than not that the net deferred tax assets of AFP would be realized. Therefore, the Company established a full valuation allowance of $0.9 million as of December 31, 2015, and continues to maintain a full valuation allowance on all AFP deferred tax assets.

In 2016, for computing its annual effective tax rate, the Company did not benefit from its losses in the states where it files separately. This had no material impact on the Company's income tax expense during the three months ended September 30, 2016, and increased the Company's income tax expense by $0.2 million during the nine months ended September 30, 2016.

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14. Stockholders' Equity

A summary of the changes in stockholders' equity for the nine months ended September 30, 2016, consisted of the following:

	Nine Months Ended September 30, 2016 (in thousands)
Stockholders' equity as of December 31, 2015	$ 295,510
Net income	13,274
Accumulated other comprehensive loss	(106)
Exercise of stock options	17,584
Issuance of common stock to employees under the ESPP	915
Nonemployee share-based compensation expense	1,122
Employee share-based compensation expense	10,482
Repurchase of common stock(1)	(1,342)
Purchase of treasury stock	(8,986)
Stockholders' equity as of September 30, 2016	$ 328,453

(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 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 85% of the lower of the fair market value of the common stock at the beginning of an offering period or on the date of purchase.

As of September 30, 2016, the Company has issued 193,849 shares of common stock under the ESPP and 1,806,151 shares of its common stock remain available for issuance.

For the three and nine months ended September 30, 2016, the Company recorded ESPP expense of $0.1 million and $0.4 million, respectively. For the three and nine months ended September 30, 2015, the Company recorded ESPP expense of $0.1 million and $0.4 million, respectively.

Share Buyback Program

On November 6, 2014, the Company’s Board of Directors authorized a $10.0 million share buyback program, which was completed in December 2015. On November 10, 2015, the Company’s Board of Directors authorized an additional $10.0 million share buyback program. The primary goal of the programs is to offset dilution created by the Company’s equity compensation programs.

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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 SEC. 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 46,333 and 710,833 shares of its common stock during the three and nine months ended September 30, 2016, for total consideration of $0.8 million and $9.0 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 lesser 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.

As of September 30, 2016, the Company reserved an aggregate of 3,938,687 shares of common stock for future issuance under the 2015 Plan, including an additional 1,129,962 shares reserved under the 2015 Plan pursuant to the evergreen provision.

Share-Based Award Activity and Balances

Stock Options

The fair value of option awards made to employees and directors is estimated at the grant date using the Black-Scholes pricing model and the portion that is ultimately expected to vest is recognized as compensation cost over the requisite service period using the straight-line method.

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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, 2016 and 2015, are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Average volatility	31.9 %	27.5 %	30.4 %	27.1 %
Risk-free interest rate	1.3 %	2.0 %	1.5 %	1.3 %
Weighted-average expected life in years	6.3	6.3	5.5	4.5
Dividend yield rate	— %	— %	— %	— %

A summary of option activity under all plans for the nine months ended September 30, 2016, 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, 2015	12,240,467	$ 15.41		
Options granted	2,395,789	12.19		
Options exercised	(1,262,020)	13.93		
Options cancelled	(174,783)	13.48		
Options expired	(245,538)	23.84		
Outstanding as of September 30, 2016	12,953,915	$ 14.82	4.50	$ 67,739
Exercisable as of September 30, 2016	8,183,715	$ 15.59	2.99	$ 41,704

(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, 2016.

For the three and nine months ended September 30, 2016, the Company recorded stock option expense related to employees and the Board of Directors under all plans of $1.9 million and $6.7 million, respectively. For the three and nine months ended September 30, 2015, the Company recorded stock option expense related to employees and the Board of Directors under all plans of $2.1 million and $6.1 million, respectively.

Information relating to option grants and exercises is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(in thousands, except per share data)			
Weighted-average grant date fair value	$ 6.34	$ 4.54	$ 3.42	$ 3.44
Intrinsic value of options exercised	4,998	268	5,980	2,721
Cash received	14,331	816	17,584	11,257
Total fair value of the options vested during the year	2,688	2,888	7,948	5,423

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A summary of the status of the Company's nonvested options as of September 30, 2016 and changes during the nine months ended September 30, 2016 is presented below:

	Options	Weighted-Average Grant Date Fair Value
Nonvested as of December 31, 2015	5,202,095	$ 3.44
Options granted	2,395,789	3.42
Options vested	(2,652,901)	3.00
Options forfeited	(174,783)	4.67
Nonvested as of September 30, 2016	4,770,200	3.63

As of September 30, 2016, there was $12.5 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 2.3 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 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, using the straight-line method. The Company recorded a total expense of $1.5 million and $4.5 million for the three and nine months ended September 30, 2016, respectively, for these RSU awards compared to the prior year expense of $1.1 million and $2.8 million for the three and nine months ended September 30, 2015, respectively.

As of September 30, 2016, there was $11.4 million of total unrecognized compensation cost, net of forfeitures, related to nonvested RSU-based compensation arrangements granted under all Plans. The cost is expected to be recognized over a weighted-average period of 2.4 years and will be adjusted for future changes in estimated forfeitures.

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, 2015	866,540	
RSUs granted	732,021	$ 8,646
RSUs forfeited	(53,157)	
Common stock delivered	(218,875)	
RSUs surrendered for taxes	(108,457)	
RSUs outstanding at September 30, 2016	1,218,072	

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

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Equity Awards to Consultants

The Company has entered into various consulting agreements with its stockholders and third-party consultants. Consulting expenses are accrued as services are rendered. Consulting services are paid in cash and/or in common stock or stock options of the Company. Share-based compensation expense is recorded over the service period based on the estimated fair value of the equity award at the date services are performed or upon completion of all services under the agreement. During the three months ended September 30, 2016, the Company recorded an immaterial amount of share-based compensation related to the issuance of equity awards for services rendered by consultants. During the nine months ended September 30, 2016, the Company recorded approximately $0.1 million, in share-based compensation related to the issuance of equity awards for services rendered by consultants. During the three and nine months ended September 30, 2015, the Company recorded approximately $0.1 million and $0.1 million, respectively, in share-based compensation related to the issuance of equity awards for services rendered by consultants.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(in thousands)			
Cost of revenues	$ 675	$ 638	$ 2,245	$ 1,856
Operating expenses:				
Selling, distribution, and marketing	45	49	176	148
General and administrative	2,593	2,536	8,339	6,676
Research and development	242	204	844	677
Total share-based compensation	$ 3,555	$ 3,427	$ 11,604	$ 9,357

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 6% of employee contributions, 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, 2016, were approximately $0.3 million and $0.7 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, 2015, 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, 2016 and December 31, 2015. 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 $1.6 million at September 30, 2016 and December 31, 2015, respectively. The Company recorded an immaterial amount of expense under the plan for the three months ended September 30, 2016, and $0.1 million for the nine months ended September 30, 2016. The Company recorded an immaterial amount of expense under the plan for the three months ended September 30, 2015, and $0.1 million for the

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nine months ended September 30, 2015.

