Amphastar Pharmaceuticals, Inc.
Form 10-Q
August 09, 2018
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2018

or

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

For the transition period from to

Commission file number 001-36509

AMPHASTAR PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

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

11570 6th Street

Rancho Cucamonga, CA 91730

(Address of principal executive offices, including zip code)

(909) 980-9484

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant (1) has submitted every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) 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	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

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 August 2, 2018 was 46,256,454.

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SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS

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

- our expectations regarding the sales and marketing of our products;
- 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;
- our expectations regarding the business expansion plans of our Chinese subsidiary, ANP;
- 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 impact of global and domestic tax reform, including the Tax Cuts and Jobs Act of 2017;
- the impact of trade tariffs or other trade barriers;

- the timing for completion of the validation of the new construction at our IMS facility; 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, 2017, particularly in Item 1A. “Risk Factors.” These forward-looking statements represent our estimates and assumptions only as of the date of this Quarterly Report

regardless of the time of delivery of this Quarterly Report, and such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this Quarterly Report.

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

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PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

AMPHASTAR PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share data)

	June 30, 2018 (unaudited)	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 48,070	$ 65,594
Short-term investments	2,818	2,635
Restricted cash and short-term investments	4,155	4,155
Accounts receivable, net	41,279	35,996
Inventories	61,678	63,609
Income tax refunds and deposits	7,542	6,036
Prepaid expenses and other assets	4,404	9,753
Total current assets	169,946	187,778
Property, plant, and equipment, net	198,241	185,339
Goodwill and intangible assets, net	43,450	45,140
Other assets	11,752	8,663
Deferred tax assets	28,257	27,745
Total assets	$ 451,646	$ 454,665
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 67,092	$ 57,555
Income taxes payable	1,607	3,325
Current portion of long-term debt and capital leases	18,891	6,312
Total current liabilities	87,590	67,192
Long-term reserve for income tax liabilities	879	879
Long-term debt and capital leases, net of current portion	33,695	40,844
Deferred tax liabilities	1,325	1,361
Other long-term liabilities	7,631	7,060

Total liabilities	131,120	117,336
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; 50,661,676 and 46,416,789 shares issued and outstanding as of June 30, 2018 and 50,039,212 and 46,623,581 shares issued and outstanding as of December 31, 2017, respectively	5	5
Additional paid-in capital	322,357	313,891
Retained earnings	66,780	76,235
Accumulated other comprehensive loss	(3,166)	(2,100)
Treasury stock	(65,450)	(50,702)
Total stockholders' equity	320,526	337,329
Total liabilities and stockholders' equity	$ 451,646	$ 454,665

See Accompanying Notes to Condensed Consolidated Financial Statements.

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AMPHASTAR PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited; in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net revenues	$ 71,040	$ 65,187	$ 129,433	$ 121,857
Cost of revenues	44,884	38,440	86,216	72,282
Gross profit	26,156	26,747	43,217	49,575
Operating (income) expenses:				
Selling, distribution, and marketing	1,876	1,596	3,597	3,075
General and administrative	11,669	12,234	22,667	23,572
Research and development	15,468	10,732	29,728	21,982
Gain on sale of intangible assets	—	—	—	(2,643)
Total operating expenses	29,013	24,562	55,992	45,986
Income (loss) from operations	(2,857)	2,185	(12,775)	3,589
Non-operating income (expenses):				
Interest income	106	87	230	178
Interest expense	(100)	(237)	(118)	(428)
Other income (expenses), net	(1,265)	1,138	(483)	1,338
Total non-operating income (expenses), net	(1,259)	988	(371)	1,088
Income (loss) before income taxes	(4,116)	3,173	(13,146)	4,677
Income tax expense (benefit)	(1,326)	1,201	(3,110)	1,812
Net income (loss)	$ (2,790)	$ 1,972	$ (10,036)	$ 2,865
Net income (loss) per share:				
Basic	$ (0.06)	$ 0.04	$ (0.22)	$ 0.06
Diluted	$ (0.06)	$ 0.04	$ (0.22)	$ 0.06
Weighted-average shares used to compute net income (loss) per share:				
Basic	46,557	46,025	46,535	46,047
Diluted	46,557	47,866	46,535	47,962

See Accompanying Notes to Condensed Consolidated Financial Statements.

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AMPHASTAR PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(Unaudited; in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net income (loss)	$ (2,790)	$ 1,972	$ (10,036)	$ 2,865
Other comprehensive income (loss), net of income taxes				
Foreign currency translation adjustment	(2,256)	1,010	(1,066)	1,476
Total other comprehensive income (loss)	(2,256)	1,010	(1,066)	1,476
Total comprehensive income (loss)	$ (5,046)	$ 2,982	$ (11,102)	$ 4,341

See Accompanying Notes to Condensed Consolidated Financial Statements.

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AMPHASTAR PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited; in thousands)

	Six Months Ended June 30,	
	2018	2017
Cash Flows From Operating Activities:		
Net income (loss)	$ (10,036)	$ 2,865
Reconciliation to net cash provided by operating activities:		
Loss (gain) on disposal and impairment of long-lived assets	743	(2,561)
Depreciation of property, plant, and equipment	6,570	6,235
Amortization of product rights, trademarks, and patents	1,451	1,426
Share-based compensation expense	8,862	8,749
Changes in operating assets and liabilities:		
Accounts receivable, net	(5,221)	2,820
Inventories	1,625	6,965
Prepaid expenses and other assets	1,715	(1,106)
Income tax refund, deposits, and payable	(3,224)	(2,758)
Accounts payable and accrued liabilities	10,408	4,337
Net cash provided by operating activities	12,893	26,972
Cash Flows From Investing Activities:		
Purchases and construction of property, plant, and equipment	(24,591)	(13,568)
Sale of intangible assets	4,400	2,000
Purchase of short-term investments	(204)	(1,261)
Maturity of short-term investments	—	1,061
Changes in short-term investments	—	(900)
Payment of deposits and other assets	(114)	(1,123)
Net cash used in investing activities	(20,509)	(13,791)
Cash Flows From Financing Activities:		
Proceeds from equity plans, net of withholding tax payments	(294)	7,278
Purchase of treasury stock	(14,851)	(17,181)
Proceeds from borrowing under lines of credit	261	—
Proceeds from issuance of long-term debt	8,000	11,118
Principal payments on long-term debt	(2,834)	(2,618)
Net cash used in financing activities	(9,718)	(1,403)
Effect of exchange rate changes on cash	(190)	277
Net increase (decrease) in cash, cash equivalents, and restricted cash	(17,524)	12,055
Cash, cash equivalents, and restricted cash at beginning of period	67,459	72,354

Cash, cash equivalents, and restricted cash at end of period	$ 49,935	$ 84,409
Noncash Investing and Financing Activities:		
Equipment acquired under capital leases	$ 14	$ —
Supplemental Disclosures of Cash Flow Information:		
Interest paid, net of capitalized interest	$ 1,078	$ 792
Income taxes paid	$ 149	$ 4,569

See Accompanying Notes to Condensed Consolidated Financial Statements.

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AMPHASTAR PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

Note 1. General

Amphastar Pharmaceuticals, Inc., a California corporation, was incorporated in February 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 if they are approved and 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, 2017, 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, 2017. 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 income (loss) and cash flows for the periods presented. Unless otherwise noted, all such adjustments are of a normal, recurring nature. The Company's results of operations, comprehensive income (loss) and cash flows for the interim periods are not necessarily indicative of the results of operations and cash flows that it may achieve in future periods.

Note 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. Effective January 1, 2018, the Company retrospectively adopted Accounting Standard Update, or ASU, No. 2016-15 Classification of Certain Cash Receipts and Cash Payments. Certain amounts in the prior year's condensed consolidated statement of cash flows have been reclassified to conform to the current quarter presentation. This reclassification has no impact on net income or cash flows. All significant intercompany activity has been eliminated in the preparation of the condensed consolidated financial statements. 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) Nanjing Hanxin Medical Technology Co., Ltd, or Hanxin, (6) Nanjing Baixin Trading Co. Ltd., or Baixin, (7) Amphastar France Pharmaceuticals, S.A.S., or AFP, (8) Amphastar UK Ltd., or AUK, and (9) International Medication Systems (UK) Limited, or IMS UK.

In July 2018, ANP completed a private placement of its equity for aggregate gross proceeds of approximately $57.2 million. The Company has retained approximately 58% of the equity interest of ANP immediately after the private placement and continues to consolidate the financial results of ANP with the Company's results of operations. (See Note 18 for additional information)

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AMPHASTAR PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

Use of Estimates

The preparation of condensed consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results could differ from those estimates. The principal accounting estimates include determination of allowances for doubtful accounts and discounts, provision for chargebacks and rebates, provision for product returns, adjustment of inventory to their net realizable values, 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, maintains its book of record in Euros. Its other Chinese subsidiaries maintain their books of record in Chinese Yuan. Its U.K. subsidiary, IMS UK, maintains its book of record in Great Britain Pounds. These local currencies have been determined to be the subsidiaries' respective functional currencies. These books of record 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 and six months ended June 30, 2018 were $1.7 million loss and $0.8 million loss, respectively, and for the three and six months ended June 30, 2017 were $2.2 million gain and $2.7 million gain, respectively.

The Company does not undertake hedging transactions to cover its foreign currency exposure.

Comprehensive Income (loss)

For the three and six months ended June 30, 2018 and 2017, the Company included its foreign currency translation gain or loss as part of its comprehensive income (loss).

Restricted Cash and Short-term Investments

Restricted cash and short-term investments are collateral required for the Company to effect a standby letter of credit and to qualify for workers' compensation self-insurance and are available to meet the Company's workers' compensation obligations on a current basis, as needed. As of June 30, 2018 and December 31, 2017, restricted cash and short-term investments include $1.9 million in cash and $2.3 million in certificates of deposit, respectively. The certificates of deposit have original maturities greater than three months and are classified as short-term investments.

Financial Instruments

The carrying amounts of cash and cash equivalents, short-term investments, restricted cash and short-term investments, accounts receivable, accounts payable, accrued expenses, and short-term borrowings approximate fair value due to the short maturity of these items. The majority of the Company's long-term obligations consist of variable rate debt, and their

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AMPHASTAR PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

carrying value approximates fair value as the stated borrowing rates are comparable to rates currently offered to the Company for instruments with similar maturities. 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. At June 30, 2018, the Company had not completed its accounting for the tax effects of the enactment of the Tax Cuts and Jobs Act of 2017, or the Tax Act.

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 presentations were disclosed.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board, or FASB, issued ASU No. 2016-02, Leases, 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. The ASU and the related clarifications subsequently issued by the FASB 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. While the Company continues to evaluate the provisions of ASC 842 to determine how it will be affected, the primary effect of adopting the new standard will be to record right-to-use assets and obligations for current operating leases on its consolidated financial statements. Note 16 provides details on the Company's current operating lease arrangements. The adoption of ASC 842 is not expected to have a material impact on the Company's results of operations or cash flows.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments – Credit Losses, which 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.

