

**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, 2019  
or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission file number 001-36509

**AMPHASTAR PHARMACEUTICALS, INC.**  
(Exact name of Registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	33-0702205 (I.R.S. Employer Identification No.)
11570 6 <sup>th</sup> Street Rancho Cucamonga, CA (Address of principal executive offices)	91730 (zip code)
(909) 980-9484 (Registrant's telephone number, including area code)	

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	AMPH	The NASDAQ Stock Market LLC

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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The number of shares outstanding of the registrant's only class of common stock as of November 1, 2019 was 46,938,027.

**AMPHASTAR PHARMACEUTICALS, INC.**  
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## SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS

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

- our expectations regarding the sales and marketing of our products;
- 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 U.S. Food and Drug Administration, or 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 for 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 active pharmaceutical ingredient, or 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 Patient Protection and Affordable Care Act (as amended) and other legislative and regulatory healthcare reforms in the countries in which we operate including the potential for drug price controls;
- the impact of global and domestic tax reforms, 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, 2018, particularly in Item 1A. “Risk Factors.” These forward-looking statements represent our estimates and assumptions only as of the date of this Quarterly Report regardless of the time of delivery of this Quarterly Report, and such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this Quarterly Report.

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

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**PART I – FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS**

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

	September 30, 2019 (unaudited)	December 31, 2018
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 85,611	\$ 86,337
Restricted cash	1,865	1,865
Short-term investments	12,666	2,831
Restricted short-term investments	2,290	2,290
Accounts receivable, net	45,255	52,163
Inventories	109,854	69,322
Income tax refunds and deposits	890	49
Prepaid expenses and other assets	10,472	5,485
Total current assets	<u>268,903</u>	<u>220,342</u>
Property, plant, and equipment, net	222,158	210,418
Finance lease right-of-use assets	896	—
Operating lease right-of-use assets	19,463	—
Goodwill and intangible assets, net	41,139	42,267
Other assets	12,331	9,918
Deferred tax assets	20,746	30,618
Total assets	<u>\$ 585,636</u>	<u>\$ 513,563</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 75,137	\$ 87,418
Income taxes payable	1,400	1,187
Current portion of long-term debt	6,969	18,229
Current portion of operating lease liabilities	3,090	—
Total current liabilities	<u>86,596</u>	<u>106,834</u>
Long-term reserve for income tax liabilities	415	415
Long-term debt, net of current portion	38,079	31,984
Long-term operating lease liabilities, net of current portion	16,940	—
Deferred tax liabilities	976	1,031
Other long-term liabilities	8,977	8,940
Total liabilities	<u>151,983</u>	<u>149,204</u>
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; 52,399,044 and 47,199,907 shares issued and outstanding as of September 30, 2019 and 51,438,675 and 46,631,118 shares issued and outstanding as of December 31, 2018, respectively	5	5
Additional paid-in capital	361,705	344,434
Retained earnings	117,396	67,485
Accumulated other comprehensive loss	(5,848)	(4,013)
Treasury stock	(83,853)	(75,476)
Total Amphastar Pharmaceuticals, Inc. stockholders' equity	<u>389,405</u>	<u>332,435</u>
Non-controlling interests	44,248	31,924
Total equity	<u>433,653</u>	<u>364,359</u>
Total liabilities and stockholders' equity	<u>\$ 585,636</u>	<u>\$ 513,563</u>

*See Accompanying Notes to Condensed Consolidated Financial Statements.*

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net revenues	\$ 80,137	\$ 75,543	\$ 238,974	\$ 204,976
Cost of revenues	44,885	46,283	140,432	132,680
Gross profit	35,252	29,260	98,542	72,296
Operating expenses:				
Selling, distribution, and marketing	3,221	1,963	9,354	5,560
General and administrative	11,021	13,407	39,774	36,074
Research and development	18,606	11,340	49,209	40,830
Total operating expenses	32,848	26,710	98,337	82,464
Income (loss) from operations	2,404	2,550	205	(10,168)
Non-operating (expenses) income:				
Interest income	450	105	741	335
Interest expense	(22)	(124)	(76)	(242)
Other (expenses) income, net	(1,250)	43	58,172	(440)
Total non-operating (expenses) income, net	(822)	24	58,837	(347)
Income (loss) before income taxes	1,582	2,574	59,042	(10,515)
Income tax provision (benefit)	598	958	13,292	(2,137)
Net income (loss)	<u>\$ 984</u>	<u>\$ 1,616</u>	<u>\$ 45,750</u>	<u>\$ (8,378)</u>
Net loss attributable to non-controlling interests	\$ (326)	\$ (773)	\$ (4,215)	\$ (773)
Net income (loss) attributable to Amphastar Pharmaceuticals, Inc.	<u>\$ 1,310</u>	<u>\$ 2,389</u>	<u>\$ 49,965</u>	<u>\$ (7,605)</u>
Net income (loss) per share attributable to Amphastar Pharmaceuticals, Inc. shareholders:				
Basic	\$ 0.03	\$ 0.05	\$ 1.06	\$ (0.16)
Diluted	\$ 0.03	\$ 0.05	\$ 1.00	\$ (0.16)
Weighted-average shares used to compute net income (loss) per share attributable to Amphastar Pharmaceuticals, Inc. shareholders:				
Basic	47,239	46,241	47,030	46,437
Diluted	50,075	48,281	50,128	46,437

*See Accompanying Notes to Condensed Consolidated Financial Statements.*

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

	<u>Three Months Ended</u> <u>September 30,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Net income (loss) attributable to Amphastar Pharmaceuticals, Inc.	\$ 1,310	\$ 2,389	\$ 49,965	\$ (7,605)
Other comprehensive loss attributable to Amphastar Pharmaceuticals, Inc., net of income taxes				
Foreign currency translation adjustment	(1,625)	(410)	(1,835)	(1,476)
Total other comprehensive loss attributable to Amphastar Pharmaceuticals, Inc.	(1,625)	(410)	(1,835)	(1,476)
Total comprehensive income (loss) attributable to Amphastar Pharmaceuticals, Inc.	<u>\$ (315)</u>	<u>\$ 1,979</u>	<u>\$ 48,130</u>	<u>\$ (9,081)</u>

*See Accompanying Notes to Condensed Consolidated Financial Statements.*

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

	Nine Months Ended September 30,	
	2019	2018
<b>Cash Flows From Operating Activities:</b>		
Net income (loss)	\$ 45,750	\$ (8,378)
Reconciliation to net cash provided by operating activities:		
Loss on impairment and disposal of assets	869	390
Depreciation of property, plant, and equipment	12,527	10,414
Amortization of product rights, trademarks, and patents	777	1,722
Operating lease right-of-use asset amortization	2,188	—
Share-based compensation expense	13,000	12,770
Changes in deferred taxes	9,872	—
Changes in operating assets and liabilities:		
Accounts receivable, net	6,722	(7,856)
Inventories	(41,146)	(1,884)
Prepaid expenses and other assets	(3,607)	(429)
Income tax refund, deposits, and payable	(631)	1,193
Operating lease right-of-use assets and liabilities, net	(1,866)	—
Accounts payable and accrued liabilities	(8,345)	20,732
Net cash provided by operating activities	<u>36,110</u>	<u>28,674</u>
<b>Cash Flows From Investing Activities:</b>		
Purchases and construction of property, plant, and equipment	(33,145)	(37,226)
Sale of intangible assets	—	4,400
Purchase of short-term investments	(9,825)	(306)
Maturity of short-term investments	—	91
Payment of deposits and other assets	(205)	(344)
Net cash used in investing activities	<u>(43,175)</u>	<u>(33,385)</u>
<b>Cash Flows From Financing Activities:</b>		
Proceeds from the private placement of ANP	18,298	26,202
Proceeds from equity plans, net of withholding tax payments	1,981	274
Purchase of treasury stock	(8,514)	(22,440)
Proceeds from borrowing under lines of credit	—	347
Repayments under lines of credit	(347)	—
Proceeds from issuance of long-term debt	—	8,000
Principal payments on long-term debt	(4,819)	(4,297)
Net cash provided by financing activities	<u>6,599</u>	<u>8,086</u>
Effect of exchange rate changes on cash	<u>(260)</u>	<u>(235)</u>
Net increase (decrease) in cash, cash equivalents, and restricted cash	(726)	3,140
Cash, cash equivalents, and restricted cash at beginning of period	88,202	67,459
Cash, cash equivalents, and restricted cash at end of period	<u>\$ 87,476</u>	<u>\$ 70,599</u>
<b>Noncash Investing and Financing Activities:</b>		
Capital expenditure included in accounts payable	\$ 5,279	\$ 5,051
Operating lease right-of-use assets	\$ 7,848	\$ —
Equipment acquired under finance leases	\$ 61	\$ 14
<b>Supplemental Disclosures of Cash Flow Information:</b>		
Interest paid, net of capitalized interest	\$ 1,874	\$ 1,728
Income taxes paid	\$ 4,189	\$ 163

*See Accompanying Notes to Condensed Consolidated Financial Statements.*

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

**Note 1. Business**

Amphastar Pharmaceuticals, Inc., a Delaware corporation (together with its subsidiaries, “we,” “us,” “our” or the “Company”), is a specialty pharmaceutical company that 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 product, Primatene® Mist, is primarily distributed through drug retailers.

**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 United States generally accepted accounting principles, or GAAP. All 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 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, 2018, 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, 2018. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with 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.