16. Commitments and Contingencies

Distribution Agreement with Actavis, Inc.

In May 2005, the Company entered into an agreement to grant certain exclusive marketing rights for its enoxaparin product to Andrx Pharmaceuticals, Inc., or Andrx, which generally extends to the U.S. retail pharmacy market. To obtain such rights, Andrx made a non-refundable, upfront payment of $4.5 million to the Company upon execution of the agreement, which was classified as deferred revenues. Under the agreement, the Company is to be paid a fixed cost per unit sold to Andrx and also shares in the gross profits (as defined) from Andrx's sales of the enoxaparin 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.

In January 2012, the Company launched its enoxaparin product, beginning the seven-year period during which Actavis 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. Actavis has an option to renew the agreement for an additional three years. As of June 30, 2016 and December 31, 2015, the balance of the deferred revenue was $1.7 million and $2.0 million, respectively. On June 30, 2016, the Company and Actavis agreed to terminate the agreement upon the earlier of (i) January 1, 2017, and (ii) such earlier date that is 30 days after Actavis notifies the Company in writing that Actavis has less than 30 days inventory of the enoxaparin product remaining in its possession or scheduled to be delivered pursuant to the pending purchase orders. The Company recognizes the remaining balance of the deferred revenue over the period from July 1, 2016 through December 31, 2016, on a straight-line basis as a result of the revised estimate of the contractual period. As of September 30, 2016, the balance of the deferred revenue was $0.8 million.

The Company manufactures its enoxaparin product for the retail market according to demand specifications of Actavis. Upon shipment of enoxaparin to Actavis, the Company recognizes product sales at an agreed transfer price and records the related cost of products sold. Based on the terms of the Company's distribution agreement with

Actavis, the Company is entitled to a share of the ultimate profits based on the eventual net revenue from enoxaparin sales by Actavis to the end user less the agreed transfer price originally paid by Actavis to the Company. Actavis provides the Company with a quarterly sales report that calculates the Company's share of Actavis enoxaparin gross profit. The Company records its share of Actavis gross profit as a component of net revenue.

Supply Agreement with MannKind Corporation

On July 31, 2014, the Company entered into a supply agreement with MannKind Corporation, or MannKind, or the Supply Agreement, pursuant to which the Company agreed to manufacture for and supply to MannKind certain quantities of RHI for use in MannKind's product, Afrezza®. Under the Supply Agreement, MannKind agreed to purchase annual minimum quantities of RHI in an aggregate amount of approximately €120.1 million, or approximately $146.0 million, over five years from calendar years 2015 through 2019. Specifically, the minimum annual purchase commitment was approximately €27.1 million in 2015, and approximately €23.3 million each year from 2016 through 2019.

On July 31, 2014, upon entering into the Supply Agreement, MannKind paid a non-refundable prepayment to the Company in the amount of €11.0 million, or approximately $14.0 million. Under the Supply Agreement, the non-refundable prepayment was applied towards the 2015 annual commitment. The Company recorded the amount as deferred revenue in 2014, and it was recognized as net revenue in 2015 at the time the products were shipped.

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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 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, or the Option Agreement, pursuant to which MannKind has the option to purchase RHI in excess of the minimum amounts specified in the Supply Agreement in calendar years 2016 through 2019. In the event MannKind elects not to exercise its minimum annual purchase option for any year under the Option Agreement, MannKind is obligated to pay the Company a specified capacity cancellation fee.

In 2015, the sales of RHI to MannKind were €17.1 million, or approximately $20.8 million, and the unfulfilled 2015 commitment under the Supply Agreement was €6.0 million as of December 31, 2015. The Company and MannKind mutually, verbally agreed that MannKind could delay a portion of the minimum contractually obligated quantities of RHI for 2015 and purchase the remaining unfulfilled 2015 commitment in 2016. No other aspects of the Supply Agreement were modified and the commitments for calendar years 2016 through 2019 as specified in the Supply Agreement remain binding and enforceable.

In October 2015, MannKind informed the Company that it was not exercising the option to purchase additional quantities of RHI for 2016 under the Option Agreement and paid the Company the specified capacity cancellation fee of $0.8 million. Such capacity cancellation fee was recorded as net revenue in the Company's consolidated statements of operations for the year ended December 31, 2015.

In the nine months ended September 30, 2016, sales of RHI to MannKind totaled $6.8 million, which fulfilled the remaining unfulfilled 2015 commitment of RHI under the Supply Agreement. MannKind had no unfulfilled purchase obligations under the Supply Agreement as of September 30, 2016, although it has not yet purchased any of its 2016 minimum purchase commitment.

The Company is currently in discussions with MannKind regarding the timing of fulfillment of its minimum purchase commitment of RHI under the Supply Agreement and its purchase of additional quantities under the Option Agreement. The Company anticipates that these discussions may result in reductions in the capacity cancellation fees, as well as extensions of the timing of MannKind's purchase commitments under the Supply Agreement.

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, 2016, the Company has paid an upfront payment of $0.5 million and $0.7 million in milestone payments under this agreement, which were classified as research and development expense. The Company is obligated to pay up to an additional $1.3 million if certain milestones are met. As of September 30, 2016, no such obligation existed. Pursuant to the collaboration agreement, if the medical device manufacturer is successful in the development of this drug delivery system and the Company’s pipeline products receive appropriate regulatory approval, the Company is obligated 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.

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Operating Lease Agreements

The Company leases real and personal property, in the ordinary 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, 2016, was approximately $0.8 million and $2.5 million, respectively, compared to $0.8 million and $2.5 million for the three and nine months ended September 30, 2015, respectively.

Purchase Commitments

As of September 30, 2016, the Company has entered into commitments to purchase equipment and raw materials for an aggregate of $17.9 million. The Company anticipates that most of these commitments will be fulfilled by 2017.

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, 2016, the Company had invested approximately $49.0 million in ANP out of its registered capital commitment of $61.0 million. The Company has committed to invest the remaining $12.0 million in ANP by December 2017. This investment in ANP will result in cash transfers 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 current pace of development of the property is behind the schedules described in the purchase agreements and, per the purchase agreement, potential monetary penalties could result if the development is delayed or not completed in accordance with the guidelines stated in the purchase agreements. The Company is in discussions with the Chinese government regarding the development and believes that the likelihood of incurring any penalty is remote.

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 Massachusetts District Court. In October 2011, the Massachusetts 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 Massachusetts 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 their infringement contentions. On January 24, 2014, the Massachusetts District Court judge entered final judgment in the Company's favor on both patents. Momenta and Sandoz also filed a motion to collect attorneys' fees and costs relating to a discovery motion which the Massachusetts District Court granted. On May 9, 2016, the Massachusetts District Court issued an order imposing fees and costs of approximately $0.4 million in relation to this discovery motion.

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This amount has been accrued in the general and administrative expense for the quarter ended March 31, 2016. 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.