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(Unaudited)

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 interim or annual periods after December 31, 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 does not believe 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. 2017-04, Simplifying the Test for Goodwill Impairment, 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 update 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 currently does not believe that the adoption of this accounting guidance will have a material impact on its consolidated financial statements and related disclosures.

In August 2017, the FASB issued ASU No. 2017-12, Targeted Improvements to Accounting for Hedging Activities, which amends the hedge accounting model in ASC 815 to enable entities to better portray the economics of their risk management activities in the financial statements and enhance the transparency and understandability of hedge results. The amendments also simplify the application of hedge accounting in certain situations. The new guidance is effective for the Company's interim and annual reporting periods during the year ending December 31, 2019. Early adoption is permitted. 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 February 2018, the FASB issued ASU No. 2018-02, Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income, which allows entities to reclassify from accumulated other comprehensive income to retained earnings stranded tax effects resulting from the Tax Act. The guidance is effective for the Company's interim and annual reporting periods during the year ending December 31, 2019. Early adoption is permitted. 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 June 2018, the FASB issued ASU No. 2018-07, Improvements to Nonemployee Share-Based Payment Accounting, which simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees. The Company will early-adopt the guidance on July 1, 2018. The adoption will not have a material impact on its consolidated financial statements and related disclosures.

Note 3. Revenue Recognition

In 2018, the Company adopted ASC 606, Revenue from Contracts with Customers, or ASC 606, using the modified retrospective transition method. The adoption of ASC 606 did not have a material impact on the Company's revenue recognition or on the condensed consolidated financial statements and related disclosures. Subsequent to the adoption of ASC 606 revenue is recognized at the time that the Company's customers obtain control of the promised goods. Revenues derived from contract manufacturing services are recognized when third-party products are shipped to customers, after the customer has accepted test samples of the products to be shipped. The results for the reporting period beginning after January 1, 2018, are presented in accordance with the new standard, although comparative information continues to be reported under the accounting standards and policies in effect for those periods. For the accounting policy related to

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AMPHASTAR PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

revenue recognition for the years ended prior to and on December 31, 2017, see Note 4, Revenue Recognition, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2017.

The Company only records revenue to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved, by estimating and recording reductions to revenue for discounts, product returns, and pricing adjustments, such as wholesaler chargebacks and retailer rebates, in the same period that the related revenue is recorded.

Provision for Chargebacks and Rebates

The provision for chargebacks and rebates is a significant estimate used in the recognition of revenue. Wholesaler chargebacks relate to sales terms under which 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 that wholesalers resell under the Company's various contractual arrangements with third parties such as hospitals and group purchasing organizations in the United States. Rebates include primarily amounts paid to retailers, payers, and providers in the United States, including those paid to state Medicaid programs, and are based on contractual arrangements or statutory requirements. The Company estimates chargebacks and rebates using the expected value method at the time of sale to wholesalers based on wholesaler inventory stocking levels, historic chargeback and rebate rates, and current contract pricing.

The provision for chargebacks and rebates is reflected in net revenues. The following table is an analysis of the chargeback and rebate provision:

	Six Months Ended June 30,	
	2018	2017
	(in thousands)	
Beginning balance	$ 18,470	$ 39,709
Provision for chargebacks and rebates	55,372	86,935

Credits and payments issued to third parties	(55,999)	(116,429)
Ending balance	$ 17,843	$ 10,215

Changes in the chargeback provision from period to period are primarily dependent on the Company's sales to its wholesalers, the level of inventory held by wholesalers, and the wholesaler's customer mix. Changes in the rebate provision from period to period are primarily dependent on retailer's and other indirect customers' purchases. 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 rebates and makes adjustments when it believes that the actual chargebacks and rebates may differ from the estimates. The settlement of chargebacks and rebates generally occurs within 30 days to 60 dates after the sale to wholesalers. Accounts receivable and/or accounts payable and accrued liabilities are reduced and/or increased by the chargebacks and rebate amounts depending on whether the Company has the right to offset with the customer. Of the provision for chargebacks and rebates as of June 30, 2018 and December 31, 2017, $6.4 million and $6.8 million were included in accounts receivable, net, on the condensed consolidated balance sheets, respectively. The remaining provision of $11.4 million and $11.7 million were included in accounts payable and accrued liabilities, respectively.

Accrual for Product Returns

The Company offers most customers the right to return qualified excess or expired inventory for partial credit; however, API product sales are generally 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 product returns estimated using the expected value method. The accrual is based, in

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part, upon the historical relationship of product returns to sales and customer contract terms. The Company also assesses other factors that could affect product returns including market conditions, product obsolescence, and the introduction of new competition. Although these factors do not normally give the Company's customers the right to return products outside of the regular return policy, the Company realizes that such factors could ultimately lead to increased returns. The Company analyzes these situations on a case-by-case basis and makes adjustments to the product return reserve as appropriate. As of June 30, 2018 and December 31, 2017, cumulative sales of approximately $0.7 million and $1.2 million, respectively, for one of the Company's products were not recognized in revenues, due to insufficient information available to determine that a significant reversal of such amount will not occur when the uncertainty associated with the return refund is subsequently resolved.

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

	Six Months Ended June 30,	
	2018	2017
	(in thousands)	
Beginning balance	$ 6,522	$ 3,143
Provision for product returns	917	2,979
Credits issued to third parties	(865)	(966)
Ending balance	$ 6,574	$ 5,156

Of the provision of product returns as of June 30, 2018 and December 31, 2017, $4.6 million and $4.1 million were included in accounts payable and accrued liabilities on the condensed consolidated balance sheets, respectively. The remaining provision of $1.9 million and $2.4 million were included in other long-term liabilities, respectively. For the six months ended June 30, 2018 and 2017, the Company's aggregate product return rate was 1.3% and 1.2% of qualified sales, respectively.

Note 4. Income (loss) per Share

Basic income (loss) per share is calculated based upon the weighted-average number of shares outstanding during the period. Diluted income (loss) per share gives effect to all potential dilutive shares outstanding during the period, such as stock options, non-vested restricted stock units, and shares issuable under the Company's Employee Stock Purchase Plan, or ESPP.

As the Company reported a net loss for the three and six months ended June 30, 2018, the diluted net loss per share, as reported, equals the basic net loss per share since the effect of the assumed exercise of stock options, vesting of non-vested RSUs, and issuance of common shares under the Company's ESPP are anti-dilutive. Total stock options, non-vested RSUs, and shares issuable under the Company's ESPP excluded from the three and six months ended June 30, 2018 net loss per share were 11,649,241 stock options; 1,232,237 non-vested RSUs, and 60,854 shares issuable under the ESPP.

For the three and six months ended June 30, 2017, options to purchase 3,170,200 shares of stock with a weighted-average exercise price of $20.52 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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(in thousands, except per share data)			
Basic and dilutive numerator:				
Net income (loss)	$ (2,790)	$ 1,972	$ (10,036)	$ 2,865
Denominator:				
Weighted-average shares outstanding — basic	46,557	46,025	46,535	46,047
Net effect of dilutive securities:				
Incremental shares from equity awards	—	1,841	—	1,915
Weighted-average shares outstanding — diluted	46,557	47,866	46,535	47,962
Net income (loss) per share — basic	$ (0.06)	$ 0.04	$ (0.22)	$ 0.06
Net income (loss) per share — diluted	$ (0.06)	$ 0.04	$ (0.22)	$ 0.06

Note 5. 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, phytonadione, lidocaine, medroxyprogesterone acetate, 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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(in thousands)			
Net revenues:				
Finished pharmaceutical products	$ 63,241	$ 63,765	$ 116,358	$ 119,699
API	7,799	1,422	13,075	2,158
Total net revenues	71,040	65,187	129,433	121,857
Gross profit:				
Finished pharmaceutical products	27,741	28,866	47,466	53,176
API	(1,585)	(2,119)	(4,249)	(3,601)
Total gross profit	26,156	26,747	43,217	49,575
Operating expenses	29,013	24,562	55,992	45,986
Income (loss) from operations	(2,857)	2,185	(12,775)	3,589
Non-operating income	(1,259)	988	(371)	1,088
Income (loss) before income taxes	$ (4,116)	$ 3,173	$ (13,146)	$ 4,677

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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017

	(in thousands)			
Finished pharmaceutical products net revenues:				
Naloxone	$ 11,133	$ 10,261	$ 20,060	$ 21,200
Phytonadione	10,806	10,003	19,987	17,890
Lidocaine	10,010	9,334	19,792	17,622
Enoxaparin	8,715	8,288	15,722	18,698
Medroxyprogesterone	6,365	—	9,071	—
Epinephrine	3,687	10,648	6,910	20,222
Other finished pharmaceutical products	12,525	15,231	24,816	24,067
Total finished pharmaceutical products net revenues	$ 63,241	$ 63,765	$ 116,358	$ 119,699

Discontinuation of epinephrine injection, USP vial product

In February 2017, the U.S. Food and Drug Administration, or FDA, requested the Company to discontinue the manufacturing and distribution of its epinephrine injection, USP vial product, which had been marketed under the "grandfather" exception to the FDA's "Prescription Drug Wrap-Up" program. The Company discontinued selling this product in the second quarter of 2017. For the year ended December 31, 2017, the Company recognized $17.8 million in net revenues for the sale of this product.

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

	Net Revenue				Long-Lived Assets	
	Three Months Ended June 30,		Six Months Ended June 30,		June 30,	December 31,
	2018	2017	2018	2017	2018	2017
	(in thousands)					
United States	$ 68,560	$ 63,799	$ 121,664	$ 119,729	$ 113,554	$ 110,235
China	—	—	—	—	47,068	41,078
France	2,480	1,388	7,769	2,128	37,619	34,026
United Kingdom	—	—	—	—	—	—
Total	$ 71,040	$ 65,187	$ 129,433	$ 121,857	$ 198,241	$ 185,339

Note 6. 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. The Company considers these three customers to be its major customers, as each individually, and these customers collectively, represented a significant percentage of the Company’s net revenue for the three and six months ended June 30, 2018 and 2017, and accounts receivable as of June 30, 2018 and December 31, 2017, respectively. The following table provides accounts receivable and net revenue information for these major customers:

	% of Total Accounts Receivable	% of Net Revenue

	June 30, 2018		December 31, 2017		Three Months Ended June 30, 2018		2017		Six Months Ended June 30, 2018		2017	
McKesson	23	%	22	%	25	%	27	%	26	%	27	%
AmerisourceBergen	25	%	33	%	27	%	29	%	26	%	29	%
Cardinal Health	20	%	12	%	20	%	26	%	21	%	25	%

Supplier Concentrations

The Company depends on suppliers for raw materials, active pharmaceutical ingredients, and other components that are subject to stringent FDA requirements. Some of these materials may only be available from one or a limited number of sources. Establishing additional or replacement suppliers for these materials may take a substantial 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.