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, the Company’s Chinese subsidiary, ANP, completed a private placement of its common equity interest to accredited investors for aggregate gross proceeds of approximately \$57 million. While investors were initially required to complete their contributions in cash by December 31, 2018, ANP granted an extension to certain investors. Certain investors contributed their payments in Chinese yuan, which resulted in a difference in U.S. dollars, or USD, due to currency fluctuations subsequent to the execution of the placement agreement. A total of \$56.3 million was received by ANP and the difference was expensed in the quarter ended March 31, 2019. The Company has retained approximately 58% of the equity interest in ANP following the private placement and continues to consolidate the financial results of



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

ANP with the Company's results of operations. ANP's net loss after July 2, 2018, was attributed to the Company in accordance with the Company's equity interest of approximately 58% in ANP.

*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 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. ANP's other Chinese subsidiaries maintain their books of record in Chinese yuan. Its U.K. subsidiary, IMS UK, maintains its book of record in British 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, 2019, were \$1.5 million loss and \$1.7 million loss, respectively, and for the three and nine months ended September 30, 2018, were \$0.2 million loss and \$1.0 million loss, respectively.

*Comprehensive Income (Loss)*

For the three and nine months ended September 30, 2019 and 2018, 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 standby letters of credit and to qualify for workers' compensation self-insurance and to guarantee certain vendor payments in France. As of September 30, 2019 and December 31, 2018, 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.

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

*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.

*Recent Accounting Pronouncements*

In June 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update, or 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 ASU and the related clarifications subsequently issued by FASB will become 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 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 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.

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

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 accordance with ASC 606, revenue is recognized at the time that the Company's customers obtain control of the promised goods.

Generally, revenue is recognized at the time of product delivery to the Company's customers. In some cases, revenue is recognized at the time of shipment when stipulated by the terms of the sale agreements. Revenues derived from contract manufacturing services are recognized when third-party products are shipped to customers, and after the customer has accepted test samples of the products to be shipped.

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.

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

*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

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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 as a component of net revenues. The following table is an analysis of the chargeback and rebate provision:

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Beginning balance	\$ 22,423	\$ 18,470
Provision for chargebacks and rebates	94,548	88,797
Credits and payments issued to third parties	(97,324)	(86,892)
Ending balance	<u>\$ 19,647</u>	<u>\$ 20,375</u>

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 wholesalers' 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, 2019 and December 31, 2018, \$14.1 million and \$12.0 million were included in accounts receivable, net, on the condensed consolidated balance sheets, respectively. The remaining provision of \$5.5 million and \$10.4 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.

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The provision for product returns is reflected as a component of net revenues. The following table is an analysis of the product return liability:

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Beginning balance	\$ 8,030	\$ 6,522
Provision for product returns	4,611	2,248
Credits issued to third parties	(3,945)	(1,995)
Ending balance	<u>\$ 8,696</u>	<u>\$ 6,775</u>

Of the provision of product returns as of September 30, 2019 and December 31, 2018, \$5.7 million and \$5.3 million were included in accounts payable and accrued liabilities on the condensed consolidated balance sheets, respectively. The remaining provision as of September 30, 2019 and December 31, 2018, of \$3.0 million and \$2.7 million was included in other long-term liabilities, respectively. For the nine months ended September 30, 2019 and 2018, the Company's aggregate product return rate was 0.9% and 1.3% 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, and the 2018 ANP Equity Incentive Plan, or the 2018 Plan.

For the three and nine months ended September 30, 2019, options to purchase 803,257 and 783,193 shares of stock, respectively, with a weighted-average exercise price of \$21.99 per share and \$22.02 per share, respectively, were excluded in the computation of diluted net income per common share attributable to Amphastar Pharmaceuticals, Inc.'s shareholders because the effect from the assumed exercise of these options would be anti-dilutive. Additionally, 3,648,932 options to purchase ANP stock were awarded to ANP employees, which represent approximately 2% of ANP's total equity, were excluded in the computation of diluted net income per common share attributable to Amphastar Pharmaceuticals, Inc.'s shareholders because the effect from the assumed exercise of these options would be anti-dilutive.

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 Company's ESPP.

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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:

	<u>Three Months Ended</u> <u>September 30,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
	(in thousands, except per share data)			
<b>Basic and dilutive numerator:</b>				
Net income (loss) attributable to Amphastar Pharmaceuticals, Inc.	\$ 1,310	\$ 2,389	\$ 49,965	\$ (7,605)
<b>Denominator:</b>				
Weighted-average shares outstanding — basic	47,239	46,241	47,030	46,437
<b>Net effect of dilutive securities:</b>				
Incremental shares from equity awards	2,836	2,040	3,098	—
Weighted-average shares outstanding — diluted	50,075	48,281	50,128	46,437
Net income (loss) per share attributable to Amphastar Pharmaceuticals, Inc. shareholders — basic	\$ 0.03	\$ 0.05	\$ 1.06	\$ (0.16)
Net income (loss) per share attributable to Amphastar Pharmaceuticals, Inc. shareholders — diluted	\$ 0.03	\$ 0.05	\$ 1.00	\$ (0.16)

**Note 5. Segment Reporting**

The Company's business is the development, manufacture, and marketing of pharmaceutical products. The Company has identified 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
- API

The finished pharmaceutical products segment manufactures, markets and distributes enoxaparin, naloxone, phytonadione, lidocaine, medroxyprogesterone acetate, Primatene® Mist, 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,	
	2019	2018	2019	2018
	(in thousands)			
<b>Net revenues:</b>				
Finished pharmaceutical products	\$ 75,729	\$ 71,767	\$ 224,003	\$ 188,125
API	4,408	3,776	14,971	16,851
Total net revenues	80,137	75,543	238,974	204,976
<b>Gross profit:</b>				
Finished pharmaceutical products	34,992	30,571	101,844	77,856
API	260	(1,311)	(3,302)	(5,560)
Total gross profit	35,252	29,260	98,542	72,296
Operating expenses	32,848	26,710	98,337	82,464
Income (loss) from operations	2,404	2,550	205	(10,168)
Non-operating income (expense)	(822)	24	58,837	(347)
Income (loss) before income taxes	<u>\$ 1,582</u>	<u>\$ 2,574</u>	<u>\$ 59,042</u>	<u>\$ (10,515)</u>

The Company manages its business segments to the gross profit level and manages its operating and other costs on a company-wide basis. The Company does not identify total assets by segment for internal purposes, as the Company's CODM does not assess performance, make strategic decisions, or allocate resources based on assets.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(in thousands)			
<b>Finished pharmaceutical products net revenues:</b>				
Enoxaparin	\$ 9,573	\$ 18,564	\$ 33,895	\$ 34,286
Lidocaine	11,670	9,875	33,731	29,667
Phytonadione	10,916	8,968	33,477	28,955
Naloxone	10,613	9,432	25,810	29,492
Medroxyprogesterone	7,879	7,552	21,788	16,623
Epinephrine	3,756	1,881	9,574	8,791
Primatene® Mist	3,654	—	9,063	—
Other finished pharmaceutical products	17,668	15,495	56,665	40,311
Total finished pharmaceutical products net revenues	<u>\$ 75,729</u>	<u>\$ 71,767</u>	<u>\$ 224,003</u>	<u>\$ 188,125</u>

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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		Nine Months Ended		September 30,	December 31,
	September 30,		September 30,			
	2019	2018	2019	2018	2019	2018
	(in thousands)					
United States	\$ 76,070	\$ 72,477	\$ 227,308	\$ 194,141	\$ 106,950	\$ 109,331
China	59	—	1,043	—	71,353	58,059
France	4,008	3,066	10,623	10,835	43,855	43,028
United Kingdom	—	—	—	—	—	—
<b>Total</b>	<b>\$ 80,137</b>	<b>\$ 75,543</b>	<b>\$ 238,974</b>	<b>\$ 204,976</b>	<b>\$ 222,158</b>	<b>\$ 210,418</b>

**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, 2019 and 2018, and accounts receivable as of September 30, 2019 and December 31, 2018, respectively. The following table provides accounts receivable and net revenue information for these major customers:

	% of Total Accounts Receivable		% of Net Revenue			
	September 30,		Three Months Ended		Nine Months Ended	
	2019	December 31, 2018	September 30,	2018	September 30,	2018
McKesson	31 %	28 %	24 %	30 %	26 %	27 %
AmerisourceBergen	10 %	19 %	26 %	30 %	24 %	28 %
Cardinal Health	21 %	21 %	21 %	23 %	22 %	22 %

*Supplier Concentrations*

The Company depends on suppliers for raw materials, APIs, 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, 2019, cash equivalents include money market accounts. Short-term investments consist of certificates of deposit as well as investment-grade corporate bonds with original expiration dates within 12 months. The 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 corporate bonds are classified as held-to-maturity and are carried at amortized cost, 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 fair value of the Company’s financial assets and liabilities measured on a recurring basis as of September 30, 2019 and December 31, 2018, are as follows:

	Total	(Level 1)	(Level 2)	(Level 3)
	(in thousands)			
Cash equivalents - money market	\$42,564	\$ 42,564	\$ —	\$ —
Restricted cash - money market	1,865	1,865	—	—
Short-term investments - certificates of deposit	8,844	—	8,844	—
Restricted short-term investments - certificates of deposit	2,290	—	2,290	—
Fair value measurement as of September 30, 2019	<u>\$55,563</u>	<u>\$ 44,429</u>	<u>\$ 11,134</u>	<u>\$ —</u>
Cash equivalents - money market	\$40,907	\$ 40,907	\$ —	\$ —
Restricted cash - money market	1,865	1,865	—	—
Short-term investments - certificates of deposit	2,831	—	2,831	—
Restricted short-term investments - certificates of deposit	2,290	—	2,290	—
Fair value measurement as of December 31, 2018	<u>\$47,893</u>	<u>\$ 42,772</u>	<u>\$ 5,121</u>	<u>\$ —</u>

The Company does not hold any significant 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, 2019 and December 31, 2018, there were no adjustments to fair value for nonfinancial assets or liabilities.