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 Massachusetts District Court granting summary judgment of non-infringement as to the Company, and it remanded the case to the Massachusetts District Court for further proceedings consistent with its opinion. The Federal Circuit panel affirmed the Massachusetts 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 Massachusetts District Court's discretion whether to reconsider on remand its denial of leave for Momenta and Sandoz to amend their infringement contentions. On January 11, 2016, the Company filed a Petition for Rehearing En Banc with the Federal Circuit. On February 17, 2016, the Federal Circuit denied the Company's Petition, and the Federal Circuit issued its mandate on February 24, 2016, whereby the case returned to the Massachusetts District Court for further proceedings.

On March 18, 2016, the parties filed a joint status report with the Massachusetts District Court. On June 21, 2016, the Massachusetts District Court granted Momenta and Sandoz's Motion for Leave to Amend its Infringement Contentions. In light of Momenta and Sandoz's Amended Infringement Contentions and recent changes in Supreme Court precedent since the case was stayed in 2012, the Company sought to amend its Non-Infringement and Invalidity Contentions. The Massachusetts District Court then held a status conference on July 6, 2016 and referred the issue of the Company's amended contentions to the Magistrate Judge for briefing and further informed the parties that replies to any Summary Judgment motion are due in May 2017 and that trial is set to begin on July 10, 2017. On July 15, 2016, the Massachusetts District Court entered the Amended Scheduling Order setting the end of any remaining fact discovery for November 22, 2016 and the end of expert discovery for March 24, 2017.

On July 18, 2016, the Company submitted its Motion for Leave to Amend Its Non-Infringement and Invalidity Contentions and Momenta and Sandoz responded on July 25, 2016. In light of the new arguments made in their response, the Company further filed a Motion For Leave to Reply in Further Support of Defendants' Motion for Leave to Amend Non-Infringement and Invalidity Contentions. The Massachusetts District Court has not yet ruled on the Company's pending motions regarding its amended contentions.

In parallel with the Massachusetts District Court proceedings, the Company appealed the Federal Circuit's decision to vacate the grant of the Company's summary judgment to the extent it was based on the determination that the Company's activities are protected under the Safe Harbor. The Company filed a Petition for a Writ of Certiorari with the Supreme Court on May 17, 2016. Momenta and Sandoz initially waived their right to respond to the petition; however, on May 31, 2016, the Supreme Court requested a response from Momenta and Sandoz. The response from Momenta and Sandoz was initially due on June 30, 2016, but they requested an extension. Momenta and Sandoz filed their response on August 1, 2016. On October 3, 2016, the Supreme Court declined the Petition for a Writ of Certiorari.

The Company will continue to vigorously defend this case in the Massachusetts District Court. The Company intends to attempt to collect the $100.1 million bond posted by Momenta and Sandoz following a decision on the merits, provided that the Company prevails in Massachusetts 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 California 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

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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 California 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 California 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 California District Court issued an order certifying for appeal its order denying Aventis' motion for summary judgment. On June 9, 2014, Aventis filed with the United States Court of Appeals for the Ninth Circuit, or the Ninth Circuit, a petition for permission to appeal the California 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 California 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 California District Court issued a ruling concluding that the Company is not an original source under the False Claims Act and entered final judgment dismissing the case for lack of subject matter jurisdiction.

On July 20, 2015, the Company filed with the Ninth Circuit a notice of appeal of the California District Court's dismissal of the case, and Aventis filed a notice of cross-appeal on August 5, 2015. On November 12, 2015, Aventis filed a pleading asking that the California 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. On November 23, 2015, the California District Court issued an order setting forth a procedure for sanctions proceedings as to the Company as well as its outside counsel. On December 24, 2015, the Company filed a pleading with the California District Court opposing the imposition of sanctions and on January 20, 2016, Aventis filed a response pleading further pressing for the imposition of sanctions. On May 4, 2016, the California District Court issued three orders requesting that the Company and its outside counsel file a document showing cause as to why sanctions should not be imposed and to set up a conference call with the partiers and the court to discuss whether any discovery and/or a hearing is necessary. On June 13, 2016, the Company and its outside counsel each filed responses to the court's order to show cause as to why sanctions should not be imposed. On July 21, 2016, Aventis filed a response contending that the court should impose sanctions. The Company intends to continue to vigorously defend against any such imposition of sanctions.

On March 28, 2016, the Company filed its opening brief with the Ninth Circuit Court of Appeals setting forth detailed arguments as to why the False Claims Act litigation should not have been dismissed by the California District Court. On June 20, 2016, Aventis filed its principal brief in the appeal, responding to the Company's arguments regarding dismissal of the False Claims Act litigation, and setting forth Aventis's argument that it should be awarded attorneys' fees and expenses. On September 19, 2016, the Company filed its reply brief to Aventis's principal brief. On October 3, 2016, Aventis filed its reply brief in support of its cross-appeal of the District Court's denial of attorneys' fees. The Ninth Circuit has scheduled oral arguments to be heard on November 10, 2016.

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,

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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 California District Court against Momenta and Sandoz, or Defendants. The Company's complaint generally asserts that Defendants have engaged in certain types of illegal, monopolistic, and anticompetitive conduct giving rise to various causes of action against them. On December 9, 2015, Defendants filed a motion to dismiss and a motion to transfer the case to the District of Massachusetts. On January 4, 2016, the Company filed oppositions to both motions. On January 26, 2016, the California District Court granted Defendants' motion to transfer and did not rule on Defendants' motion to dismiss. Accordingly, the case was transferred to the District of Massachusetts. On February 9, 2016, the Company filed a writ of mandamus with the Ninth Circuit to attempt to appeal the California District Court's granting of Defendants' motion to transfer to the District of Massachusetts. The Ninth Circuit denied this petition on May 20, 2016, and as such the case will remain before the District of Massachusetts. On July 27, 2016, the Massachusetts District Court granted Defendants' motion to dismiss based upon an antitrust immunity doctrine, without addressing the substantive merits of the claims.

On August 25, 2016, the Company filed with the First Circuit Court of Appeals a notice of appeal of the Massachusetts District Court's dismissal of the antitrust case. On October 31, 2016, the Company filed its appeal brief with the First Circuit. Defendants' opposition brief is due December 5, 2016 and the Company's reply brief is due December 22, 2016.

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 material 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.

18. Subsequent Events

On November 7, 2016, the Company's Board of Directors authorized an increase of $20.0 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 SEC.

