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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2021
or

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

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

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

Delaware	**33-0702205**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
11570 6th Street **Rancho Cucamonga, CA**	**91730**
(Address of principal executive offices)	**(zip code)**

(909) 980-9484
(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

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

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

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

The number of shares outstanding of the registrant's only class of common stock as of May 3, 2021 was 47,635,351.

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 impact of the COVID-19 pandemic and related responses of business and governments to the pandemic on our operations and personnel, and on commercial activity and demand across our business operations and results of operations;
- interruptions to our manufacturing and production as a result of natural catastrophic events or other causes beyond our control such as power disruptions or widespread disease outbreaks, such as the COVID-19 pandemic;
- global, national and local economic and market conditions, specifically with respect to geopolitical uncertainty, and the COVID-19 pandemic;
- 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, including its restructuring;
- 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;
- the impact of trade tariffs, export or import restrictions, 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, as amended by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act;
- the timing for completion and the validation of the new construction at our ANP and Amphastar facilities;
- the timing and extent of share buybacks; 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. In particular, the extent of COVID-19's impact on our business will depend on several factors, including the severity, duration and extent of the pandemic, all of which continue to evolve and remain uncertain at this time. 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, 2020, particularly in Item 1A. "Risk Factors." These forward-looking statements represent our estimates and assumptions only as of the date of this Quarterly Report regardless of the time of delivery of this Quarterly Report, and such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this Quarterly Report.

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

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2021 (unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 101,601	$ 92,642
Restricted cash	235	1,865
Short-term investments	13,531	12,977
Restricted short-term investments	2,200	2,200
Accounts receivable, net	77,938	66,005
Inventories	97,110	96,831
Income tax refunds and deposits	800	385
Prepaid expenses and other assets	6,749	6,777
Total current assets	300,164	279,682
Property, plant, and equipment, net	253,265	260,055
Finance lease right-of-use assets	594	612
Operating lease right-of-use assets	19,280	20,042
Goodwill and intangible assets, net	40,243	40,615
Other assets	7,212	5,250
Deferred tax assets	24,980	24,980
Total assets	$ 645,738	$ 631,236
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 108,545	$ 95,504
Income taxes payable	2,676	1,077
Current portion of long-term debt	12,173	12,263
Current portion of operating lease liabilities	3,702	3,357
Total current liabilities	127,096	112,201
Long-term reserve for income tax liabilities	4,709	4,709
Long-term debt, net of current portion	32,334	34,186
Long-term operating lease liabilities, net of current portion	16,464	17,464
Deferred tax liabilities	755	741
Other long-term liabilities	13,420	13,212
Total liabilities	194,778	182,513
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; 55,184,000 and 47,718,003 shares issued and outstanding as of March 31, 2021 and 54,760,922 and 47,495,439 shares issued and outstanding as of December 31, 2020, respectively	6	5
Additional paid-in capital	413,926	410,061
Retained earnings	122,814	117,773
Accumulated other comprehensive loss	(5,642)	(3,721)
Treasury stock	(125,546)	(121,812)
Total Amphastar Pharmaceuticals, Inc. stockholders’ equity	405,558	402,306
Non-controlling interests	45,402	46,417
Total equity	450,960	448,723
Total liabilities and stockholders’ equity	$ 645,738	$ 631,236

See Accompanying Notes to Condensed Consolidated Financial Statements.

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

	Three Months Ended March 31,	
	2021	2020
Net revenues	$ 103,020	$ 84,688
Cost of revenues	58,074	47,865
Gross profit	44,946	36,823
Operating expenses:		
Selling, distribution, and marketing	4,537	3,294
General and administrative	15,338	10,746
Research and development	14,765	15,303
Total operating expenses	34,640	29,343
Income from operations	10,306	7,480
Non-operating (expenses) income:		
Interest income	161	153
Interest expense	(104)	(76)
Other expenses, net	(5,249)	(1,752)
Total non-operating (expenses) income, net	(5,192)	(1,675)
Income before income taxes	5,114	5,805
Income tax provision	1,155	2,280
Net income	$ 3,959	$ 3,525
Net loss attributable to non-controlling interests	$ (1,082)	$ (424)
Net income attributable to Amphastar Pharmaceuticals, Inc.	$ 5,041	$ 3,949
Net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders:		
Basic	$ 0.11	$ 0.09
Diluted	$ 0.10	$ 0.08
Weighted-average shares used to compute net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders:		
Basic	47,520	46,408
Diluted	49,518	48,248

See Accompanying Notes to Condensed Consolidated Financial Statements.

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

	Three Months Ended March 31,	
	2021	2020
Net income attributable to Amphastar Pharmaceuticals, Inc.	$ 5,041	$ 3,949
Other comprehensive loss attributable to Amphastar Pharmaceuticals, Inc., net of income taxes		
Foreign currency translation adjustment	(1,921)	(774)
Total other comprehensive loss attributable to Amphastar Pharmaceuticals, Inc.	(1,921)	(774)
Total comprehensive income attributable to Amphastar Pharmaceuticals, Inc.	$ 3,120	$ 3,175

See Accompanying Notes to Condensed Consolidated Financial Statements.

AMPHASTAR PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited; in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive loss	Treasury Stock		Total Amphastar Stockholders' Equity	Non-controlling Interest	Total
	Shares	Amount				Shares	Amount			
Balance as of December 31, 2020	54,760,922	$ 5	$ 410,061	$ 117,773	$ (3,721)	(7,265,483)	$ (121,812)	$ 402,306	$ 46,417	$ 448,723
Net income attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	5,041	—	—	—	5,041	—	5,041
Other comprehensive loss attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	—	(1,921)	—	—	(1,921)	—	(1,921)
Net loss attributable to non-controlling interest	—	—	—	—	—	—	—	—	(1,082)	(1,082)
Purchase of treasury stock	—	—	—	—	—	(204,698)	(3,783)	(3,783)	—	(3,783)
Issuance of treasury stock in connection with the Company's equity plans	—	—	(49)	—	—	4,184	49	—	—	—
Issuance of common stock in connection with the Company's equity plans	423,078	1	(853)	—	—	—	—	(852)	—	(852)
Share-based compensation expense	—	—	4,767	—	—	—	—	4,767	67	4,834
Balance as of March 31, 2021	55,184,000	$ 6	$ 413,926	$ 122,814	$ (5,642)	(7,465,997)	$ (125,546)	$ 405,558	$ 45,402	$ 450,960

	Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive loss	Treasury Stock		Total Amphastar Stockholders' Equity	Non-controlling Interest	Total
	Shares	Amount				Shares	Amount			
Balance as of December 31, 2019	52,495,483	$ 5	$ 367,305	$ 116,370	$ (4,687)	(5,918,515)	$ (97,627)	$ 381,366	$ 46,162	$ 427,528
Net income attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	3,949	—	—	—	3,949	—	3,949
Other comprehensive loss attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	—	(774)	—	—	(774)	—	(774)
Net loss attributable to non-controlling interest	—	—	—	—	—	—	—	—	(424)	(424)
Purchase of treasury stock	—	—	—	—	—	(647,246)	(10,950)	(10,950)	—	(10,950)
Issuance of treasury stock in connection with the Company's equity plans	—	—	(84)	—	—	6,873	84	—	—	—
Issuance of common stock in connection with the Company's equity plans	369,508	—	(1,238)	—	—	—	—	(1,238)	—	(1,238)
Share-based compensation expense	—	—	5,161	—	—	—	—	5,161	121	5,282
Balance as of March 31, 2020	52,864,991	$ 5	$ 371,144	$ 120,319	$ (5,461)	(6,558,888)	$ (108,493)	$ 377,514	$ 45,859	$ 423,373

See Accompanying Notes to Condensed Consolidated Financial Statements

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

	Three Months Ended March 31,	
	2021	2020
Cash Flows From Operating Activities:		
Net income	$ 3,959	$ 3,525
Reconciliation to net cash provided by operating activities:		
Loss on disposal of assets	6	14
Depreciation of property, plant, and equipment	5,686	4,716
Amortization of product rights, trademarks, and patents	276	258
Operating lease right-of-use asset amortization	863	848
Share-based compensation expense	4,834	5,282
Changes in deferred taxes, net	—	1,638
Changes in operating assets and liabilities:		
Accounts receivable, net	(12,078)	(12,487)
Inventories	(1,144)	2,241
Prepaid expenses and other assets	1,119	1,494
Income tax refunds, deposits, and payable, net	1,182	451
Operating lease liabilities	(754)	(824)
Accounts payable and accrued liabilities	18,876	(5,679)
Net cash provided by operating activities	22,825	1,477
Cash Flows From Investing Activities:		
Purchases and construction of property, plant, and equipment	(7,618)	(8,006)
Sales of short-term investments	—	21
Purchase of short-term investments	(4,501)	(4,561)
Maturity of short-term investments	3,944	4,030
Payment of deposits and other assets	(520)	(206)
Net cash used in investing activities	(8,695)	(8,722)
Cash Flows From Financing Activities:		
Proceeds from equity plans, net of withholding tax payments	(854)	(1,238)
Purchase of treasury stock	(3,783)	(10,950)
Proceeds from issuance of long-term debt	—	3,067
Principal payments on long-term debt	(2,002)	(2,328)
Net cash used in financing activities	(6,639)	(11,449)
Effect of exchange rate changes on cash	(162)	(146)
Net increase (decrease) in cash, cash equivalents, and restricted cash	7,329	(18,840)
Cash, cash equivalents, and restricted cash at beginning of period	94,507	75,550
Cash, cash equivalents, and restricted cash at end of period	$ 101,836	$ 56,710
Noncash Investing and Financing Activities:		
Capital expenditure included in accounts payable	$ 6,238	$ 5,840
Operating lease right-of-use assets	$ 103	$ —
Equipment acquired under finance leases	$ 74	$ —
Supplemental Disclosures of Cash Flow Information:		
Interest paid, net of capitalized interest	$ 508	$ 559
Income taxes paid	$ 30	$ 209

See Accompanying Notes to Condensed Consolidated Financial Statements.

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

Note 1. General

Amphastar Pharmaceuticals, Inc., a Delaware corporation (together with its subsidiaries, hereinafter referred to as the "Company") is a bio-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.

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, 2020 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, 2020. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with generally accepted accounting principles, or GAAP, have been condensed or omitted from the accompanying condensed consolidated financial statements. The accompanying year-end condensed consolidated balance sheet was derived from the audited financial statements. The accompanying interim financial statements are unaudited, but reflect all adjustments which are, in the opinion of management, necessary for a fair statement of the Company's consolidated financial position, results of operations, comprehensive income (loss), stockholders' equity, and cash flows for the periods presented. Unless otherwise noted, all such adjustments are of a normal, recurring nature. The Company's results of operations, comprehensive income (loss) and cash flows for the interim periods are not necessarily indicative of the results of operations and cash flows that it may achieve in future periods.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited condensed consolidated financial statements include the accounts of the Company and its subsidiaries, and are prepared in accordance with United States generally accepted accounting principles, or GAAP. Certain prior period amounts have been reclassified within the investing activities of the statement of cash flows to conform to the current period presentation. 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, which are of a normal recurring nature, necessary to present fairly the consolidated financial position, results of operations, and cash flows of the Company.

The Company's subsidiaries include: (1) International Medication Systems, Limited, or IMS, (2) Armstrong Pharmaceuticals, Inc., or Armstrong, (3) Amphastar Nanjing Pharmaceuticals Inc., or ANP, (4) Nanjing Letop Biological Technology Co., Ltd., or Letop, (5) Nanjing Hanxin Pharmaceutical Technology Co., Ltd., or Hanxin, (6) Nanjing Hanxin Biomedical Testing Service Co., Ltd., or Hanxin Biomedical, (7) Nanjing Baixin Trading Co., Ltd., or Baixin, (8) Amphastar France Pharmaceuticals, S.A.S., or AFP, (9) Amphastar UK Ltd., or AUK, and (10) 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 and received approximately $56.3 million of cash proceeds, a portion of which was received in 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 ANP with the Company's results of operations. ANP's net income after July 2, 2018, was attributed to the Company in accordance with the Company's equity interest of approximately 58% in ANP.

COVID-19 Pandemic

The Company is subject to risks and uncertainties as a result of the ongoing novel coronavirus pandemic, or COVID-19. The complete extent of the impact of the COVID-19 pandemic on the Company's business is highly uncertain and difficult to predict, as the information is constantly evolving. The Company considered the impact of COVID-19 on the assumptions and estimates used to determine the results reported and asset valuations as of March 31, 2021.

All of the Company's production facilities continued to operate during the quarter as they had prior to the COVID-19 pandemic with very little change, other than for enhanced safety measures intended to prevent the spread of the virus.

It is not possible at this time to estimate the complete impact that COVID-19 could have on the Company's business, including its customers and suppliers, as the impact will depend on future developments, which are highly uncertain and cannot be predicted. The Company will continue to monitor the impact of COVID-19 on all aspects of its business.

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 credit losses, allowance for 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, 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 US Dollar. ANP maintains its books of record in Chinese yuan. These books are remeasured into the functional currency of USD using 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 condensed consolidated statements of operations.