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**Note 8. Investments**

A summary of the Company's debt investment securities classified as held-to-maturity are as follows:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
Corporate bonds	\$ 3,795	\$ —	\$ (2)	\$ 3,793
Total investments as of September 30, 2019	<u>\$ 3,795</u>	<u>\$ —</u>	<u>\$ (2)</u>	<u>\$ 3,793</u>

The Company believes that the unrealized losses disclosed above were primarily driven by interest rate changes rather than by unfavorable changes in the credit ratings associated with these securities and as a result, the Company continues to expect to collect the principal and interest due on its debt securities that have an amortized cost in excess of fair value. At each reporting period, the Company evaluates securities for impairment when the fair value of the investment is less than its amortized cost. The Company evaluated the underlying credit quality and credit ratings of the issuers, noting neither a significant deterioration since purchase nor any other factors that would lead us to believe that any impairment is not temporary.

**Note 9. Goodwill and Intangible Assets**

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

	Weighted-Average Life (Years)	Original Cost	Accumulated Amortization	Net Book Value
	(in thousands)			
<i>Definite-lived intangible assets</i>				
IMS (UK) international product rights	10	8,606	2,725	5,881
Patents	12	486	244	242
Land-use rights	39	2,540	535	2,005
Other intangible assets	4	69	69	—
Subtotal	13	<u>11,701</u>	<u>3,573</u>	<u>8,128</u>
<i>Indefinite-lived intangible assets</i>				
Trademark	*	29,225	—	29,225
Goodwill - Finished pharmaceutical products	*	3,786	—	3,786
Subtotal	*	<u>33,011</u>	<u>—</u>	<u>33,011</u>
As of September 30, 2019	*	<u>\$ 44,712</u>	<u>\$ 3,573</u>	<u>\$ 41,139</u>

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	Weighted- Average	Original Cost	Accumulated Amortization	Net Book Value
	Life (Years)	(in thousands)		
<i>Definite-lived intangible assets</i>				
Cortrosyn® product rights	12	\$ 27,134	\$ 27,134	\$ —
IMS (UK) international product rights	10	8,911	2,153	6,758
Patents	12	486	213	273
Land-use rights	39	2,540	486	2,054
Other intangible assets	4	69	63	6
Subtotal	12	39,140	30,049	9,091
<i>Indefinite-lived intangible assets</i>				
Trademark	*	29,225	—	29,225
Goodwill - Finished pharmaceutical products	*	3,951	—	3,951
Subtotal	*	33,176	—	33,176
As of December 31, 2018	*	\$ 72,316	\$ 30,049	\$ 42,267

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

*Sale of Fourteen Injectable ANDAs*

In February 2017, the Company sold the 14 ANDAs it acquired in March 2016 from Hikma Pharmaceuticals, Inc. 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. In 2017, the Company recognized a gain of \$2.6 million within operating (income) expenses on its consolidated statement of operations.

*Goodwill*

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

	September 30, 2019	December 31, 2018
	(in thousands)	
Beginning balance	\$ 3,951	\$ 4,461
Currency translation	(165)	(510)
Ending balance	\$ 3,786	\$ 3,951

*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, recorded at the allocated fair value of \$29.2 million, which is its carrying value as of September 30, 2019.

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.

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As a result of environmental concerns about chlorofluorocarbons, or CFCs, the FDA required the CFC formulation of Primatene<sup>®</sup> Mist to be phased out on December 31, 2011.

In 2013, the Company filed a new drug application, or NDA, for Primatene<sup>®</sup> Mist, which utilizes a non-CFC propellant. In November 2018, the FDA granted over-the-counter approval of the NDA for Primatene<sup>®</sup> Mist, and the Company re-launched this product in December 2018.

**Note 10. Inventories**

Inventories consist of the following:

	September 30, 2019	December 31, 2018
	(in thousands)	
Raw materials and supplies	\$ 57,043	\$ 30,153
Work in process	37,208	30,272
Finished goods	15,603	8,897
Total inventories	<u>\$ 109,854</u>	<u>\$ 69,322</u>

Charges totaling \$0.4 million and \$6.1 million were included in the cost of revenues in the Company's consolidated statements of operations for the three and nine months ended September 30, 2019, 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, 2018, charges totaling \$3.5 million and \$6.6 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.

**Note 11. Property, Plant, and Equipment**

Property, plant, and equipment consist of the following:

	September 30, 2019	December 31, 2018
	(in thousands)	
Buildings	\$ 98,968	\$ 96,287
Leasehold improvements	29,398	26,755
Land	7,570	7,628
Machinery and equipment	152,090	143,299
Furniture, fixtures, and automobiles	20,497	19,151
Construction in progress	73,690	66,390
Total property, plant, and equipment	382,213	359,510
Less accumulated depreciation	(160,055)	(149,092)
Total property, plant, and equipment, net	<u>\$ 222,158</u>	<u>\$ 210,418</u>

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**Note 12. Accounts Payable and Accrued Liabilities**

Accounts payable and accrued liabilities consisted of the following:

	<b>September 30,</b>	<b>December 31,</b>
	<b>2019</b>	<b>2018</b>
	<b>(in thousands)</b>	
Accrued customer fees and rebates	\$ 10,323	\$ 15,215
Accrued payroll and related benefits	22,845	19,430
Accrued product returns, current portion	5,724	5,349
Reserve for net loss on firm purchase commitments	2,094	5,355
Other accrued liabilities	12,107	10,746
Total accrued liabilities	<u>53,093</u>	<u>56,095</u>
Accounts payable	22,044	31,323
Total accounts payable and accrued liabilities	<u>\$ 75,137</u>	<u>\$ 87,418</u>

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**Note 13. Debt**

Debt consists of the following:

	September 30, 2019	December 31, 2018
	(in thousands)	
<b><i>Loans with East West Bank</i></b>		
Equipment loan paid off January 2019	\$ —	\$ 128
Line of credit facility due December 2020	—	—
Mortgage payable due February 2021	3,423	3,491
Equipment loan due June 2021	2,143	3,061
Equipment loan due December 2022	6,500	8,000
Line of credit facility due February 2024	—	—
Mortgage payable due October 2026	3,416	3,463
Mortgage payable due June 2027	8,695	8,801
<b><i>Loans with Cathay Bank</i></b>		
Line of credit facility due May 2020	—	—
Mortgage payable due August 2027	7,497	7,627
Acquisition loan due June 2024	11,462	13,025
<b><i>Loans with Bank of Nanjing</i></b>		
Working capital loan paid off June 2019	—	347
<b><i>Loans with Seine-Normandie Water Agency</i></b>		
French government loan due June 2020	26	55
French government loan due July 2021	109	172
French government loans due December 2026	423	436
<b><i>Payment Obligation to Merck</i></b>	<b>541</b>	<b>552</b>
<b><i>Equipment under Finance Leases</i></b>	<b>813</b>	<b>—</b>
<b><i>Equipment under Capital Leases</i></b>	<b>—</b>	<b>1,055</b>
<b>Total debt</b>	<b>45,048</b>	<b>50,213</b>
Less current portion of long-term debt	6,969	18,229
<b>Long-term debt, net of current portion</b>	<b>\$ 38,079</b>	<b>\$ 31,984</b>

As of September 30, 2019, the fair value of the loans listed above approximated 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 contracts had an aggregate fair value of \$0.5 million and \$0.2 million as of September 30, 2019 and December 31, 2018, 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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*Acquisition loan – Due June 2024*

In July 2019, the Company amended the acquisition loan relating to the AFP acquisition. The amendment was effective in June 2019. Under the amended loan agreement, the maturity date was extended to June 2024. The acquisition loan bears a variable interest rate at the prime rate as published by *The Wall Street Journal*, with a minimum interest rate of 5.00%. Beginning in August 2019, and through the maturity date, the Company must make monthly payments of principal and interest based on the then outstanding amount of the loan amortized over a 60-month period.

**Covenants**

At September 30, 2019 and December 31, 2018, the Company was in compliance with its debt covenants, which include a minimum current ratio, minimum debt service coverage, minimum tangible net worth, maximum debt-to-effective-tangible-net-worth ratio, and minimum deposit requirement computed on a consolidated basis. The profitability-related covenants for loans with Cathay Bank will become effective as of December 31, 2019.

**Note 14. Income Taxes**

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

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2019</b>	<b>2018</b>	<b>2019</b>	<b>2018</b>
	(in thousands)			
Income (loss) before taxes	\$ 1,582	\$ 2,574	\$ 59,042	\$ (10,515)
Income tax provision (benefit)	598	958	13,292	(2,137)
Net income (loss)	<u>\$ 984</u>	<u>\$ 1,616</u>	<u>\$ 45,750</u>	<u>\$ (8,378)</u>
Income tax provision (benefit) as a percentage of income (loss) before income taxes	37.8 %	37.2 %	22.5 %	20.3 %

The increase in the Company's effective tax rate for the three and nine months ended September 30, 2019, was primarily due to differences in pre-tax income (loss) positions.