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 is a discussion and analysis of our financial condition and the results of operations as of and for the periods presented below. The following discussion and analysis 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 based on the beliefs of our management, as well as assumptions made by, and information currently available to our management, and 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 and described in greater detail elsewhere in this Quarterly Report and in our Annual Report on Form 10-K for the year ended December 31, 2015, particularly in Item 1A. "Risk Factors"

Overview

Amphastar Pharmaceuticals, Inc., together with our wholly-owned subsidiaries, International Medication Systems, Limited, or IMS; Armstrong Pharmaceuticals, Inc., or Armstrong; Amphastar Nanjing Pharmaceuticals Co., Ltd., or ANP; Nanjing Letop Fine Chemistry Co., Ltd., or Letop; Amphastar France Pharmaceuticals, S.A.S., or AFP; Amphastar UK Ltd., or AUK; and International Medication Systems (UK) Limited, or IMS UK, is a specialty pharmaceutical company that focuses primarily on developing, manufacturing, marketing and selling technically-challenging generic and proprietary injectable, inhalation and intranasal products. Additionally, we sell insulin active pharmaceutical ingredient, or API products. We currently manufacture and sell 19 products including Amphadase®, which we re-launched in the fourth quarter of 2015. Additionally, we are developing a portfolio of 15 generic abbreviated new drug applications, or ANDAs, three generic biosimilar 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 Actavis Inc., or Actavis, to distribute enoxaparin, which is marketed under Actavis' label. On June 30, 2016, Actavis and Amphastar agreed to terminate the agreement upon the earlier of (i) January 1, 2017, and (ii) such earlier date that is 30 days after Actavis notifies us in writing that Actavis has less than 30 days inventory of the enoxaparin product remaining in its possession or scheduled to be delivered pursuant to the pending purchase orders.

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 for the dispersion and absorption of other injected drugs.

Our pipeline of over 20 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 four abbreviated new drug applications, or ANDAs, and two NDAs on file 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.

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Included in these acquisitions are 14 ANDAs representing 11 different injectable chemical entities from Hikma Pharmaceuticals PLC in March 2016, and marketing authorizations for 33 products in the UK, Ireland, Australia, and New Zealand, representing 11 different injectable chemical entities, from UCB Pharma GmbH. We plan to transfer these products to our facilities in California, which will require approvals from the FDA, UK Medicines and Healthcare products Regulatory Agency, or other related regulatory agencies before the product candidates can be launched or re-launched by us.

Business Segments

Our performance is assessed and resources will be allocated based on the following two reportable segments: (1) finished pharmaceutical products and (2) API products. The finished pharmaceutical products segment currently manufactures, markets and distributes enoxaparin, Cortrosyn®, Amphadase®, naloxone, lidocaine jelly, as well as various other critical and non-critical care drugs. The API segment currently manufactures and distributes recombinant human insulin, or RHI, 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.

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

Results of Operations

Three Months Ended September 30, 2016 Compared to Three Months Ended September 30, 2015

Net revenues

	Three Months Ended September 30,		Change	
	2016	2015	Dollars	%
	(in thousands)			
Net revenues				
Finished pharmaceutical products				
Enoxaparin	$ 15,363	$ 21,264	$ (5,901)	(28)%
Other products	43,695	36,638	7,057	19 %

Total finished pharmaceutical products	$ 59,058	$ 57,902	$ 1,156	2 %
API	5,165	5,966	(801)	(13)%
Total net revenues	$ 64,223	$ 63,868	$ 355	1 %
Cost of revenues				
Finished pharmaceutical products	$ 30,438	$ 38,601	$ (8,163)	(21)%
API	6,173	7,689	(1,516)	(20)%
Total cost of revenues	$ 36,611	$ 46,290	$ (9,679)	(21)%
Gross profit	$ 27,612	$ 17,578	$ 10,034	57 %
as % of net revenues	43 %	28 %		

Net revenues were $64.2 million and $63.9 million for the three months ended September 30, 2016 and 2015, respectively, representing an increase of $0.3 million. Sales of phytonadione increased to $8.7 million from $5.9 million, as a result of an increase in average selling price. Sales of lidocaine increased to $8.3 million from $6.2 million, representing an increase of $2.1 million, of which $1.6 million was due to an increase in unit volume and $0.5 million was due to an increase in average selling price. Sales of naloxone increased to $12.4 million from $10.5 million, primarily as a result of an increase in unit volumes, which were partially offset by increased rebates of $0.9 million. These revenue increases were partially offset by a decrease in sales of enoxaparin by $5.9 million to $15.4 million for the third quarter of 2016 from $21.3 million for the third quarter of 2015 due to lower unit volumes in the retail market, as a result of the termination agreement with Actavis. We completed shipments to Actavis under our supply agreement in August 2016. Additionally, our insulin API business had an overall decrease in sales of RHI and porcine insulin to $5.2 million in the third quarter of 2016 from $6.0 million in the third quarter of 2015, as MannKind purchased the remaining

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unfulfilled 2015 commitments during the third quarter of 2016, but has not purchased any of its 2016 commitments under the supply agreement entered into in 2014, or the Supply Agreement.

We expect that the average selling price and unit volumes of enoxaparin will decline in the near term as a result of increased competition. In addition, the timing of sales into the retail channel may be adversely affected in the near term, as we stopped shipping to Actavis in the third quarter, and we cannot sell directly into the retail market directly until the contract termination date which is the earlier of (i) January 1, 2017, and (ii) such earlier date that is 30 days after Actavis notifies us in writing that it has less than 30 days inventory of the enoxaparin product remaining in its possession or scheduled to be delivered pursuant to the pending purchase orders. We believe that pricing increases on several other finished pharmaceutical products will partially offset lower enoxaparin sales; however, we expect that net revenues for the remainder of 2016 may be negatively impacted. 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.

We anticipate that sales of insulin API will continue to fluctuate and decrease due to the inherent uncertainties related to sales of RHI to MannKind. We are currently in discussion with MannKind regarding its purchases of the 2016 minimum purchase commitments under the Supply Agreement and the 2017 minimum quantities under the supply option agreement entered into in 2015, or the Option Agreement. We anticipate that these discussions may result in reductions in the capacity cancellation fees, as well as extensions of the timing of MannKind's purchase commitments under the Supply Agreement. In addition, most of our API sales are denominated in Euros, and the fluctuation in the value of the Euro versus the dollar compared to 2015 has had, and will continue to have, an impact on API sales revenues in the near term.

Cost of revenues

Cost of revenues were $36.6 million and $46.3 million for the three months ended September 30, 2016 and 2015, respectively, representing a decrease of $9.7 million. Cost of revenue of enoxaparin decreased by $6.7 million, primarily due to a decrease in average cost per unit of $1.8 million as a result of lower heparin input costs and a decrease in unit volume of $4.9 million. In addition, there was an increase in manufacturing volumes in the third quarter of 2016, which increased overhead absorption. This benefit was partially offset by increased personnel costs at our U.S. manufacturing sites.

Declining prices and unit volume of enoxaparin will put downward pressure on gross margins, but we believe this trend will be partially offset by increases in prices of several other finished pharmaceutical products. As a result, gross margin is expected to be variable depending on revenue mix.

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

	Three Months Ended September 30,		Change		
	2016	2015	Dollars	%	
	(in thousands)				
Selling, distribution, and marketing	$ 1,291	$ 1,171	$ 120	10	%
General and administrative	10,801	9,034	1,767	20	%
Impairment of long-lived assets	—	4	(4)	(100)	%

Selling, distribution, and marketing expenses were $1.3 million and $1.2 million for the three months ended September 30, 2016 and 2015, respectively. General and administrative expenses were $10.8 million and $9.0 million for the three months ended September 30, 2016 and 2015, respectively, representing an increase of $1.8 million. The increase was primarily due to an increase in personnel cost and legal fees.

