Amphastar Pharmaceuticals, Inc.
Form 10-Q
November 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 SEPTEMBER 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 has submitted electronically 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 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 November 2, 2018 was 46,098,467.

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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;

- global, national and local economic and market conditions, specifically with respect to geopolitical uncertainty;

- the impact of trade tariffs or other trade barriers;

- the impact of the Patient Protection and Affordable Care Act (as amended) and other legislative and regulatory healthcare reforms in the countries in which we operate;

- the impact of global and domestic tax reform, including the Tax Cuts and Jobs Act of 2017, or the Tax Act;

- the timing for completion of the validation of the new construction at our ANP and IMS facilities; 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.

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

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PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

AMPHASTAR PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share data)

	September 30, 2018 (unaudited)	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 68,734	$ 65,594
Short-term investments	2,829	2,635
Restricted cash and short-term investments	4,155	4,155
Accounts receivable, net	43,816	35,996
Inventories	65,414	63,609
Income tax refunds and deposits	3,186	6,036
Prepaid expenses and other assets	6,670	9,753
Total current assets	194,804	187,778
Property, plant, and equipment, net	202,526	180,545
Goodwill and intangible assets, net	42,727	45,140
Other assets	11,127	8,663
Deferred tax assets	29,458	28,946
Total assets	$ 480,642	$ 451,072
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 76,362	$ 57,555
Income taxes payable	1,667	3,325
Current portion of long-term debt and capital leases	18,592	6,312
Total current liabilities	96,621	67,192
Long-term reserve for income tax liabilities	879	879
Long-term debt and capital leases, net of current portion	32,606	40,844
Deferred tax liabilities	1,303	1,361
Other long-term liabilities	7,963	7,060

Total liabilities	139,372	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; 50,883,467 and 46,159,652 shares issued and outstanding as of September 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	330,265	313,891
Retained earnings	65,618	72,642
Accumulated other comprehensive loss	(3,576)	(2,100)
Treasury stock	(72,896)	(50,702)
Total Amphastar Pharmaceuticals, Inc. stockholders’ equity	319,416	333,736
Non-controlling interests	21,854	—
Total equity	341,270	333,736
Total liabilities and stockholders’ equity	$ 480,642	$ 451,072

See Accompanying Notes to Condensed Consolidated Financial Statements.

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AMPHASTAR PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited; in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net revenues	$ 75,543	$ 57,916	$ 204,976	$ 179,773
Cost of revenues	46,283	37,363	132,680	109,754
Gross profit	29,260	20,553	72,296	70,019
Operating (income) expenses:				
Selling, distribution, and marketing	1,963	1,756	5,560	4,831
General and administrative	13,407	11,665	36,074	35,237
Research and development	11,340	10,075	40,830	32,117
Gain on sale of intangible assets	—	—	—	(2,643)
Total operating expenses	26,710	23,496	82,464	69,542
Income (loss) from operations	2,550	(2,943)	(10,168)	477
Non-operating income (expenses):				
Interest income	105	124	335	302
Interest expense	(124)	(264)	(242)	(692)
Other income (expenses), net	43	969	(440)	2,307
Total non-operating income (expenses), net	24	829	(347)	1,917
Income (loss) before income taxes	2,574	(2,114)	(10,515)	2,394
Income tax expense (benefit)	958	(2,213)	(2,137)	(466)
Net income (loss)	$ 1,616	$ 99	$ (8,378)	$ 2,860
Net loss attributable to non-controlling interests	$ (773)	$ —	$ (773)	$ —
Net income (loss) attributable to Amphastar Pharmaceuticals, Inc.	$ 2,389	$ 99	$ (7,605)	$ 2,860
Net income (loss) per share attributable to Amphastar Pharmaceuticals, Inc. shareholders:				
Basic	$ 0.05	$ 0.00	$ (0.16)	$ 0.06
Diluted	$ 0.05	$ 0.00	$ (0.16)	$ 0.06
Weighted-average shares used to compute net income (loss) per share attributable to Amphastar				

Pharmaceuticals, Inc. shareholders:				
Basic	46,241	46,101	46,437	46,065
Diluted	48,281	48,215	46,437	48,046

See Accompanying Notes to Condensed Consolidated Financial Statements.