*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.

In 2019, for purposes of computing its annual effective tax rate, the Company did not benefit from its losses in the states where it files separately. This increased the Company's income tax provision by an immaterial amount during the three and nine months ended September 30, 2019.

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**Note 15. Stockholders' Equity**

The changes in stockholders' equity for the three and nine months ended September 30, 2019 and 2018 consisted of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(in thousands)			
Stockholders' equity beginning balance	\$ 432,288	\$ 316,975	\$ 364,359	\$ 333,736
Beginning balance adjustment as a result of the adoption of new accounting standards	—	—	(54)	582
Net income (loss) attributable to Amphastar Pharmaceuticals, Inc.	1,310	2,389	49,965	(7,605)
Other comprehensive income (loss) attributable to Amphastar Pharmaceuticals, Inc.	(1,625)	(410)	(1,835)	(1,476)
Net proceeds from the private placement of ANP	—	26,202	18,966	26,202
Net loss attributable to non-controlling interests	(326)	(773)	(4,215)	(773)
Net proceeds from equity plans, net of withholding tax payments	2,138	568	1,981	274
Share-based compensation expense	4,294	3,908	13,000	12,770
Purchase of treasury stock	(4,426)	(7,589)	(8,514)	(22,440)
Stockholders' equity ending balance	<u>\$ 433,653</u>	<u>\$ 341,270</u>	<u>\$ 433,653</u>	<u>\$ 341,270</u>

The Company issued 186,284 and 960,369 of common shares during the three and nine months ended September 30, 2019 and 171,191 and 794,255 of common shares during the three and nine months ended September 30, 2018, respectively, in connection with the Company's equity plans.

*Share Buyback Program*

Pursuant to the Company's existing share buyback program, the Company purchased 206,686 and 403,145 shares of its common stock during the three and nine months ended September 30, 2019, for total consideration of \$4.4 million and \$8.5 million, respectively. 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.

In November 2019, 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 and applicable laws. The timing and actual number of treasury share purchases will depend on a variety of factors including price, corporate and regulatory requirements, and other conditions. These treasury share purchases are accounted for under the cost method and are included as a component of treasury stock in the Company's consolidated balance sheets.



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*The 2015 Equity Incentive Plan*

As of September 30, 2019, the Company reserved an aggregate of 6,209,600 shares of common stock for future issuance under the 2015 Equity Incentive Plan, or the 2015 Plan, including 1,165,778 shares which were reserved in January 2019 pursuant to the evergreen provision in the 2015 Plan.

*Share-Based Award Activity and Balances (excluding the ANP Equity Plan)*

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 in July 2018, stock options held by non-employees are no longer revalued after grant. 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 nine months ended September 30, 2019 and 2018, are as follows:

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2019</b>	<b>2018</b>	<b>2019</b>	<b>2018</b>
Average volatility	41.9 %	40.3 %	42.5 %	39.9 %
Risk-free interest rate	1.5 %	2.8 %	2.4 %	2.7 %
Weighted-average expected life in years	6.3	6.3	5.7	5.7
Dividend yield rate	— %	— %	— %	— %

A summary of option activity for the nine months ended September 30, 2019, is presented below:

	<b>Options</b>	<b>Weighted-Average Exercise Price</b>	<b>Weighted-Average Remaining Contractual Term (Years)</b>	<b>Aggregate Intrinsic Value<sup>(1)</sup></b>
				<b>(in thousands)</b>
Outstanding as of December 31, 2018	10,105,565	\$ 14.69		
Options granted	1,058,314	20.99		
Options exercised	(1,262,741)	15.14		
Options cancelled	(7,778)	18.47		
Options expired	(92,881)	20.12		
Outstanding as of September 30, 2019	<u>9,800,479</u>	\$ 15.26	5.00	\$ 46,815
Exercisable as of September 30, 2019	<u>7,047,266</u>	\$ 14.15	3.95	\$ 40,285

(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, 2019.

For the three and nine months ended September 30, 2019, the Company recorded expenses of \$2.0 million and \$6.2 million, respectively, related to stock options granted. 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.

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Information relating to option grants and exercises is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(in thousands, except per share data)			
Weighted-average grant date fair value per option share	\$ 9.50	\$ 7.90	\$ 8.48	\$ 7.79
Intrinsic value of options exercised	1,700	2,302	7,522	3,640
Cash received from options exercised	2,234	1,537	7,281	4,048
Total fair value of the options vested during the year	85	93	7,587	7,963

A summary of the status of the Company's non-vested options as of September 30, 2019, and changes during the nine months ended September 30, 2019, is presented below:

	Options	Weighted-Average Grant Date Fair Value
	Non-vested as of December 31, 2018	3,279,026
Options granted	1,058,314	8.48
Options vested	(1,576,349)	4.81
Options forfeited	(7,778)	7.93
Non-vested as of September 30, 2019	2,753,213	6.99

As of September 30, 2019, there was \$13.6 million of total unrecognized compensation cost, net of forfeitures, related to non-vested stock option based compensation arrangements granted. 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.

*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, 2019, the Company recorded expenses of \$2.1 million and \$6.2 million, respectively, related to RSU awards granted. 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.

As of September 30, 2019, there was \$14.8 million of total unrecognized compensation cost, net of forfeitures, related to non-vested RSU-based compensation arrangements granted. 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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Information relating to RSU grants and deliveries is as follows:

	<u>Total RSUs Issued</u>	<u>Total Fair Market Value of RSUs Issued as Compensation<sup>(1)</sup> (in thousands)</u>
RSUs outstanding at December 31, 2018	1,206,661	
RSUs granted	442,371	\$ 8,970
RSUs forfeited	(4,842)	
RSUs vested <sup>(2)</sup>	(541,437)	
<u>RSUs outstanding at September 30, 2019</u>	<u>1,102,753</u>	

- (1) The total fair market value is derived from the number of RSUs granted times the stock price on the date of grant.  
(2) Of the vested RSUs, 238,000 shares of common stock were surrendered to fulfill tax withholding obligations.

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
	(in thousands)			
Cost of revenues	\$ 701	\$ 884	\$ 2,939	\$ 3,025
Operating expenses:				
Selling, distribution, and marketing	96	86	285	297
General and administrative	3,138	2,615	8,577	8,251
Research and development	359	323	1,199	1,197
Total share-based compensation	<u>\$ 4,294</u>	<u>\$ 3,908</u>	<u>\$ 13,000</u>	<u>\$ 12,770</u>

*The 2018 ANP Equity Incentive Plan*

In December 2018, ANP's board of directors approved the 2018 Plan, which is set to expire in December 2023. The 2018 Plan permits the grant of stock options and other equity awards in ANP shares to ANP employees. In June 2019, ANP issued 3,648,932 stock options to its employees under the 2018 Plan all of which were still outstanding at September 30, 2019. The options vest over a period of approximately four years and have up to a 10 year contractual term. The total fair value of the options awarded was \$2.1 million. For the three and nine months ended September 30, 2019, the Company recorded expense of \$0.1 million and \$0.2 million related to stock options issued by ANP under the 2018 Plan, respectively.

**Note 16. 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 nine months ended September 30, 2019 were approximately \$0.3 million and \$1.0 million, respectively, compared to the prior year expense of \$0.3 million and \$0.9 million for the three and nine months ended September 30, 2018, respectively.

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*Defined Benefit Pension Plan*

In connection with the AFP acquisition, 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 0.9% and 1.70% as of September 30, 2019 and December 31, 2018, 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 \$2.2 million and \$2.2 million at September 30, 2019 and December 31, 2018, respectively. The Company recorded an immaterial amount of expense under the plan for the three months ended September 30, 2019, and \$0.2 million for the nine months ended September 30, 2019. The Company recorded an immaterial amount of expense under the plan for the three months ended September 30, 2018, and \$0.2 million for the nine months ended September 30, 2018.

**Note 17. Commitments and Contingencies**

*Lease Liabilities*

On January 1, 2019, the Company adopted ASC 842, which resulted in the recognition of right-of-use, or ROU, assets of approximately \$13.9 million and related lease liabilities in the consolidated balance sheets of approximately \$14.1 million related to its operating lease commitments. ROU assets represent the Company's right to control an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. ROU assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. As most of its leases do not provide an implicit rate, the Company used its incremental borrowing rate based on the information available at the commencement date in determining the discount rate used to present value the lease payments. 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.