Note 7. 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;

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- 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.

As of June 30, 2018, cash equivalents include money market accounts. Short-term investments consist of certificates of deposit with original expiration dates within 12 months. These certificates of deposit are carried at amortized cost in the Company's consolidated balance sheet, which approximates their fair value determined based on Level 2 inputs. The restrictions on restricted cash and short-term investments have a negligible effect on the fair value of these financial assets.

The Company does not hold any Level 2 or Level 3 instruments that are measured for fair value on a recurring basis.

Nonfinancial assets and liabilities are not measured at fair value on a recurring basis but are subject to fair value adjustments in certain circumstances. These items primarily include long-lived assets, goodwill, and intangible assets for which the fair value of assets is determined as part of the related impairment test. As of June 30, 2018 and December 31, 2017, there were no significant adjustments to fair value for nonfinancial assets or liabilities.

Note 8. 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) (in thousands)	Original Cost	Accumulated Amortization	Net Book Value
Definite-lived intangible assets				
Cortrosyn® product rights	12	$ 27,134	$ 27,134	$ —
IMS (UK) international product rights	10	9,239	1,771	7,468
Patents	12	486	191	295
Land-use rights	39	2,540	453	2,087
Other intangible assets	4	69	55	14
Subtotal	12	39,468	29,604	9,864
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill - Finished pharmaceutical products	*	4,361	—	4,361
Subtotal	*	33,586	—	33,586
As of June 30, 2018	*	$ 73,054	$ 29,604	$ 43,450

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	Weighted-Average Life (Years) (in thousands)	Original Cost	Accumulated Amortization	Net Book Value
Definite-lived intangible assets				
Cortrosyn® product rights	12	$ 27,134	$ 26,243	$ 891
IMS (UK) international product rights	10	9,440	1,337	8,103
Patents	12	486	170	316
Land-use rights	39	2,540	419	2,121
Other intangible assets	4	69	46	23
Subtotal	12	39,669	28,215	11,454
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill - Finished pharmaceutical products	*	4,461	—	4,461
Subtotal	*	33,686	—	33,686
As of December 31, 2017	*	$ 73,355	$ 28,215	$ 45,140

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

Sale of Fourteen Injectable ANDAs

In March 2016, the Company acquired 14 abbreviated new drug applications, or ANDAs, representing 11 different injectable chemical entities from Hikma Pharmaceuticals PLC, or Hikma. In February 2017, the Company sold the 14 ANDAs 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, $1.0 million was received in the second quarter of 2017 and the remaining $4.4 million was received in January 2018. 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 has not recognized any royalty fee revenue. The Company recognized a gain of $2.6 million within operating (income) expenses on its condensed consolidated statement of operations for the six months ended June 30, 2017.

Goodwill

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

	June 30, 2018	December 31, 2017
	(in thousands)	
Beginning balance	$ 4,461	$ 3,976
Currency translation	(100)	485
Ending balance	$ 4,361	$ 4,461

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, its carrying value as of June 30, 2018.

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

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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 submitted a responsive NDA amendment in June 2016 and received a second 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 product correctly to support approval in the over-the-counter setting. After several meetings with the FDA in 2017, the Company further revised its packaging and label and plans to perform another human factors study based on such revisions. In November 2017, the Company submitted its proposed protocol to the FDA. In March 2018, the Company received as Advice Letter from the FDA regarding its proposed protocol. Based on that feedback, the Company has conducted an additional human factors study. The Company believes it has received acceptable results from the study, and the Company has resubmitted the NDA. The Company intends to continue to work with the FDA 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), 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 required based on the Company's qualitative assessment as of June 30, 2018.

Note 9. Inventories

Inventories consist of the following:

	June 30, 2018	December 31, 2017
	(in thousands)	
Raw materials and supplies	$ 27,640	$ 19,973
Work in process	22,298	22,469
Finished goods	11,740	21,167
Total inventories	$ 61,678	$ 63,609

Charges totaling $1.2 million and $3.1 million were included in the cost of revenues in the Company's condensed consolidated statements of operations for the three and six months ended June 30, 2018, respectively, to adjust the Company's inventory and related firm inventory purchase commitments to their net realizable value. For the three and six months ended June 30, 2017, charges totaling $4.7 million and $5.1 million were included in the cost of revenues, respectively, to adjust the Company's inventory and related firm inventory purchase commitments to their net realizable value.

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Note 10. Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

	June 30, 2018	December 31, 2017
	(in thousands)	
Buildings	$ 90,844	$ 89,124
Leasehold improvements	30,050	29,847
Land	7,654	7,110
Machinery and equipment	136,716	118,056
Furniture, fixtures, and automobiles	17,561	16,385
Construction in progress	55,126	58,145
Total property, plant, and equipment	337,951	318,667
Less accumulated depreciation	(139,710)	(133,328)
Total property, plant, and equipment, net	$ 198,241	$ 185,339

As of June 30, 2018 and December 31, 2017, the Company had $2.1 million and $2.3 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® indefinite lived intangible assets in determining if there is an impairment of these related fixed assets (see Note 8).

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Note 11. Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consisted of the following:

	June 30, 2018	December 31, 2017
	(in thousands)	
Accrued customer fees and rebates	$ 15,664	$ 15,981
Accrued payroll and related benefits	18,190	15,680
Accrued product returns, current portion	4,627	4,133
Other accrued liabilities	6,948	5,132
Total accrued liabilities	45,429	40,926
Accounts payable	21,663	16,629
Total accounts payable and accrued liabilities	$ 67,092	$ 57,555

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Note 12. Debt

Debt consists of the following:

	June 30, 2018	December 31, 2017
	(in thousands)	
Loans with East West Bank		
Line of credit facility due December 2018	$ —	$ —
Equipment loan due January 2019	898	1,668
Mortgage payable due February 2021	3,535	3,577
Equipment loan due June 2021	3,673	4,286
Equipment line of credit due December 2022	8,000	—
Mortgage payable due October 2026	3,494	3,524
Mortgage payable due June 2027	8,871	8,936
Loans with Cathay Bank		
Line of credit facility due May 2020	—	—
Acquisition loan due April 2019	14,053	15,073
Mortgage payable due August 2027	7,712	7,795
Loans with Bank of Nanjing		
Working capital loan due June 2019	260	—
Loans with Seine-Normandie Water Agency		
French government loan 1 paid March 2018	—	17
French government loan 2 due June 2020	54	85
French government loan 3 due July 2021	238	239
Payment Obligation to Merck	573	599
Equipment under Capital Leases	1,225	1,357
Total debt and capital leases	52,586	47,156

Less current portion of long-term debt and capital leases	18,891	6,312
Long-term debt and capital leases, net of current portion	$ 33,695	$ 40,844

As of June 30, 2018, the fair value of the loans approximates their carrying amount. The interest rate used in the fair value estimation was determined to be a Level 2 input. For certain loans with East West Bank, the Company has entered into fixed interest rate swap contracts to exchange the variable interest rates for fixed interest rates over the life of certain debt instruments without the exchange of the underlying notional debt amount. The interest rate swap contracts do not qualify for hedge accounting and are recorded at fair value based on Level 2 inputs. These swap contacts have an aggregate fair value of $0.5 million and $0.1 million as of June 30, 2018 and December 31, 2017, respectively. The change in fair value is recorded in other income (expense) in the Company’s condensed consolidated statement of operations.

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Loans with East West Bank

Equipment Credit Line—Due December 2022

In June 2018, the Company drew down $8.0 million on the equipment credit line from East West Bank, which is due in December 2022. The loan bears a variable interest rate at the Prime Rate as published by The Wall Street Journal. Subsequent to the quarter end, 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 5.87% 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 will be recorded at fair value based on Level 2 inputs. As of June 30, 2018, the Company had $8.0 million outstanding under this facility.

Covenants

At June 30, 2018 and December 31, 2017, 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 requirements, 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 2022. The cost of equipment under capital leases was $1.6 million and $1.6 million at June 30, 2018 and December 31, 2017, respectively.

Note 13. Income Taxes

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(in thousands)			
Income (loss) before taxes	$ (4,116)	$ 3,173	$ (13,146)	$ 4,677
Income tax expense (benefit)	(1,326)	1,201	(3,110)	1,812
Net income (loss)	$ (2,790)	$ 1,972	$ (10,036)	$ 2,865
Income tax provision as a percentage of income before income taxes	32.2 %	37.9 %	23.7 %	38.7 %

The decrease in the Company's effective tax rate for the three and six months ended June 30, 2018 was primarily due to the Tax Act, which was enacted on December 22, 2017. The Tax Act, among other things, reduces the statutory U.S. federal corporate income tax rate from 35% to 21% and requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred. In March 2018, the FASB issued ASU No. 2018-05 to incorporate Staff Accounting Bulletin, or SAB 118, pursuant to which the Company's final analysis will be completed over a one-year measurement period ending December 22, 2018, and any adjustments during this measurement period will be included in net earnings from continuing operations as an adjustment to income tax expense in the reporting period when such adjustments are determined. During the three and six months ended June 30, 2018, the Company has made no changes to the provisional amounts recorded at December 31, 2017. The Company will continue to refine its calculations as additional analysis and changes to certain amounts and estimates are completed and tax returns are filed. The Company's estimates may also be affected as it gains a more thorough understanding of the tax law.

During the three months ended June 30, 2018, the Company recognized a discrete tax benefit of $1.3 million for previously unrecognized tax benefits upon a favorable state audit resolution.

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Effective January 1, 2018, the Company adopted ASU No. 2016-16, Intra-Entity Transfers of Assets Other Than Inventory, pursuant to which the income tax consequences of intra-entity transfer of an asset other than inventory is required to be recognized in the period in which the transfer occurs. The Company adopted the standard on a modified retrospective basis resulting in an increase of deferred tax assets and the beginning balance of retained earnings by $0.5 million, respectively.

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.

The Company has discontinued recognizing AFP income tax benefits by recording a full valuation allowance until it is determined that it is more likely than not that AFP will generate sufficient taxable income to realize its deferred income tax assets.