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AMPHASTAR PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(Unaudited; in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net income (loss) attributable to Amphastar Pharmaceuticals, Inc.	$ 2,389	$ 99	$ (7,605)	$ 2,860
Other comprehensive income (loss) attributable to Amphastar Pharmaceuticals, Inc., net of income taxes				
Foreign currency translation adjustment	(410)	625	(1,476)	2,101
Total other comprehensive income (loss) attributable to Amphastar Pharmaceuticals, Inc.	(410)	625	(1,476)	2,101
Total comprehensive income (loss) attributable to Amphastar Pharmaceuticals, Inc.	$ 1,979	$ 724	$ (9,081)	$ 4,961

See Accompanying Notes to Condensed Consolidated Financial Statements.

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AMPHASTAR PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited; in thousands)

	Nine Months Ended September 30, 2018	2017
Cash Flows From Operating Activities:		
Net income (loss)	$ (8,378)	$ 2,860
Reconciliation to net cash provided by operating activities:		
Loss (gain) on disposal and impairment of long-lived assets	390	(2,283)
Depreciation of property, plant, and equipment	10,414	9,668
Amortization of product rights, trademarks, and patents	1,722	2,139
Share-based compensation expense	12,770	12,905
Changes in operating assets and liabilities:		
Accounts receivable, net	(7,856)	2,909
Inventories	(1,884)	12,382
Prepaid expenses and other assets	(429)	(3,791)
Income tax refund, deposits, and payable	1,193	(5,325)
Accounts payable and accrued liabilities	20,732	(2,020)
Net cash provided by operating activities	28,674	29,444
Cash Flows From Investing Activities:		
Purchases and construction of property, plant, and equipment	(37,226)	(24,981)
Sale of intangible assets	4,400	2,000
Purchase of short-term investments	(306)	(5,645)
Maturity of short-term investments	91	3,650
Changes in restricted short-term investments	—	(900)
Payment of deposits and other assets	(344)	(885)
Net cash used in investing activities	(33,385)	(26,761)
Cash Flows From Financing Activities:		
Proceeds from the private placement of ANP	26,202	—
Proceeds from equity plans, net of withholding tax payments	274	7,255
Purchase of treasury stock	(22,440)	(24,773)
Proceeds from borrowing under lines of credit	347	—
Proceeds from issuance of long-term debt	8,000	18,983
Principal payments on long-term debt	(4,297)	(8,381)
Net cash provided by (used in) financing activities	8,086	(6,916)
Effect of exchange rate changes on cash	(235)	664
Net increase (decrease) in cash, cash equivalents, and restricted cash	3,140	(3,569)

Cash, cash equivalents, and restricted cash at beginning of period	67,459	72,354
Cash, cash equivalents, and restricted cash at end of period	$ 70,599	$ 68,785
Noncash Investing and Financing Activities:		
Equipment acquired under capital leases	$ 14	$ —
Supplemental Disclosures of Cash Flow Information:		
Interest paid, net of capitalized interest	$ 1,728	$ 1,334
Income taxes paid	$ 163	$ 4,876

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 when they are brought to market.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements of the Company for the year ended December 31, 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 subsidiaries, and are prepared in accordance with the requirements of the SEC for interim reporting. 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 Pharmaceutical 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 common equity interest to accredited investors for aggregate gross proceeds of approximately $57.2 million, of which $26.2 million has been received by ANP as of September 30, 2018. The investors are required to complete their contributions in cash by December 31, 2018. The Company has retained approximately 58% of the equity interest in ANP immediately after the private placement and continues to consolidate the financial results of ANP with the Company's results of operations. ANP's net income or loss after July 2, 2018, was attributed to the Company in accordance with the Company's equity interest of approximately 58% in ANP.

During the quarter ended September 30, 2018, the Company identified errors in its accounting primarily related to the depreciation of certain leasehold improvements within property, plant and equipment. The errors were not material to any of the Company's prior period annual or interim financial statements. However, for comparative purposes, the Company has revised the prior period condensed consolidated financial statements included herein. As a result, the net income for the three and nine months ended September 30, 2017 was reduced by $0.1 million and $0.2 million, respectively. The errors did not result in a change to the basic or diluted net income per share for the three months ended September 30, 2017. The basic net income per share for the nine months ended September 30, 2017, was reduced by $0.01. The error did not result in a change to the diluted net income per share for the nine months ended September 30, 2017. The balances of property, plant, and equipment, net and retained earnings as of December 31, 2017, were reduced by $4.8 million and $3.6 million, respectively. The error did not result in a change to the net cash provided by operating activities in the Company's condensed consolidated statement of cash flows for the nine months ended September 30, 2017. The Company will revise additional financial statements and disclosures as applicable in future filings.