The components of lease costs for the three and nine months ended September 30, 2019 were as follows:

	<u>Three Months Ended</u> <u>September 30,</u> <u>2019</u>	<u>Nine Months Ended</u> <u>September 30,</u> <u>2019</u>
	(in thousands)	
Operating lease costs	\$ 1,082	\$ 2,872
Short-term lease costs	150	457
Finance lease costs		
Amortization of right-of-use assets	86	257
Interest on lease liabilities	12	36
Total finance lease costs	\$ 98	\$ 293
Total lease costs	\$ 1,330	\$ 3,622

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Other information pertaining to leases is as follows:

	<b>Nine Months Ended September 30, 2019</b> <small>(in thousands, except lease term and discount rate)</small>
<b>Supplemental cash flow information</b>	
<b>Cash paid for amounts included in the measurement of lease liabilities</b>	
Operating cash flows from operating leases	\$ 2,523
Operating cash flows from finance leases	36
Financing cash flows from finance leases	262
<b>Right-of use assets obtained in exchange for lease liabilities</b>	
Operating leases	7,830
Finance leases	59
<b>Weighted-average remaining lease term (years)</b>	
Operating leases	8.3
Finance leases	2.7
<b>Weighted-average discount rate</b>	
Operating leases	5.9 %
Finance leases	4.6 %

Future minimum rental payments under operating leases that have initial or remaining non-cancelable lease terms in excess of 12 months as of September 30, 2019, are as follows:

	<b>Operating Leases</b>	<b>Finance Leases</b>	<b>Total</b>
	<small>(in thousands)</small>		
2019 (excluding the Nine Months Ended September 30, 2019)	\$ 1,006	\$ 8	\$ 1,014
2020	4,128	375	4,503
2021	4,353	298	4,651
2022	3,669	174	3,843
2023	2,472	14	2,486
Thereafter	10,167	5	10,172
<b>Total lease payments</b>	<b>\$ 25,795</b>	<b>\$ 874</b>	<b>\$ 26,669</b>
Less: interest	5,765	61	5,826
<b>Total</b>	<b>\$ 20,030</b>	<b>\$ 813</b>	<b>\$ 20,843</b>

*Purchase Commitments*

As of September 30, 2019, the Company has entered into commitments to purchase equipment and raw materials for an aggregate amount of approximately \$42.4 million. The Company anticipates that most of these commitments with remaining terms in excess of one year will be fulfilled by 2020.

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In accordance with certain agreements between ANP and the Chinese government, in January 2010 and November 2012, the Company acquired certain land-use rights for \$1.2 million and \$1.3 million, respectively. As required by these agreements, the Company committed to spend approximately \$15.0 million in the related land development, which primarily includes the construction of fixed assets according to a specific timetable. As of September 30, 2019, the Company has spent \$8.3 million on such construction. The Company anticipates that this spending commitment will be met by the end of 2019.

**Note 18. Related-Party Transactions**

*ANP Private Placement*

As discussed in footnote 2, in July 2018, ANP completed a private placement of its common equity interest and received approximately \$56.3 million of cash proceeds. In connection with the private placement, all of the executive officers of the Company, Stephen Shohet, Howard Lee, and Richard Koo, directors of the Company, and certain employees of ANP 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, or Zhongpan, Chinese partnerships. The aggregate gross proceeds received from management and directors were approximately \$29.7 million.

**Note 19. Litigation**

*Momenta/Sandoz Enoxaparin Patent and Antitrust 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.

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 May 20, 2019, the Company and the Plaintiffs entered into a Settlement Agreement to fully settle the patent litigation and antitrust litigation. The Settlement Agreement was contingent upon the District Court’s granting a Joint Motion to Vacate the Patent Judgment and thereafter, the Plaintiffs’ payment of \$59.9 million to the Company. On June 18, 2019, the parties filed a Joint Motion to Vacate the Patent Judgment with the District Court, and on the same day, the District Court granted such motion. Accordingly, on June 19, 2019, the parties filed Joint Stipulations with the District Court to dismiss the patent litigation and the antitrust litigation, each of which is self-executing and effective upon filing pursuant to the Federal Rules of Civil Procedure 41(a)(1)(A)(ii). Furthermore, on June 26, 2019, the Federal Circuit issued an Order and a Mandate dismissing the appeal of the patent litigation. On June 27, 2019, pursuant to the Settlement Agreement, the Plaintiffs paid the Company \$59.9 million. The Company is not entitled to future rights or royalties related to this settlement. Accordingly, the Company recorded the settlement amount as other income (expenses), in its condensed consolidated statements of operations.

*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

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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<sup>®</sup> product.

On May 11, 2017, the Company's lawsuit against Aventis was dismissed. On July 14, 2017, Aventis filed an application with the District Court for entitlement to attorneys' fees and expenses. On November 20, 2017, the District Court issued its order granting Aventis' application for fees, stating that it would refer the matter to a magistrate judge for a report and recommendation regarding the amount of the award to be made.

On August 7, 2018, Aventis filed its Application for Fees and Expenses. On November 26, 2018, the Company filed its Opposition to Aventis' Application for Fees and Expenses. On February 12, 2019, following further briefing on the attorneys' fee issue, the District Court approved of the parties' consent for the Magistrate Judge to conduct all further proceedings in this matter at the district court level, including determining the amount of attorneys' fees to be awarded and entering a final judgment. The Magistrate Judge held a hearing on the Application on May 8, 2019. At the May 8, 2019 hearing, the Magistrate Judge did not rule on the Application, but indicated that a written opinion on this Application for Fees and Expenses would be forthcoming. The Company intends to continue to vigorously defend against any imposition of attorneys' fees and expenses in this case.

*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 (the "'197 Patent'"), 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 3, 2019, the Parties filed a Joint Stipulation to stay the litigation pending the Court's ruling on the outcome of Belcher's trial with Hospira. On August 19, 2019, the judge signed the order staying the litigation pending the Court's ruling on the outcome of Belcher's trial with Hospira. The Company intends to vigorously defend this lawsuit.

*Vasopressin (20 units/mL) Patent Litigation*

On December 20, 2018, Par Pharmaceutical, Inc., Par Sterile Products, LLC and Endo Par Innovation Company (collectively, "Par") initiated a patent lawsuit by filing a Complaint against the Company for infringement of U.S. Patent Nos. 9,375,478 ("the '478 Patent'"), 9,687,526 ("the '526 Patent'"), 9,744,209 ("the '209 Patent'"), 9,744,239 ("the '239 Patent'"), 9,750,785 ("the '785 Patent'") and 9,937,223 ("the '223 Patent'") (collectively, "Par Patents") with regard to the Company's Abbreviated New Drug Application, or ANDA No. 211,857 for FDA approval to manufacture and sell Vasopressin (20 units/ mL). The Company filed its Answer to this Complaint on February 19, 2019. On April 18, 2019, the Court held a scheduling conference and entered a Scheduling Order.

On September 27, 2019, the Court entered a Revised Scheduling Order that consolidates the Company's vasopressin patent lawsuit with two other vasopressin patent lawsuits filed by Par in the same Court, Par v. Amneal Pharmaceuticals GMBH et al., and Par v. American Regent, Inc. (collectively, the "Consolidated Vasopressin Patent Lawsuits"). In the Revised Scheduling Order, trial is still scheduled for January 2021 and the Company's 30-month FDA stay is maintained at May 21, 2021. On the same day, the Court entered a Protective Order on the Consolidated Vasopressin Patent Lawsuits. The Company intends to vigorously defend this patent lawsuit.

*Employment Litigation*

On September 11, 2019, a former employee ("Plaintiff") initiated an employment litigation against IMS et al. by filing a Class Action Complaint for alleged violations of various California labor laws pertaining to wage and hour, and other state laws (collectively, "Employment Litigation"). This Class Action Complaint was filed in the Superior Court of California. The Company intends to vigorously defend this Employment Litigation.

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*Other Litigation*

The Company is also subject to various other claims and lawsuits from time to time arising in the ordinary course of business.

The Company records a provision for contingent losses when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. In the opinion of management, the ultimate resolution of any such matters is not expected to have a material adverse effect on its financial position, results of operations, or cash flows; however, the results of litigation and claims are inherently unpredictable and the Company's view of these matters may change in the future. Regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources, and other factors.



## **ITEM 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following is a discussion and analysis of the consolidated operating results, financial condition, liquidity and cash flows of our company as of and for the periods presented below. The following discussion and analysis should be read in conjunction with the “Condensed Consolidated Financial Statements” and the related notes thereto included in this Quarterly Report on Form 10-Q, or Quarterly Report. This discussion contains forward-looking statements that are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Actual results could differ materially from those discussed in or implied by forward-looking statements. These risks, uncertainties, and other factors include, among others, those identified under the “Special Note About Forward-Looking Statements,” above and described in greater detail elsewhere in this Quarterly Report and in our Annual Report on Form 10-K for the year ended December 31, 2018, 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. In November 2018, the FDA granted over-the-counter approval for our NDA for Primatene® Mist in a new CFC-free formulation.

We are currently developing a portfolio of 15 generic abbreviated new drug applications, or ANDAs, three biosimilar product candidates and four proprietary product candidates, which are in various stages of development and target a variety of indications. Five of the ANDAs and one new drug application, or NDA, are currently on file with the FDA.

Our largest products by net revenues currently include enoxaparin sodium injection, naloxone hydrochloride injection, lidocaine jelly and sterile solution, phytonadione, medroxyprogesterone acetate, and Primatene® Mist. We launched Primatene® Mist in the fourth 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, our Chinese subsidiary, ANP, completed a private placement of its common equity interest and received approximately \$56.3 million of cash proceeds. We have retained approximately 58% of the equity interest in ANP following the private placement. ANP’s net income or loss after July 2, 2018, is attributed to us in accordance with our equity interest of approximately 58% in ANP.

On May 20, 2019, we entered into a settlement relating to the enoxaparin patent and antitrust litigation with Momenta Pharmaceuticals, Inc. and Sandoz Inc. Pursuant to the settlement agreement, the plaintiffs paid us \$59.9 million on June 27, 2019. For more information regarding the enoxaparin patent and antitrust litigation, see Note 19 to the condensed consolidated financial statements for more information regarding litigation matters.