The Company's French subsidiary, AFP, maintains its book of record in euros. ANP's subsidiaries maintain their books of record in Chinese yuan. AUK's 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 months ended March 31, 2021 and 2020 were $1.5 million loss and $0.6 million loss, respectively.

Comprehensive Income (Loss)

For the three months ended March 31, 2021 and 2020, the Company included its foreign currency translation gain or loss as part of its comprehensive income (loss). No income tax expense (benefit) was allocated to other comprehensive income (loss) for the three months ended March 31, 2021 and 2020.

Advertising Expense

Advertising expenses, primarily associated with Primatene Mist®, are recorded as they are incurred, except for expenses related to the development of a major commercial or media campaign, which are expensed in the period in which the commercial or campaign is first presented, and are reflected as a component of selling, distribution and marketing in the Company's condensed consolidated statement of operations. For the three months ended March 31, 2021 and 2020, advertising expense was $2.2 million and $1.0 million, respectively.

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.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash, money market accounts, certificates of deposit and highly liquid investments purchased with original maturities of three months or less.

Short-Term Investments

Short-term investments as of March 31, 2021 and December 31, 2020 consisted of certificates of deposit and investment grade debt securities with original expiration dates within 12 months.

Restricted Cash

Restricted cash is collateral required for the Company to guarantee certain vendor payments in France. As of March 31, 2021 and December 31, 2020, the restricted cash balance was $0.2 million and $1.9 million, respectively.

Restricted Short-Term Investments

Restricted short-term investments consist of certificates of deposit that are collateral for standby letters of credit to qualify for workers' compensation self-insurance. The certificates of deposit have original maturities greater than three months, but less than one year. As of March 31, 2021 and December 31, 2020, the balance of restricted short-term investments was $2.2 million.

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 December 2019, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update, or ASU,

No. 2019-12 *Simplifying the Accounting for Income Taxes (Topic 740)*. The amendment removes certain exceptions for performing intra-period tax allocations, recognizing deferred taxes for investment, and calculating income taxes in interim periods. The guidance also simplifies the accounting for franchise taxes, transactions that result in a step-up in the tax basis of goodwill, and the effect of enacted changes in tax laws or rates in interim periods. The guidance is effective for the Company's interim and annual reporting periods during the year ended December 31, 2021. The adoption of this accounting guidance did not have a material impact on the Company's condensed consolidated financial statements and related disclosures.

Note 3. Revenue Recognition

In accordance with Accounting Standard Codification, or ASC, 606 *Revenue from Contracts with Customers*, 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.

The consideration the Company receives in exchange for its goods or services is only recognized when it is probable that a significant reversal will not occur. The consideration to which the Company expects to be entitled includes a stated list price, less various forms of variable consideration. The Company makes significant estimates for related variable consideration at the point of sale, including chargebacks, rebates, product returns, other discounts and allowances.

The Company's payment terms vary by types and locations of customers and the products or services offered. Payment terms differ by jurisdiction and customers, but payment is generally required in a term ranging from 30 to 75 days from date of shipment or satisfaction of the performance obligation. For certain products or services and certain customer types, we may require payment before products are delivered or services are rendered to customers.

Provisions for estimated chargebacks, rebates, discounts, product returns and credit losses are made at the time of sale and are analyzed and adjusted, if necessary, at each balance sheet date.

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'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 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:

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Beginning balance	$ 20,380	$ 21,644
Provision for chargebacks and rebates	47,031	35,987
Credits and payments issued to third parties	(46,881)	(39,353)
Ending balance	$ 20,530	$ 18,278

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 March 31, 2021 and December 31, 2020, $16.4 million and $16.4 million were included in accounts receivable, net, on the condensed consolidated balance sheets, respectively. The remaining provision as of March 31, 2021 and December 31, 2020 of $4.1 million and $4.0 million, respectively, were included in accounts payable and accrued liabilities.

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.

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

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Beginning balance	$ 14,204	$ 10,339
Provision for product returns	3,233	3,099
Credits issued to third parties	(2,517)	(2,239)
Ending balance	$ 14,920	$ 11,199

Of the provision for product returns as of March 31, 2021 and December 31, 2020, $10.7 million and $10.2 million, were included in accounts payable and accrued liabilities on the condensed consolidated balance sheets, respectively. The remaining provision as of March 31, 2021 and December 31, 2020 of $4.2 million and $4.0 million, respectively, were included in other long-term liabilities. For the three months ended March 31, 2021 and 2020, the Company's aggregate product return rate was 1.4% and 1.1% of qualified sales, respectively.

Note 4. Income per Share Attributable to Amphastar Pharmaceuticals, Inc. Stockholders

Basic net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders is calculated based upon the weighted-average number of shares outstanding during the period. Diluted net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders 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 reallocation of net income attributable to non-controlling interest from the assumed dilutive effect of stock options issued under the 2018 ANP Equity Incentive Plan, or the 2018 Plan.

For the three months ended March 31, 2021, options to purchase 1,899,833 shares of stock with a weighted-average exercise price of $20.85 per share, and the reallocation of net income attributable to non-controlling interests were excluded in the computation of diluted net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders because the effect would be anti-dilutive.

For the three months ended March 31, 2020, options to purchase 1,999,083 shares of stock with a weighted-average exercise price of $20.81 per share, and the reallocation of net income attributable to non-controlling interest were excluded in the computation of diluted net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders because the effect would be anti-dilutive.

The following table provides the calculation of basic and diluted net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders for each of the periods presented:

	Three Months Ended March 31,	
	2021	2020
	(in thousands, except per share data)	
Basic and dilutive numerator:		
Net income attributable to Amphastar Pharmaceuticals, Inc.	$ 5,041	$ 3,949
Denominator:		
Weighted-average shares outstanding — basic	47,520	46,408
Net effect of dilutive securities:		
Incremental shares from equity awards	1,998	1,840
Weighted-average shares outstanding — diluted	49,518	48,248
Net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders — basic	$ 0.11	$ 0.09
Net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders — diluted	$ 0.10	$ 0.08

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 Primatene Mist®, glucagon, enoxaparin, naloxone, phytonadione, lidocaine, epinephrine, 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.

