
**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 MARCH 31, 2017

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
(State or other jurisdiction of
incorporation or organization)

33-0702205
(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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>
	<input checked="" type="checkbox"/>	Emerging growth company	<input checked="" type="checkbox"/>

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 May 3, 2017 was 45,737,887.

AMPHASTAR PHARMACEUTICALS, INC.
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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,” “predict,” “project,” “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 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 for 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, divestitures or investments, including the anticipated benefits of such acquisitions, divestitures 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;
- the timing for completion of construction at our IMS facility;
- our remediation efforts for a material weakness in our internal control over financial reporting; and
- our financial performance expectations, including our expectations regarding our backlog, 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, 2016, 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.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2017	December 31, 2016
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 76,766	\$ 72,354
Short-term investments	746	527
Restricted short-term investments	1,519	1,390
Accounts receivable, net	25,892	26,777
Inventories	78,137	79,754
Income tax refunds and deposits	210	22
Prepaid expenses and other assets	8,147	3,272
Total current assets	191,417	184,096
Property, plant, and equipment, net	157,389	152,944
Goodwill and intangible assets, net	45,993	50,307
Other assets	8,939	9,390
Deferred tax assets	31,874	31,001
Total assets	<u>\$ 435,612</u>	<u>\$ 427,738</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 19,302	\$ 16,196
Accrued liabilities	22,597	15,703
Income taxes payable	8,099	7,705
Accrued payroll and related benefits	15,533	13,847
Current portion of product return accrual	2,067	1,800
Current portion of long-term debt and capital leases	5,263	5,366
Total current liabilities	72,861	60,617
Long-term product return accrual	1,676	1,343
Long-term reserve for income tax liabilities	845	845
Long-term deferred revenue	280	97
Long-term debt and capital leases, net of current portion	31,148	32,356
Deferred tax liabilities	1,473	1,455
Other long-term liabilities	1,768	1,770
Total liabilities	110,051	98,483
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; 48,003,777 and 45,958,244 shares issued and outstanding as of March 31, 2017 and 47,765,149 and 46,248,622 shares issued and outstanding as of December 31, 2016, respectively	5	5
Additional paid-in capital	285,356	283,123
Retained earnings	72,620	70,855
Accumulated other comprehensive loss	(4,230)	(4,696)
Treasury stock	(28,190)	(20,032)
Total stockholders' equity	325,561	329,255
Total liabilities and stockholders' equity	<u>\$ 435,612</u>	<u>\$ 427,738</u>

See Accompanying Notes to Condensed Consolidated Financial Statements.

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

	Three Months Ended	
	March 31,	
	2017	2016
Net revenues	\$ 56,670	\$ 59,366
Cost of revenues	33,842	34,464
Gross profit	22,828	24,902
Operating (income) expenses:		
Selling, distribution, and marketing	1,479	1,352
General and administrative	11,338	10,870
Research and development	11,250	8,605
Gain on sale of intangible assets	(2,643)	—
Total operating expenses	21,424	20,827
Income from operations	1,404	4,075
Non-operating income (expense):		
Interest income	91	74
Interest expense	(191)	(384)
Other income, net	200	51
Total non-operating income (expense), net	100	(259)
Income before income taxes	1,504	3,816
Income tax expense	611	1,327
Net income	\$ 893	\$ 2,489
Net income per share:		
Basic	\$ 0.02	\$ 0.06
Diluted	\$ 0.02	\$ 0.05
Weighted-average shares used to compute net income per share:		
Basic	46,069	45,041
Diluted	48,057	46,810

See Accompanying Notes to Condensed Consolidated Financial Statements.

AMPHASTAR PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Unaudited; in thousands)

	Three Months Ended	
	March 31,	
	2017	2016
Net income	\$ 893	\$ 2,489
Other comprehensive income, net of income taxes		
Foreign currency translation adjustment	466	436
Total other comprehensive income	466	436
Total comprehensive income	\$ 1,359	\$ 2,925

See Accompanying Notes to Condensed Consolidated Financial Statements.

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

	Three Months Ended	
	March 31,	
	2017	2016
Cash Flows From Operating Activities:		
Net income	\$ 893	\$ 2,489
Reconciliation to net cash provided by operating activities:		
Loss (gain) on disposal and impairment of long-lived assets	(2,643)	236
Depreciation of property, plant, and equipment	3,100	2,947
Amortization of product rights, trademarks, and patents	721	481
Imputed interest accretion	9	18
Share-based compensation	4,451	3,851
Changes in operating assets and liabilities:		
Accounts receivable, net	920	10,198
Inventories	1,891	(10,774)
Prepaid expenses and other assets	344	1,392
Income tax refund, deposits, and payable	394	1,011
Accounts payable and accrued liabilities	12,318	2,081
Net cash provided by operating activities	<u>22,398</u>	<u>13,930</u>
Cash Flows From Investing Activities:		
Business Acquisitions	—	(4,761)
Purchases and construction of property, plant, and equipment	(7,267)	(3,946)
Sale of intangible assets	1,000	—
Purchase of short-term investments	(1,564)	—
Maturity of short-term investments	1,345	—
Changes in restricted short-term investments	(129)	—
Payment of deposits and other assets	521	(713)
Net cash used in investing activities	<u>(6,094)</u>	<u>(9,420)</u>
Cash Flows From Financing Activities:		
Proceeds from equity plans, net of withholding tax payments	(2,173)	(979)
Purchase of treasury stock	(8,203)	(4,722)
Proceeds from issuance of long-term debt	—	3,725
Principal payments on long-term debt	(1,342)	(5,057)
Net cash used in financing activities	<u>(11,718)</u>	<u>(7,033)</u>
Effect of exchange rate changes on cash	(174)	(219)
Net increase (decrease) in cash and cash equivalents	4,412	(2,742)
Cash and cash equivalents at beginning of period	72,354	66,074
Cash and cash equivalents at end of period	<u>\$ 76,766</u>	<u>\$ 63,332</u>
Noncash Investing and Financing Activities:		
Equipment acquired under capital leases	\$ —	\$ 301
Supplemental Disclosures of Cash Flow Information:		
Interest paid, net of capitalized interest	\$ 390	\$ 517
Income taxes paid	\$ 440	\$ 367

See Accompanying Notes to Condensed Consolidated Financial Statements.

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, 2016 and the notes thereto as filed with the Securities and Exchange Commission, or SEC, in the Company’s Annual Report on Form 10-K for the year ended December 31, 2016. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with generally accepted accounting principles, or GAAP, have been condensed or omitted from the accompanying condensed consolidated financial statements. The accompanying year-end condensed consolidated balance sheet was derived from the audited financial statements. The accompanying interim financial statements are unaudited, but reflect all adjustments which are, in the opinion of management, necessary for a fair statement of the Company’s consolidated financial position, results of operations, comprehensive loss and cash flows for the periods presented. Unless otherwise noted, all such adjustments are of a normal, recurring nature. The Company’s results of operations, comprehensive loss and cash flows for the interim periods are not necessarily indicative of the results of operations and cash flows that it may achieve in future periods.

2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, and are prepared in accordance with the requirements of the SEC for interim reporting. Certain amounts in the prior quarter’s condensed consolidated statements of operations have been reclassified to conform to the current quarter presentation. All significant intercompany activity has been eliminated in the preparation of the condensed consolidated financial statements. Effective January 1, 2017, the Company prospectively adopted certain requirements of Auditing Standards Update, or ASU, No. 2016-09 to classify cash flows related to excess tax benefits in operating activities without adjusting prior periods. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments (consisting only of normal recurring adjustments) necessary to present fairly the consolidated financial position, results of operations, and cash flows of the Company.

The Company’s subsidiaries include: (1) International Medication Systems, Limited, or IMS, (2) Armstrong Pharmaceuticals, Inc., or Armstrong, (3) Amphastar Nanjing Pharmaceuticals Inc., or ANP, (4) Nanjing Letop Fine Chemistry Co., Ltd., or Letop, (5) Amphastar France Pharmaceuticals, S.A.S., or AFP, (6) Amphastar UK Ltd., or AUK, and (7) International Medication Systems (UK) Limited, or IMS UK.

Use of Estimates

The preparation of consolidated financial statements in accordance 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. The principal accounting estimates include: determination of allowances

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

for doubtful accounts and discounts, provision for chargebacks, liabilities for product returns, adjustment to cost 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 domestic subsidiaries, 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 accumulated comprehensive income (loss). The unrealized gains or losses of intercompany foreign currency transactions that are of a long-term investment nature are reported in other accumulated comprehensive income (loss). The unrealized gains and losses of intercompany foreign currency transactions that are of a long-term investment nature for the three months ended March 31, 2017 and 2016 \$0.5 million gain, and a \$0.9 million gain, respectively.

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

Comprehensive Income

For the three months ended March 31, 2017 and 2016, the Company included its foreign currency translation as part of its comprehensive income.

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). The Company at times enters into fixed interest rate swap contracts to exchange the variable interest rates for fixed interest rates without the exchange of the underlying notional debt amounts. Such interest rate swap contracts are recorded at their fair values.

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.