### **Business Segments**

As of September 30, 2019, 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 manufactures, markets, and distributes enoxaparin, naloxone, phytonadione, lidocaine, medroxyprogesterone acetate, Primatene® Mist, as well as various other critical and non-critical care drugs. The API segment manufactures and

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distributes RHI API and porcine insulin API for external customers and internal product development. 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. (see Note 5 to the condensed consolidated financial statements for more information regarding our segment reporting).

**Results of Operations**

*Three Months Ended September 30, 2019 Compared to Three Months Ended September 30, 2018*

**Net revenues**

	<b>Three Months Ended</b>		<b>Change</b>	
	<b>September 30,</b>	<b>September 30,</b>	<b>Dollars</b>	<b>%</b>
	<b>2019</b>	<b>2018</b>		
	<b>(in thousands)</b>			
<b>Net revenues</b>				
Finished pharmaceutical products	\$ 75,729	\$ 71,767	\$ 3,962	6 %
API	4,408	3,776	632	17 %
<b>Total net revenues</b>	<b>\$ 80,137</b>	<b>\$ 75,543</b>	<b>\$ 4,594</b>	<b>6 %</b>
<b>Cost of revenues</b>				
Finished pharmaceutical products	\$ 40,737	\$ 41,196	\$ (459)	(1)%
API	4,148	5,087	(939)	(18)%
<b>Total cost of revenues</b>	<b>\$ 44,885</b>	<b>\$ 46,283</b>	<b>\$ (1,398)</b>	<b>(3)%</b>
<b>Gross profit</b>	<b>\$ 35,252</b>	<b>\$ 29,260</b>	<b>\$ 5,992</b>	<b>20 %</b>
<i>as % of net revenues</i>	<i>44 %</i>	<i>39 %</i>		

The increase in net revenues of finished pharmaceutical products for the three months ended September 30, 2019 was primarily due to the following changes:

	<b>Three Months Ended</b>		<b>Change</b>	
	<b>September 30,</b>	<b>September 30,</b>	<b>Dollars</b>	<b>%</b>
	<b>2019</b>	<b>2018</b>		
	<b>(in thousands)</b>			
<b>Finished pharmaceutical products net revenues</b>				
Lidocaine	\$ 11,670	\$ 9,875	\$ 1,795	18 %
Phytonadione	10,916	8,968	1,948	22 %
Naloxone	10,613	9,432	1,181	13 %
Enoxaparin	9,573	18,564	(8,991)	(48)%
Medroxyprogesterone	7,879	7,552	327	4 %
Epinephrine	3,756	1,881	1,875	100 %
Primatene <sup>®</sup> Mist	3,654	—	3,654	N/A
Other finished pharmaceutical products	17,668	15,495	2,173	14 %
<b>Total finished pharmaceutical products net revenues</b>	<b>\$ 75,729</b>	<b>\$ 71,767</b>	<b>\$ 3,962</b>	<b>6 %</b>

The increase in sales of lidocaine was driven equally by a higher average selling price and higher unit volumes, with each factor having an impact of \$0.9 million. The increase in sales of phytonadione during the third quarter of 2019 was driven by a higher average selling price. The increase in sales of epinephrine and naloxone were both primarily driven by higher unit volumes. Other finished pharmaceutical products sales increased primarily due to higher unit sales volumes of atropine, calcium chloride and dextrose, which were in high demand due to market shortages. Enoxaparin sales decreased due to lower unit volumes as a result of increased competition.

We anticipate that sales of naloxone, enoxaparin, and medroxyprogesterone will continue to fluctuate in the future as a result of competition.

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Sales of API primarily depend on the timing of customer purchases. In August 2019, we amended the Supply Agreement with MannKind Corporation, or MannKind, whereby MannKind's aggregate total commitment of RHI API under the Supply Agreement was modified and extended for an additional two years through 2026, which timeframe would have previously lapsed after calendar year 2024. MannKind has agreed to pay us an amendment fee of \$2.75 million. We recognized the first payment of the amendment fee of \$1.5 million in net revenues during the three months ended September 30, 2019. The remaining balance of the amendment fee is due in December 2019.

We anticipate that sales of API will continue to fluctuate and may 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 September 30, 2019. Historically, our backlog has not been a meaningful indicator in any given period of our ability to achieve any particular level of overall revenue or financial performance.

### **Gross margins**

The launch of Primatene<sup>®</sup> Mist, which is a higher margin product, as well as the higher average selling price of phytonadione, helped increase our gross margins for the third quarter of 2019. Gross margins for Primatene<sup>®</sup> Mist were magnified by the use of API and components which were expensed to pre-launch inventory in prior years.

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, isoproterenol and Primatene<sup>®</sup> Mist, which were launched over the past two years.

### **Selling, distribution and marketing, and general and administrative**

	Three Months Ended		Change	
	September 30, 2019	September 30, 2018	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	\$ 3,221	\$ 1,963	\$ 1,258	64 %
General and administrative	\$11,021	\$13,407	\$(2,386)	(18)%

The increase in selling, distribution, and marketing expenses was primarily due to marketing expenses related to Primatene<sup>®</sup> Mist, including the cost of a television and radio marketing campaign which began in July 2019. The decrease in general and administrative expense was primarily due to a decrease in legal expenses as a result of the enoxaparin patent and antitrust litigation settlement (see Note 19 to the condensed consolidated financial statements for more information regarding litigation matters).

We expect that selling, distribution and marketing expenses will increase due to the increase in marketing expenditures for Primatene<sup>®</sup> Mist. 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.

**Research and development**

	Three Months Ended		Change	
	September 30,		Dollars	%
	2019	2018		
	(in thousands)			
Salaries and personnel-related expenses	\$ 6,979	\$ 4,313	\$2,666	62 %
Clinical trials	2,238	193	2,045	1,060 %
FDA fees	194	229	(35)	(15)%
Testing, operating and lab supplies	4,770	4,286	484	11 %
Depreciation	2,171	1,291	880	68 %
Other expenses	2,254	1,028	1,226	119 %
Total research and development expenses	<u>\$18,606</u>	<u>\$11,340</u>	<u>\$7,266</u>	64 %

Research and development costs consist primarily of costs associated with the research and development of our product candidates including the cost of developing APIs. We expense research and development costs as incurred.

Salaries and personnel-related expenses as well as depreciation expense increased during the third quarter of 2019 primarily due to API and key component development at our ANP facility. Clinical trial expense increased due to external studies related to our generic product pipeline, primarily for our inhalation ANDAs. Testing, operating and lab supplies increased due to expenditures on materials for our pipeline products.

We have made, and expect to continue to make, substantial investments in research and development to expand our product portfolio and grow our business. We expect that research and development expenses will increase on an annual basis due to increased clinical trial costs related to our biosimilar and inhalation product candidates. These expenditures will include costs of APIs developed internally as well as APIs purchased externally, the cost of purchasing reference listed drugs and the costs of performing the clinical trials. 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.

**Income tax provision**

	Three Months Ended		Change	
	September 30,		Dollars	%
	2019	2018		
	(in thousands)			
Income tax provision	\$ 598	\$ 958	\$(360)	NM
<i>Effective tax rate</i>	38 %	37 %		

The difference in income tax provision was primarily due to differences in pre-tax income positions.

*Nine Months Ended September 30, 2019 Compared to Nine Months Ended September 30, 2018*

**Net revenues**

	<b>Nine Months Ended September 30,</b>		<b>Change</b>	
	<b>2019</b>	<b>2018</b>	<b>Dollars</b>	<b>%</b>
	(in thousands)			
<b>Net revenues</b>				
Finished pharmaceutical products	\$224,003	\$188,125	\$35,878	19 %
API	14,971	16,851	(1,880)	(11)%
Total net revenues	<u>\$238,974</u>	<u>\$204,976</u>	<u>\$33,998</u>	<u>17 %</u>
<b>Cost of revenues</b>				
Finished pharmaceutical products	\$122,159	\$110,269	\$11,890	11 %
API	18,273	22,411	(4,138)	(18)%
Total cost of revenues	<u>\$140,432</u>	<u>\$132,680</u>	<u>\$ 7,752</u>	<u>6 %</u>
Gross profit	<u>\$ 98,542</u>	<u>\$ 72,296</u>	<u>\$26,246</u>	<u>36 %</u>
<i>as % of net revenues</i>	<i>41 %</i>	<i>35 %</i>		

The increase in net revenues of the finished pharmaceutical products for the nine months ended September 30, 2019, was primarily due to the following changes:

	<b>Nine Months Ended September 30,</b>		<b>Change</b>	
	<b>2019</b>	<b>2018</b>	<b>Dollars</b>	<b>%</b>
	(in thousands)			
<b>Finished pharmaceutical products net revenues</b>				
Enoxaparin	\$ 33,895	\$ 34,286	\$ (391)	(1)%
Lidocaine	33,731	29,667	4,064	14 %
Phytonadione	33,477	28,955	4,522	16 %
Naloxone	25,810	29,492	(3,682)	(12)%
Medroxyprogesterone	21,788	16,623	5,165	31 %
Epinephrine	9,574	8,791	783	9 %
Primatene <sup>®</sup> Mist	9,063	—	9,063	N/A
Other finished pharmaceutical products	<u>56,665</u>	<u>40,311</u>	<u>16,354</u>	<u>41 %</u>
Total finished pharmaceutical products net revenues	<u>\$ 224,003</u>	<u>\$ 188,125</u>	<u>\$35,878</u>	<u>19 %</u>

\$2.3 million of the increase in sales of lidocaine was due to higher unit volumes, while the remainder was due to higher average selling prices. The increase in sales of phytonadione was primarily driven by a higher average selling price. The decrease in sales of naloxone was primarily driven by lower average selling prices, with an impact of \$2.2 million, while volume reductions accounted for the remainder of the decrease. The increase in sales of medroxyprogesterone was due to increased unit sales as it was launched in the first quarter of 2018, therefore, the prior year did not have a full quarter of sales during the first quarter of 2018. Other finished pharmaceutical products sales increased primarily due to higher unit sales volumes of Cortrosyn<sup>®</sup>, atropine, calcium chloride, and dextrose, which were in high demand due to market shortages. Sales of isoproterenol, which we launched in the third quarter of 2018, also contributed to the increase in other finished pharmaceutical sales.