Note 14. Stockholders’ Equity

The changes in stockholders’ equity for the six months ended June 30, 2018, consisted of the following:

	Six Months Ended June 30, 2018

	(in thousands)
Stockholders' equity as of December 31, 2017	$ 337,329
Beginning balance adjustment as a result of the adoption of new accounting standards	582
Net loss	(10,036)
Other comprehensive loss	(1,066)
Net proceeds from equity plans, net of withholding tax payments	(294)
Share-based compensation expense	8,862
Purchase of treasury stock	(14,851)
Stockholders' equity as of June 30, 2018	$ 320,526

Share Buyback Program

Pursuant to the Company's share buyback program, the Company purchased 430,137 and 837,741 shares of its common stock during the three and six months ended June 30, 2018, for total consideration of $7.2 million and $14.8 million, respectively. The Company purchased 579,388 and 1,112,282 shares of its common stock during the three and six months ended June 30, 2017, for total consideration of $9.0 million and $17.2 million, respectively.

On May 7, 2018, the Company's Board of Directors authorized an increase of $20.0 million to the Company's share buyback program, which is expected to continue for an indefinite period of time. The primary goal of the program is to offset dilution created by the Company's equity compensation programs.

Purchases are made through 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

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requirements of the SEC. The timing and actual number of shares repurchased will depend on a variety of factors including price, corporate and regulatory requirements, and other conditions. These repurchased shares are accounted for under the cost method and are included as a component of treasury stock in the Company's consolidated balance sheets.

The 2015 Equity Incentive Plan

As of June 30, 2018, the Company reserved an aggregate of 4,659,989 shares of common stock for future issuance under the 2015 Equity Incentive Plan, or the 2015 Plan. In January 2018, an additional 1,165,590 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 and directors. Under these standards, the fair value of option awards and the option components of the Employee Stock Purchase Plan 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 at each balance sheet date. The portion that is ultimately expected to vest is amortized and recognized in compensation expense on a straight-line basis over the requisite service period, generally from the grant date to the vesting date.

The weighted-averages for key assumptions used in determining the fair value of options granted during the three and six months ended June 30, 2018 and 2017, are as follows:

	Three Months Ended June 30,	Six Months Ended June 30,

	2018		2017		2018		2017	
Average volatility	41.7	%	40.2	%	39.9	%	37.0	%
Risk-free interest rate	2.8	%	1.5	%	2.7	%	2.1	%
Weighted-average expected life in years	4.9		3.0		5.7		5.4	
Dividend yield rate	—	%	—	%	—	%	—	%

A summary of option activity under all plans for the six months ended June 30, 2018, 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, 2017	10,898,701	$ 14.65		
Options granted	1,086,414	20.16		
Options exercised	(200,120)	12.55		
Options cancelled	(124,129)	13.21		
Options expired	(11,625)	31.60		
Outstanding as of June 30, 2018	11,649,241	$ 15.20	4.80	$ 17,152
Exercisable as of June 30, 2018	8,343,518	$ 15.09	3.58	$ 12,499

(1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the estimated fair value of the Company’s common stock for those awards that have an exercise price below the estimated fair value at June 30, 2018.

For the three and six months ended June 30, 2018, the Company recorded expenses of $1.9 million and $4.3 million, respectively, related to stock options granted to employees under all plans and expenses of $0.2 million and $0.3 million,

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respectively, related to stock options granted to the Board of Directors under all plans. For the three and six months ended June 30, 2017, the Company recorded expenses of $2.0 million and $4.0 million, respectively, related to stock options granted to employees under all plans and expenses of $0.2 million and $0.3 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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(in thousands, except per share data)			
Weighted-average grant date fair value per option share	$ 6.53	$ 5.01	$ 7.79	$ 4.92
Intrinsic value of options exercised	277	3,037	1,338	3,062
Cash received from options exercised	650	8,643	2,511	8,739
Total fair value of the options vested during the year	1,383	1,424	7,790	6,205

A summary of the status of the Company's non-vested options as of June 30, 2018, and changes during the six months ended June 30, 2018, is presented below:

	Options	Weighted-Average Grant Date Fair Value
Non-vested as of December 31, 2017	4,310,241	$ 4.21
Options granted	1,086,414	7.79
Options vested	(1,966,803)	3.96
Options forfeited	(124,129)	4.82
Non-vested as of June 30, 2018	3,305,723	5.47

As of June 30, 2018, there was $14.5 million of total unrecognized compensation cost, net of forfeitures, related to non-vested stock option based compensation arrangements granted under all plans. The cost is expected to be recognized over a weighted-average period of 2.5 years and will be adjusted for future changes in estimated

forfeitures.

Restricted Stock Units

The Company grants restricted stock units, or RSUs, to certain employees and members of the Board of Directors with a vesting period of up to five years. 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 and six months ended June 30, 2018, the Company recorded expenses of $1.9 million and $3.6 million, respectively, related to RSU awards granted to employees under all plans and expenses of $0.2 million and $0.3 million, respectively, related to RSU awards granted to the Board of Directors. During the three and six months ended June 30, 2017, the Company recorded expenses of $1.7 million and $3.7 million, respectively, related to RSU awards granted to employees under all plans and expenses of $0.2 million and $0.3 million, respectively, related to RSU awards granted to the Board of Directors.

As of June 30, 2018, there was $16.0 million of total unrecognized compensation cost, net of forfeitures, related to non-vested RSU-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.

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Information relating to RSU grants and deliveries is as follows:

	Total RSUs Issued	Total Fair Market Value of RSUs Issued as Compensation(1) (in thousands)
RSUs outstanding at December 31, 2017	1,392,781	
RSUs granted	435,474	$ 8,469
RSUs forfeited	(45,431)	
RSUs vested(2)	(550,587)	
RSUs outstanding at June 30, 2018	1,232,237	

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

(2) Of the vested RSUs, 199,868 shares of common stock were surrendered to fulfill tax withholding obligations.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(in thousands)			
Cost of revenues	$ 981	$ 897	$ 2,141	$ 2,028
Operating expenses:				
Selling, distribution, and marketing	104	65	211	149
General and administrative	2,743	2,985	5,636	5,768
Research and development	368	351	874	804
Total share-based compensation	$ 4,196	$ 4,298	$ 8,862	$ 8,749

Note 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. Total employer contributions for the three and six months ended June 30, 2018 were approximately $0.3 million and $0.6 million, respectively, compared to the prior year expense of $0.2 million and $0.5 million for the three and six months ended June 30, 2017, 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 AFP employee turnover rate.

The liability under the plan is based on a discount rate of 1.60% as of June 30, 2018 and December 31, 2017, 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 $2.1 million and $2.1 million at June 30, 2018 and December 31, 2017, respectively. The Company recorded an immaterial amount of expense under the plan for the three months ended

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June 30, 2018, and $0.1 million for the six months ended June 30, 2018. The Company recorded an immaterial amount of expense under the plan for the three months ended June 30, 2017, and $0.1 million for the six months ended June 30, 2017.

Note 16. Commitments and Contingencies

Supply Agreement with MannKind Corporation

On July 31, 2014, the Company entered into a supply agreement with MannKind Corporation, or MannKind, or the Supply Agreement, pursuant to which the Company agreed to manufacture for and supply to MannKind certain quantities of recombinant human insulin, or RHI API for use in MannKind's product Afrezza®. In January 2015, the Company entered into a supply option agreement with MannKind, or the Option Agreement, pursuant to which MannKind has the option to purchase additional RHI API. The Supply Agreement and the Option Agreement were subsequently amended in November 2016. For the year ended December 31, 2017, sales of RHI API to MannKind totaled $3.2 million, which fulfilled the 2017 commitment of RHI API under the amended Supply Agreement. Under the Option Agreement, the Company recognized the cancellation fee for 2018 of $0.9 million in net revenues in its consolidated statement of operations for the year ended December 31, 2017. For the three and six months ended June 30, 2018, sales of RHI API to MannKind totaled $5.3 million. The Company did not have any sales of RHI API to MannKind for the three and six months ended June 30, 2017.

Collaboration Agreements with Medical Device Manufacturers

In August 2014, the Company 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 June 30, 2018, the Company has paid an upfront payment of $0.5 million and $1.5 million in milestone payments under this agreement, which were classified as research and development expense as the milestones were met. The Company is obligated to pay up to an additional $0.5 million if certain research and development milestones are met. As of June 30, 2018, 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 intends to enter into a commercial supply agreement with such medical device manufacturer for a minimum purchase of 1.0 million units during the first 12 months.

In October 2017, the Company 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 for a total of $1.6 million. As of June 30, 2018, the Company has paid and expensed an upfront payment of $0.4 million, and is obligated to pay up to an additional $1.2 million, if certain research and development milestones are met. As of June 30, 2018, no such obligation existed for the milestones. In addition, 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 intends to enter into a commercial supply agreement with such medical device manufacturer under which the Company is obligated to pay an additional $1.0 million if certain commercial development milestones are met and to purchase a minimum of 100,000 units per year for three years.

Operating Lease Agreements

The Company leases real and personal property in the normal course of business under various non-cancelable operating leases. The Company, at its option, can renew a substantial portion of its leases, at the market rate, for various renewal periods ranging from one to six years. Rental expense under these leases for the three and six months ended June 30, 2018, was approximately $1.0 million and $2.1 million, respectively, compared to $0.9 million and $1.7 million for the three and six months ended June 30, 2017, respectively.

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Purchase Commitments

As of June 30, 2018, the Company has entered into commitments to purchase equipment and raw materials for an aggregate amount of approximately $44.1 million. The Company anticipates that most of these commitments with remaining terms in excess of one year will be fulfilled by 2019. In addition, the Company is obligated to pay a supplier certain payments up to $1.5 million based on the sale of one of the Company's products.

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 completed its investment of 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 agreements, 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.

Note 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

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District Court for further proceedings consistent with its opinion. The Federal Circuit panel affirmed the Massachusetts District Court's holding in the Company's favor that the Company does not infringe under 35 U.S.C. 271(g), and the panel vacated the grant of summary judgment to the extent it was based on the determination that the Company's activities fall within the 35 U.S.C. 271(e)(1) safe harbor. The Federal Circuit panel also left to the Massachusetts District Court's discretion whether to reconsider on remand its denial of leave for Momenta and Sandoz to amend their infringement contentions. On January 11, 2016, the Company filed a Petition for Rehearing En Banc with the Federal Circuit. On February 17, 2016, the Federal Circuit denied the Company's Petition, and the Federal Circuit issued its mandate on February 24, 2016, whereby the case returned to the Massachusetts District Court for further proceedings.

On March 18, 2016, the parties filed a joint status report with the Massachusetts District Court. On June 21, 2016, the Massachusetts District Court granted Momenta and Sandoz's Motion for Leave to Amend its Infringement Contentions. In light of Momenta and Sandoz's Amended Infringement Contentions and recent changes in Supreme Court precedent since the case was stayed in 2012, the Company sought to amend its Non-Infringement and Invalidity Contentions.

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. 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. Oppositions to the motions for summary judgment were filed on May 5, 2017. Replies in support of the motions for summary judgment were filed on May 19, 2017. On June 16, 2017, the District Court issued an order denying the summary judgment motions. The District Court also denied Plaintiffs' motion for summary judgment dismissing the Company's defenses of implied waiver and equitable estoppel, and denied Plaintiffs' alternative request for a separate hearing on the implied waiver and equitable estoppel defenses holding that the defenses would be submitted to the jury for an advisory verdict.