AMPHASTAR PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
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Business Combinations

If an acquired set of activities and assets is capable of being operated as a business consisting of inputs and processes from the viewpoint of a market participant, the asset acquired and liabilities assumed are a business. Business combinations are accounted for 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. When the operations of the acquired businesses were not material to the Company's condensed consolidated financial statements, no pro forma presentation is disclosed.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued ASU No. 2014-09 which creates a single source of revenue guidance for companies in all industries. Subsequently, the FASB issued multiple updates. 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. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required regarding customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. This guidance permits two methods of adoption: retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the cumulative catch-up transition method). Based on ASU No. 2015-14 issued in August 2015, this guidance will be effective for the Company in 2018, including interim periods within the year. The Company is in the process of evaluating the effect of the adoption on its condensed consolidated financial statements and is currently assessing its contracts with customers and sale of nonfinancial assets. The Company anticipates it will expand its consolidated financial statement disclosures in order to comply with the new guidance. The Company expects to select the modified retrospective transition method upon adoption.

In February 2016, the FASB issued ASU No. 2016-02 that is aimed at making leasing activities more transparent and comparable, and which requires substantially all leases 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 required to use a modified retrospective approach for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements for the reporting periods in which the guidance is adopted. The Company is currently evaluating the impact that the adoption of this guidance will have on its consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09 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

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Company adopted this guidance effective January 1, 2017.

In June 2016, the FASB issued ASU No. 2016-13 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. Early adoption is permitted for annual periods after 2019. The Company will be required to apply the standard's provisions as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective. The Company is currently evaluating the impact that the adoption of this guidance will have on its consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU No. 2016-15 that is aimed at addressing certain issues regarding classifications of certain cash receipts and cash payments 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 will be required to apply the guidance retrospectively in the first interim and annual periods in which the guidance is adopted. The Company does not believe that the adoption of this accounting guidance will have a material impact on the Company's consolidated financial statements and related disclosures.

In October 2016, the FASB issued ASU No. 2016-16 that requires an entity to recognize the income tax consequences of intra-entity transfer of an asset other than inventory when the transfer occurs. The guidance is effective for the Company's interim and annual reporting periods during the year ending December 31, 2018. Early adoption is permitted as of the beginning of an annual reporting period for which financial statements, interim or annual, have not been issued. The amendments will be applied on a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings as of the beginning of the period of adoption. The Company is currently evaluating the impact that the adoption of this guidance will have on its consolidated financial statements and related disclosures.

In November 2016, the FASB issued ASU No. 2016-18 which requires entities to show the changes in the total of cash, cash equivalents, restricted cash and restricted cash equivalents in the statement of cash flows. As a result, the Company will no longer present transfers between cash and cash equivalents and restricted cash and restricted cash equivalents in the statement of cash flows. The guidance is effective for the Company's interim and annual reporting periods during the year ending December 31, 2018. Early adoption is permitted, including adoption in an interim period. The amendments will be applied using a retrospective transition method to each period presented. The Company will be required to apply the guidance retrospectively when adopted. The Company does not believe that the adoption of this accounting guidance will have a material impact on its consolidated financial statements and related disclosures.

In January 2017, the FASB issued ASU No. 2017-01 which provides guidance to assist entities with evaluating when a set of transferred assets and activities is a business. Under the updated guidance, a set is not a business if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar assets. If the threshold is not met, the update requires that, to be a business, the set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs. The definition of outputs was also aligned with Accounting Standard Codification, or ASC, 606 by focusing on revenue-generating activities. The guidance is effective for the Company's interim and annual reporting periods during the year ending December 31, 2018, and prospectively applicable to any transactions occurring within the period of adoption. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of this guidance will have on its consolidated financial statements and related disclosures.

In January 2017, the FASB issued ASU No. 2017-04 which eliminates the requirement to calculate the implied fair value

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

of goodwill. An entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. The FASB also eliminated the requirements for any reporting unit with a zero or negative carrying amount to perform a qualitative assessment and, if it fails that qualitative test, to perform Step 2 of the goodwill impairment test. An entity is required to disclose the amount of goodwill allocated to each reporting unit with a zero or negative carrying amount of net assets. The guidance is effective for the Company's interim and annual reporting periods during the year ending December 31, 2020, and applied on a prospective basis. Early adoption is permitted for interim and annual goodwill impairment testing dates after January 1, 2017. The Company is currently evaluating the impact that the adoption of this guidance will have on its 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 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 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.

Acquisition of fourteen injectable products from Hikma Pharmaceuticals PLC

In March 2016, the Company acquired 14 abbreviated new drug application, or ANDAs, representing 11 different injectable chemical entities from Hikma Pharmaceuticals PLC, or Hikma, for \$4.0 million. This transaction was accounted for as a business combination in accordance with ASC 805. The ANDAs had an estimated fair value of \$4.0 million, and were subject to a straight-line amortization over a useful life of approximately 15 years.

In February 2017, the Company sold these products to an unrelated party (see Note 9).

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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.

Acquisition of Merck's API Manufacturing Business

On April 30, 2014, the Company completed the acquisition of the Merck Sharpe & Dohme's API manufacturing business in Éragny-sur-Epte, France, or the Merck API Transaction, which manufactures porcine insulin API and recombinant human insulin API, 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):

	<u>Euros</u>	<u>U.S. Dollars</u>
	<u>(in thousands)</u>	
At Closing, April 2014	€ 13,252	\$ 18,352
December 2014	4,899	5,989
December 2015	3,186	3,483
December 2016	3,186	3,427
December 2017	500	534
	<u>€ 25,023</u>	<u>\$ 31,785</u>

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. Currently, the Company is in the process of transferring the manufacturing of starting material for RHI API from Merck to AFP. This process will require capital expenditures at AFP and is expected to take two or more years to complete.

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. 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. On June 30, 2016, the Company and Actavis amended the distribution agreement, which terminated the agreement in December 2016. Profit-sharing revenue under this agreement was recognized at the time Actavis sold the products to its customers.

The Company does not recognize product revenue unless the following fundamental criteria are met: (i) persuasive evidence of an arrangement exists, (ii) transfer of title has occurred, (iii) the price to the customer is fixed or determinable, and (iv) collection is reasonably assured. Furthermore, the Company does not recognize revenue until all customer acceptance requirements have been met. The Company estimates and records reductions to revenue for

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discounts, product returns, and pricing adjustments, such as wholesaler chargebacks, in the same period that the related revenue is recorded.

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

Provision for Wholesaler Chargebacks

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

The provision for chargebacks is reflected in net revenues. Accounts receivable and/or accrued liabilities are also reduced and/or increased by the chargebacks amount depending on whether the Company has the right of offset with the customer. The following table is an analysis of the chargeback provision:

	Three Months Ended	
	March 31,	
	2017	2016
	(in thousands)	
Beginning balance	\$ 37,820	\$ 15,217
Provision related to sales made in the current period	56,945	32,548
Credits issued to third parties	(74,982)	(36,703)
Ending balance	<u>\$ 19,783</u>	<u>\$ 11,062</u>

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. Of the provision for chargebacks of \$19.8 million as of March 31, 2017, \$10.5 million was included in accounts receivable, net, on the condensed consolidated balance sheet. The remaining provision for chargebacks of \$9.3 million was included in accrued liabilities, after netting with the related accounts receivable, net, of \$3.0 million. The chargebacks liability of \$37.8 million as of December 31, 2016 was included in accounts receivable, net on the condensed consolidated balance sheet.

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 and API product sales 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

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Company analyzes these situations on a case-by-case basis and makes adjustments to the product return reserve as appropriate. If the available information is not sufficient to estimate a reasonable product return accrual, revenues from the sales of the new product would not be recognized until the product is consumed by the end customer or rights of return granted under the return policy have expired. As of March 31, 2017 and December 31, 2016, cumulative sales of approximately \$0.7 million and \$0.5 million, respectively, for one of the Company's products were not recognized in revenues, due to insufficient information available to estimate a reasonable product return accrual.

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

	Three Months Ended	
	March 31,	
	2017	2016
	(in thousands)	
Beginning balance	\$ 3,143	\$ 2,621
Provision for product returns	1,062	(255)
Credits issued to third parties	(462)	(493)
Ending balance	<u>\$ 3,743</u>	<u>\$ 1,873</u>

For the three months ended March 31, 2017 and 2016, the Company's aggregate product return rate was 1.1% and 1.1% of qualified sales, respectively.

5. Income per Share

Basic income 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 herein as "RSUs") and shares issuable under the Company's Employee Stock Purchase Plan, or the ESPP.

For the three months ended March 31, 2017, options to purchase 2,376,234 shares of stock with a weighted-average exercise price of \$22.44 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 three months ended March 31, 2016, options to purchase 10,013,154 shares of stock with a weighted-average exercise price of \$16.37 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.