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 nine months ended September 30, 2018, were $0.2 million loss and $1.0 million loss, respectively, and for the three and nine months ended September 30, 2017, were $1.1 million gain and $3.8 million gain, respectively.

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

Comprehensive Income (loss)

For the three and nine months ended September 30, 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 September 30, 2018 and December 31, 2017, restricted cash and short-term investments included $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 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 September 30, 2018, the Company was in the process of completing its accounting for the tax effects of the enactment of 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 assets 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

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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. 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 Non-employee Share-Based Payment Accounting, which simplifies the accounting for share-based payments to non-employees by aligning it with the accounting for share-based payments to employees. The Company early adopted the guidance on July 1, 2018. The adoption did not have a material impact on its consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement, which removes, modifies, and adds certain disclosure requirements to ASC 820, Fair Value

AMPHASTAR PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

Measurement. The guidance is effective for the Company's interim and annual reporting periods during the year ending December 31, 2020. 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 August 2018, the FASB issued ASU No. 2018-14, Disclosure Framework – Changes to the Disclosure Requirements for Defined Benefit Plans, which removes, modifies, and adds certain disclosure requirements to ASC 715-20, Defined Benefit Plans. The guidance is effective for the Company's interim and annual reporting periods during the year ending December 31, 2021. 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 October 2018, the FASB issued ASU No. 2018-17, Targeted Improvements to Related Party Guidance for Variable Interest Entities, which requires indirect interests held through related parties in common control arrangements be considered on a proportional basis for determining whether fees paid to decision makers and service providers are variable interests. The guidance is effective for the Company's interim and annual reporting periods during the year ending December 31, 2020. Early adoption is permitted. 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 November 2018, the FASB issued ASU No. 2018-18, Clarifying the Interaction between Topic 808 and Topic 606, which requires transactions in collaborative arrangements to be accounted for under ASC 606, Revenue from Contracts with Customers, or ASC 606, if the counterparty is a customer for a good or service that is a distinct unit of account. The amendments also preclude entities from presenting consideration from transactions with a collaborator that is not a customer together with revenue recognized from contracts with customers. The guidance is effective for the Company's interim and annual reporting periods during the year ending December 31, 2020. Early adoption is permitted, including in any interim period. The Company is currently evaluating the impact that the adoption of this guidance will have on its consolidated financial statements and related disclosures.

Note 3. Revenue Recognition

In 2018, the Company adopted 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 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

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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:

	Nine Months Ended September 30,	
	2018	2017
	(in thousands)	
Beginning balance	$ 18,470	$ 39,709
Provision for chargebacks and rebates	88,797	120,546
Credits and payments issued to third parties	(86,892)	(148,037)
Ending balance	$ 20,375	$ 12,218

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 days 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 September 30, 2018 and December 31, 2017, $8.5 million and $6.8 million were included in accounts receivable, net, on the condensed consolidated balance sheets, respectively. The remaining provision of $11.9 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 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 September 30, 2018 and December 31, 2017, cumulative sales of approximately $0.6 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.

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

	Nine Months Ended September 30,	
	2018	2017
	(in thousands)	
Beginning balance	$ 6,522	$ 3,143
Provision for product returns	2,248	4,196
Credits issued to third parties	(1,995)	(1,825)
Ending balance	$ 6,775	$ 5,514

Of the provision of product returns as of September 30, 2018 and December 31, 2017, $4.7 million and $4.1 million were included in accounts payable and accrued liabilities on the condensed consolidated balance sheets, respectively. The remaining provision of $2.1 million and $2.4 million were included in other long-term liabilities, respectively. For the nine months ended September 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 attributable to Amphastar Pharmaceuticals, Inc. shareholders

Basic net income (loss) per share attributable to Amphastar Pharmaceuticals, Inc. shareholders is calculated based upon the weighted-average number of shares outstanding during the period. Diluted net income (loss) per share attributable to Amphastar Pharmaceuticals, Inc. shareholders 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.

For the three months ended September 30, 2018, options to purchase 1,273,884 shares of stock with a weighted-average exercise price of $20.46 per share were excluded in the computation of diluted net income per common share attributable to Amphastar Pharmaceuticals, Inc. shareholders because the effect from the assumed exercise of these options would be anti-dilutive.