Trial in the Massachusetts District Court on all claims and defenses began on July 10, 2017. On July 21, 2017, the jury returned a unanimous verdict finding that although the Company's tests infringed the asserted patent, the patent was

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invalid for lack of enablement and lack of written description and the jury further found that Plaintiffs are entitled to zero ($0) damages. As for the Company's defenses of implied waiver and equitable estoppel, the jury found that Plaintiffs waived their right to recover for infringement of the asserted patent and that Plaintiffs are estopped from enforcing the asserted patent against the Company. The verdict on these equitable defenses was briefed by the parties and submitted to the Court. In the post-trial briefing, the Company requested the Court to adopt the findings of the jury on the equitable defenses, and to set aside the jury's finding of infringement. In Plaintiffs' post-trial briefing, Plaintiffs requested a new trial, and requested the Court to set aside the jury's finding that the asserted patent was invalid for lack of enablement and lack of written description. In a February 7, 2018 Memorandum and Order and with respect to the equitable defenses, the Court found that Plaintiffs waived their right to enforce the '866 patent against the Company for its use of one of its test, and are equitably estopped from enforcing the '866 patent against the Company for its use of that same test. The Court also found that Plaintiffs have not waived their right to enforce the '866 patent against the Company for its use of a second test, and are not equitable estopped from enforcing the '866 patent against the Company for its use of that same second test. On February 7, 2018, the Court also denied all other post-trial motions. On March 20, 2018, the Court entered final judgment in this matter reflecting the jury's verdict and the Court's February 7, 2018 Memorandum and Order.

On March 23, 2018, the Company filed a motion to enforce liability on the bonds related to the preliminary injunction issued in October 2011, stayed in January 2012, and reversed by the Federal Circuit in August 2012. On March 27, 2018, Plaintiffs filed a notice of appeal with the Federal Circuit. On April 3, 2018, Plaintiffs filed a motion with the District Court to defer decision on the Company's motion to enforce liability on the bonds pending their appeal. On July 13, 2018, the District Court allowed Momenta's motion to defer consideration of the Company's motion to enforce liability on the bonds until the appeal is resolved. The appeal is ongoing.

The Company will continue to vigorously defend the jury's verdict, including against any potential appeal by the Plaintiffs. The Company intends to continue to pursue its attempt to collect the $100.1 million bond posted by Momenta and Sandoz.

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 filed their respective appeal briefs with the Ninth Circuit. On November 10, 2016, the Ninth Circuit heard oral argument on the appeal.

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.

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On July 20, 2015, the Company filed with the Ninth Circuit a notice of appeal of the California District Court's dismissal of the case, and Aventis filed a notice of cross-appeal on August 5, 2015. On November 12, 2015, Aventis filed a pleading asking that the California District Court impose various monetary penalties and fines against the Company, including disgorgement of enoxaparin revenues and attorneys' fees expended by Aventis in this action, based on Aventis's allegations that the Company engaged in sanctionable conduct. On November 23, 2015, the California District Court issued an order setting forth a procedure for sanctions proceedings as to the Company as well as its outside counsel. On December 24, 2015, the Company filed a pleading with the California District Court opposing the imposition of sanctions, and on January 20, 2016, Aventis filed a response pleading further pressing for the imposition of sanctions. On May 4, 2016, the California District Court issued three orders requesting that the Company and its outside counsel file a document showing cause as to why sanctions should not be imposed and to set up a conference call with the partiers and the court to discuss whether any discovery and/or a hearing is necessary. On June 13, 2016, the Company and its outside counsel each filed responses to the court's order to show cause as to why sanctions should not be imposed. On July 21, 2016, Aventis filed a response contending that the court should impose sanctions. On February 10, 2017, the Court held a show cause hearing regarding the potential imposition of sanctions and took the matter under submission. On September 18, 2017, the District Court issued its decision that no sanctions will be imposed on either the Company or its counsel.

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. On November 10, 2016, the Ninth Circuit heard oral argument on the appeals.

On May 11, 2017, the Ninth Circuit issued an opinion affirming the California District Court's dismissal of the action for lack of subject matter jurisdiction; dismissing as moot Aventis's appeal from the District Court's denial of its motion for summary judgment on the issue of the adequacy of the Company's notice letter to the government; reversing the District Court's denial of Aventis's motion for attorneys' fees; and remanding the case to the District Court for resolution of the attorneys' fees issue. On July 14, 2017, Aventis filed an application with the District Court for entitlement to attorneys' fees and expenses. The Company intends to continue to vigorously defend against any such imposition of attorneys' fees or sanctions.

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

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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 20, 2017, Defendants filed their supplemental motion to dismiss and the Company filed its opposition on May 4, 2017. On March 19, 2018, the District Court entirely denied the Defendants' motion to dismiss. On April 19, 2018, the Defendants filed a motion to seek interlocutory appeal of the District Court's motion to dismiss opinion. The Company filed its opposition to interlocutory appeal on May 1, 2018.

On March 19, 2018, the District Court granted the parties' joint motion to extend the case schedule and accepted their proposed dates with a few modifications. Under the schedule, fact discovery will close on October 1, 2018. Summary judgment arguments are due on April 26, 2019, oppositions are due on June 14, 2019, and replies are due on July 10, 2019. Trial is scheduled for September 9, 2019.

Epinephrine Injection, 0.1 mg/mL Litigation

On June 28, 2018, Belcher Pharmaceuticals, LLC, or Belcher initiated a lawsuit by filing a complaint against IMS for infringement of U.S. Patent No. 9,283,197 with regard to IMS's New Drug Application No. 211363, filed under 21 U.S.C. § 355(b)(2) of the Hatch-Waxman Act, for FDA approval to manufacture and sell 0.1 mg/mL epinephrine injections. On July 20, 2018, the Company filed a motion to dismiss Belcher's complaint for patent infringement under Federal Rule of Civil Procedure 12(b)(6). Belcher's opposition to the Company's motion to dismiss is currently due on August 17, 2018.

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.

Note 18. Subsequent Events and Related-Party Transactions

ANP Private Placement

In July 2018, ANP completed a private placement of its equity for aggregate gross proceeds of approximately $57.2 million. In connection with the private placement, all of the executive officers of the Company and Stephen Shohet, Howard Lee, and Richard Koo, directors of the Company, entered into subscription agreements (each, a "Subscription Agreement") for the indirect investment in ANP. These Subscription Agreements were transacted either through an investment in Amphastar Cayman, a Cayman Islands limited liability company, or Qianqia, a Chinese partnership. The total aggregate gross proceeds from such executive officers and directors were approximately $23.5 million. The Company has retained approximately 58% of the equity interest of ANP immediately after the private placement.

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

The following is a discussion and analysis of 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, 2017, 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 as well as insulin API products. We currently manufacture and sell over 20 products.

We are currently developing a portfolio of 15 generic abbreviated new drug applications, or ANDAs, three generic biosimilar product candidates and six proprietary product candidates, which are in various stages of development and target a variety of indications. With respect to these product candidates, we have two ANDAs, and two NDAs on file with the FDA.

Our largest products by net revenues currently include medroxyprogesterone acetate, naloxone hydrochloride injection, lidocaine jelly and sterile solution, phytonadione, and enoxaparin sodium injection. We launched neostigmine methysulfate in the fourth quarter of 2017, medroxyprogesterone acetate in the first quarter of 2018. We also launched isoproterenol hydrochloride injection in the third quarter of 2018.

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 are in the process of transferring the manufacturing of these products to our facilities in California, which will require approvals from the UK Medicines and Healthcare products Regulatory Agency before we can relaunch the products.

In July 2018, ANP completed a private placement of its equity to accredited investors for aggregate gross proceeds of approximately $57.2 million. In connection with the private placement, all of the executive officers of the Company and Stephen Shohet, Howard Lee, and Richard Koo, directors of the Company, entered into subscription agreements for the indirect investment in ANP. The total aggregate gross proceeds from such executive officers and directors were approximately $23.5 million. We have retained approximately 58% of the equity interest of ANP immediately after the private placement. ANP intends to use the net proceeds from the private placement for its business expansion plans.

Business Segments

As of June 30, 2018, 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, naloxone, phytonadione, lidocaine, as well as various other critical and non-critical care drugs. The API segment currently manufactures and distributes recombinant human insulin, or 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 Note 5 of Notes to Condensed Consolidated Financial Statements of this Quarterly Report on Form 10-Q.

Results of Operations

Three Months Ended June 30, 2018 Compared to Three Months Ended June 30, 2017

Net revenues

	Three Months Ended June 30, 2018	2017	Change Dollars	%
	(in thousands)			
Net revenues				
Finished pharmaceutical products	$ 63,241	$ 63,765	$ (524)	(1) %
API	7,799	1,422	6,377	448 %
Total net revenues	$ 71,040	$ 65,187	$ 5,853	9 %
Cost of revenues				
Finished pharmaceutical products	$ 35,500	$ 34,899	$ 601	2 %
API	9,384	3,541	5,843	165 %
Total cost of revenues	$ 44,884	$ 38,440	$ 6,444	17 %
Gross profit	$ 26,156	$ 26,747	$ (591)	(2) %
as % of net revenues	37 %	41 %		

The decrease in net revenues of the finished pharmaceutical products for the three months ended June 30, 2018, was primarily due to the following changes:

	Three Months Ended June 30, 2018	2017	Change Dollars	%
	(in thousands)			
Finished pharmaceutical products net revenues				
Naloxone	$ 11,133	$ 10,261	$ 872	8 %
Phytonadione	10,806	10,003	803	8 %

Lidocaine	10,010	9,334	676	7	%
Enoxaparin	8,715	8,288	427	5	%
Medroxyprogesterone	6,365	—	6,365	N/A	
Epinephrine	3,687	10,648	(6,961)	(65)	%
Other finished pharmaceutical products	12,525	15,231	(2,706)	(18)	%
Total finished pharmaceutical products net revenues	$ 63,241	$ 63,765	$ (524)	(1)	%

We launched medroxyprogesterone acetate in a vial form in January 2018 and in a pre-filled syringe form in February 2018. These products were both approved by the FDA in November 2017.

The increase in sales of naloxone was primarily driven by higher unit volumes. The increase in sales of phytonadione and lidocaine were driven by a higher average selling price. The increase in sales of enoxaparin was driven by higher unit volumes, resulting in an increase of approximately $1.2 million, which was partially offset by a lower average selling price. We anticipate that sales of naloxone and enoxaparin will continue to fluctuate in the future as a result of competition.