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

	Three Months Ended	
	March 31,	
	2017	2016
	(in thousands, except per share data)	
Basic and dilutive numerator:		
Net income	\$ 893	\$ 2,489
Denominator:		
Weighted-average shares outstanding — basic	46,069	45,041
Net effect of dilutive securities:		
Incremental shares from equity awards	1,988	1,769
Weighted-average shares outstanding — diluted	48,057	46,810
Net income per share — basic	\$ 0.02	\$ 0.06
Net income per share — diluted	\$ 0.02	\$ 0.05

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, naloxone, lidocaine, as well as various other critical and non-critical care drugs. The API segment manufactures and distributes recombinant human insulin API and porcine insulin API for external customers and internal product development.

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Selected financial information by reporting segment is presented below:

	Three Months Ended March 31,	
	2017	2016
(in thousands)		
Net revenues:		
Finished pharmaceutical products	\$ 55,934	\$ 58,554
API	736	812
Total net revenues	<u>56,670</u>	<u>59,366</u>
Gross profit:		
Finished pharmaceutical products	24,310	25,824
API	(1,482)	(922)
Total gross profit	<u>22,828</u>	<u>24,902</u>
Operating expenses	<u>21,424</u>	<u>20,827</u>
Income from operations	1,404	4,075
Non-operating income (expenses)	100	(259)
Income before income taxes	<u>\$ 1,504</u>	<u>\$ 3,816</u>

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.

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

	Three Months Ended March 31,	
	2017	2016
(in thousands)		
Finished pharmaceutical products net revenues:		
Enoxaparin	\$ 10,410	\$ 18,358
Naloxone	10,939	10,254
Epinephrine	9,574	4,392
Lidocaine	8,289	9,908
Phytonadione	7,886	6,126
Other finished pharmaceutical products	8,836	9,516
Total finished pharmaceutical products net revenues	<u>\$ 55,934</u>	<u>\$ 58,554</u>

Discontinuation of epinephrine injection, USP vial product

In March 2017, the FDA requested the Company to discontinue the manufacturing and distribution of its epinephrine injection, USP vial product, which has been marketed under the "grandfather" exception to the FDA's "Prescription Drug Wrap-Up" program. Unless the FDA grants the Company's request for an extension of time to sell epinephrine vials, the Company will discontinue selling this product in the second quarter of 2017. For the year ended December 31, 2016, the Company recognized \$18.6 million in net revenues for the sale of this product. A charge of \$3.3 million was included in the cost of revenues in its consolidated statements of operations for the year ended December 31, 2016 to adjust the related inventory items and firm purchase commitments to their net realizable value due to the anticipated

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discontinuation of the product.

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

	<u>Net Revenue</u>		<u>Long-Lived Assets</u>	
	<u>Three Months Ended</u>		<u>March 31,</u>	<u>December 31,</u>
	<u>March 31,</u>	<u>2016</u>		
	2017	2016	2017	2016
	(in thousands)			
United States	\$ 55,930	\$ 58,538	\$ 106,352	\$ 104,110
China	—	—	36,034	35,085
France	740	828	14,914	13,659
United Kingdom	—	—	89	90
Total	\$ 56,670	\$ 59,366	\$ 157,389	\$ 152,944

7. Customer and Supplier Concentration

Customer Concentrations

Three large wholesale drug distributors, AmerisourceBergen Corporation, or AmerisourceBergen, Cardinal Health, Inc., or Cardinal, and McKesson Corporation, or McKesson, are all distributors of the Company's products, as well as suppliers of a broad range of health care products. Actavis had exclusive marketing rights of the Company's enoxaparin product to the U.S. retail pharmacy market (see Note 16). The Company considers these four 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 months ended March 31, 2017 and 2016 and accounts receivable as of March 31, 2017 and December 31, 2016. The following table provides accounts receivable and net revenue information for these major customers:

	<u>% of Total Accounts</u>		<u>% of Net</u>	
	<u>Receivable</u>		<u>Revenue</u>	
	<u>March 31,</u>	<u>December 31,</u>	<u>Three Months Ended</u>	
	<u>2017</u>	<u>2016</u>	<u>March 31,</u>	<u>2016</u>
Actavis ⁽¹⁾	—	1 %	—	22 %
AmerisourceBergen	21 %	30 %	30 %	19 %
Cardinal Health	28 %	28 %	24 %	21 %
McKesson	29 %	19 %	26 %	20 %

(1) The Agreement with Actavis was terminated in December 2016.

Supplier Concentrations

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

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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 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 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 March 31, 2017 and December 31, 2016, 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	\$ 43,939	\$	43,939	\$	—	\$	—
Restricted short-term investments	1,519		1,519		—		—
Fair value measurement as of March 31, 2017	<u>\$ 45,458</u>	<u>\$</u>	<u>45,458</u>	<u>\$</u>	<u>—</u>	<u>\$</u>	<u>—</u>
Cash equivalents	\$ 36,082	\$	36,082	\$	—	\$	—
Restricted short-term investments	1,390		1,390		—		—
Fair value measurement as of December 31, 2016	<u>\$ 37,472</u>	<u>\$</u>	<u>37,472</u>	<u>\$</u>	<u>—</u>	<u>\$</u>	<u>—</u>

The fair value of the Company’s cash equivalents includes money market accounts, money market funds, Money Market Insured Deposit Account Service, or MMIDAS and Insured Cash Sweep, or ICS 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 and performance bonds.

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

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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 March 31, 2017 and December 31, 2016, 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:

	Weighted- Average Life (Years)	Original Cost	Accumulated Amortization	Net Book Value
(in thousands)				
<i>Definite-lived intangible assets</i>				
Cortrosyn® product rights	12	\$ 27,134	\$ 24,906	\$ 2,228
IMS (UK) international product rights ⁽¹⁾	10	8,738	583	8,155
Patents	10	293	144	149
Land-use rights	39	2,540	370	2,170
Other intangible assets	4	69	34	35
Subtotal	12	<u>38,774</u>	<u>26,037</u>	<u>12,737</u>
<i>Indefinite-lived intangible assets</i>				
Trademark	*	29,225	—	29,225
Goodwill - Finished pharmaceutical products	*	4,031	—	4,031
Subtotal	*	<u>33,256</u>	<u>—</u>	<u>33,256</u>
As of March 31, 2017	*	<u>\$ 72,030</u>	<u>\$ 26,037</u>	<u>\$ 45,993</u>

	Weighted- Average Life (Years)	Original Cost	Accumulated Amortization	Net Book Value
(in thousands)				
<i>Definite-lived intangible assets</i>				
Cortrosyn® product rights	12	\$ 27,134	\$ 24,461	\$ 2,673
IMS (UK) international product rights ⁽¹⁾	10	8,632	359	8,273
Acquired ANDAs ⁽²⁾	15	4,000	222	3,778
Patents	10	293	137	156
Land-use rights	39	2,540	354	2,186
Other intangible assets	1	574	534	40
Subtotal	12	<u>43,173</u>	<u>26,067</u>	<u>17,106</u>
<i>Indefinite-lived intangible assets</i>				
Trademark	*	29,225	—	29,225
Goodwill - Finished pharmaceutical products	*	3,976	—	3,976
Subtotal	*	<u>33,201</u>	<u>—</u>	<u>33,201</u>
As of December 31, 2016	*	<u>\$ 76,374</u>	<u>\$ 26,067</u>	<u>\$ 50,307</u>

* 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 (see Note 3).

⁽²⁾ In February 2017, the Company sold the 14 ANDAs it had acquired from Hikma to an unrelated party purchaser for \$6.4 million.

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Sale of Fourteen Injectable ANDAs

In February 2017, the Company sold the 14 ANDAs it acquired in March 2016 from Hikma to an unrelated party. The consideration included a purchase price of \$6.4 million of which the amount of \$1.0 million was received upon closing, and the remaining \$5.4 million will be paid upon certain milestones. If the purchaser is not able to achieve these milestones by December 31, 2017, the purchaser will pay the remaining payments within 30 days of December 31, 2017. In addition to the purchase price, the purchaser agreed to pay the Company a royalty fee equal to 2% of net sales derived from purchaser's sales of the products for the period from February 2017 through February 2027. The Company is also subject to certain indemnification liability payable to the purchaser, which is limited up to \$0.6 million. The Company recognized a gain of \$2.6 million within operating (income) expenses on its condensed consolidated statement of operations for the three months ended March 31, 2017, and a receivable of \$5.4 million in current other assets on its condensed consolidated balance sheet as of March 31, 2017.

Goodwill

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

	March 31, 2017	December 31, 2016
	(in thousands)	
Beginning balance	\$ 3,976	\$ 3,726
Goodwill related to acquisition of business	—	391
Currency translation and other adjustments	55	(141)
Ending balance	<u>\$ 4,031</u>	<u>\$ 3,976</u>

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, which are recorded at the allocated fair value of \$29.2 million, which is its carrying value as of March 31, 2017.

The trademark was determined to have an indefinite life. In determining its indefinite life, 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, 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 process of generating the remaining data required by the CRL and plans to submit human factor studies accordingly. The Company submitted a responsive NDA

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amendment in June 2016 and received another CRL from the FDA in December 2016, which requires additional packaging and label revisions and follow-up studies to assess consumers' ability to use the device correctly to support approval of the product in the over-the-counter setting. The Company intends to continue to work with the FDA during the post-action phase to address their concerns in the CRL and bring Primatene[®] Mist back to the over-the-counter market. However, there can be no guarantee that any future 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 long history of the Primatene[®] trademark (marketed since 1963), and the Company's perpetual rights to the trademark, the nature of the CRL received in December 2016, the plan that the HFA version will be marketed under the same trademark if approved by the FDA, and other factors previously considered, the trademark continues to have an indefinite useful life, and an impairment charge is not be required based on the Company's qualitative assessment as of March 31, 2017.