As the Company reported a net loss for the nine months ended September 30, 2018, the diluted net loss per share attributable to Amphastar Pharmaceuticals, Inc. shareholders, as reported, equals the basic net loss per share attributable to Amphastar Pharmaceuticals, Inc. shareholders 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 nine months ended September 30, 2018, net loss per share were 10,646,602 stock options; 1,210,718 non-vested RSUs, and 60,854 shares issuable under the ESPP.

For the three and nine months ended September 30, 2017, options to purchase 1,162,850 and 2,424,430 shares of stock with a weighted-average exercise price of $27.87 per share and $21.93 per shares, respectively, were excluded in the computation of diluted net income per common share attributable to Amphastar Pharmaceuticals, Inc. shareholders 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 (loss) per share attributable to Amphastar Pharmaceuticals, Inc. shareholders for each of the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(in thousands, except per share data)			
Basic and dilutive numerator:				
Net income (loss) attributable to Amphastar Pharmaceuticals, Inc.	$ 2,389	$ 99	$ (7,605)	$ 2,860
Denominator:				
Weighted-average shares outstanding — basic	46,241	46,101	46,437	46,065
Net effect of dilutive securities:				
Incremental shares from equity awards	2,040	2,114	—	1,981
Weighted-average shares outstanding — diluted	48,281	48,215	46,437	48,046
Net income (loss) per share attributable to Amphastar Pharmaceuticals, Inc. shareholders — basic	$ 0.05	$ 0.00	$ (0.16)	$ 0.06
Net income (loss) per share attributable to Amphastar Pharmaceuticals, Inc. shareholders — diluted	$ 0.05	$ 0.00	$ (0.16)	$ 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(in thousands)			
Net revenues:				
Finished pharmaceutical products	$ 71,767	$ 54,455	$ 188,125	$ 174,154
API	3,776	3,461	16,851	5,619
Total net revenues	75,543	57,916	204,976	179,773
Gross profit:				
Finished pharmaceutical products	30,571	21,222	77,856	74,289
API	(1,311)	(669)	(5,560)	(4,270)
Total gross profit	29,260	20,553	72,296	70,019
Operating expenses	26,710	23,496	82,464	69,542
Income (loss) from operations	2,550	(2,943)	(10,168)	477
Non-operating income	24	829	(347)	1,917
Income (loss) before income taxes	$ 2,574	$ (2,114)	$ (10,515)	$ 2,394

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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017

	(in thousands)			
Finished pharmaceutical products net revenues:				
Enoxaparin	$ 18,564	$ 6,549	$ 34,286	$ 25,247
Lidocaine	9,875	9,596	29,667	27,218
Naloxone	9,432	12,709	29,492	33,909
Phytonadione	8,968	9,352	28,955	27,242
Medroxyprogesterone	7,552	—	16,623	—
Epinephrine	1,881	2,027	8,791	22,249
Other finished pharmaceutical products	15,495	14,222	40,311	38,289
Total finished pharmaceutical products net revenues	$ 71,767	$ 54,455	$ 188,125	$ 174,154

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 September 30,		Nine Months Ended September 30,		September 30,	December 31,
	2018	2017	2018	2017	2018	2017
	(in thousands)					
United States	$ 72,477	$ 55,346	$ 194,141	$ 175,075	$ 109,394	$ 105,441
China	—	—	—	—	50,955	41,078
France	3,066	2,570	10,835	4,698	42,177	34,026
United Kingdom	—	—	—	—	—	—
Total	$ 75,543	$ 57,916	$ 204,976	$ 179,773	$ 202,526	$ 180,545

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 nine months ended September 30, 2018 and 2017, and accounts receivable as of September 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

	September 30, 2018	December 31, 2017	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
McKesson	19 %	22 %	30 %	27 %	27 %	27 %
AmerisourceBergen	30 %	33 %	30 %	24 %	28 %	27 %
Cardinal Health	24 %	12 %	23 %	25 %	22 %	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.

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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;

- 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 September 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 September 30, 2018 and

December 31, 2017, there were no significant adjustments to fair value for nonfinancial assets or liabilities.

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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)	Original Cost	Accumulated Amortization	Net Book Value
	(in thousands)			
Definite-lived intangible assets				
Cortrosyn® product rights	12	$ 27,134	$ 27,134	$ —
IMS (UK) international product rights	10	9,114	1,974	7,140
Patents	12	486	202	284
Land-use rights	39	2,540	469	2,071
Other intangible assets	4	69	59	10
Subtotal	12	39,343	29,838	9,505
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill - Finished pharmaceutical products	*	3,997	—	3,997
Subtotal	*	33,222	—	33,222
As of September 30, 2018	*	$ 72,565	$ 29,838	$ 42,727

	Weighted-Average Life (Years)	Original Cost	Accumulated Amortization	Net Book Value
	(in thousands)			
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. 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 $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 nine months ended September 30, 2017.