Sales of epinephrine decreased primarily as a result of the discontinuation of our epinephrine injection, USP vial product in the second quarter of 2017 in accordance with the FDA’s request. Our epinephrine injection, USP vial product, was marketed under the “grandfather” exception to the FDA’s “Prescription Drug Wrap-Up” program. In the second quarter

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of 2017, we recognized $9.9 million in net revenues for the sale of the discontinued vial product. The remainder of our epinephrine sales was from our pre-filled syringe product, which remains on the market.

Sales of API increased primarily due to the timing of customer purchases and, in particular, MannKind purchases of RHI API. We anticipate that sales of API will continue to fluctuate and will likely decrease due to the inherent uncertainties related to sales to MannKind. In addition, most of our API sales are denominated in Euros, and the fluctuation in the value of the Euro versus the U.S. 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. We had no significant backlog as of June 30, 2018. 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

Gross margins declined primarily due to the effects of increased production expenses and the discontinuation of our epinephrine injection, USP vial product in the second quarter of 2017. Production expenses increased due to increased labor costs resulting from the implementation of new quality standards and increased hourly rates. These trends were partially offset by sales of higher margin medroxyprogesterone acetate products. In addition, for the three months ended June 30, 2018, a charge of $1.2 million was recorded to adjust certain inventory items and related purchase commitments to their net realizable value, as compared with $4.7 million recorded for the three months ended June 30, 2017.

In June 2018, we received FDA approval for our ANDA supplement for the manufacture of semi-purified heparin at ANP, our subsidiary in China, and the manufacture of heparin sodium at IMS, our subsidiary in South El Monte, California. The cost of heparin, which is the starting material for enoxaparin, has increased and is expected to increase further putting downward pressure on our gross margins. However, we believe that this trend will be offset by sales of our higher-margin products, such as medroxyprogesterone acetate, neostigmine, and isoproterenol that were recently launched.

Selling, distribution and marketing, and general and administrative

Three Months Ended

	June 30, 2018	2017	Change Dollars	%
	(in thousands)			
Selling, distribution, and marketing	$ 1,876	$ 1,596	$ 280	18 %
General and administrative	$ 11,669	$ 12,234	$ (565)	(5) %

The increase in selling, distribution, and marketing expenses is primarily due to increased freight costs and increased expenses at the ANP business. The decrease in general and administrative expense was primarily due to lower legal expenses compared to the same period in 2017 (see Note 17 to the condensed consolidated financial statements for more information regarding litigation matters).

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 and an increase in legal fees associated with patent challenges.

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Research and development

	Three Months Ended June 30,		Change	
	2018	2017	Dollars	%
	(in thousands)			
Salaries and personnel-related expenses	$ 4,294	$ 3,490	$ 804	23 %
Pre-launch inventory	835	—	835	N/A
Clinical trials	1,218	1,216	2	0 %
FDA fees	235	85	150	176 %
Testing, operating and lab supplies	6,292	4,003	2,289	57 %
Depreciation	1,356	1,111	245	22 %
Other expenses	1,238	827	411	50 %
Total research and development expenses	$ 15,468	$ 10,732	$ 4,736	44 %

Research and development costs consist primarily of costs associated with the research and development of our product candidates. We expense research and development costs as incurred. Pre-launch inventory expense relates to the production of Primatene® Mist ahead of our planned launch later this year.

Testing, operating, and lab supplies increased due to expenditures on materials for our pipeline products, particularly production of APIs for our ANP facility.

We expect that research and development expenses will increase on an annual basis due increased clinical trial costs related to our biosimilar and inhalation product candidates. These expenditures will include costs of APIs developed internally and purchased externally, the cost of purchasing reference listed drugs and the costs of performing the clinical trials.

Provision for income tax expense (benefit)

	Three Months Ended June 30,		Change	
	2018	2017	Dollars	%
	(in thousands)			
Income tax expense (benefit)	$ (1,326)	$ 1,201	$ (2,527)	NM
Effective tax rate	32 %	38 %		

The decrease in the effective tax rate for the three months ended June 30, 2018, was primarily due to the Tax Act, which was enacted on December 22, 2017. The Tax Act reduces the statutory U.S. federal corporate income tax rate from 35% to 21%. During the three months ended June 30, 2018, we recognized a discrete tax benefit for previously unrecognized tax benefits upon a favorable state audit resolution.

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Six Months Ended June 30, 2018 Compared to Six Months Ended June 30, 2017

Net revenues

	Six Months Ended June 30, 2018	2017	Change Dollars	%
	(in thousands)			
Net revenues				
Finished pharmaceutical products	$ 116,358	$ 119,699	$ (3,341)	(3) %
API	13,075	2,158	10,917	506 %
Total net revenues	$ 129,433	$ 121,857	$ 7,576	6 %
Cost of revenues				
Finished pharmaceutical products	$ 68,892	$ 66,523	$ 2,369	4 %
API	17,324	5,759	11,565	201 %
Total cost of revenues	$ 86,216	$ 72,282	$ 13,934	19 %
Gross profit	$ 43,217	$ 49,575	$ (6,358)	(13) %
as % of net revenues	33 %	41 %		

The decrease in net revenues of the finished pharmaceutical products for the six months ended June 30, 2018, was primarily due to the following changes:

	Six Months Ended June 30, 2018	2017	Change Dollars	%
	(in thousands)			
Finished pharmaceutical products net revenues				
Naloxone	$ 20,060	$ 21,200	$ (1,140)	(5) %
Phytonadione	19,987	17,890	2,097	12 %
Lidocaine	19,792	17,622	2,170	12 %
Enoxaparin	15,722	18,698	(2,976)	(16) %
Medroxyprogesterone	9,071	—	9,071	N/A
Epinephrine	6,910	20,222	(13,312)	(66) %
Other finished pharmaceutical products	24,816	24,067	749	3 %
Total finished pharmaceutical products net revenues	$ 116,358	$ 119,699	$ (3,341)	(3) %

We launched medroxyprogesterone acetate in a vial form in January 2018 and in a pre-filled syringe form in February 2018. These products were both approved by the FDA in November 2017.

The decrease in sales of naloxone was primarily driven by lower unit volumes. The increase in sales of phytonadione was driven by a higher average selling price, which resulted in an increase of approximately $2.9 million, as partially offset by lower unit volumes. Higher average selling price of lidocaine led to an increase in sales of approximately $1.3 million, while higher unit volumes caused the remaining increase in sales. The decrease in sales of enoxaparin was primarily driven by lower average selling price. We anticipate that the sales of naloxone and enoxaparin will continue to fluctuate in the future as a result of competition.

Sales of epinephrine decreased primarily as a result of the discontinuation of our epinephrine injection, USP vial product in the second quarter of 2017 in accordance with the FDA's request. Our epinephrine injection, USP vial product, was marketed under the "grandfather" exception to the FDA's "Prescription Drug Wrap-Up" program. In fiscal 2017, we recognized $17.8 million in net revenues for the sale of the discontinued vial product. The remainder of our epinephrine sales was from our pre-filled syringe product, which remains on the market.

Sales of API increased primarily due to the timing of customer purchases, and in particular, MannKind purchases of RHI API. We anticipate that sales of API will continue to fluctuate and will likely decrease due to the inherent uncertainties related to sales to MannKind. In addition, most of our API sales are denominated in Euros, and the fluctuation in the

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value of the Euro versus the U.S. 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. We had no significant backlog as of June 30, 2018. 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

Changes in cost of revenues and the resulting gross margins decline were primarily due to increased production expenses and the discontinuation of our epinephrine injection, USP vial product in the second quarter of 2017. Production expenses increased due to increased labor costs resulting from the implementation of new quality standards and increased hourly rates. This trend was partially offset by the sales of higher margin medroxyprogesterone acetate products which were launched in the first quarter of 2018. In addition, for the six months ended June 30, 2018, a charge of $3.1 million was recorded to adjust certain inventory items and related purchase commitments to their net realizable value, as compared with $5.1 million recorded for the six months ended June 30, 2017.

In June 2018, we received FDA’s approval of our ANDA supplement for the manufacture of semi-purified heparin at ANP, our subsidiary in China, and the manufacture of heparin sodium at IMS, our subsidiary in South El Monte, California. The cost of heparin, which is the starting material for enoxaparin, has increased and is expected to increase further putting downward pressure on our gross margins. However, we believe that this trend will be offset by sales of our higher-margin products, such as medroxyprogesterone acetate, neostigmine, and isoproterenol that were recently launched, as well as sodium nitroprusside which we plan to launch.

Selling, distribution and marketing, and general and administrative

	Six Months Ended June 30,		Change	
	2018	2017	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	$ 3,597	$ 3,075	$ 522	17 %
General and administrative	$ 22,667	$ 23,572	$ (905)	(4) %

The increase in selling, distribution, and marketing expenses is primarily due to increased freight costs and increased expenses at the ANP business. The decrease in general and administrative expense was primarily due to lower legal expenses compared to the same period in 2017 (see Note 17 to the condensed consolidated financial statements for more information regarding litigation matters).

Research and development

	Six Months Ended June 30,		Change		
	2018	2017	Dollars	%	
	(in thousands)				
Salaries and personnel-related expenses	$ 8,379	$ 7,470	$ 909	12	%
Pre-launch inventory	1,573	711	862	121	%
Clinical trials	2,026	2,051	(25)	(1)	%
FDA fees	1,461	100	1,361	1,361	%
Testing, operating and lab supplies	11,063	7,762	3,301	43	%
Depreciation	2,576	2,185	391	18	%
Other expenses	2,650	1,703	947	56	%
Total research and development expenses	$ 29,728	$ 21,982	$ 7,746	35	%

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Research and development costs consist primarily of costs associated with the research and development of our product candidates. We expense research and development costs as incurred. Pre-launched inventory expenses relates to the production of Primatene® Mist and purchases of APIs for an ANDA candidate ahead of our planned launches later this year.

Testing, operating, and lab supplies increased due to expenditures on materials for our pipeline products, particularly production of APIs for our ANP facility. FDA fees increased due to the NDA and ANDA filing fees for products we currently market or previously marketed under the grandfather exception.

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 costs will increase significantly over the next several quarters and years.

Gain on sale of intangible assets

	Six Months Ended June 30,		Change	
	2018	2017	Dollars	%
	(in thousands)			
Gain on sale of intangible assets	$ —	$ (2,643)	$ 2,643	(100) %

In February 2017, we sold the ANDAs that we acquired in March 2016 and recognized a gain of $2.6 million (see Note 8).

Provision for income tax expense (benefit)

	Six Months Ended June 30,		Change	
	2018	2017	Dollars	%
	(in thousands)			

Income tax expense (benefit)	$ (3,110)		$ 1,812		$ (4,922)	NM
Effective tax rate	24	%	39	%		

The decrease in the effective tax rate for the six months ended June 30, 2018, was primarily due to the Tax Act, which was enacted on December 22, 2017. The Tax Act reduces the statutory U.S. federal corporate income tax rate from 35% to 21%. During the six months ended June 30, 2018, we recognized a discrete tax benefit for previously unrecognized tax benefits upon a favorable state audit resolution.