Selected financial information by reporting segment is presented below:

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Net revenues:		
Finished pharmaceutical products	$ 97,882	$ 81,298
API	5,138	3,390
Total net revenues	103,020	84,688
Gross profit (loss):		
Finished pharmaceutical products	45,286	38,810
API	(340)	(1,987)
Total gross profit	44,946	36,823
Operating expenses	34,640	29,343
Income from operations	10,306	7,480
Non-operating expense	(5,192)	(1,675)
Income before income taxes	$ 5,114	$ 5,805

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

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

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Finished pharmaceutical products net revenues:		
Primatene Mist®	$ 18,383	$ 12,877
Epinephrine	15,578	3,990
Enoxaparin	10,658	9,168
Phytonadione	9,565	11,029
Lidocaine	9,071	10,657
Glucagon	7,984	—
Naloxone	6,341	8,875
Other finished pharmaceutical products	20,302	24,702
Total finished pharmaceutical products net revenues	$ 97,882	$ 81,298

The amount of depreciation and amortization expense included in cost of revenues, by reporting segments is presented below:

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Depreciation and amortization expense		
Finished pharmaceutical products	$ 1,435	$ 1,464
API	1,048	582
Total depreciation and amortization expense	$ 2,483	$ 2,046

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

	Net Revenue		Long-Lived Assets	
	Three Months Ended March 31,		March 31,	December 31,
	2021	2020	2021	2020
	(in thousands)			
United States	$ 99,170	$ 81,065	$ 125,861	$ 129,401
China	1,121	228	97,847	98,538
France	2,729	3,395	49,431	52,770
Total	$ 103,020	$ 84,688	$ 273,139	$ 280,709

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 months ended March 31, 2021 and 2020 and accounts receivable as of March 31, 2021 and

December 31, 2020, respectively. The following table provides accounts receivable and net revenue information for these major customers:

	% of Total Accounts Receivable		% of Net Revenue Three Months Ended March 31,	
	March 31, 2021	December 31, 2020	2021	2020
AmerisourceBergen	14 %	9 %	25 %	24 %
McKesson	21 %	24 %	20 %	22 %
Cardinal Health	16 %	17 %	15 %	19 %

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.

Note 7. Fair Value Measurements

GAAP defines 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 March 31, 2021, cash equivalents include money market accounts. Short-term investments consist of certificates of deposit as well as investment-grade corporate and municipal bonds with original expiration dates within 12 months. The certificates of deposit are carried at amortized cost in the Company's condensed consolidated balance sheet, which approximates their fair value determined based on Level 2 inputs. The corporate and municipal bonds are classified as held-to-maturity and are carried at amortized cost net of allowance for credit losses, 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 March 31, 2021 and December 31, 2020, are as follows:

	Total	(Level 1)	(Level 2)	(Level 3)
		(in thousands)		
Cash equivalents - money market	$ 76,536	$ 76,536	$ —	$ —
Restricted cash - money market	235	235	—	—
Short-term investments - certificates of deposit	9,284	—	9,284	—
Restricted short-term investments - certificates of deposit	2,200	—	2,200	—
Corporate and municipal bonds	4,199	—	4,199	—
Interest rate swap liabilities related to variable rate loans	(723)	—	(723)	—
Fair value measurement as of March 31, 2021	$ 91,731	$ 76,771	$ 14,960	$ —
Cash equivalents - money market	$ 58,710	$ 58,710	$ —	$ —
Restricted cash - money market	1,865	1,865	—	—
Short-term investments - certificates of deposit	9,089	—	9,089	—
Restricted short-term investments - certificates of deposit	2,200	—	2,200	—
Corporate and municipal bonds	3,855	—	3,855	—
Interest rate swap liabilities related to variable rate loans	(902)	—	(902)	—
Fair value measurement as of December 31, 2020	$ 74,817	$ 60,575	$ 14,242	$ —

The Company does not hold any Level 3 instruments that are measured at 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 March 31, 2021 and December 31, 2020, there were no significant adjustments to fair value for nonfinancial assets or liabilities.

Note 8. Investments

A summary of the Company's investments that are classified as held-to-maturity are as follows:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(in thousands)		
Corporate bonds	$ 1,053	$ —	$ (1)	$ 1,052
Municipal bonds	3,148	—	(1)	3,147
Total investments as of March 31, 2021	$ 4,201	$ —	$ (2)	$ 4,199
Corporate bonds	$ 1,560	$ —	$ (1)	$ 1,559
Municipal bonds	2,297	—	(1)	2,296
Total investments as of December 31, 2020	$ 3,857	$ —	$ (2)	$ 3,855

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 indicate a material credit loss.

The Company measures expected credit losses on held-to-maturity investments on a collective basis. All the Company's held-to-maturity investments were considered to be one pool. The estimate for credit losses considers historical loss

information that is adjusted for current conditions and reasonable and supportable forecasts. Expected credit losses on held-to-maturity investments were not material to the condensed consolidated financial statements.

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)		
Definite-lived intangible assets				
IMS (UK) international product rights	10	$ 9,640	$ 4,499	$ 5,141
Patents	12	486	308	178
Land-use rights	39	2,540	634	1,906
Subtotal	12	12,666	5,441	7,225
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill - Finished pharmaceutical products	*	3,793	—	3,793
Subtotal	*	33,018	—	33,018
As of March 31, 2021	*	$ 45,684	$ 5,441	$ 40,243

	Weighted-Average Life (Years)	Original Cost	Accumulated Amortization	Net Book Value
		(in thousands)		
Definite-lived intangible assets				
IMS (UK) international product rights	10	$ 9,561	$ 4,223	$ 5,338
Patents	12	486	297	189
Land-use rights	39	2,540	617	1,923
Subtotal	12	12,587	5,137	7,450
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill - Finished pharmaceutical products	*	3,940	—	3,940
Subtotal	*	33,165	—	33,165
As of December 31, 2020	*	$ 45,752	$ 5,137	$ 40,615

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

Goodwill

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

	March 31, 2021	December 31, 2020
	(in thousands)	
Beginning balance	$ 3,940	$ 3,634
Currency translation	(147)	306
Ending balance	$ 3,793	$ 3,940

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 March 31, 2021.

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.

Note 10. Inventories

Inventories consist of the following:

	March 31, 2021	December 31, 2020
	(in thousands)	
Raw materials and supplies	$ 43,258	$ 47,051
Work in process	35,081	37,257
Finished goods	18,771	12,523
Total inventories	$ 97,110	$ 96,831

Charges of $9.5 million and $2.1 million were included in the cost of revenues in the Company's condensed consolidated statements of operations for the three months ended March 31, 2021 and 2020, respectively, to adjust the Company's inventory and related firm purchase commitments to their net realizable value.

Losses on firm purchase commitments related to raw materials on order were $8.6 million and $2.1 million as of March 31, 2021 and 2020, respectively.