We expect that general and administrative expenses will increase on an annual basis due to increased costs associated with ongoing compliance with public company reporting obligations as well as legal fees associated with our enoxaparin patent litigation..

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Research and development

	Three Months Ended September 30,		Change	
	2016	2015	Dollars	%
	(in thousands)			
Research and development	$ 9,723	$ 11,117	$ (1,394)	(13)%

Research and development expenses were $9.7 million and $11.1 million for the three months ended September 30, 2016 and 2015, respectively, representing a decrease of $1.4 million. This decrease was primarily due to a decrease in clinical trials expense.

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 quarters and years.

The following table sets forth our research and development expenses for the three months ended September 30, 2016 and 2015:

	Three Months Ended September 30,		Change	
	2016	2015	Dollars	%
	(in thousands)			
Salaries and personnel-related expenses	$ 3,955	$ 3,777	$ 178	5 %
Pre-launch inventory	—	933	(933)	(100)%
Clinical trials	248	1,963	(1,715)	(87) %
FDA fees	14	41	(27)	(66) %
Testing, operating and lab supplies	3,313	2,765	548	20 %
Depreciation	1,174	893	281	31 %

Other expenses	1,019	745	274	37 %
Total research and development expenses	$ 9,723	$ 11,117	$ (1,394)	(13) %

Provision for income tax expense (benefit)

	Three Months Ended September 30,		Change	
	2016	2015	Dollars	%
	(in thousands)			
Income tax expense (benefit)	$ 2,111	$ (1,268)	$ 3,379	NM
Effective tax rate	35 %	(30) %		

Provision for income tax expense was $2.1 million for the three months ended September 30, 2016, compared to an income tax benefit of $1.3 million for the three months ended September 30, 2015, representing an increase in income tax expense of $3.4 million. The increase in income tax expense is related to a pre-tax income during the third quarter of 2016 compared to a pre-tax loss during the third quarter of 2015.

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Nine Months Ended September 30, 2016 Compared to Nine Months Ended September 30, 2015

Net revenues

	Nine Months Ended September 30,		Change	
	2016	2015	Dollars	%
	(in thousands)			
Net revenues				
Finished pharmaceutical products				
Enoxaparin	$ 51,049	$ 64,647	$ (13,598)	(21)%
Other products	130,319	94,202	36,117	38 %
Total finished pharmaceutical products	$ 181,368	$ 158,849	$ 22,519	14 %
API	10,254	15,758	(5,504)	(35)%
Total net revenues	$ 191,622	$ 174,607	$ 17,015	10 %
Cost of revenues				
Finished pharmaceutical products	$ 96,326	$ 114,061	$ (17,735)	(16)%
API	11,068	16,370	(5,302)	(32)%
Total cost of revenues	$ 107,394	$ 130,431	$ (23,037)	(18)%
Gross profit	$ 84,228	$ 44,176	$ 40,052	91 %
as % of net revenues	44 %	25 %		

Net revenues were $191.6 million and $174.6 million for the nine months ended September 30, 2016 and 2015, respectively, representing an increase of $17.0 million. Sales of naloxone increased to $38.2 million from $27.9 million, primarily as a result of an increase in unit volumes, but were offset by lower pricing in the form of increased rebates of $2.2 million. Sales of phytonadione increased to $23.6 million from $10.3 million, due to an increase in average selling price. Sales of lidocaine increased to $26.4 million from $20.7 million, representing an increase of $5.7 million, of which, $4.1 million was due to an increase in average selling price and $1.6 million was due to an increase in unit volumes. Sales of epinephrine increased to $14.9 million from $10.0 million, primarily due to an increase in average selling price, partially offset by a decrease in unit volumes of $1.8 million. These increases were partially offset by a decrease in sales of enoxaparin to $51.0 million from $64.6 million for the nine months ended September 30, 2015, representing a decrease of $13.6 million, of which $7.1 million was due to lower average selling price and $6.5 million was due to lower unit volumes, as a result of the termination of the agreement with Actavis. Additionally, sales of RHI and porcine insulin within our insulin API business decreased to $10.3 million from $15.8 million primarily because MannKind had only fulfilled its 2015 commitments under the Supply Agreement as of September 30, 2016, and has not purchased any of its 2016 commitments under the Supply Agreement.

Cost of revenues

Cost of revenues was $107.4 million and $130.4 million for the nine months ended September 30, 2016 and 2015, respectively, representing a decrease of $23.0 million. Cost of revenues of enoxaparin decreased by $11.7 million, primarily due to a decrease in average cost per unit of $6.1 million as a result of lower heparin input costs and a decrease in unit volumes of $5.6 million. Cost of revenue of RHI and porcine insulin decreased by $4.0 million primarily due to a decrease in unit volumes sold. In addition, there was an increase in manufacturing volume during the nine months ended September 30, 2016, which increased overhead absorption by $6.1 million. This benefit was partially offset by increased personnel costs at our U.S. manufacturing sites.

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

	Nine Months Ended September 30,		Change	
	2016	2015	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	$ 3,975	$ 4,163	$ (188)	(5) %
General and administrative	31,129	32,793	(1,664)	(5) %
Impairment of long-lived assets	331	78	253	324%

Selling, distribution, and marketing expenses were $4.0 million and $4.2 million for the nine months ended September 30, 2016 and 2015, respectively. General and administrative expenses were $31.1 million and $32.8 million for the nine months ended September 30, 2016 and 2015, respectively, representing a decrease of $1.7 million. The decrease was primarily due to a $3.3 million settlement in 2015 relating to our California employment litigation, which was partially offset by a decrease in our consulting fees during the nine months ended September 30, 2016. These decrease were partially offset by an increase in personnel cost and legal fees.

Research and development

	Nine Months Ended September 30,		Change	
	2016	2015	Dollars	%
	(in thousands)			
Research and development	$ 28,591	$ 28,411	$ 180	1 %

Research and development expenses were $28.6 million and $28.4 million for the nine months ended September 30, 2016 and 2015, respectively, representing an increase of $0.2 million, primarily due to an increase in FDA fees pertaining to the filing of the NDA for our intranasal naloxone product candidate, and was partially offset by a decrease in clinical trials expense.

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.

The following table sets forth our research and development expenses for the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,		Change	
	2016	2015	Dollars	%
	(in thousands)			
Salaries and personnel-related expenses	$ 10,911	$ 10,464	$ 447	4 %
Pre-launch inventory	—	933	(933)	(100) %
Clinical trials	1,246	3,833	(2,587)	(67) %
FDA fees	2,416	215	2,201	1,024 %
Testing, operating and lab supplies	7,741	7,933	(192)	(2) %
Depreciation	3,571	2,894	677	23 %
Other expenses	2,706	2,139	567	27 %
Total research and development expenses	$ 28,591	$ 28,411	$ 180	1 %

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Provision for income tax expense (benefit)

	Nine Months Ended September 30,		Change	
	2016	2015	Dollars	%
	(in thousands)			
Income tax expense (benefit)	$ 6,295	$ (10,382)	$ 16,677	NM
Effective tax rate	32 %	(50) %		

Provision for income tax expense was $6.3 million for the nine months ended September 30, 2016, compared to an income tax benefit of $10.4 million for the nine months ended September 30, 2015, representing an increase in income tax expense of $16.7 million. The increase in income tax expense is related to a pre-tax income during the nine months ended September 30, 2016, compared to a pre-tax loss during the nine months ended September 30, 2015. Additionally, in 2015 there was a reversal of a deferred tax valuation allowance which had previously been reserved that contributed to the income tax benefit.