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 June 30, 2018, our foreign subsidiaries collectively held $5.9 million in cash and cash equivalents. 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

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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.

In July 2018, ANP completed a private placement of its equity to accredited investors for aggregate gross proceeds of approximately $57.2 million. The proceeds from this private placement will be used to fund the cash requirements of the expansion of our manufacturing facility in China.

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, depositary shares, warrants, units, or debt securities. If we require or elect to seek additional capital through debt or equity financing in the future, we may not be able to raise capital on terms acceptable to us or at all. To the extent we raise additional capital through the sale of equity or convertible debt securities, the issuance of such securities will result in dilution to our stockholders. If we are required and unable to raise additional capital when desired, our business, operating results and financial condition may be adversely affected.

Working capital decreased by $38.2 million to $82.4 million at June 30, 2018, compared to $120.6 million at December 31, 2017.

Cash Flows from Operations

The following table summarizes our cash flows used in operating, investing, and financing activities for the six months ended June 30, 2018:

	Six Months Ended June 30, 2018 (in thousands)
Statement of Cash Flow Data:	
Net cash provided by (used in)	
Operating activities	$ 12,893
Investing activities	(20,509)
Financing activities	(9,718)
Effect of exchange rate changes on cash	(190)
Net decrease in cash, cash equivalents, and restricted cash	$ (17,524)

Sources and Use of Cash

Operating Activities

Net cash provided by operating activities was $12.9 million for the six months ended June 30, 2018, which included net loss of $10.0 million. Non-cash items were primarily comprised of $8.0 million of depreciation and amortization, and $8.9 million of share-based compensation expense. Operating assets and liabilities changed primarily due to the timing of sales and purchases activities in the normal course of business and the timing of the related cash receipts and disbursements.

Investing Activities

Net cash used in investing activities was $20.5 million for the six months ended June 30, 2018, primarily as a result of $24.6 million in purchases of property, machinery, and equipment, which included $8.4 million incurred in the United States, $7.0 million in France, and $9.2 million in China. The cash used was partially offset by the $4.4 million receipt of the remaining consideration of the sale of the various ANDAs in February 2017 (see Note 8 to the condensed consolidated financial statements for more information).

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Financing Activities

Net cash used in financing activities was $9.7 million for the six months ended June 30, 2018, primarily as a result of $14.9 million used to purchase treasury stock. Additionally, we made $2.8 million in principal payments on our long-term debt, and drew down $8.0 million on the equipment line of credit from East West Bank, which is due December 2022.

Indebtedness

For more information regarding our outstanding indebtedness, see Note 12 of Notes to Condensed Consolidated Financial Statements of this Quarterly Report on Form 10-Q.

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, 2017, except that our outstanding debt obligations have changed as follows:

	June 30, 2018	December 31, 2017	Change
	(in thousands)		
Short-term debt and current portion of long-term debt	$ 18,891	$ 6,312	$ 12,579
Long-term debt	33,695	40,844	(7,149)
Total debt	$ 52,586	$ 47,156	$ 5,430

As of June 30, 2018, we had $35.0 million in unused borrowing capacity under revolving lines of credit with Cathay Bank and East West Bank.

Critical Accounting Policies

The preparation of our condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the notes to the financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions. A summary of our critical accounting policies is presented in Part II, Item 7, of our Annual Report on Form 10-K for the year ended December 31, 2017.

There were no material changes to our critical accounting policies during the three and six months ended June 30, 2018, other than the adoption of ASC 606, Revenue from Contracts with Customers, or ASC 606, using the modified retrospective transition method. The adoption of ASC 606 did not have a material impact on the Company's revenue recognition or on the condensed consolidated financial statements and related disclosures. The results for the reporting period beginning after January 1, 2018, are presented in accordance with the new standard, although comparative information has not been restated and continues to be reported under the accounting standards and policies in effect for those periods.

Recent Accounting Pronouncements

For information regarding recent accounting pronouncements, see Note 2 of Notes to Condensed Consolidated Financial Statements of this Quarterly Report on Form 10-Q.

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.

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Government Regulation

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

From April 19, 2018 to April 27, 2018, two contract laboratories that provide testing services for heparin sodium raw materials were inspected. The first inspection was for the laboratory providing testing services for our current heparin supplier. There was one Form 483 observation issued. The current heparin supplier has responded to the Form 483 and we expect the response to satisfy the requirements of the FDA and that no further actions will be necessary. The second inspection was for the laboratory providing testing services of heparin sodium for the pending submission for our facility in Nanjing China. These vendors are related to our filing for the heparin sodium. There were no Form 483 observations issued. The inspections covered compliance with Good Laboratory Practice regarding the analytical testing performed for heparin sodium release.

From June 26, 2018 to June 29, 2018, our French subsidiary, AFP, had a routine inspection performed by the FDA. The routine inspection covered compliance with cGMPs. There were five Form 483 observations issued. A response was sent to the FDA within the 15 working day requirement which we expect will satisfy the requirements of the FDA and that no further actions will be necessary

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

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

Investment Risk

We regularly review the carrying value of our investments and identify and recognize losses, for income statement purposes, when events and circumstances indicate that any declines in the fair values of such investments below our accounting basis are other than temporary. As of June 30, 2018, we did not have any such investments.

As of June 30, 2018, we had $1.1 million deposited in seven banks located in China, $4.6 million deposited in one bank located in France, and $0.1 million deposited in one bank located in the United Kingdom. We also maintained $36.0 million in cash equivalents that include money market accounts, as of June 30, 2018. The remaining amounts of our cash equivalent as of June 30, 2018 are in non-interest bearing accounts.

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 June 30, 2018, we had $52.6 million in long-term debt and capital leases outstanding. Of this amount, $22.3 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 5.0% at June 30, 2018. An increase in the index underlying these rates of 1% (100 basis points) would increase our annual interest expense on the debt with variable interest rate exposure by approximately $0.2 million per year.

Foreign Currency Exchange Risk

Our finished pharmaceutical products are primarily sold in the U.S. domestic market, and 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 frequently denominated in Euros, which are subject to fluctuations relative to the U.S. Dollar, or USD.

Our Chinese subsidiary, ANP, maintains its books of record in Chinese Yuan. These books are remeasured into the functional currency of USD, using the current or historical exchange rates. The resulting currency remeasurement adjustments and other transactional foreign exchange gains and losses are reflected in our statement of operations.

Our French subsidiary, AFP, maintains its books of record in Euros. Our U.K. subsidiary, IMS UK, maintains 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.

We are also exposed to the potential earnings effects from intercompany foreign currency assets and liabilities that arise from normal trade receivables and payables and other intercompany loans.

We do not undertake hedging transactions to cover our foreign currency exposure. As of June 30, 2018, a 10%

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unfavorable change in the exchange rate of the U.S. Dollar strengthening against the foreign currencies to which we have exposure would result in approximately $1.3 million reduction of foreign currency gains, and approximately $4.3 million reduction in other comprehensive income.

As of June 30, 2018, our foreign subsidiaries had cash balances denominated in foreign currencies in the amount of $5.7 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 quarter ended June 30, 2018, 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.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The information set forth under the "Legal Proceedings" subheading in Note 17 of Notes to Consolidated Financial Statements in Part I, Item 1, of this Quarterly Report on Form 10-Q is incorporated herein by reference.

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, 2017, filed with the Securities and Exchange Commission on March 14, 2018.

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 Federal Food, Drug, and Cosmetic Act, or FFDCA. The FDA has assessed these products in a program known as the "Prescription Drug Wrap-Up" and has stated that these drugs cannot be lawfully marketed unless they comply with certain "grandfather" exceptions to the definition of "new drug" in the FFDCA. These exceptions have been strictly construed by FDA and by the courts, and the FDA has stated that it is unlikely that any of the unapproved prescription drugs on the market, including certain of our drugs, qualify for the exceptions. At any time, the FDA may require that some or all of our unapproved prescription drugs be submitted for approval and may direct us to 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 an injunction, product seizure and/or 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.

In February 2017, the FDA requested that we discontinue the manufacturing and distribution of our epinephrine injection, USP vial product, which had been marketed under the “grandfather” exception to the FDA’s Prescription Drug Wrap-Up program. We discontinued selling this product in the second quarter of 2017. For the years ended December 31, 2017, 2016, and 2015, we recognized $17.8 million, $18.6 million, and $7.8 million in net revenues for the sale of this product, respectively.

The FDA granted approval of our ANDAs for Sodium Bicarbonate injection and Calcium Chloride injection in September 2017 and May 2018, respectively.

For the years ended December 31, 2017, 2016, and 2015, we recorded net revenues of $22.0 million, $17.4 million, and $19.8 million, respectively, from our unapproved products. For the six months ended June 30, 2018 and 2017, we recorded net revenues of $14.9 million and $8.5 million, respectively from our unapproved products. Our unapproved products currently on the market include: atropine, morphine, dextrose and epinephrine prefilled syringes. We have filed two ANDAs and one NDA with respect to our remaining unapproved products in order to mitigate all risk associated with the marketing of unapproved drug products. Prior to the approval of our ANDA and NDA submissions, we continue to operate in compliance with the FDA Compliance Policy Guide, CPG Sec. 440.100 Marketed New Drugs Without Approved NDAs and ANDAs.

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Because a portion of our manufacturing takes place in China, a significant disruption in the construction or operation of our manufacturing facility in China, political unrest in China, tariffs or changes in social, political and economic conditions or in laws, regulations and policies governing foreign trade could materially and adversely affect our business, financial condition and results of operations.

We currently manufacture the starting material for Amphadase® and the API for Nitroprusside at our manufacturing facility in China, and we plan to use this facility to manufacture several of the APIs for products in our pipeline. Additionally, we intend to continue to invest in the expansion of this manufacturing facility. Our manufacturing facility and operations in China involve significant risks, including:

- disruptions in the construction of the manufacturing facility;
- interruptions to our operations in China or the inability of our manufacturing facility to produce adequate quantities of raw materials or APIs to meet our needs as a result of natural catastrophic events or other causes beyond our control such as power disruptions;
- product supply disruptions and increased costs as a result of heighten exposure to change in the policies of the Chinese government, political unrest or unstable economic conditions in China;
- the imposition of tariffs or other trade barriers as a result of changes in social, political, and economic conditions or in laws, regulations, and policies governing foreign trade, including the tariffs recently implemented and additional tariffs that have been proposed by the U.S. government on various imports from China and by the Chinese government on certain U.S. goods, the scope and duration of which, if implemented, remain uncertain;
- the nationalization or other expropriation of private enterprises by the Chinese government, which could result in the total loss of our investment in China;

Any of these matters could materially and adversely affect our business and results of operations. These interruptions or failures could impair our ability to operate our business, impede the commercialization of our product candidates or delay the introduction of new products, impact our product quality, or impair our competitive position.