Note 11. Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

	March 31, 2021	December 31, 2020
	(in thousands)	
Buildings	$ 124,952	$ 124,326
Leasehold improvements	30,093	30,028
Land	7,659	7,719
Machinery and equipment	210,776	211,666
Furniture, fixtures, and automobiles	26,862	26,482
Construction in progress	42,165	43,981
Total property, plant, and equipment	442,507	444,202
Less accumulated depreciation	(189,242)	(184,147)
Total property, plant, and equipment, net	$ 253,265	$ 260,055

Note 12. Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consisted of the following:

	March 31, 2021	December 31, 2020
	(in thousands)	
Accrued customer fees and rebates	$ 10,466	$ 9,029
Accrued payroll and related benefits	26,742	24,597
Accrued product returns, current portion	10,676	10,190
Accrued loss on firm purchase commitments	8,625	1,223
Accrued litigation and settlements	19,449	13,780
Other accrued liabilities	9,600	12,328
Total accrued liabilities	85,558	71,147
Accounts payable	22,987	24,357
Total accounts payable and accrued liabilities	$ 108,545	$ 95,504

Note 13. Debt

Debt consists of the following:

	March 31, 2021	December 31, 2020
	(in thousands)	
Line of Credit Facilities		
Line of credit facility with China Everbright Bank due June 2021	$ 763	$ 764
Line of credit facility with China Merchant Bank due August 2021	381	382
Line of credit facility with Bank of Nanjing due October 2021	153	153
Line of credit facility with Cathay Bank due May 2022	—	—
Line of credit facility with East West Bank due December 2022	—	—
Equipment line of credit facility with East West Bank due September 2025	3,216	3,216
Mortgage Loans		
Mortgage payable with East West Bank due May 2021	3,282	3,306
Mortgage payable with East West Bank due October 2026	3,317	3,334
Mortgage payable with East West Bank due June 2027	8,472	8,510
Mortgage payable with Cathay Bank due August 2027	7,220	7,268
Equipment Loans		
Equipment loan with East West Bank due June 2021	306	612
Equipment loan with East West Bank due December 2022	3,500	4,000
Equipment loan with East West Bank due February 2024	4,839	5,254
Other Loans and Payment Obligations		
Acquisition loan with Cathay Bank due June 2024	8,137	8,710
French government loan due July 2021	64	64
French government loans due December 2026	338	350
Equipment under Finance Leases	519	526
Total debt	44,507	46,449
Less current portion of long-term debt	12,173	12,263
Long-term debt, net of current portion	$ 32,334	$ 34,186

As of March 31, 2021, 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.

Covenants

At March 31, 2021 and December 31, 2020, the Company was in compliance with its debt covenants.

Note 14. Income Taxes

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

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Income before taxes	$ 5,114	$ 5,805
Income tax provision	1,155	2,280
Net income	$ 3,959	$ 3,525
Income tax provision as a percentage of income before income taxes	22.6 %	39.3 %

The Company's effective tax rate for the three months ended March 31, 2021 decreased in comparison to the three months ended March 31, 2020, primarily due to differences in pre-tax income positions and timing of discrete tax items.

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 income tax assets will be realized. Ultimately, realization 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 continues to record a full valuation allowance on the net deferred income tax assets of its subsidiaries AFP and Hanxin and will continue to do so until the subsidiaries generate sufficient taxable income to realize their respective deferred income tax assets.

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 expense by $0.1 million and $0.2 million during the three months ended March 31, 2021 and 2020, respectively.

Note 15. Stockholders' Equity

Share Buyback Program

Pursuant to the Company's existing share buyback program, the Company purchased 204,698 and 646,715 shares of its common stock during the three months ended March 31, 2021 and 2020, totaling $3.8 million and $10.9 million, respectively.

In August 2020, 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 condensed consolidated balance sheets.

Amended and Restated 2015 Equity Incentive Plan

As of March 31, 2021, the Company reserved an aggregate of 6,181,926 shares of common stock for future issuance under the Amended and Restated 2015 Equity Incentive Plan, or the 2015 Plan, including 1,187,386 shares, which were reserved in January 2021 pursuant to the evergreen provision in the 2015 Plan.

2014 Employee Stock Purchase Plan

As of March 31, 2021, the Company has issued 807,550 shares of common stock under the ESPP and 1,192,450 shares of its common stock remains available for issuance under the ESPP.

For the three months ended March 31, 2021 and 2020, the Company recorded ESPP expense of $0.1 million and $0.1 million, respectively.

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. 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 months ended March 31, 2021 and 2020, are as follows:

	Three Months Ended March 31,	
	2021	2020
Average volatility	42.2 %	43.0 %
Average risk-free interest rate	1.3 %	0.8 %
Weighted-average expected life in years	6.3	5.8
Dividend yield rate	— %	— %

A summary of option activity for the three months ended March 31, 2021, is presented below:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value[1] (in thousands)
Outstanding as of December 31, 2020	8,580,475	$ 15.00		
Options granted	1,166,702	17.99		
Options exercised	(173,436)	12.64		
Options cancelled	(51,506)	15.67		
Options expired	(31,854)	11.66		
Outstanding as of March 31, 2021	9,490,381	$ 15.42	5.63	$ 32,322
Exercisable as of March 31, 2021	6,588,157	$ 14.83	4.28	$ 26,310

(1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the estimated fair value of the Company's common stock for those awards that have an exercise price below the estimated fair value at March 31, 2021.

For the three months ended March 31, 2021 and 2020, the Company recorded an expense of $2.4 million and $2.6 million, respectively, related to stock options granted under all plans.

Information relating to option grants and exercises is as follows:

	Three Months Ended March 31,	
	2021	2020
	(in thousands, except per share data)	
Weighted-average grant date fair value per option share	$ 7.66	$ 5.33
Intrinsic value of options exercised	1,029	488
Cash received from options exercised	2,169	1,251
Total fair value of the options vested during the year	6,772	7,432

A summary of the status of the Company's non-vested options as of March 31, 2021, and changes during the three months ended March 31, 2021, is presented below:

	Options	Weighted-Average Grant Date Fair Value
Non-vested as of December 31, 2020	2,825,652	$ 6.50
Options granted	1,166,702	7.66
Options vested	(1,038,624)	6.52
Options forfeited	(51,506)	6.77
Non-vested as of March 31, 2021	2,902,224	6.96

As of March 31, 2021, there was $16.3 million of total unrecognized compensation cost, net of forfeitures, related to non-vested stock option based compensation arrangements granted under all plans. The cost is expected to be recognized over a weighted-average period of 3.0 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 months ended March 31, 2021 and 2020, the Company recorded expenses of $2.2 million and $2.4 million, respectively, related to RSU awards granted under all plans.

As of March 31, 2021, there was $17.6 million of total unrecognized compensation cost, net of forfeitures, related to non-vested RSU-based compensation arrangements granted under all plans. The cost is expected to be recognized over a weighted-average period of 3.0 years and will be adjusted for future changes in estimated forfeitures.