Liquidity and Capital Resources

Cash Requirements and Sources

We need capital resources to maintain and expand our business. We expect our cash requirements to increase significantly in the foreseeable future as we sponsor clinical trials for, seek regulatory approvals of, and develop, manufacture and market our current development stage product candidates and pursue strategic acquisitions of businesses or assets. Our future capital expenditures 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 and lease payments, as described below and throughout this Quarterly Report on Form 10-Q. We believe that our cash reserves, operating cash flows, and borrowings availability under our credit facilities will be sufficient to fund our operations for the next 12 months. We expect additional cash flows to be generated in the longer term from future product introductions, although there can be no assurance as to the receipt of regulatory approval for any product candidates or the timing of any product introductions, which could be lengthy or ultimately unsuccessful.

We maintain a shelf registration statement on Form S-3 pursuant to which we may, from time to time, sell up to an aggregate of $250.0 million of our common stock, preferred stock, depositary shares, warrants, units, or debt securities. 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. To the extent we raise additional capital through the sale of equity or convertible debt securities, the issuance of such securities will result in dilution to our stockholders. If we are

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

Working capital increased by $13.3 million to $129.3 million at September 30, 2016, compared to $116.0 million at December 31, 2015.

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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, 2016:

	Nine Months Ended September 30, 2016 (in thousands)
Statement of Cash Flow Data:	
Net cash provided by (used in)	
Operating activities	$ 24,554
Investing activities	(32,388)
Financing activities	8,401
Effect of exchange rate changes on cash	(43)
Net increase in cash and cash equivalents	$ 524

Sources and Use of Cash

Operating Activities

Net cash provided by operating activities was $24.6 million for the nine months ended September 30, 2016, which included net income of $13.3 million. Non-cash items were comprised of $10.8 million of depreciation and amortization, $11.6 million of share-based compensation expense, and a $3.2 million change in tax related items. This was partially offset by a change of $15.3 million in operating assets and liabilities which was primarily due to the decrease of accounts receivable and an increase in inventory.

Accounts receivable declined by approximately $6.8 million as of September 30, 2016, as compared to December 31, 2015, primarily due to a decrease of sales of $12.7 million to $64.2 million in the third quarter of 2016 as compared to $76.9 million in the fourth quarter of 2015.

Inventories increased by approximately $19.5 million as of September 30, 2016, as compared to December 31, 2015. Enoxaparin related inventory increased $9.9 million as a result of the timing of component and raw material purchases. Inventory relating to other finished pharmaceutical products increased by $8.4 million due to higher forecasted future demands, and RHI and porcine insulin inventory increased by $1.2 million in the API segment due to the timing of sales deliveries.

Investing Activities

Net cash used in investing activities was $32.4 million for the nine months ended September 30, 2016, primarily as a result of $7.7 million for the purchase of IMS UK, $4.0 million for the purchase of the 14 ANDAs from Hikma Pharmaceuticals PLC, $0.8 million relating to the acquisition of Nanjing Letop Medical Technology Co. Ltd., or Letop, and $16.0 million in purchases of property, machinery, and equipment, including the associated capitalized labor and interest on self-constructed assets. Additionally, $2.9 million in deposits were made for machinery and equipment in 2016.

Financing Activities

Net cash provided by financing activities was $8.4 million for the nine months ended September 30, 2016. This cash inflow is a result of $18.5 million of proceeds received from stock options exercises related to our equity plans and purchases of our common stock through the Employee Stock Purchase Plan, which was offset by payments of $10.3 million relating to the repurchase of our common stock. Additionally, we refinanced two existing mortgages which led to the receipts of $10.2 million, and these inflows were offset by $10.0 million of principal repayments, primarily related to these mortgage loans.

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Indebtedness

For more information regarding our outstanding indebtedness, see "Part I – Item 1. Financial Statements – Notes to Condensed Consolidated Financial Statements – Debt."

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, 2015, except that our outstanding debt obligations have changed as follows:

	September 30, 2016	December 31, 2015	Change
	(in thousands)		
Short-term debt and current portion of long-term debt	$ 8,541	$ 10,934	$ (2,393)
Long-term debt	34,163	30,165	3,998
Total debt	$ 42,704	$ 41,099	$ 1,605

As of September 30, 2016, we had $37.1 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, 2016, we have paid an upfront payment of $0.5 million and $0.7 million in milestone payments under this agreement, which were classified as research and development expense. We are obligated to pay up to an additional $1.3 million if certain milestones are met. As of September 30, 2016, no such obligation existed. Pursuant to the collaboration agreement, if the medical device manufacturer is successful in the development of this drug delivery system and our pipeline products receive appropriate regulatory approval, we are obligated 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.

Critical Accounting Policies

We prepare our consolidated financial statements in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying

notes. Actual results could differ from those estimates. In some cases, changes in the accounting estimates are reasonably likely to occur from period to period. Accordingly, actual results could differ materially from our estimates. To the extent that there are material differences between these estimates and actual results, our financial condition and results of operations will be affected. We base our estimates on past experience and other assumptions that we believe are reasonable under the circumstances, and we evaluate these estimates on an ongoing basis.

For a description of our critical accounting policies and estimates, refer to the “Critical Accounting Policies” section of our Management’s Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the SEC. In addition, for information regarding recent accounting pronouncements, refer to “Recent Accounting Pronouncements” in Note 2 in the accompanying “Notes to Condensed Consolidated Financial Statements” in this Quarterly Report.

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.

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Government Regulation

Our products and facilities are subject to regulation by a number of U.S. federal and state governmental agencies as well as foreign regulatory agencies. The FDA, in particular, maintains oversight of the formulation, manufacture, distribution, packaging, and labeling of the majority of our products. The Drug Enforcement Administration, or DEA, maintains oversight over our products that are considered controlled substances.

From January 19, 2015 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, or EU-GMP 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 our facility was issued a certificate of EU-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, California was subject to an inspection by the FDA. The inspection included a review of our compliance with cGMP regulations and preapproval inspections for ANDAs 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. We believe that our responses to the Form 483 will satisfy the requirements of the FDA and that no significant further actions will be necessary.

From February 29, 2016 through March 4, 2016, our facility in Éragny-sur-Epte, France was subject to an inspection by the FDA. The inspection included a review of Quality Systems, Production Controls, Laboratory Controls, Material Management, and Facilities and Equipment Maintenance. The inspection resulted in multiple observations on Form 483. We responded to those observations on March 24, 2016. We believe that our response to the Form 483 will satisfy the requirements of the FDA and that no further actions will be necessary.