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

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

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

- requirements or preferences for domestic products or solutions, which could reduce demand for our products;
- differing existing or future regulatory and certification requirements;
- management communication and integration problems resulting from cultural and geographic dispersion;
- greater difficulty in collecting accounts receivable and longer collection periods;

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- difficulties in enforcing contracts;
- difficulties and costs of staffing and managing non-U.S. operations;
- difficulty hiring and retaining appropriate personnel due to intense competition for such resources and resulting wage inflation in the cities where our operations are located;
- different labor regulations, especially in the European Union, where labor laws are generally more advantageous to employees as compared to the United States, including deemed hourly wage and overtime regulations in these locations;
- the uncertainty of protection for intellectual property rights in some countries and resulting exposure to misappropriation of intellectual property or information that is proprietary to us, our customers and other third parties;
- tariffs and trade barriers, export regulations and other regulatory and contractual limitations on our ability to sell our products;
- changes in social, political, and economic conditions or in laws, regulations and policies governing foreign trade, manufacturing, development and investment both domestically as well as in other countries and jurisdictions into which we manufacture or sell our products;
- exposure to liabilities under both U.S. and foreign laws, including export and antitrust regulations, anti-corruption and anti-money laundering laws, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, and similar applicable laws and regulations in other jurisdictions, and any trade regulations ensuring fair trade practices;
- uneven electricity supply that can negatively impact manufacturing;
- heightened risk of unfair or corrupt business practices in certain geographies and of improper or fraudulent sales arrangements that may impact financial results and result in restatements of, or irregularities in, financial statements;
- fluctuations in currency exchange rates and regulatory compliance;
- delays, inefficiencies, and other challenges inherent to efficiently managing an increased number of employees over large geographic distances, including the need to implement appropriate systems, policies, benefits, and compliance programs;
- potentially adverse tax consequences, including multiple and possibly overlapping tax structures; and
- political and economic instability, political unrest and terrorism.

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

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Enhanced trade tariffs, import restrictions, export restrictions, Chinese regulations or other trade barriers may materially harm our business.

We are continuing to expand our international operations as part of our growth strategy. In July 2018, the Trump Administration announced a list of thousands of categories of goods that could face tariffs of 10%. It is expected that these tariffs will be finalized after a public comment period ending in early September 2018. If the tariff list remains unaltered, non-U.S. sourced APIs and starting materials used in our products could be subject to a 10% tariff assessed on these goods, raising our cost of goods. Furthermore, if tariffs, trade restrictions, or trade barriers are placed on products such as ours by foreign governments, especially China, it could raise prices for our products, which may result in the loss of customers and our business, financial condition and results of operations may be harmed. Additionally, the Trump Administration continues to signal that it may alter trade agreements and terms between China and the United States, including limiting trade with China, and may impose additional tariffs on imports from China. Therefore, it is possible further tariffs may be imposed that could cover imports of APIs and starting materials used in our products, or our business may be adversely impacted by retaliatory trade measures taken by China or other countries, including restricted access to APIs or starting materials used in our products, causing us to raise prices or make changes to our products, which could materially harm our business, financial condition and results of operations. Further, the continued threats of tariffs, trade restrictions, and trade barriers could have a generally disruptive impact on the global economy and, therefore, negatively impact our sales. Given the relatively fluid regulatory environment in China and the United States, there could be additional tax or other regulatory changes in the future. Any such changes could directly and adversely impact our financial results and results of operations.

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

The U.S. Foreign Corrupt Practices Act of 1977, as amended and similar applicable laws and regulations in other jurisdictions generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Our policies mandate compliance with these anti-bribery laws, which often carry substantial penalties. We are currently expanding our operation abroad, including expanding our facilities in China, a country which has experienced governmental and private sector corruption to some degree, and in certain circumstances, strict compliance with anti-bribery laws may conflict with certain local customs and practices. Our internal control policies and procedures may not always protect us from acts committed by our affiliates, employees or agents which may violate these laws and regulations. Violations of foreign and U.S. laws and regulations could result in fines and penalties, criminal sanctions against us, our officers or our employees, prohibitions on the conduct of our business and on our ability to offer our products in one or more countries, and could also materially affect our brand, our international growth efforts, our ability to attract and retain employees, our business, and our operating results. There can be no assurance that our partners, our employees, contractors, or agents will not subject us to potential claims or penalties. Any violations of these laws, or allegations of such violations, could have a material adverse effect on our business, financial position, and results of operations and could cause the market value of our common stock to decline.

Movements in foreign currency exchange rates could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

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

The Chinese government has exercised, and continues to exercise, substantial control over virtually every sector of the

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

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

Unlike common law systems, such as the United States, the Chinese legal system is based on written statutes and decided legal cases have little precedential value. Our Chinese operating subsidiary, ANP, is subject to laws and regulations applicable to foreign investments in China in general and laws and regulations applicable to foreign invested enterprises in particular. ANP is also subject to laws and regulations governing the formation and conduct of domestic Chinese companies. Relevant Chinese laws, regulations and legal requirements may change frequently, and their interpretation and enforcement involve uncertainties. For example, we may have to resort to administrative and court proceedings to enforce the legal protections under law or contract. However, since Chinese administrative and court authorities have significant discretion in interpreting and implementing statutory and contract terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and our level of legal protection in China compared to other legal systems. Such uncertainties, including the inability to enforce our contracts and intellectual property rights, could materially and adversely affect our business and operations. In addition, confidentiality protections in China may not be as effective as in the U.S. or other countries. Accordingly, future developments in the Chinese legal system, including the promulgation of new laws, changes to existing laws or the interpretation or enforcement thereof, or the preemption of local requirements by national laws, could limit the legal protections available to us.

Our financial performance is impacted by the financial performance of our Chinese operating subsidiary, ANP.

Because we consolidate ANP's financial results in our results of operations, our financial performance is impacted by the financial performance of ANP. ANP's financial performance may be affected by a number of factors, including, but not limited to:

- ANP's ability to execute on its expansion plans;
- the commercial success of ANP's APIs, starting materials and finished pharmaceutical products;
- results of clinical trials of our product candidates or those of ANP's customers;

- pricing actions by competitors;

- the timing of orders or any cancellation of orders from ANP's customers;

- manufacturing or supply interruptions;

- actions by regulatory bodies, such as the FDA;

    - changes or developments in laws or regulations;

- disputes or other developments relating to patents or other proprietary rights;

- litigation or investigations involving ANP, our industry, or both; and

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· ANP's ability to control costs, including its operating expenses.

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

As of August 2, 2018, Jack Y. Zhang and Mary Z. Luo, each of whom serves as one of our directors and executive officers, and their affiliates beneficially own approximately 27.6% of our outstanding common stock, including shares of common stock subject to options exercisable within 60 days of August 2, 2018. Our directors, executive officers and each of our stockholders who own greater than 5% of our outstanding common stock and their affiliates, in the aggregate, own approximately 31.7% of the outstanding, including shares of our common stock, based on the number of shares outstanding and shares of our common stock subject to options exercisable within 60 days of August 2, 2018. As a result, these stockholders, if acting together, will be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may also have interests that differ from yours and may vote in a way with which you disagree and which may be adverse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, depriving our stockholders of an opportunity to receive a premium for their common stock as part of a sale of us and might ultimately affect the market price of our common stock.

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

Since September 2015, UBS Bank USA, or UBS USA, has made extensions of credit in the aggregate amount of $7.8 million to Applied Physics & Chemistry Laboratories, Inc., or APCL, which is controlled by Jack Y. Zhang and Mary Z. Luo. The loan is secured by a pledge of 2,000,000 shares of our common stock currently held by APCL. Interest on the loan accrues at market rates. UBS received customary fees and expense reimbursements in connection with these loans.

Since May 2017, UBS Bank Utah, or UBS Utah, has made an extension of credit in the aggregate amount of $7.8 million to APCL. The loan is secured by a pledge of 1,907,898 shares of our common stock currently held by APCL. Interest on the loan accrues at market rates. UBS Utah received customary fees and expense reimbursements in connection with these loans.

In October 2017, East West Bank, or East West, entered into an agreement with Drs. Zhang and Luo whereby East West would loan them up to $5.0 million. The loan is secured by a pledge of 650,000 shares of our common stock held by Dr. Zhang and 550,000 shares of our common stock held by Dr. Luo. Interest on the loan accrues at market rates.

In May 2018, Drs. Zhang and Luo entered into a business loan agreement with Cathay Bank, or Cathay, for the extension of credit in the aggregate amount of $25.0 million. The loan is secured by pledged shares of our common stock currently held by APCL. Interest on the loan accrues at market rates. Cathay received customary fees and expense reimbursements in connection with this loan.

We are not a party to these loans, which are full recourse against APCL and each of Drs. Zhang and Luo, respectively, and are secured by pledges of a portion of the shares of our common stock currently beneficially owned by Drs. Zhang and Luo.

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

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

(c)Issuer Purchases of Equity Securities

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

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
April 1 – April 30, 2018	80,098	$ 18.82	80,098	—
May 1 – May 31, 2018	119,456	16.23	119,456	—
June 1 – June 30, 2018	230,583	16.33	230,583	—

(1) During the second quarter of 2018, we repurchased shares of our common stock as part of the share buyback program authorized by our Board of Directors on August 7, 2017 and May 7, 2018. As of June 30, 2018, $14.3 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.

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ITEM 6. EXHIBITS

Exhibit No.	Description
10.1	Subscription Agreement between Amphastar Cayman, LLC and Jason B. Shandell dated June 28, 2018
10.2	Subscription Agreement between Amphastar Cayman, LLC and William J. Peters dated June 28, 2018
10.3	Subscription Agreement between Amphastar Cayman, LLC and Rong Zhou dated June 28, 2018
10.4	Subscription Agreement between Amphastar Cayman, LLC and Yakob Liawatidewi dated June 28, 2018
10.5	Subscription Agreement between Amphastar Cayman, LLC and Stephen B. Shohet dated June 28, 2018
10.6	Subscription Agreement between Amphastar Cayman, LLC and Chieh-Lin J. Lee dated June 28, 2018
10.7	Subscription Agreement between Amphastar Cayman, LLC and Yu-Chieh W. Lee dated June 28, 2018
10.8	Subscription Agreement between Amphastar Cayman, LLC and KYW Investment partnership dated June 28, 2018
10.9	Partnership Agreement by and between Zhang Chongqing, Bill Zhang and Applied Physics & Chemistry Laboratories, Inc. dated July 27, 2018
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.

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SIGNATURES

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

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

Date: August 9, 2018

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

Date: August 9, 2018