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Goodwill

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

	September 30, 2018	December 31, 2017
	(in thousands)	
Beginning balance	$ 4,461	$ 3,976
Currency translation	(464)	485
Ending balance	$ 3,997	$ 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 September 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 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.

In 2013, the Company filed a new drug application, or NDA, for Primatene® Mist, which is delivered by a metered dose inhaler with a non-CFC propellant. In November 2018, the FDA approved the NDA for Primatene® Mist.

Note 9. Inventories

Inventories consist of the following:

	September 30, 2018	December 31, 2017
	(in thousands)	
Raw materials and supplies	$ 28,560	$ 19,973
Work in process	26,308	22,469
Finished goods	10,546	21,167
Total inventories	$ 65,414	$ 63,609

Charges totaling $3.5 million and $6.6 million were included in the cost of revenues in the Company's condensed consolidated statements of operations for the three and nine months ended September 30, 2018, respectively, to adjust the Company's inventory and related firm inventory purchase commitments to their net realizable value. For the three and nine months ended September 30, 2017, charges totaling $2.2 million and $7.3 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:

	September 30, 2018	December 31, 2017
	(in thousands)	
Buildings	$ 90,990	$ 89,124
Leasehold improvements	30,033	29,847
Land	7,645	7,110
Machinery and equipment	138,727	118,056
Furniture, fixtures, and automobiles	18,324	16,385
Construction in progress	64,821	58,145
Total property, plant, and equipment	350,540	318,667
Less accumulated depreciation	(148,014)	(138,122)
Total property, plant, and equipment, net	$ 202,526	$ 180,545

Note 11. Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consisted of the following:

	September 30, 2018	December 31, 2017
	(in thousands)	
Accrued customer fees and rebates	$ 18,037	$ 15,981
Accrued payroll and related benefits	20,331	15,680

Accrued product returns, current portion	4,685	4,133
Other accrued liabilities	10,641	5,132
Total accrued liabilities	53,694	40,926
Accounts payable	22,668	16,629
Total accounts payable and accrued liabilities	$ 76,362	$ 57,555

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Note 12. Debt

Debt consists of the following:

	September 30, 2018	December 31, 2017
	(in thousands)	
Loans with East West Bank		
Line of credit facility due December 2018	$ —	$ —
Equipment loan due January 2019	513	1,668
Mortgage payable due February 2021	3,513	3,577
Equipment loan due June 2021	3,367	4,286
Equipment line of credit due December 2022	8,000	—
Mortgage payable due October 2026	3,479	3,524
Mortgage payable due June 2027	8,836	8,936
Loans with Cathay Bank		
Line of credit facility due May 2020	—	—
Acquisition loan due April 2019	13,542	15,073
Mortgage payable due August 2027	7,670	7,795
Loans with Bank of Nanjing		
Working capital loan due June 2019	347	—
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	172	239
Payment Obligation to Merck	575	599
Equipment under Capital Leases	1,130	1,357
Total debt and capital leases	51,198	47,156

Less current portion of long-term debt and capital leases	18,592	6,312
Long-term debt and capital leases, net of current portion	$ 32,606	$ 40,844

As of September 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 September 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. 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 September 30, 2018, the Company had $8.0 million outstanding under this facility.

Covenants

At September 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 2023. The cost of equipment under capital leases was $1.6 million at September 30, 2018 and December 31, 2017.

Note 13. Income Taxes

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(in thousands)			
Income (loss) before taxes	$ 2,574	$ (2,114)	$ (10,515)	$ 2,394
Income tax expense (benefit)	958	(2,213)	(2,137)	(466)
Net income (loss)	$ 1,616	$ 99	$ (8,378)	$ 2,860
Income tax provision as a percentage of income before income taxes	37.2 %	104.7 %	20.3 %	(19.5) %

The difference in the Company's effective tax rate for the three and nine months ended September 30, 2018 was primarily due to differences in income (loss) before taxes and timing of discrete items, as well as 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 nine months ended September 30, 2018, the Company has made no material 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 nine months ended September 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’s 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

Changes in stockholders’ equity consisted of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(in thousands)			