From April 25, 2016 through April 28, 2016, our facility in Nanjing, China was subject to an inspection by the FDA. The inspection included a review of Quality Systems, Production Controls, Laboratory Controls, Material Management, and Facilities and Equipment Maintenance. The inspection resulted in no observations on Form 483.

From August 22, 2016 through August 26, 2016, our facility in Rancho Cucamonga, California, was subject to an inspection of the bioanalytical data and operations for the conduct of the bioequivalence studies conducted by us. The inspection resulted in multiple observations on Form 483. We responded to those observations on September 16,

2016. We believe that our response to the Form 483 will satisfy the requirements of the FDA and that no further actions will be necessary.

From October 6, 2016 through October 14, 2016, our third party contract clinical study site was subject to a biomedical inspection by the FDA covering pharmacokinetic (PK) clinical studies, executed per our in-house designed protocols. There were no Form 483 observations issued at the end of the inspection.

From October 17, 2016 through October 21, 2016, our facility in Chino, California, was subject to inspection of the facility's compliance with Good Laboratory Practices regulations, and associated operations for the conduct of the non-clinical safety/toxicity studies conducted by us. The inspection resulted in multiple observations on Form 483. We plan to respond to those observations by November 11, 2016, in accordance with FDA requirements.

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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 rate fluctuations (Foreign Currency Exchange Rate 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, 2016, we did not have any such investments.

As of September 30, 2016, we had $3.3 million deposited in four banks located in China, $2.1 million deposited in one bank located in France, and $0.2 million deposited in one bank located in the United Kingdom. We also maintained $44.7 million in cash equivalents that include money market accounts, money market funds, Money Market Insured Deposit Account Service, or MMIDAS, and Insured Cash Sweep, or ICS, accounts as of September 30, 2016. The remaining amounts of our cash equivalent as of September 30, 2016, 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 $250.0 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 do we believe that 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, we believe that we are not subject to any material interest rate risk with respect to our short-term investments.

As of September 30, 2016, we had $42.7 million in long-term debt and capital leases outstanding. Of this amount, $21.2 million had variable interest rates with a weighted-average interest rate of 3.9% at September 30, 2016. 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 $0.2 million per year.

Foreign Currency Exchange Rate Risk

Our products are primarily sold in the U.S. domestic market, and for the three and nine months ended September 30, 2016 and 2015, foreign sales were minimal. Therefore, we have little exposure to foreign currency exchange rate fluctuations. However, as a result of our acquisition of the API manufacturing business in Éragny-sur-Epte, France, we are exposed to market risks 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 would not 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. 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 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. Our U.K. subsidiary, International Medication Systems (UK) Limited, or IMS UK, maintains its book of record in Great Britain Pounds. These books are translated to USD at the average exchange rates during the period. Assets and liabilities are translated at the exchange rate prevailing on the balance sheet date. Equity is translated at the prevailing exchange rate at the date of the equity transactions. Translation adjustments are reflected in stockholders' equity and are included as a component of other comprehensive income (loss). We do not undertake hedging transactions to cover our foreign currency exposure.

As of September 30, 2016, 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 Exchange Act of 1934, as amended, or 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 not effective at the reasonable level of assurance due to a material weakness in internal control over financial reporting discussed below (a) to ensure 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 and (b) 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.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. For the year ended December 31, 2015, we identified a material weakness in our internal control over financial reporting in the area of non-standard and complex transactions. The accounting for certain non-standard and complex transactions were not analyzed and/or reviewed in sufficient detail by knowledgeable personnel to reach the appropriate accounting conclusion to properly record the transaction. The number of errors identified and the commonality of the root cause of the adjustments (namely, inadequate resources to provide for a more thorough and precise review in these areas), leads us to conclude that there is a material weakness in our internal controls. Recognizing this material weakness and the resulting errors identified, management performed additional analyses and supplementary review procedures and has concluded that the effects of these errors were not material to any prior year or prior quarters' previously reported amounts. Despite the existence of this material weakness, we believe that the condensed consolidated financial statements included in this Quarterly Report

on Form 10-Q present, in all material respects, our financial position, results of operations, comprehensive income (loss) and cash flows for the periods presented in conformity with GAAP.

We are currently in process of remediating the material weakness described above. The remediation efforts are focused on addressing the underlying causes of the material weakness and include hiring additional accounting and finance personnel with technical accounting and financial reporting experience, enhancing and segregating duties within our accounting and finance department, and enhancing our internal review procedures during the financial closing process. We believe these additional resources, processes and procedures will enable us to broaden the scope and quality of our controls relating to the oversight and review of financial statements and our application of relevant accounting policies.

Changes in Internal Control over Financial Reporting

Except for the remediation efforts described above, there have been no changes in our internal control over financial reporting that occurred during the three months ended September 30, 2016, 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

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15d-15(f) under the Exchange Act), other than the remediation efforts as discussed above. 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 errors 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 overriding 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

Except as noted below, 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, 2015, filed with the SEC on March 15, 2016.

Jack Yongfeng Zhang and Mary Ziping Luo have pledged shares of our common stock to secure certain borrowed funds. The forced sale of these shares pursuant to a margin call could cause our stock price to decline and negatively impact our business.

Since September 30, 2015, UBS Bank USA, has made extensions of credit in the aggregate amount of $4.8 million to Applied Physics & Chemistry Laboratories, Inc., which is owned solely by Jack Yongfeng Zhang and Mary Ziping Luo. The loan is pledged by 1,907,898 shares of our common stock currently held by Dr. Zhang and Dr. Luo. Interest on the loan accrues at market rates. UBS Bank USA received customary fees and expense reimbursements in connection with these loans.

We are not a party to these loans, which are full recourse against Applied Physics & Chemistry Laboratories, Inc. and are secured by pledges of a portion of our common stock currently beneficially owned by Dr. Zhang and Dr. Luo.

If the price of our common stock declines, Dr. Zhang and Dr. Luo may be forced by UBS Bank USA to provide additional collateral for the loans or to sell shares of our common stock held by them in order to remain within the margin limitations imposed under the terms of their loans. The loans between these banking institutions on the one hand, and Dr. Zhang and Dr. Luo on the other hand, prohibit the non-pledged shares currently owned by Dr. Zhang and Dr. Luo from being pledged to secure any other loans. These factors may limit Dr. Zhang and Dr. Luo’s ability to either pledge additional shares of our common stock or sell shares of our common stock held by them as a means to avoid or satisfy a margin call with respect to their pledged common stock in the event of a decline in our stock price that is large enough to trigger a margin call. Any sales of common stock following a margin call that is not satisfied may cause the price of our common stock to decline further.