10. Inventories

Inventories consist of the following:

	March 31, 2017	December 31, 2016
(in thousands)		
Raw materials and supplies	\$ 33,486	\$ 36,209
Work in process	23,990	22,266
Finished goods	20,661	21,279
Total inventories	<u>\$ 78,137</u>	<u>\$ 79,754</u>

11. Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

	March 31, 2017	December 31, 2016
(in thousands)		
Buildings	\$ 85,568	\$ 85,283
Leasehold improvements	29,250	24,619
Land	6,873	6,857
Machinery and equipment	112,718	111,041
Furniture, fixtures, and automobiles	15,359	15,113
Construction in progress	31,956	32,044
Total property, plant, and equipment	281,724	274,957
Less accumulated depreciation	(124,335)	(122,013)
Total property, plant, and equipment, net	<u>\$ 157,389</u>	<u>\$ 152,944</u>

As of March 31, 2017 and December 31, 2016, the Company had \$2.5 million and \$2.6 million, respectively, 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[®] Mist indefinite lived intangible assets 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:

	March 31, 2017	December 31, 2016
(in thousands)		
Loans with East West Bank		
Equipment loan due April 2017	\$ 109	\$ 433
Line of credit facility due September 2017	—	—
Equipment loan due January 2019	2,823	3,208
Mortgage payable due February 2021	3,640	3,660
Equipment credit line due September 2021	2,882	2,882
Mortgage payable due October 2026	3,568	3,582
Loans with Cathay Bank		
Line of credit facility due May 2018	—	—
Acquisition loan due April 2019	16,580	17,079
Mortgage payable due April 2021	4,342	4,367
Loans with Seine-Normandie Water Agency		
French government loan 1 due March 2018	15	30
French government loan 2 due June 2020	101	99
French government loan 3 due July 2021	268	262
Payment Obligation to Merck	519	506
Equipment under Capital Leases	1,564	1,614
Total debt and capital leases	36,411	37,722
Less current portion of long-term debt and capital leases	5,263	5,366
Long-term debt and capital leases, net of current portion	<u>\$ 31,148</u>	<u>\$ 32,356</u>

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. 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 March 31, 2017, 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.

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.

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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 March 31, 2017, 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 equipment. As of March 31, 2017, 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 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 interest rate swap contract does not qualify for hedge accounting and is recorded at fair value for an immaterial amount based on Level 2 inputs.

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 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*. As of March 31, 2017, 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 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 interest rate swap contract does not qualify for hedge accounting, and is recorded at fair value for an immaterial amount based on Level 2 inputs.

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 equipment, and bear a variable interest rate at the prime rate as published by *The Wall Street Journal*. This facility matures in September 2021. As of March 31, 2017, 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 March 31, 2017, the Company has drawn \$2.9 million from the equipment line of credit.

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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 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. As of March 31, 2017, 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 interest rate swap contract does not qualify for hedge accounting, and is recorded at fair value for an immaterial amount based on Level 2 inputs.

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 March 31, 2017, 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 March 31, 2017, 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 a principal balance outstanding of \$4.6 million. The loan is payable in monthly installments with a final balloon payment of \$3.9 million. The loan is secured by the building at the Company's Canton, Massachusetts location and bears interest at a fixed rate of 5.42% and matures in April 2021. As of March 31, 2017, 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 fluctuations. The life of the loans range between three to six years, and includes annual equal payments and bears no interest over the life of the loans.

As of March 31, 2017, 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 2016 and 2015, the Company made a principal payment of €3.2 million, or \$3.4 million and €3.2 million, or \$3.5 million, respectively.

As of March 31, 2017, the payment obligation had a book value of €0.5 million, or \$0.5 million, which approximates fair value. The fair value of the payment obligation was determined by using the interest rate associated with the Company's acquisition loan with Cathay Bank that bears a variable interest rate at the prime rate as published by *The Wall Street Journal*, with a minimum interest rate of 4.00%. Such interest rate is deemed to be a Level 2 input for measuring fair value.

Covenants

At March 31, 2017 and December 31, 2016, the Company was in compliance with its debt covenants, which include a minimum current ratio, minimum debt service coverage, minimum tangible net worth, maximum debt-to-effective-tangible-net-worth ratio, and minimum deposit requirement, computed on a consolidated basis.

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 \$1.9 million and \$2.0 million at March 31, 2017 and December 31, 2016, respectively.

The accumulated depreciation of equipment under capital leases was \$0.3 million and \$0.2 million at March 31, 2017

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and December 31, 2016, respectively. Depreciation of assets recorded under capital leases is included in depreciation expense in the accompanying consolidated financial statements.

13. Income Taxes

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

	Three Months Ended	
	March 31,	
	2017	2016
	(in thousands)	
Income before taxes	\$ 1,504	\$ 3,816
Income tax expense	611	1,327
Net income	<u>\$ 893</u>	<u>\$ 2,489</u>
Income tax provision as a percentage of income before income taxes	40.6 %	34.8 %

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 Company has calculated an estimated annual effective income tax rate of 44.0% for the year ended December 31, 2017, based upon its forecasted income. This estimated effective tax rate factors in various permanent differences, including domestic deductions, the impact of foreign operations, and various credits. The Company also factors in certain discrete tax items that are recognized in the quarter. The Company's income tax provision of 34.8% during the three months ended March 31, 2016, factored in similar permanent items, as well as the impact of its foreign operations and discrete tax items recognized in the quarter.

Effective January 1, 2017, the Company adopted ASU 2016-09. Under ASU 2016-09, differences between the tax deduction for share based awards and the related compensation expenses recognized under ASC 718 are prospectively accounted for as a component of the provision for income taxes. In addition, ASU 2016-09 eliminated the requirement that excess tax benefits from share based compensation reduce taxes payable prior to being recognized in the financial statements. As a result of the adoption of ASU 2016-09, the cumulative excess benefits of stock compensation of \$0.9 million that was not previously recognized was established on the balance sheet resulting in an increase in deferred tax assets and retained earnings.

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 2015, the Company assessed the realizability of the deferred tax assets of AFP and 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.

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14. Stockholders' Equity

A summary of the changes in stockholders' equity for the three months ended March 31, 2017, consisted of the following:

	Three Months Ended March 31, 2017 (in thousands)
Stockholders' equity as of December 31, 2016	\$ 329,255
Beginning balance adjustment to retained earnings as a result of the adoption of ASU 2016-09	872
Adjusted stockholders' equity as of January 1, 2017	330,127
Net income	893
Accumulated other comprehensive income	466
Issuance of common stock in connection with the Company's equity plans	(2,173)
Share-based compensation expense	4,451
Treasury stock acquired	(8,203)
Stockholders' equity as of March 31, 2017	\$ 325,561

2014 Employee Stock Purchase Plan

In June 2014, the Company adopted the Employee Stock Purchase Plan, or ESPP, in connection with its initial public offering. A total of 2,000,000 shares of common stock are reserved for issuance under this plan. The Company's ESPP permits eligible employees to purchase common stock at a discount through payroll deductions during defined offering periods. Under the ESPP, the Company may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of its common stock will be purchased for employees participating in the offering. An offering may be terminated under certain circumstances. The price at which the stock is purchased is equal 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 March 31, 2017, the Company has issued 248,587 shares of common stock under the ESPP and 1,751,413 shares of its common stock remained available for issuance.

For the three months ended March 31, 2017 and 2016, the Company recorded ESPP expense of \$0.1 million and \$0.1 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 to the Company's share buyback program. The primary goal of the programs is to offset dilution created by the Company's equity compensation programs. 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.

Purchases are being made through the open market and private block transactions pursuant to Rule 10b5-1 plans, privately negotiated transactions or other means as determined by the Company's management and in accordance with the requirements of the Securities and Exchange Commission. The timing and actual number of shares repurchased will depend on a variety of factors including price, corporate and regulatory requirements, and other conditions. These

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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 532,894 and 398,600 shares of its common stock during the three months ended March 31, 2017 and 2016, totaling \$8.2 million and \$4.7 million, respectively.

2015 Equity Incentive Plan

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

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

As of March 31, 2017, the Company reserved an aggregate of 3,296,136 shares of common stock for future issuance under the 2015 Plan. In January 2017, an additional 1,156,216 shares were reserved under the 2015 Plan pursuant to the evergreen provision.

Share-Based Award Activity and Balances

The Company accounts for share-based compensation payments in accordance with ASC 718, which requires measurement and recognition of compensation expense at fair value for all share-based payment awards made to employees, directors, and nonemployees. Under these standards, the fair value of option awards and the option components of the ESPP awards are estimated at the grant date using the Black-Scholes option-pricing model. The fair value of RSUs is estimated at the grant date using the Company's common share price. Non-vested stock options held by non-employees are revalued using the Company's estimate of fair value at each balance sheet date. The portion that is ultimately expected to vest is amortized and recognized in the compensation expenses on a straight-line basis over the requisite service period, generally from the grant date to the vesting date.