Information relating to RSU grants and deliveries is as follows:

	Total RSUs Issued	Total Fair Market Value of RSUs Issued as Compensation[1] (in thousands)
RSUs outstanding at December 31, 2020	1,156,518	
RSUs granted	496,742	$ 8,936
RSUs forfeited	(22,627)	
RSUs vested[2]	(416,973)	
RSUs outstanding at March 31, 2021	1,213,660	

(1) The total fair market value is derived from the number of RSUs granted times the current stock price on the date of grant.
(2) Of the vested RSUs, 161,147 shares of common stock were surrendered to fulfill tax withholding obligations.

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. As of March 31, 2021, ANP granted 6,082,377 stock options to its employees under the 2018 Plan. The number of stock options outstanding as of March 31, 2021 was 5,037,280. The options vest over a period of approximately four years and have up to a 10 year contractual term. For the three months ended March 31, 2021 and 2020, the Company recorded expense of $0.1 million and $0.1 million related to stock options issued by ANP under the 2018 Plan, respectively.

Share-based Compensation Expense

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

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Cost of revenues	$ 1,146	$ 1,359
Operating expenses:		
Selling, distribution, and marketing	127	107
General and administrative	2,968	3,219
Research and development	593	597
Total share-based compensation	$ 4,834	$ 5,282

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 months ended March 31, 2021 and 2020, were approximately $0.5 million and $0.5 million, respectively.

Defined Benefit Pension Plan

The Company's subsidiary, AFP, has an obligation associated with a defined-benefit plan for its eligible employees. 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 0.30% as of March 31, 2021 and December 31, 2020. The liability is included in accrued liabilities in the accompanying condensed consolidated balance sheets. The plan is currently unfunded, and the benefit obligation under the plan was $2.9 million and $3.0 million at March 31, 2021 and December 31, 2020. The Company recorded an immaterial amount of expense under the plan for the three months ended March 31, 2021 and 2020.

Deferred Compensation Plan

In December 2019, the Company established a non-qualified deferred compensation plan. The deferred compensation plan allows certain eligible participants to defer a portion of their cash compensation and provides a matching contribution at the discretion of the Company. The plan obligations are payable upon retirement, termination of employment and/or certain other times in a lump-sum distribution or in installments, as elected by the participant in accordance with the plan. Participants can allocate their deferred compensation amongst various investment options with earnings accruing to the participant. The Company has established a Rabbi Trust to fund the plan obligations and to hold the plan assets. Eligible participants began contributing to the plan in January 2020. As of March 31, 2021, the plan assets and liabilities were valued at approximately $2.0 million and $2.1 million, respectively. As of December 31, 2020, the plan assets and liabilities were valued at approximately $1.6 million and $1.7 million, respectively.

Note 17. Commitments and Contingencies

Purchase Commitments

As of March 31, 2021, the Company has entered into commitments to purchase equipment and raw materials for an aggregate amount of approximately $52.4 million. The Company anticipates that most of these commitments with a remaining term in excess of one year will be fulfilled by 2022.

Note 18. Litigation

Amphastar Pharmaceuticals, Inc. v. Aventis Pharma, SA

In January 2009, the Company filed a *qui tam* complaint in the U.S. District Court for the Central District of California, alleging that Aventis Pharma S.A., or Aventis, through its acquisition of a patent through false and misleading statements to the U.S. Patent and Trademark Office, as well as through false and misleading statements to the FDA, overcharged the federal and state governments for its Lovenox® product.

On May 11, 2017, the Company's lawsuit against Aventis was dismissed for lack of jurisdiction. 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.

On November 13, 2020, the Court issued an Order ("November Order") awarding Aventis $12.1 million in attorneys' fees and $0.7 million in costs and expenses, and ordered Aventis to submit updated calculations on accrued interest.

On May 3, 2021, the Court issued a further Order based upon supplemental application to the Court seeking fees, expenses, and interest for the period after, and not covered by, the November Order. The Court awarded Aventis an additional $4.4 million bringing the total awarded Aventis to $17.2 million.

The Company had previously accrued $12.8 million as of December 31, 2020, based upon the November Order. As a result of the most recent ruling, the Company recorded an additional charge of $4.4 million for the three months ended March 31, 2021, in other income (expenses), in the condensed consolidated statement of operations. This amount represents management's best estimate of the probable loss at this time. There is a reasonable possibility that the final fee award could change; however, at this time, the range of loss cannot be estimated. The Company intends to continue to vigorously defend against any imposition of attorneys' fees and expenses in this case.

Regadenoson (0.4 mg/5 mL, 0.08 mg/mL) Patent Litigation

On February 25, 2020, Astellas US LLC, Astellas Pharma US, Inc., and Gilead Sciences, Inc. (collectively, "Astellas-Gilead") filed a Complaint in the United States District Court for the District of Delaware against IMS for infringement of U.S. Patent Nos. 8,106,183 (the "'183 patent"), RE47,301 (the "'301 patent"), and 8,524,883 (the "'883 patent") (collectively, "Astellas-Gilead Patents") with regard to IMS's ANDA No. 214,252 for approval to manufacture and sell 0.4 mg/5 mL (0.08 mg/mL) intravenous solution of Regadenoson. On March 4, 2020, IMS filed its Answer and Counterclaims. On March 30, 2020, the Court issued an Order allowing the Company to join pending consolidated litigation with five other generic Regadenoson ANDA filers involving similar claims. Trial is currently scheduled for June 14, 2021. The Company's 30-month FDA stay expires August 10, 2022. The Company intends to vigorously defend this patent lawsuit.

Employee Litigation

Brenes v. International Medication Systems, Limited

On September 11, 2019, a former employee, Raquel Brenes, ("Brenes"), initiated an employment litigation against IMS et al. by filing a Complaint in the Superior Court of California, Los Angeles County alleging individual and class action claims for alleged violations of various California labor laws pertaining to wage and hour, and other state laws. On September 18, 2019, Brenes filed a First Amended Complaint maintaining the individual and class action claims.

On January 21, 2020, Brenes filed a Second Amended Complaint that alleges only Private Attorney General Act, or PAGA, claims and omitted the individual and class action claims. On February 9, 2021, the parties reached a settlement for $1.0 million. The settlement was approved by the Court on April 7, 2021. The Company accrued the amount of $1.0 million for this litigation as of December 31, 2020.

Navarrette v. International Medication Systems, Limited

On January 30, 2020, a former employee, Robert Navarrette ("Navarrette"), provided written notice, through his counsel to IMS that he intends to file a PAGA lawsuit for alleged violation of various California labor laws pertaining to wage and hour. On April 7, 2020, Navarrette filed his PAGA lawsuit against IMS and Amphastar Pharmaceuticals, Inc. in the Superior Court of California, Los Angeles County, Central District. As to IMS, the *Brenes* settlement subsumes the claims of Navarrette.

Ramirez v. Amphastar Pharmaceuticals, Inc.