We anticipate that sales of naloxone, enoxaparin, and medroxyprogesterone will continue to fluctuate in the future as a result of competition.

Sales of API primarily depend on the timing of customer purchases. In August 2019, we amended the Supply Agreement with MannKind, and recognized the first payment of the amendment fee of \$1.5 million in net revenues during the nine months ended September 30, 2019. The remaining balance of the amendment fee is due in December 2019.

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We anticipate that sales of API will continue to fluctuate and may 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 euros 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 September 30, 2019. Historically, our backlog has not been a meaningful indicator in any given period of our ability to achieve any particular level of overall revenue or financial performance.

### **Gross margins**

The launch of Primatene® Mist and an increase in sales of medroxyprogesterone and Cortrosyn®, which are higher margin products, as well as the higher average selling price of enoxaparin and phytonadione, helped increase our gross margins for the nine months ended September 30, 2019. Gross margins for Primatene® Mist were magnified by the use of API and components which were expensed to pre-launch inventory in prior years.

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, isoproterenol, and Primatene® Mist, which were launched over the past two years.

### **Selling, distribution and marketing, and general and administrative**

	Nine Months Ended September 30,		Change	
	2019	2018	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	\$ 9,354	\$ 5,560	\$3,794	68 %
General and administrative	\$39,774	\$36,074	\$3,700	10 %

The increase in selling, distribution, and marketing expenses was primarily due to marketing expenses related to Primatene® Mist, including the cost of a television marketing campaign which began in July 2019. The increase in general and administrative expense was primarily due to an increase in personnel-related expenses, as well as legal expenses (see Note 19 to the condensed consolidated financial statements for more information regarding litigation matters).

We expect that selling, distribution and marketing expenses will increase due to the increase in marketing expenditure for Primatene® Mist. 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.

### **Research and development**

	Nine Months Ended September 30,		Change	
	2019	2018	Dollars	%
	(in thousands)			
Salaries and personnel-related expenses	\$19,621	\$12,691	\$ 6,930	55 %
Pre-launch inventory	158	1,573	(1,415)	(90)%
Clinical trials	5,471	2,219	3,252	147 %
FDA fees	598	1,690	(1,092)	(65)%
Testing, operating and lab supplies	11,220	15,349	(4,129)	(27)%
Depreciation	6,447	3,852	2,595	67 %
Other expenses	5,694	3,456	2,238	65 %
Total research and development expenses	<u>\$49,209</u>	<u>\$40,830</u>	<u>\$ 8,379</u>	21 %

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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.

Salaries and personnel-related expenses as well as depreciation expense increased during the nine months ended September 30, 2019 primarily due to API and key component development at our ANP facility. Clinical trial expense increased due to external studies related to our generic product pipeline, primarily for our inhalation ANDAs. These increases were partially offset by a decrease in pre-launch inventory compared to the same period last year relating to the production of Primatene<sup>®</sup> Mist in anticipation for the launch at the end of 2018. FDA fees decreased for the period, as we filed an NDA and ANDA for products we currently market or previously marketed under the grandfather exception in 2018.

We have made, and expect to continue to make, substantial investments in research and development to expand our product portfolio and grow our business. We expect that research and development expenses will increase on an annual basis due to increased clinical trial costs related to our biosimilar and inhalation product candidates. These expenditures will include costs of APIs developed internally as well as APIs purchased externally, the cost of purchasing reference listed drugs and the costs of performing the clinical trials. 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.

**Other income (expenses), net**

	Nine Months Ended		Change	
	September 30,		Dollars	%
	2019	2018		
	(in thousands)			
Other income (expenses), net	\$58,172	\$ (440)	\$58,612	NM

In June 2019, we recognized a gain of \$59.9 million relating to our settlement of the enoxaparin patent and antitrust litigation with Momenta Pharmaceuticals, Inc. and Sandoz Inc. For more information regarding the enoxaparin patent and antitrust litigation, see Note 19 to the condensed consolidated financial statements for more information regarding litigation matters.

**Income tax provision (benefit)**

	Nine Months Ended		Change	
	September 30,		Dollars	%
	2019	2018		
	(in thousands)			
Income tax provision (benefit)	\$ 13,292	\$ (2,137)	\$ 15,429	NM
<i>Effective tax rate</i>	23 %	20 %		

The difference in income tax provision (benefit) was primarily due to differences in pre-tax income (loss) positions.

**Liquidity and Capital Resources*****Cash Requirements and Sources***

We need capital resources to maintain and expand our business. We expect our cash requirements to increase significantly in the foreseeable future as we sponsor clinical trials for, seek regulatory approvals of, and develop, manufacture and market our current development-stage product candidates and pursue strategic acquisitions of businesses or assets. Our future capital expenditures include projects to upgrade, expand, and improve our manufacturing facilities in the United States, China, and France. Our cash obligations include the principal and interest payments due on our existing loans and lease payments, as described below and throughout this Quarterly Report. As of September 30, 2019, our foreign subsidiaries collectively held \$33.4 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

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cash reserves, operating cash flows, and borrowing availability under our credit facilities will be sufficient to fund our operations for at least the next 12 months. We expect additional cash flows to be generated in the longer term from future product introductions, although there can be no assurance as to the receipt of regulatory approval for any product candidates that we are developing or the timing of any product introductions, which could be lengthy or ultimately unsuccessful.

We maintain a shelf registration statement on Form S-3 pursuant to which we may, from time to time, sell up to an aggregate of \$250 million of our common stock, preferred stock, depositary shares, warrants, units, or debt securities. If we require or elect to seek additional capital through debt or equity financing in the future, we may not be able to raise capital on terms acceptable to us or at all. To the extent we raise additional capital through the sale of equity or convertible debt securities, the issuance of such securities will result in dilution to our stockholders. If we are required and unable to raise additional capital when desired, our business, operating results and financial condition may be adversely affected.

Working capital increased by \$68.8 million to \$182.3 million at September 30, 2019, compared to \$113.5 million at December 31, 2018 as a result of the \$59.9 million settlement received relating to the enoxaparin patent and antitrust litigation with Momenta Pharmaceuticals, Inc. and Sandoz Inc. For more information regarding the enoxaparin patent and antitrust litigation, see Note 19 to the condensed consolidated financial statements.

### ***Cash Flows from Operations***

The following table summarizes our cash flows used in operating, investing, and financing activities for the nine months ended September 30, 2019 and 2018:

	<b>Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2019</b>	<b>2018</b>
	<b>(in thousands)</b>	
<b>Statement of Cash Flow Data:</b>		
Net cash provided by (used in)		
Operating activities	\$ 36,110	\$ 28,674
Investing activities	(43,175)	(33,385)
Financing activities	6,599	8,086
Effect of exchange rate changes on cash	(260)	(235)
Net increase (decrease) in cash, cash equivalents, and restricted cash	<u>\$ (726)</u>	<u>\$ 3,140</u>

### ***Sources and Use of Cash***

#### **Operating Activities**

Net cash provided by operating activities was \$36.1 million for the nine months ended September 30, 2019, which included net income of \$45.8 million. Non-cash items were primarily comprised of \$13.3 million of depreciation and amortization, and \$13.0 million of share-based compensation expense.

Additionally, there was a net cash outflow from changes in operating assets and liabilities of \$48.9 million which resulted from the decrease in accounts receivable, offset by an increase in inventory, as well as a decrease in accounts payable and accrued liabilities. The decrease in accounts receivable was due to the timing of sales in the quarter. The increase in inventory was partially due to increased purchases of raw materials and production of finished goods resulting in a net increase of \$31.0 million of enoxaparin and a net increase of \$8.9 million of Primatene<sup>®</sup> Mist inventory. We plan to utilize our deferred tax credits to offset a significant portion of the tax liability related to 2019 U.S. federal and California state taxable income. Accounts payable and accrued liabilities decreased primarily due to the timing of payments.



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Net cash provided by operating activities was \$28.7 million for the nine months ended September 30, 2018, which included net loss of \$8.4 million. Non-cash items were primarily comprised of \$12.1 million of depreciation and amortization, and \$12.8 million of share-based compensation expense.

The increase in accounts receivable was due to an increase in sales. An increase in inventory, due to increased purchases of raw materials for enoxaparin and other products in the U.S., was partially offset by a decrease in finished RHI API at AFP. Accounts payable and accrued liabilities increased, primarily due to the timing of payments.