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The weighted-averages for key assumptions used in determining the fair value of options granted during the three months ended March 31, 2017 and 2016, are as follows:

	Three Months Ended March 31,	
	2017	2016
Average volatility	36.7 %	30.2 %
Risk-free interest rate	2.2 %	1.6 %
Weighted-average expected life in years	5.7	5.7
Dividend yield rate	— %	— %

A summary of option activity under all plans for the three months ended March 31, 2017, 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, 2016	12,530,297	\$ 14.57		
Options granted	1,621,222	13.93		
Options exercised	(8,063)	11.87		
Options cancelled	(9,880)	12.97		
Options expired	(6,250)	25.36		
Outstanding as of March 31, 2017	<u>14,127,326</u>	\$ 14.50	4.64	\$ 20,642
Exercisable as of March 31, 2017	<u>9,409,292</u>	\$ 14.99	3.09	\$ 14,611

(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 March 31, 2017.

For the three months ended March 31, 2017 and 2016, the Company recorded of \$2.0 million and \$2.1 million, respectively, related to stock options granted to employees under all plans, and expenses of \$0.1 million and \$0.2 million, respectively, related to stock options granted to the Board of Directors under all plans.

Information relating to option grants and exercises is as follows:

	Three Months Ended March 31,	
	2017	2016
	(in thousands, except per share data)	
Weighted-average grant date fair value	\$ 4.87	\$ 3.37
Intrinsic value of options exercised	24	15
Cash received	96	104
Total fair value of the options vested during the year	4,781	3,259

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A summary of the status of the Company's nonvested options as of March 31, 2017, and changes during the three months ended March 31, 2017, are presented below:

	Options	Weighted-Average Grant Date Fair Value
Nonvested as of December 31, 2016	4,592,187	\$ 3.61
Options granted	1,621,222	4.87
Options vested	(1,485,495)	3.22
Options forfeited	(9,880)	4.51
Nonvested as of March 31, 2017	<u>4,718,034</u>	4.16

As of March 31, 2017, there was \$15.7 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 2.6 years and will be adjusted for future changes in estimated forfeitures.

Deferred Stock Units/Restricted Stock Units

Beginning in 2007, the Company granted deferred stock units, or DSUs, to certain employees and members of the Board of Directors with a vesting period of up to five years, and commencing in 2015, such equity was issued as restricted stock units, or RSUs (such RSUs and DSUs are collectively referred to herein as RSUs). The grantee receives one share of common stock at a specified future date for each RSU awarded. The RSUs may not be sold or otherwise transferred until certificates of common stock have been issued, recorded, and delivered to the participant. The RSUs do not have any voting or dividend rights prior to the issuance of certificates of the underlying common stock. The share-based expense associated with these grants was based on the Company's common stock fair value at the time of grant and is amortized over the requisite service period, which generally is the vesting period using the straight-line method. During the three months ended March 31, 2017 and 2016, the Company recorded a total expense of \$2.0 million and \$1.2 million, respectively, related to RSU awards granted to employees under all plans and expenses of \$0.1 million and \$0.2 million, respectively, related to RSU awards granted to the Board of Directors.

As of March 31, 2017, there was \$16.6 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 2.8 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, 2016	1,215,786	
RSUs granted	589,165	\$ 7,865
RSUs forfeited	(2,154)	
Common stock delivered	(234,328)	
RSUs surrendered for taxes	(163,510)	
RSUs outstanding at March 31, 2017	<u>1,404,959</u>	

(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 Company 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. Share-based compensation expense is recorded over the service period based on the estimated fair market 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 March 31, 2017, the Company recorded an immaterial amount of share-based compensation related to the issuance of equity awards for services rendered by consultants. During the three months ended March 31, 2016, the Company recorded approximately \$0.1 million, 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 is included in the Company's consolidated statement of operations as follows:

	Three Months Ended	
	March 31,	
	2017	2016
	(in thousands)	
Cost of revenues	\$ 1,131	\$ 799
Operating expenses:		
Selling, distribution, and marketing	84	66
General and administrative	2,783	2,646
Research and development	453	340
Total share-based compensation	<u>\$ 4,451</u>	<u>\$ 3,851</u>

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 months ended March 31, 2017 and 2016, were approximately \$0.3 million and \$0.2 million, 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 employed by 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 1.60% and 1.75% as of March 31, 2017 and December 31, 2016, respectively. 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 \$1.7 million at March 31, 2017 and December 31, 2016, respectively. The Company recorded an immaterial amount of expense under the plan for the three months ended March 31, 2017 and 2016.

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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 paid a fixed cost per unit sold to Andrx and also shares in the gross profits (as defined) from Andrx's sales of the product in the U.S. retail pharmacy market. In November 2006, Watson Pharmaceuticals, Inc., or Watson, acquired Andrx and all of the rights and obligations associated with the agreement. In January 2013, Watson adopted Actavis, Inc. as its new global name. In March 2015, Actavis acquired Allergan plc and adopted Allergan plc as its new global name in June 2015.

In January 2012, the Company launched enoxaparin, beginning the seven-year period in which Actavis had 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. On June 30, 2016, the Company and Actavis amended the distribution agreement, which terminated the agreement in December 2016. The Company recognized 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 December 31, 2016, the balance of the deferred revenue has been fully recognized.

Supply Agreement with MannKind Corporation

On July 31, 2014, the Company entered in 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 API for use in MannKind's product Afrezza[®]. Under the Supply Agreement, MannKind agreed to purchase annual minimum quantities of RHI API in an aggregate amount of approximately €120.1 million, or approximately \$146.0 million, over five years from in 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 product shipped.

In January 2015, the Company entered into a supply option agreement with MannKind, or the Option Agreement, pursuant to which MannKind will have the option to purchase RHI API, 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 October 2015, MannKind informed the Company that it was not exercising the option to purchase additional quantities of RHI API 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 statement of operations for the year ended December 31, 2015.

For the year ended December 31, 2016, sales of RHI API to MannKind totaled \$6.8 million, which fulfilled the remaining unfulfilled 2015 commitment of RHI under the Supply Agreement.

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In November 2016, the Company amended the Supply Agreement with MannKind, whereby MannKind's aggregate total commitment of RHI API under the Supply Agreement has not been reduced; however, the annual minimum purchase commitments of RHI API under the Supply Agreement have been modified and extended through 2023, which timeframe had previously lapsed after calendar year 2019. Specifically, the minimum annual purchase commitment in calendar year 2016 has been cancelled, and the minimum annual purchase commitments in calendar years 2017 through 2023 have been modified to be €2.7 million of insulin in the fourth quarter of 2017, €8.9 million in 2018, €11.6 million in 2019, €15.5 million in 2020 and in 2021, and €19.4 million in 2022 and in 2023. MannKind may request to purchase additional quantities of RHI API in excess of its annual minimum purchase commitments. The Supply Agreement Amendment also (i) shortened the required expiry dates for RHI API delivered to MannKind pursuant to the Supply Agreement, (ii) modified the timing of MannKind's payment for the minimum annual purchase commitment in calendar year 2017, and (iii) added a pre-payment requirement for purchases of RHI API by MannKind in calendar years 2017 and 2018. The amendment can be renewed for additional, successive two-year terms upon 12 months' written notice, given prior to the end of the initial term or any additional two-year term.

Concurrently with the amendment of the Supply Agreement, the Company amended the Option Agreement with MannKind, whereby the amendment to the Option Agreement extends the timing for payment of the capacity cancellation fee for 2017 and decreases the amounts payable as capacity cancellation fees for 2018 and 2019 in the event MannKind fails to exercise its minimum annual purchase option for any given year. The Company recognized the cancellation fee for 2017 of \$1.5 million in net revenues in its consolidated statement of operations for the year ended December 31, 2016, and subsequently collected on this receivable.

In addition to, and in consideration of the amended timeframe and other amendments contained in the amendment to the Supply Agreement in the amendment to the Option Agreement, the Supply Agreement Amendment provided the Company right of first refusal to participate in the development and commercialization of Afrezza® in China through a collaborative arrangement.

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 March 31, 2017, the Company has paid an upfront payment of \$0.5 million and \$1.2 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 \$0.8 million if certain milestones are met. As of March 31, 2017, 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.

Operating Lease Agreements

The Company leases real and personal property, in the normal course of business, under various non-cancelable operating leases. The Company, at its option, can renew a substantial portion of its leases, at the market rate, for various renewal periods ranging from one to six years. Rental expense under these leases for the three months ended March 31, 2017 and 2016, was approximately \$0.9 million and \$0.8 million, respectively.

Purchase Commitments

As of March 31, 2017, the Company has entered into commitments to purchase equipment and raw materials for an aggregate amount of approximately \$45.6 million. The Company anticipates that most of these commitments with remaining term in excess of one year will be fulfilled by 2018. In addition, the Company is obligated to pay a supplier certain payments up to \$1.5 million based on its launch and sale of one of the Company's pipeline products.