Risks Relating to Our Business and Industry

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

Sales from our enoxaparin product, which is our largest selling product, represented 34%, 51%, and 64% of our total net revenues for the years ended December 31, 2015, 2014, and 2013, respectively. We are currently experiencing declining revenue from enoxaparin and some of our other existing products and we may operate at a loss in the near term while continuing to invest in developing new products. If the sales volume or pricing of enoxaparin continues to decline, or if we are unable to satisfy market demand for this product, our business, financial position and results of operations could be materially and adversely affected, and the market value of our common stock could decline. For example, due to intense pricing competition in the pharmaceutical industry, we have experienced significant declines in the per unit pricing and gross margins attributable to our enoxaparin product since its commercial launch. Our enoxaparin product could be rendered obsolete or negatively impacted by numerous factors, many of which are beyond our control, including:

· decreasing average sales prices;
· development by others of new pharmaceutical products that are more effective than ours;

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- entrance of new competitors into our markets;
- loss of key relationships with suppliers, group purchasing organizations or end-user customers;
- manufacturing or supply interruptions;
- changes in the prescribing practices of physicians;
- changes in third-party reimbursement practices;
- product liability claims; and
- product recalls or safety alerts.

Any factor adversely affecting the sale of enoxaparin may cause our revenues to decline, and we may not be able to achieve and maintain profitability. In addition, on June 30, 2016, we and Actavis agreed to terminate the agreement upon the earlier of (i) January 1, 2017, and (ii) such earlier date that is 30 days after Actavis notifies us in writing that Actavis has less than 30 days inventory of the enoxaparin product remaining in its possession or scheduled to be delivered pursuant to the pending purchase orders. If we are unable to engage another marketing and distribution partner, or if we are unable to market and distribute our enoxaparin product ourselves, revenues could be delayed from this product, and our profitability would be adversely affected.

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

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

For example, we have a profit sharing agreement with Actavis to market and distribute our enoxaparin product to the retail market in the United States. On June 30, 2016, we and Actavis agreed to terminate the agreement upon the earlier of (i) January 1, 2017, and (ii) such earlier date that is 30 days after Actavis notifies us in writing that Actavis has less than 30 days inventory of the enoxaparin product remaining in its possession or scheduled to be delivered pursuant to the pending purchase orders. If we are unable to engage another marketing and distribution partner, or if we are unable to market and distribute our enoxaparin product ourselves, revenues could be delayed from this product, and our profitability would be adversely affected.

Underutilization of our manufacturing capacity could negatively impact our gross margins.

We have invested significantly in our manufacturing capacity in order to vertically integrate our business, contain the costs of raw materials and reduce the risks imposed by relying on third-party single source suppliers. We currently own and operate facilities that manufacture raw materials and APIs for our products and product candidates and those of our customers and partners, including insulin API for MannKind. However, if market demand decreases or if market supply surpasses demand, whether because of macroeconomic factors, pharmaceutical industry volatility, or deficiencies specific to our customers, we may not be able to reduce manufacturing expenses or overhead costs proportionately. For example, a significant portion of our manufacturing capacity in our facility in Éragny-sur-Epte, France is utilized for the manufacture of insulin API for MannKind, and a significant portion of our manufacturing capacity in Rancho Cucamonga is utilized for the manufacture of enoxaparin. We anticipate that sales of insulin API for MannKind will decrease. We are currently in discussion with MannKind regarding its purchases of the 2016 minimum purchase commitments under the Supply Agreement and the 2017 minimum quantities under the Option Agreement and anticipate that these discussions will result in reductions in the capacity cancellation fees, as well as extensions of the timing of MannKind's purchase commitments under the Supply Agreement. If an increase in supply outpaces the increase in

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market demand, or if demand decreases, such as a reduction in sales of insulin API for MannKind, the resulting oversupply could adversely impact our sales and result in the underutilization of our manufacturing capacity, high inventory levels, changes in revenue mix and rapid price erosion, which would lower our margins and adversely impact our financial results.

The United Kingdom's vote to leave the European Union will have uncertain effects and could adversely affect us.

On June 23, 2016, a referendum was held on the UK's membership in the European Union, or the EU, the outcome of which was a vote in favor of leaving the EU, or the Brexit. Negotiations are expected to commence shortly to determine the future terms of the UK's relationship with the EU, including the terms of trade between the UK and the EU and the rest of the world.

Article 50 of the Treaty of the European Union, or Article 50, allows a member state to decide to withdraw from the European Union in accordance with its own constitutional requirements. The formal process for leaving the European Union will be triggered only when the United Kingdom delivers an Article 50 notice to the European Council, although informal negotiations around the terms of any exit may be held before such notice is given. The UK Prime Minister has stated that the UK will deliver an Article 50 notice by the end of March 2017. Following the ruling of the UK High Court on November 3, 2016, that the UK Parliament must vote on whether the UK can start the process of leaving the European Union, it is unclear whether it will be possible for the UK Government to stick to this timeline, although the Prime Minister has indicated that it remains her intention to do so. The UK Government is appealing the ruling of the High Court to the UK Supreme Court, which appeal is due to be heard in December 2016.

Delivery of the Article 50 notice will start a two-year period for the United Kingdom to exit from the European Union, although this period can be extended with the unanimous agreement of the European Council. Without any such extension (and assuming that the terms of withdrawal have not already been agreed), the United Kingdom's membership in the European Union would end automatically on the expiration of that two-year period.

The effects of Brexit will depend on agreements the UK makes to retain access to EU markets either during a transitional period or more permanently. Brexit creates an uncertain political and economic environment in the UK and potentially across other EU member states for the foreseeable future, including during any period while the terms of Brexit are being negotiated and such uncertainties could impair or limit our ability to transact business in the member EU states.

Further, Brexit could adversely affect European and worldwide economic or market conditions and could contribute to instability in global financial markets, and the value of the Pound Sterling currency or other currencies, including the Euro. We are exposed to the economic, market and fiscal conditions in the UK and the EU and to changes in any of these conditions. Depending on the terms reached regarding Brexit, it is possible that there may be adverse practical and/or operational implications on our business.

A significant amount of the regulatory regime that applies to us in the UK is derived from EU directives and regulations. For so long as the UK remains a member of the EU, those sources of legislation will (unless otherwise repealed or amended) remain in effect. However, Brexit could change the legal and regulatory framework within the UK where we operate and is likely to lead to legal uncertainty and potentially divergent national laws and regulations as the UK determines which EU laws to replace or replicate. Consequently, no assurance can be given as to the impact of Brexit and, in particular, no assurance can be given that our operating results, financial condition and prospects

would not be adversely impacted by the result.

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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, 2016	22,900	$ 16.85	22,900	—
August 1 – August 30, 2016	12,700	16.48	12,700	—
September 1 – September 30, 2016	10,733	18.58	10,733	—

(1) During the third quarter of 2016, 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 2015. As of September 30, 2016, $0.8 million remained available under such program. In November 2016, our Board of Directors authorized a $20.0 million increase to the share buyback program.

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 9, 2016

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

Date: November 9, 2016

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EXHIBIT INDEX TO FORM 10-Q

For the Quarterly Period Ended September 30, 2016

Exhibit No.	Description
10.1	Business Loan Agreement, dated September 8, 2016, between Amphastar Pharmaceuticals, Inc. and East West Bank in the original principal sum of $3,591,250.
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1#	Certification of Chief Executive Officer pursuant to 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 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.