On May 29, 2020, Priscilla Ramirez, ("Ramirez"), a former employee filed a PAGA lawsuit for alleged violations of various California labor laws pertaining to wage and hour against the Company. On April 5, 2021, the parties reached a settlement for $1.0 million. The agreement is still subject to approval by the Court. The Company accrued the amount of

$1.0 million for this litigation as of March 31, 2021.

Other Litigation

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

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

Note 19. Subsequent Events

In May 2021, the board of directors approved a plan for the restructuring of the equity ownership of ANP, whereby the Company will purchase an additional ownership interest in ANP from certain equity holders of ANP (the "Sellers"), and spin-off of certain subsidiaries of ANP.

The Company entered into three agreements relating to the restructuring of the equity ownership of ANP and its subsidiaries and the spin-off of certain subsidiaries of ANP:

- The Company entered into a Share Purchase Agreement, or SPA, to acquire an additional approximately 18% of ownership interest in ANP for approximately $29.4 million from the Sellers, who had initially acquired shares in the previously disclosed July 2018 private placement, or the ANP Private Placement.
- ANP entered into a Share Repurchase Agreement, or SRA, with the Sellers and Nanjing Qianqia Enterprise Management Consulting LLP, or Qianqia, to issue shares in Hanxin, including Hanxin's existing subsidiaries, Baixin and Letop, both of which will be included in the spin-off of Hanxin, in exchange for an additional approximately 9% of ownership interest in ANP.
- ANP entered into a Separation Agreement with Hanxin which sets forth certain assets to be held by each entity, as well as certain responsibilities and obligations of ANP and Hanxin following completion of the spin-off.

Upon completion of the restructuring, the Company will own approximately 85% of ANP, and ANP will retain approximately 20% of ownership interest in Hanxin.

Certain of the Sellers are the Company's executive officers, directors and other related parties. The Sellers who are participating in the SPA include William J. Peters, Rong Zhou, Jacob Liawatidewi, Howard Lee, Richard Koo, Stephen Shohet, Henry Zhang, Qingqing Chen, Chongqing Zhang, Lu Zhang, and James Luo. Neither Dr. Mary Luo nor Dr. Jack Zhang are participating in the SPA.

The Sellers who are participating in the SRA include Dr. Mary Luo, Dr Jack Zhang, Henry Zhang, Qingqing Chen, Chongqing Zhang, Bill Zhang, and Lu Zhang.

As part of the restructuring, the Company will terminate the 2018 ANP Equity Incentive Plan.

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, 2020, particularly in Item 1A. "Risk Factors".

Overview

We are a bio-pharmaceutical company that focuses primarily on developing, manufacturing, marketing and selling technically challenging generic and proprietary injectable, inhalation, and intranasal products as well as insulin API products. We currently manufacture and sell over 20 products.

We are currently developing a portfolio of 12 generic abbreviated new drug applications, or ANDAs, three biosimilar insulin 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 NDA are currently on file with the FDA.

Our largest products by net revenues currently include Primatene Mist®, glucagon, epinephrine, enoxaparin sodium injection, phytonadione, lidocaine jelly and sterile solution, and naloxone hydrochloride injection. During the second quarter of 2020, we launched our epinephrine injection, USP 30mg/mL multiple dose vial product. In December 2020, the FDA granted approval of our glucagon for injection emergency kit, 1mg, which we launched in February 2021.

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, API 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. 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.

In May 2021, the board of directors approved a plan for the restructuring of the equity ownership of ANP, whereby we would purchase additional ownership interest in ANP from certain equity holders of ANP (the "Sellers"), and spin-off certain subsidiaries of ANP. The Sellers include some of the Company's executive officers, directors and other related parties who participated in the ANP Private Placement in 2018.

As part of the transaction, we will pay approximately $29.4 million in cash and contribute approximately 80% of Hanxin Pharmaceutical Technology Co., Ltd, or Hanxin, to the Sellers in exchange for additional ownership interest in ANP, such that we will own approximately 85% of ANP and ANP will retain approximately 20% of ownership in Hanxin after the completion of the restructuring.

Hanxin's wholly owned subsidiaries, Nanjing Baixin Trading Co., Ltd., and Nanjing Letop Biological Technology Co., Ltd., will be included in the spin-off of Hanxin.

COVID-19 Pandemic

In March 2020, the World Health Organization declared the outbreak of a novel coronavirus, or COVID-19, as a pandemic, which continues to spread throughout the world, including locations where we operate, such as the United States, China and France. We have been actively monitoring the COVID-19 pandemic and its impact globally. Currently, our production facilities in all of our locations continue to operate as they had prior to the COVID-19 pandemic with few changes, other than for enhanced safety measures intended to prevent the spread of the virus.

As a result of the COVID-19 pandemic, during the first half of 2020, sales of Primatene Mist® and certain hospital products increased, while sales of certain products frequently used in elective procedures, such as Cortrosyn® and lidocaine products decreased. We saw these trends continue in late 2020 and early 2021 when COVID cases trended higher. Some of our ongoing clinical trials experienced short-term interruptions in the recruitment of patients due to the COVID-19 pandemic, as hospitals prioritize their resources towards the COVID-19 pandemic and governments impose travel restrictions. Some clinical trials experienced increased expenses due to new protocols to protect participants from COVID-19. Additionally, certain suppliers had difficulties meeting their delivery commitments.

It is not possible at this time to estimate the complete impact that COVID-19 could have on our business, including our customers and suppliers, as the impact will depend on future developments, which are highly uncertain and cannot be predicted. Infections may resurge or become more widespread and the limitation on our ability to travel and timely sell and distribute our products, as well as any closures or supply disruptions, may be extended for longer periods of time, all of which would have a negative impact on our business, financial condition and operating results.

The COVID-19 pandemic has and will continue to adversely affect global economies and financial markets, resulting in an economic downturn that could affect demand for our products and impact our operating results. Even after the COVID-19 pandemic has subsided, we may continue to experience an adverse impact to our business as a result of the continued global economic impact of the pandemic. We cannot anticipate all of the ways in which health epidemics such as COVID-19 could adversely impact our business. See the Risk Factors section for further discussion of the possible impact of the COVID-19 pandemic on our business.

Business Segments

As of March 31, 2021, 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 Primatene Mist®, glucagon, enoxaparin, naloxone, phytonadione, lidocaine, epinephrine, as well as various other critical and non-critical care drugs. The API segment manufactures and 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.