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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 December 31, 2016, the Company had invested its total registered capital commitment of \$61.0 million to ANP. This investment in ANP resulted in cash being transferred from the U.S. parent company to ANP.

Per these agreements, in January 2010, the Company acquired certain land-use rights with a carrying value of \$1.2 million. In addition, the Company purchased additional land-use rights in November 2012 for \$1.3 million. The Company committed to spend approximately \$15.0 million in land development. The agreements require the construction of fixed assets on the property and specified a timetable for the construction of these fixed assets. The 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. 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

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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 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, which was granted. A hearing was held on August 23, 2016, where the Magistrate Judge ordered the Company to file its proposed amended contentions, which it filed on August 31, 2016. On February 4, 2017, the Magistrate Judge issued an order denying the Company leave to amend its contentions. The Company filed objections to this order with the District Court on February 21, 2017. On April 13, 2017, the District Court rejected the determination of the Magistrate Judge with respect to the Company's amended non-infringement contentions, and allowed the Company to amend its non-infringement contentions. With respect to the Company's amended invalidity contentions, the District Court accepted the Magistrate Judge's determination; however, the District Court specifically stated that the Company can argue changes in law at the summary judgment stage or at trial.

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.

Fact discovery in the Massachusetts District Court proceedings closed on November 22, 2016, and the parties proceeded with expert discovery and exchanged opening and rebuttal expert reports. Expert discovery closed on March 24, 2017. On April 14, 2017, Plaintiffs filed a Motion for Summary Judgment seeking to dismiss the Company's equitable defenses. Even if Plaintiffs prevail on this motion, the patent litigation would still go to trial. On April 14, 2017, the Company filed Defendants' Motion for Summary Judgment of Invalidity and Noninfringement. In the Motion, the Company moved for the District Court to grant summary judgment in favor of the Company on the following issues: (1) the '886 patent is invalid under 35 U.S.C. § 101 as claiming non-patentable subject matter; (2) the '886 patent is invalid under 35 U.S.C. § 112 because the claims are indefinite; and (3) the Company's tests do not infringe the claims of the '886 patent. If the Company prevails on any of these issues, the District Court would dismiss the patent litigation against the Company and the case would not go to trial. Oppositions to the motions for summary judgment were filed on May 5, 2017. Replies in support of the motions for summary judgment are due May 19, 2017.

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.

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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 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. On November 10, 2016, the Ninth Circuit heard oral argument on the pending appeal and took the matter under submission.

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 parties 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. On February 10, 2017, the Court held a show cause hearing regarding the potential imposition of sanctions and took the matter under submission. 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. On November 10, 2016, the Ninth Circuit heard oral argument on the pending appeals and took them under submission.

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California Employment Litigation

On January 6, 2015, the Company received a formal demand from Plaintiff's counsel in an employment related lawsuit captioned *Eva Hernandez v. International Medication Systems Limited*, in connection with a complaint originally filed on February 4, 2013, in the Superior Court of California County of Los Angeles, or the Court, by plaintiff Eva Hernandez on behalf of herself and others similarly situated. Plaintiff's complaint included alleged violations of the California Labor Code stemming from the Company's alleged timekeeping practices, as well as other similar and related claims brought under California law. In the complaint, Plaintiff sought damages and related remedies under California law, as well as various penalty payments under the California Labor Code, on behalf of herself and others similarly situated. On April 7, 2015, solely to resolve the dispute, minimize disruption to the Company due to ongoing litigation, and other similar and related factors (but unrelated to the alleged merits of Plaintiff's claims), the Company reached an agreement in principle to settle this matter on a class wide basis for a total amount of \$3.2 million, plus applicable payroll taxes. The Joint Stipulation of Settlement as executed by the parties was filed with the Court on June 2, 2015. On July 1, 2015, the Court preliminarily approved the settlement, and on November 5, 2015, the Court entered an order granting final approval of the settlement. On May 13, 2016, the court reviewed and approved the final distribution report. The case was removed from the Court's Civil Active Case List.

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 the 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 on 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. On December 5, 2016, Defendants' filed their response brief with the First Circuit Court of Appeals. On December 19, 2016, the Company filed its rely brief with the First Circuit Court of Appeals, which concluded the briefing on this appeal. On February 9, 2017, the First Circuit Court of Appeals heard oral arguments. On March 6, 2017, the First Circuit Court of Appeals issued its decision, in which it held 3 to 0 that the District Court of Massachusetts erred in dismissing the Company's antitrust case and sent the case back to the District Court to consider additional arguments.

On April 6, 2017, the District Court held a status conference to address scheduling matters for the rest of the case. The Court set a briefing schedule for Defendants' supplemental motion to dismiss and a full case schedule in the event that it denies Defendants' supplemental motion to dismiss. On April 20, 2017, Defendants filed their supplemental motion to dismiss and the Company filed its opposition on May 4, 2017. There are no reply briefs allowed and the Court has promised to rule on the motion to dismiss by the end of May. If the Court denies Defendants' supplemental motion to dismiss, discovery will commence. Summary judgment arguments would be due on November 15, 2018; oppositions would be due on December 15, 2018; and replies would be due on January 15, 2019. Trial is currently scheduled for April 1, 2019.

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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.

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

The following is a discussion and analysis of the consolidated operating results, financial condition, liquidity and cash flows of our company 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 the related notes thereto included 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. Actual results could differ materially from those discussed in or implied by 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, 2016, particularly in Item 1A. "Risk Factors".

Overview

We are 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 API products. We currently manufacture and sell 18 products. Additionally, we are developing a portfolio of 16 generic ANDAs, three generic biosimilar product candidates and six proprietary injectable and inhalation product candidates.

One of our largest products by net revenues is 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 has 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 had a distribution agreement with Actavis Inc., or Actavis, to distribute enoxaparin, which was marketed under Actavis' label. On June 30, 2016, we amended the distribution agreement with Actavis, to, among other things, amend the termination date of such agreement. In December 2016, our distribution agreement was terminated pursuant to such amendment.

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 six 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.

Included in these acquisitions are 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 the manufacturing of these products to our facilities in California, which will require approvals from the UK Medicines and Healthcare products Regulatory Agency before the product candidates can be re-launched by us.

Business Segments

Our performance is assessed and resources are 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 RHI API and porcine insulin API. Information reported herein is consistent with how it is reviewed and evaluated by our chief operating decision maker. Factors used to identify our segments include markets, customers and products.

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

Results of Operations

Three Months Ended March 31, 2017 Compared to Three Months Ended March 31, 2016

Net revenues

	Three Months Ended March 31,		Change	
	2017	2016	Dollars	%
	(in thousands)			
Net revenues				
Finished pharmaceutical products	\$55,934	\$58,554	\$(2,620)	(4)%
API	736	812	(76)	(9)%
Total net revenues	\$56,670	\$59,366	\$(2,696)	(5)%
Cost of revenues				
Finished pharmaceutical products	\$31,624	\$32,729	\$(1,105)	(3)%
API	2,218	1,735	483	28 %
Total cost of revenues	\$33,842	\$34,464	\$ (622)	(2)%
Gross profit	\$22,828	\$24,902	\$(2,074)	(8)%
as % of net revenues	40 %	42 %		

The increase in net revenues of the finished pharmaceutical products for the three months ended March 31, 2017, was primarily due to the following changes:

	Three Months Ended March 31,		Change	
	2017	2016	Dollars	%
	(in thousands)			
Finished pharmaceutical products net revenues				
Enoxaparin	\$ 10,410	\$ 18,358	\$(7,948)	(43)%
Naloxone	10,939	10,254	685	7 %
Lidocaine	8,289	9,908	(1,619)	(16)%
Phytonadione	7,886	6,126	1,760	29 %
Epinephrine	9,574	4,392	5,182	118 %
Other finished pharmaceutical products	8,836	9,516	(680)	(7)%
Total finished pharmaceutical products net revenues	\$ 55,934	\$ 58,554	\$(2,620)	(4)%

The decrease in sales of enoxaparin was primarily driven by lower unit volumes, which resulted in a decrease of approximately \$5.6 million, as well as lower average selling prices, which resulted in a decrease of approximately \$2.3 million. We expect that the average selling price and unit volumes of enoxaparin will continue to fluctuate in the near term as a result of competition.

The increase in sales of naloxone in the three months ended March 31, 2017, was primarily a result of an increase in unit volumes, which was partially offset by increased rebates of \$0.2 million. We anticipate that sales of this product may decline due to increased competition driven by future competitor launches.

The decrease in sales of lidocaine was primarily a result of a decrease in unit volumes. The increase in phytonadione sales was primarily the result of higher unit volumes. An increase in average selling prices of epinephrine caused an increase of approximately \$2.4 million in net revenues, while higher unit volumes led to an increase in sales of approximately \$2.8 million. The FDA recently requested that we discontinue the manufacturing and distribution of our epinephrine injection, USP vial product, which has been marketed under the “grandfather” exception to the FDA’s “Prescription Drug Wrap-Up” program. Unless the FDA grants our request for an extension of time to sell epinephrine

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vials, we will discontinue selling this product in the second quarter of 2017. For the three months ended March 31, 2017, we recognized \$8.0 million in net revenues for the sale of this product.