### Investing Activities

Net cash used in investing activities was \$43.2 million for the nine months ended September 30, 2019, primarily as a result of \$33.1 million in purchases of property, plant, and equipment, which included \$7.3 million incurred in the United States, \$6.6 million in France, and \$19.2 million in China. Additionally, we purchased \$9.8 million in short-term investments.

Net cash used in investing activities was \$33.4 million for the nine months ended September 30, 2018, primarily as a result of \$37.2 million in purchases of property, machinery, and equipment, which included \$12.3 million incurred in the United States, \$8.6 million in France, and \$16.3 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.

### Financing Activities

Net cash provided by financing activities was \$6.6 million for the nine months ended September 30, 2019, primarily as a result of the receipt of \$18.3 million for ANP private placement, and \$2.0 million in net proceeds received from our equity plans. This was partially offset by \$8.5 million used to purchase treasury stock. Additionally, we made \$5.2 million in principal payments on our long-term debt and lines of credit.

Net cash provided by financing activities was \$8.1 million for the nine months ended September 30, 2018, primarily as a result of \$26.2 million received from the ANP private placement, which was partially offset by \$22.4 million used to purchase treasury stock. Additionally, we made \$4.3 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 13 of Notes to Condensed Consolidated Financial Statements of this Quarterly Report.

### ***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, 2018, except that our outstanding debt obligations have changed as follows:

	September 30, 2019	December 31, 2018	Change
	(in thousands)		
Short-term debt and current portion of long-term debt	\$ 6,969	\$ 18,229	\$ (11,260)
Long-term debt	38,079	31,984	6,095
Total debt	<u>\$ 45,048</u>	<u>\$ 50,213</u>	<u>\$ (5,165)</u>

As of September 30, 2019, we had \$45.0 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, 2018.

There were no material changes to our critical accounting policies during the three and nine months ended September 30, 2019, other than the adoption of ASC 2016-02, Leases, or ASC 2016-02, using the alternative transition method. The results for the reporting period beginning after January 1, 2019, 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 to the condensed consolidated financial statements for more information regarding summary of Significant Accounting Policies.

### ***Off-Balance Sheet Arrangements***

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

### **Government Regulation**

The 340(B) Public Health Services drug pricing program provides drugs at reduced rates to certain qualifying customers. As of January 1, 2019, the program provided for increased discounts for certain products we sell, including Cortrosyn®.

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

From February 5, 2019 through February 12, 2019, our Amphastar facility in Rancho Cucamonga, California was subject to a preapproval inspection by the FDA. The inspection included a review of our corrective actions taken from the previous cGMP inspection in March 2017, as well as review of data to support our pending applications. The inspections resulted in multiple observations on Form 483. We fully responded to those observations on March 6, 2019. We believe that our responses to the observations will satisfy the requirements of the FDA and that no significant further actions will be necessary.

From February 25 through March 1, 2019, our IMS facility in South El Monte, California was subject to a preapproval inspection by the FDA. The inspection included a review of our corrective actions taken from the 2017 inspection as well as review of data to support our pending applications. The inspection resulted in multiple observations on Form 483. We responded to those observations on March 22, 2019. We believe that our responses to the observations will satisfy the requirements of the FDA and that no significant further actions will be necessary.

From July 23 through July 25, 2019, our Amphastar facility in Rancho Cucamonga, California was subject to a routine, post-marketing adverse drug experience reporting inspection, or PADE, by the FDA. The inspection included a review of our processes for collecting, reviewing, investigating and reporting post-marketing adverse drug experiences reported through various sources. The inspection resulted in no Form 483 findings. No further actions will be necessary.

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From August 27 through September 04, 2019, one of our California clinical trial sites was subject to a pre-approval biomonitoring inspection by the FDA. The inspection included a review of the clinical trial data to support one of our pending applications. The inspection resulted in no Form 483 findings. No further actions will be necessary.

From October 7 through October 11, 2019, our Chinese subsidiary ANP, was subject to a cGMP inspection by the FDA. The inspection included a review of compliance with FDA regulations relating to Good Manufacturing Practices. The inspection resulted in one observation on Form 483. We responded to that observation. We believe that our response to the observation will satisfy the requirements of the FDA and that no significant further actions will be necessary.

From October 24 to November 5, 2019, our IMS facility in South El Monte, California was subject to a preapproval inspection by the FDA. The inspection included a review of data to support our pending applications. The inspection resulted in observations on Form 483. We will respond to those observations within the required timeframe. We believe that our responses to the observations will satisfy the requirements of the FDA and that no significant further actions will be necessary.

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

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

#### *Investment Risk*

We regularly review the carrying value of our investments and identify and recognize losses, for income statement purposes, when events and circumstances indicate that any declines in the fair values of such investments below our accounting basis are other than temporary. As of September 30, 2019, none of our investments experienced any declines in fair value that are other than temporary. We do not enter into investments for trading or speculative purposes.

As of September 30, 2019, we had \$28.3 million deposited in seven banks located in China, \$4.3 million deposited in one bank located in France, and \$0.8 million deposited in one bank located in the United Kingdom. We also maintained \$42.6 million in cash equivalents that include money market accounts as of September 30, 2019. Additionally, we maintain approximately \$3.8 million in corporate bonds as of September 30, 2019. The remaining amounts of our cash equivalent as of September 30, 2019, 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 September 30, 2019, we had \$45.0 million in long-term debt and finance leases outstanding. Of this amount, \$11.5 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 5.3% at September 30, 2019. 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 \$0.1 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 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 British pounds. The results of operations are translated to USD at the average exchange rates during the period. Assets and liabilities are translated at the rate of exchange prevailing on the balance sheet date. Equity is translated at the prevailing exchange rate at the date of the equity transactions. Translation adjustments are reflected in stockholders' equity and are included as a component of other comprehensive income (loss).

We 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.

As of September 30, 2019, a 10% 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 \$3.2 million reduction of foreign currency gains, and approximately \$3.5 million reduction in other comprehensive income.

As of September 30, 2019, our foreign subsidiaries had cash balances denominated in foreign currencies of \$7.0 million.

#### **ITEM 4. CONTROLS AND PROCEDURES**

##### ***Evaluation of Disclosure Controls and Procedures***

Our management, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, our principal executive and principal financial officers, respectively, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934, as amended, as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that as of such date, 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 September 30, 2019, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act).

##### ***Inherent Limitations of Internal Controls***

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

## PART II. OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

For information regarding legal proceedings, see “Part I – Item 1. Financial Statements – Notes to Consolidated Financial Statements – Litigation.”

### 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, 2018, filed with the Securities and Exchange Commission on March 15, 2019.

***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 the 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 FDCA. The FDA has assessed these products in a program known as the “Prescription Drug Wrap-Up” and has stated that these drugs cannot be lawfully marketed unless they comply with certain “grandfather” exceptions to the definition of “new drug” in the FDCA. These exceptions have been strictly construed by FDA and by the courts, and the FDA has stated that it is unlikely that any of the unapproved prescription drugs on the market, including certain of our drugs, qualify for the exceptions. At any time, the FDA may require that some or all of our unapproved prescription drugs be submitted for approval and may direct 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 the 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, morphine, dextrose, and epinephrine prefilled syringes.

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, 2018, 2017, and 2016, we recorded net revenues of \$26.4 million, \$22.0 million, and \$17.4 million, respectively, from our unapproved products. For the nine months ended September 30, 2019 and 2018, we recorded net revenues of \$29.1 million and \$19.8 million, respectively, from our unapproved products. Our unapproved products currently on the market include: atropine, morphine, dextrose and epinephrine prefilled syringes. We have filed three 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.

**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:

<b>Period</b>	<b>Total Number of Shares Purchased <sup>(1)</sup></b>	<b>Average Price Paid per Share</b>	<b>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs</b>	<b>Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs</b>
July 1 – July 31, 2019	—	\$ —	—	—
August 1 – August 31, 2019	72,125	21.50	72,125	—
September 1 – September 30, 2019	134,561	21.32	134,561	—

(1) During the third quarter of 2019, we repurchased shares of our common stock as part of the share buyback program authorized by our Board of Directors on May 6, 2019. As of September 30, 2019, \$35.6 million remained available under such program.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

Not applicable.

**ITEM 6. EXHIBITS**

Exhibit No.	Description	Incorporated by reference herein		
		Form	Exhibit No.	Filing Date
10.1	<a href="#">Ninth Amendment to the Acquisition Loan, dated July 19, 2019 between Amphastar Pharmaceuticals, Inc. and Cathay Bank</a>	10-Q	10.1	August 9, 2019
10.2*	<a href="#">Fifth Amendment to the Supply Agreement by and between MannKind Corporation and Amphastar Pharmaceuticals, Inc., dated August 2, 2019</a>	10-Q	10.2	August 9, 2019
31.1	<a href="#">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</a>			
31.2	<a href="#">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</a>			
32.1#	<a href="#">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</a>			
32.2#	<a href="#">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</a>			
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.

\* Portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10).





5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2019

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

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**Exhibit 31.2**

**Certification**

I, William J. Peters, certify that:

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

Date: November 8, 2019

By:                     /s/ WILLIAM J. PETERS                      
William J. Peters

**Exhibit 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**

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

(i) the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2019 (the “Report”) fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and

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

Date: November 8, 2019

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

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

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**Exhibit 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**

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

(i) the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2019 (the “Report”) fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and

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

Date: November 8, 2019

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

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

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