Stockholders’ equity beginning balance	$ 316,975	$ 330,478	$ 333,736	$ 326,523
Beginning balance adjustment as a result of the adoption of new accounting standards	—	—	582	872
Net income (loss) attributable to Amphastar Pharmaceuticals, Inc.	2,389	99	(7,605)	2,860
Other comprehensive income (loss) attributable to Amphastar Pharmaceuticals, Inc.	(410)	625	(1,476)	2,101
Proceeds from the private placement of ANP	26,202	—	26,202	—
Net loss attributable to non-controlling interests	(773)	—	(773)	—
Net proceeds from equity plans, net of withholding tax payments	568	(23)	274	7,255
Share-based compensation expense	3,908	4,156	12,770	12,905
Purchase of treasury stock	(7,589)	(7,592)	(22,440)	(24,773)
Stockholders’ equity ending balance	$ 341,270	$ 327,743	$ 341,270	$ 327,743

Share Buyback Program

Pursuant to the Company’s share buyback program, the Company purchased 441,175 and 1,278,916 shares of its common stock during the three and nine months ended September 30, 2018, for total consideration of $7.6 million and $22.4 million, respectively. The Company purchased 472,379 and 1,584,661 shares of its common stock during the three and nine months ended September 30, 2017, for total consideration of $7.6 million and $24.8 million, respectively.

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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 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 September 30, 2018, the Company reserved an aggregate of 5,511,252 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. Prior to the adoption of ASU No. 2018-07, Improvements to Non-employees Share-Based Payment Accounting, non-vested stock options held by non-employees were revalued at each balance sheet date. As a result of the Company's early adoption of the guidance on July 1, 2018, stock options held by non-employees are no longer revalued after grant. The portion that is 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 nine months ended September 30, 2018 and 2017, are as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2018		2017		2018		2017	
Average volatility	40.3	%	36.9	%	39.9	%	37.0	%
Risk-free interest rate	2.8	%	2.0	%	2.7	%	2.1	%
Weighted-average expected life in years	6.3		6.3		5.7		5.5	
Dividend yield rate	—	%	—	%	—	%	—	%

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A summary of option activity under all plans for the nine months ended September 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	1,088,313	20.15		
Options exercised	(824,003)	12.32		
Options cancelled	(131,530)	13.47		
Options expired	(384,879)	34.99		
Outstanding as of September 30, 2018	10,646,602	$ 14.67	4.94	$ 50,196
Exercisable as of September 30, 2018	7,361,813	$ 14.32	3.73	$ 36,501

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

For the three and nine months ended September 30, 2018, the Company recorded expenses of $1.8 million and $6.4 million, respectively, related to stock options granted under all plans. For the three and nine months ended September 30, 2017, the Company recorded expenses of $2.1 million and $6.4 million, respectively, related to stock options granted under all plans.

Information relating to option grants and exercises is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(in thousands, except per share data)			
Weighted-average grant date fair value per option share	$ 7.90	$ 6.23	$ 7.79	$ 4.95

Intrinsic value of options exercised	2,302	1,668	3,640	4,730
Cash received from options exercised	1,537	782	4,048	9,521
Total fair value of the options vested during the year	93	779	7,963	6,984

A summary of the status of the Company's non-vested options as of September 30, 2018, and changes during the nine months ended September 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	1,088,313	7.79
Options vested	(1,982,235)	4.02
Options forfeited	(131,530)	5.00
Non-vested as of September 30, 2018	3,284,789	5.47

As of September 30, 2018, there was $12.9 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 2.4 years and will be adjusted for future changes in estimated forfeitures.

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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 nine months ended September 30, 2018, the Company recorded expenses of $1.9 million and $5.9 million, respectively, related to RSU awards granted under all plans. During the three and nine months ended September 30, 2017, the Company recorded expenses of $1.9 million and $5.9 million, respectively, related to RSU awards granted under all plans.

As of September 30, 2018, there was $14.1 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 2.4 years and will be adjusted for future changes in estimated forfeitures.

Information relating to RSU grants and deliveries is as follows:

	Total RSUs Issued	Total Fair Market Value of RSUs Issued as Compensation(1) (in thousands)
RSUs outstanding at December 31, 2017	1,392,781	
RSUs granted	436,309	$ 8,484
RSUs forfeited	(49,480)	
RSUs vested(2)	(568,892)	
RSUs outstanding at September 30, 2018	1,210,718	

(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, 206,430 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	Nine Months Ended