Our API business had sales of \$0.7 million in the three months ended March 31, 2017, as compared to \$0.8 million in the three months ended March 31, 2016. We anticipate that sales of API will continue to fluctuate and will likely decrease due to the inherent uncertainties related to sales of RHI API to MannKind. In addition, most of our API sales are denominated in Euros, and the fluctuation in the value of the Euro versus the dollar has had, and will continue to have, an impact on API sales revenues in the near term.

A significant portion of our customer shipments in any period relate to orders received and shipped in the same period, generally resulting in low product backlog relative to total shipments at any time. However, we had a backlog of approximately \$8.0 million as of March 31, 2017, primarily due to decreased production at our IMS facility resulting from a partial plant shutdown. The sterile filling area of the facility was shut down for the month of December 2016 and for part of the month on January 2017, for construction and installation of equipment in a new sterile suite. During 2017, we expect to complete construction, finish installing new equipment and undergo a validation process, all of which need to be completed before the new sterile suite can be used in production. There was no significant backlog in prior periods. Our backlog is generally not a meaningful indicator in any given period of our ability to achieve any particular level of overall revenue or financial performance.

Cost of revenues

Cost of revenue of enoxaparin decreased by \$5.6 million compared to the three months ended March 31, 2017, primarily due to a reduction in the number of units shipped. This decrease was partially offset by an increase in the unabsorbed manufacturing expense related to decreased production at our IMS facility resulting from the partial plant shutdown noted above.

Volatility in average selling prices and unit volume of enoxaparin and a decline in unit volume of one of our epinephrine products will put downward pressure on gross margins. However, 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, and general and administrative

	Three Months Ended		Change	
	March 31, 2017	2016	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	\$ 1,479	\$ 1,352	\$ 127	9 %
General and administrative	11,338	10,870	468	4 %

The increase in general and administrative expenses during the three months ended March 31, 2017, was primarily due to an increase in 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.

Research and development

	Three Months Ended March 31,		Change	
	2017	2016	Dollars	%
	(in thousands)			
Salaries and personnel-related expenses	\$ 3,980	\$ 3,587	\$ 393	11 %
Pre-launch inventory	711	—	711	N/A
Clinical trials	835	845	(10)	(1)%
FDA fees	15	14	1	7 %
Testing, operating and lab supplies	3,756	1,885	1,871	99 %
Depreciation	1,074	1,215	(141)	(12)%
Other expenses	879	1,059	(180)	(17)%
Total research and development expenses	<u>\$ 11,250</u>	<u>\$ 8,605</u>	<u>\$ 2,645</u>	31 %

Pre-launch inventory expense increased due to purchases related to Primatene[®] Mist. Testing, operating and lab supplies increased due to expenditures on materials for our pipeline products, particularly production of APIs for our pipeline at our ANP facility.

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.

Gain on sale of intangible assets

	Three Months Ended March 31,		Change	
	2017	2016	Dollars	%
	(in thousands)			
Gain on sale of intangible assets	\$(2,643)	\$ —	\$(2,643)	N/A

In February 2017, we sold the ANDAs that we acquired in March 2016 and recognized a gain of \$2.6 million (see Note 3 and Note 9).

Provision for income tax expense

	Three Months Ended March 31,		Change	
	2017	2016	Dollars	%
	(in thousands)			
Income tax expense	\$ 611	\$ 1,327	\$(716)	(54)%
<i>Effective tax rate</i>	<i>41 %</i>	<i>35 %</i>		

The difference in income tax expense was primarily due to the change in pre-tax income positions.

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. As of March 31, 2017, our foreign subsidiaries collectively held \$16.8 million in cash and cash equivalents. We do not plan to repatriate foreign earnings to the United States. Cash or cash equivalents held at foreign subsidiaries are not available to fund the parent company's operations in the United States. We believe that our cash reserves, operating cash flows, and borrowing availability under our credit facilities will be sufficient to fund our operations for at least 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 that we are developing 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 million of our common stock, preferred stock, depository 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 decreased \$4.9 million to \$118.6 million at March 31, 2017, compared to \$123.5 million at December 31, 2016.

Cash Flows from Operations

The following table summarizes our cash flows used in operating, investing, and financing activities for the three months ended March 31, 2017:

	Three Months Ended March 31, 2017 (in thousands)
Statement of Cash Flow Data:	
Net cash provided by (used in)	
Operating activities	\$ 22,398
Investing activities	(6,094)
Financing activities	(11,718)
Effect of exchange rate changes on cash	(174)
Net increase in cash and cash equivalents	<u>\$ 4,412</u>

Sources and Use of Cash

Operating Activities

Net cash provided by operating activities was \$22.4 million for the three months ended March 31, 2017, which included net income of \$0.9 million. Non-cash items were comprised of \$3.8 million of depreciation and amortization, \$4.5 million of share-based compensation expense, and a gain of \$2.6 million on the sale of long-lived assets. Operating assets and liabilities changed by \$15.5 million, which was primarily due to an increase in accounts payable and accrued

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liabilities. The changes in accounts payable and accrued liabilities were related to the timing of certain payments to vendors and customers which will lead to cash outflows in the second quarter.

Investing Activities

Net cash used in investing activities was \$6.1 million for the three months ended March 31, 2017, primarily as a result of \$7.3 million in purchases of property, machinery, and equipment, including the associated capitalized labor and interest on self-constructed assets. This was partially offset by the receipt of the \$1.0 million initial payment relating to the sale of the various ANDAs in February 2017 (see Note 9).

Financing Activities

Net cash used in financing activities was \$11.7 million for the three months ended March 31, 2017, primarily as a result of \$10.5 million relating to the repurchase of our common stock. Additionally, we made \$1.3 million in principal payments on our long-term debt.

Indebtedness

For more information regarding our outstanding indebtedness, see “Part I – Item 1. Financial Statements – Notes to 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, 2016, except that our outstanding debt obligations have changed as follows:

	March 31, 2017	December 31, 2016	Change
	(in thousands)		
Short-term debt and current portion of long-term debt	\$ 5,263	\$ 5,366	\$ (103)
Long-term debt	31,148	32,356	(1,208)
Total debt	<u>\$ 36,411</u>	<u>\$ 37,722</u>	<u>\$(1,311)</u>

As of March 31, 2017, we had \$37.1 million in unused borrowing capacity under revolving lines of credit with Cathay Bank and East West Bank.

Collaboration Agreement with a Medical Device Manufacturer

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 March 31, 2017, we have paid an upfront payment of \$0.5 million and \$1.2 million in milestone payments under this agreement, which were classified as research and development expense. We are obligated to pay up to an additional \$0.8 million if certain milestones are met. As of March 31, 2017, 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 intend to enter into a commercial supply agreement with such medical device manufacturer for a minimum purchase of 1.0 million units during the first 12 months.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU No. 2014-09 which creates a single source of revenue guidance for companies in all industries. Subsequently, the FASB issued multiple updates. 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. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required regarding customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. This guidance permits two methods of adoption: retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the cumulative catch-up transition method). Based on ASU No. 2015-14 issued in August 2015, this guidance will be effective for us in 2018, including interim periods within the year. We are in the process of evaluating the effect of the adoption on our condensed consolidated financial statements and are currently assessing our contracts with customers and sale of nonfinancial assets. We anticipate expanding our consolidated financial statement disclosures in order to comply with the new guidance. We expect to select the modified retrospective transition method upon adoption.

In February 2016, the FASB issued ASU No. 2016-02 that is aimed at making leasing activities more transparent and comparable, and which requires substantially all leases 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 our interim and annual reporting periods during the year ending December 31, 2019, and all annual and interim reporting periods thereafter. Early adoption is permitted. We are required to use a modified retrospective approach for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements for the reporting periods in which the guidance is adopted. We are currently evaluating the impact that the adoption of this guidance will have on our consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09 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 Company adopted this guidance effective January 1, 2017.

In June 2016, the FASB issued ASU No. 2016-13 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 our interim and annual reporting periods during the year ending December 31, 2020. Early adoption is permitted for annual periods after 2019. We will be required to apply the standard's provisions as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective. We are currently evaluating the impact that the adoption of this guidance will have on our consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU No. 2016-15 that is aimed at addressing certain issues regarding classifications of certain cash receipts and cash payments on the statement of cash flows where diversity in practice was identified. The guidance is effective for our interim and annual reporting periods during the year ending December 31, 2018. Early adoption is permitted. We will be required to apply the guidance retrospectively in the first interim and annual periods in which the guidance is adopted. We do not believe that the adoption of this accounting guidance will have a material impact on our consolidated financial statements and related disclosures.

In October 2016, the FASB issued ASU No. 2016-16 which requires an entity to recognize the income tax consequences of intra-entity transfer of an asset other than inventory when the transfer occurs. The guidance is effective for our interim and annual reporting periods during the year ending December 31, 2018. Early adoption is permitted as of the beginning of an annual reporting period for which financial statements, interim or annual, have not been issued. The amendments will be applied on a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings as of the beginning of the period of adoption. We are currently evaluating the impact that the adoption of this guidance will have on our consolidated financial statements and related disclosures.

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In November 2016, the FASB issued ASU No. 2016-18 which requires entities to show the changes in the total of cash, cash equivalents, restricted cash and restricted cash equivalents in the statement of cash flows. As a result, we will no longer present transfers between cash and cash equivalents and restricted cash and restricted cash equivalents in the statement of cash flows. The guidance is effective for our interim and annual reporting periods during the year ending December 31, 2018. Early adoption is permitted, including adoption in an interim period. The amendments will be applied using a retrospective transition method to each period presented. We will be required to apply the guidance retrospectively when adopted. We do not believe that the adoption of this accounting guidance will have a material impact on our consolidated financial statements and related disclosures.

In January 2017, the FASB issued ASU No. 2017-01 which provides guidance to assist entities with evaluating when a set of transferred assets and activities is a business. Under the updated guidance, a set is not a business if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar assets. If the threshold is not met, the update requires that, to be a business, the set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs. The definition of outputs was also aligned with ASC 606 by focusing on revenue-generating activities. The guidance is effective for our interim and annual reporting periods during the year ending December 31, 2018, and prospectively applicable to any transactions occurring within the period of adoption. Early adoption is permitted. We are currently evaluating the impact that the adoption of this guidance will have on our consolidated financial statements and related disclosures.

In January 2017, the FASB issued ASU No. 2017-04 which eliminates the requirement to calculate the implied fair value of goodwill. An entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. The FASB also eliminated the requirements for any reporting unit with a zero or negative carrying amount to perform a qualitative assessment and, if it fails that qualitative test, to perform Step 2 of the goodwill impairment test. An entity is required to disclose the amount of goodwill allocated to each reporting unit with a zero or negative carrying amount of net assets. The guidance is effective for our interim and annual reporting periods during the year ending December 31, 2020, and applied on a prospective basis. Early adoption is permitted for interim and annual goodwill impairment testing dates after January 1, 2017. We are currently evaluating the impact that the adoption of this guidance will have on our consolidated financial statements and related disclosures.

Off-Balance Sheet Arrangements

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

Government Regulation

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

From November 29, 2016 through December 7, 2016, 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 verification of corrective actions implemented from a previous inspection in July 2015. The inspection 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 December 29, 2016, within the required 15-working day window of the issuance of the Form 483. A follow up letter to the FDA District Office was additionally sent on January 31, 2017, outlining additional progress on our corrective action plan submitted in December. We believe that our responses to Form 483 will satisfy the requirements of the FDA and that no significant further actions will be necessary.

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From January 30, 2017 through February 09, 2017, our IMS facility in South El Monte, California was subject to a preapproval inspection by the FDA. The inspection included a review of our corrective actions taken from the recent cGMP inspection as well as review of data to support our pending application. The inspections resulted in multiple observations on Form 483. We responded to those observations on February 14, 2017. We believe that our responses to Form 483 will satisfy the requirements of the FDA and that no significant further actions will be necessary.

From March 13, 2017 through March 31, 2017, our Amphastar facility in Rancho Cucamonga, California was subject to a preapproval inspection by the FDA. The inspection included a review of our corrective actions taken from the previous cGMP inspection in July 2014 as well as review of data to support our pending applications. The inspections resulted in multiple observations on Form 483. We fully responded to those observations on April 22, 2017. We believe that our responses to Form 483 will satisfy the requirements of the FDA and that no significant further actions will be necessary.

From April 24, 2017 through April 28, 2017, our facility in Nanjing, China was subject to an inspection by the FDA. The purpose was a pre-approval inspection for the manufacture of API. The inspection resulted in several observations on Form 483. We plan to respond to those observations by May 19, 2017 and believe that our response will satisfy the requirements of the FDA and that no significant further actions will be necessary.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

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

Investment Risk

We regularly review the carrying value of our investments and identify and recognize losses, for income statement purposes, when events and circumstances indicate that any declines in the fair values of such investments below our accounting basis are other than temporary. As of March 31, 2017, we did not have any such investments.

As of March 31, 2017, we had \$15.0 million deposited in five banks located in China, \$1.6 million deposited in one bank located in France, and \$0.2 million deposited in one bank located in the United Kingdom. We also maintained \$43.9 million in cash equivalents that include money market accounts, money market funds, MMIDAS, and ICS accounts as of March 31, 2017. The remaining amounts of our cash equivalent as of March 31, 2017, 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 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 March 31, 2017, we had \$36.4 million in long-term debts and capital leases outstanding. Of this amount, \$19.6 million had variable interest rates which were not locked-in through fixed interest rate swap contracts. The debt with variable interest rate exposure had a weighted-average interest rate of 4.0% at March 31, 2017. An increase in the index underlying these rates of 1% (100 basis points) would increase our annual interest expense on the debts with variable interest rate exposure by approximately \$0.2 million per year.

Foreign Currency Exchange Risk

Our products are primarily sold in the U.S. domestic market, and for the three months ended March 31, 2017 and 2016, foreign sales were minimal. Therefore, we have little exposure to foreign currency price fluctuations. However, as a result of our acquisition of the API manufacturing business in Éragny-sur-Epte, France, we are exposed to market risk related to changes in foreign currency exchange rates. Specifically, our insulin sales contracts are primarily denominated in Euros, which are subject to fluctuations relative to the 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, ANP, maintains their 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, AFP, maintains their books of record in Euros. Our U.K. subsidiary, IMS UK, maintain its books 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 rate of exchange 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 March 31, 2017, our foreign subsidiaries had cash balances denominated in foreign currencies in the amount of \$3.0 million.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, our principal executive and principal financial officers, respectively, 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, as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were effective (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) to include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the three months ended March 31, 2017, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act).

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 of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

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, 2016, filed with the Securities and Exchange Commission on March 15, 2017.

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

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

As a result of our meetings with the FDA in 2009, we decided to discontinue all of our products that were subject to the Prescription Drug Wrap-Up program, with the exception of epinephrine in vial form. These products were all produced at our subsidiary, IMS. During the third quarter of 2010, the FDA requested that we reintroduce several of the withdrawn products to cope with a drug shortage, while we prepared and filed applications for approval of the products. Between August and October, 2010, we reintroduced atropine, calcium chloride, morphine, dextrose, epinephrine prefilled syringes, epinephrine injection, USP vial, and sodium bicarbonate injections, and continue to market these products without FDA approval. For the years ended December 31, 2016, 2015, and 2014, we recorded net revenues of \$52.1 million, \$40.2 million, and \$27.0 million, respectively, from unapproved products. For the three months ended March 31, 2017 and 2016, we recorded net revenues of \$15.1 million and \$11.4 million, respectively. The FDA recently requested us to discontinue the manufacturing and distribution of our epinephrine injection, USP vial product, which has been marketed under the “grandfather” exception to the FDA’s “Prescription Drug Wrap-Up” program. Unless the FDA grants our request for an extension of the time to sell epinephrine vials, we will discontinue selling this product in the second quarter of 2017. For the three months ended March 31, 2017 and for the year ended December 31, 2016, we recognized \$8.0 million and \$18.6 million, in net revenues for the sale of this product, respectively. The charge of \$3.3 million was included in the cost of revenues in our consolidated statements of operations for the year ended December 31, 2016 to adjust the related inventory items and firm purchase commitment to their net realizable value due to the anticipated discontinuation of the product. We have filed five ANDAs and are preparing additional applications with respect to other products in order to finally mitigate all risk associated with the marketing of unapproved drug products. In the interim, we continue to operate within the FDA Compliance Policy Guide, CPG Sec. 440.100 Marketed New Drugs Without Approved NDAs and ANDAs.

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
January 1 – January 31, 2017	118,794	\$ 16.79	118,794	—
February 1 – February 28, 2017	159,900	15.88	159,900	—
March 1 – March 31, 2017	254,200	14.37	254,200	—

(1) During the first quarter of 2017, we repurchased shares of our common stock as part of the share buyback program authorized by our Board of Directors on November 7, 2016. As of March 31, 2017, \$11.7 million remained available under such 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.

AMPHASTAR PHARMACEUTICALS, INC.
EXHIBIT INDEX TO FORM 10-Q
For the Quarterly Period Ended March 31, 2017

Exhibit No.	Description
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.

Certification

I, Jack Y. Zhang, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Amphastar Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2017

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

Certification

I, William J. Peters, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Amphastar Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2017

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

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

The undersigned officer of Amphastar Pharmaceuticals, Inc. (the "Company"), hereby certifies, to the best of such officer's knowledge, that:

(i) the Quarterly Report on Form 10-Q of the Company for the quarter ended March 31, 2017 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

Date: May 10, 2017

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

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. §1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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

The undersigned officer of Amphastar Pharmaceuticals, Inc. (the "Company"), hereby certifies, to the best of such officer's knowledge, that:

(i) the Quarterly Report on Form 10-Q of the Company for the quarter ended March 31, 2017 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

Date: May 10, 2017

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

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. §1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.