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

Results of Operations

Three Months Ended March 31, 2021 Compared to Three Months Ended March 31, 2020

Net revenues

	Three Months Ended March 31,		Change	
	2021	2020	Dollars	%
		(in thousands)		
Net revenues				
Finished pharmaceutical products	$ 97,882	$ 81,298	$ 16,584	20 %
API	5,138	3,390	1,748	52 %
Total net revenues	$ 103,020	$ 84,688	$ 18,332	22 %
Cost of revenues				
Finished pharmaceutical products	$ 52,596	$ 42,488	$ 10,108	24 %
API	5,478	5,377	101	2 %
Total cost of revenues	$ 58,074	$ 47,865	$ 10,209	21 %
Gross profit	$ 44,946	$ 36,823	$ 8,123	22 %
as % of net revenues	*44 %*	*43 %*		

The increase in net revenues of the finished pharmaceutical products for the three months ended March 31, 2021, was due to the following changes:

	Three Months Ended March 31,		Change	
	2021	2020	Dollars	%
		(in thousands)		
Finished pharmaceutical products net revenues				
Primatene Mist®	$ 18,383	$ 12,877	$ 5,506	43 %
Epinephrine	15,578	3,990	11,588	290 %
Enoxaparin	10,658	9,168	1,490	16 %
Phytonadione	9,565	11,029	(1,464)	(13)%
Lidocaine	9,071	10,657	(1,586)	(15)%
Glucagon	7,984	—	7,984	N/A
Naloxone	6,341	8,875	(2,534)	(29)%
Other finished pharmaceutical products	20,302	24,702	(4,400)	(18)%
Total finished pharmaceutical products net revenues	$ 97,882	$ 81,298	$ 16,584	20 %

In February 2021, we launched our glucagon for injection emergency kit, 1mg, which was approved by the FDA in December 2020.

The increase in sales of Primatene Mist® for the three months ended March 31, 2021, was a result of the continued success of our nationwide digital, television and radio campaign, which will continue throughout 2021 as well as an expansion of our distribution channels throughout 2020 and during the first quarter of 2021, including Target which began selling Primatene Mist® in March 2021. The increase in sales of epinephrine was primarily due to the launch of our epinephrine injection, USP 30mg/30mL multiple dose vial product in the second quarter of 2020, as well as an increase in unit volumes, as a result of higher demand due to a market shortage for pre-filled syringe. The increase in sales of enoxaparin was primarily due to an increase in unit volume, as a result of a competitor leaving the market. The decrease in sales of Naloxone was split evenly between lower unit volume and lower average selling price as a result of a competitor entering the market. The decrease in sales of phytonadione and lidocaine products was primarily due to lower unit volumes as a result of decreased market demand. The decrease in other finished pharmaceutical products was primarily due to lower unit volumes as a result of competitors returning to their normal distribution levels.

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

Sales of API primarily depend on the timing of customer purchases. We anticipate that sales of API will continue to fluctuate and may decrease due to the inherent uncertainties related to sales to MannKind Corporation pursuant to our supply agreement with them. In addition, most of our API sales are denominated in euros, and the fluctuation in the value of 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 March 31, 2021. 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 increase in sales of Primatene Mist®, the launch of glucagon for injection emergency kit during the first quarter of 2021, as well as, the launch of our epinephrine injection multiple dose vial in the second quarter of 2020, which are higher-margin products, helped increase our gross margins for the three months ended March 31, 2021. These increases in gross margins were offset by lower pricing and increased costs for enoxaparin, particularly the cost for heparin raw materials, which is used as the starting material for enoxaparin.

The cost of heparin 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 Primatene Mist®, and epinephrine multi dose vials, which were launched over the past few years and by glucagon which was launched in 2021. Additionally, we have not seen significant supply disruptions due to the COVID-19 pandemic at this time, but we are continuing to monitor our supply chain for any potential problems.

Selling, distribution and marketing, and general and administrative

	Three Months Ended March 31,		Change	
	2021	2020	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	$ 4,537	$ 3,294	$ 1,243	38 %
General and administrative	$ 15,338	$ 10,746	$ 4,592	43 %

The increase in selling, distribution, and marketing expenses was primarily due to marketing and distribution expenses related to Primatene Mist®, including the cost of creating a new commercial for our national digital, television and radio marketing campaign. The increase in general and administrative expense was primarily due to an increase in legal expenses, including a reserve of $1.3 million to settle employment litigation, subsequent to the end of the first quarter.

We expect that selling, distribution and marketing expenses will increase due to the increase in marketing expenditures 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. Legal fees may fluctuate due to the timing of patent challenges and other litigation matters.

Research and development

	Three Months Ended March 31,		Change	
	2021	2020	Dollars	%
	(in thousands)			
Salaries and personnel-related expenses	$ 6,979	$ 6,220	$ 759	12 %
Clinical trials	738	2,455	(1,717)	(70)%
FDA fees	40	44	(4)	(9)%
Testing, operating and lab supplies	2,153	2,688	(535)	(20)%
Depreciation	2,938	2,348	590	25 %
Other expenses	1,917	1,548	369	24 %
Total research and development expenses	$ 14,765	$ 15,303	$ (538)	(4)%

Clinical trial expense decreased due to the completion of one of our clinical trial studies at the end of 2020 and delays in other studies. This was partially offset by an increase in salaries and personnel-related expenses as well as depreciation expense.

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.

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. Some of our ongoing clinical trials have experienced short term interruptions in the recruitment of patients due to the COVID-19 pandemic, as hospitals prioritize their resources towards the COVID-19 pandemic and governments impose travel restrictions. These conditions may in turn delay spending and delay the results of these trials.

Other income (expense), net

	Three Months Ended March 31,		Change	
	2021	2020	Dollars	%
	(in thousands)			
Other income (expenses), net	$ (5,249)	$ (1,752)	$ 3,497	NM

In March 2021, we recorded an additional $4.4 million of expense in connection with the Aventis litigation. For more information regarding our litigation matters, see Note 18 to the condensed consolidated financial statements.

Income tax provision

	Three Months Ended March 31,		Change	
	2021	2020	Dollars	%
	(in thousands)			
Income tax provision	$ 1,155	$ 2,280	$ (1,125)	(49)%
Effective tax rate	*23 %*	*39 %*		

Our effective tax rate for the three months ended March 31, 2021 decreased in comparison to the three months ended March 31, 2020, primarily due to differences in pre-tax income positions and timing of discrete tax items.

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 March 31, 2021, our foreign subsidiaries collectively held $12.6 million in cash and cash equivalents. Cash or cash equivalents held at foreign subsidiaries are not available to fund the parent company's operations in the United States. We believe that our cash reserves, operating cash flows, and borrowing availability under our credit facilities will be sufficient to fund our operations for at least the next 12 months from the date of filing of this Quarterly Report on Form 10-Q. 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 $5.6 million to $173.1 million at March 31, 2021, compared to $167.5 million at December 31, 2020.

Cash Flows from Operations

The following table summarizes our cash flows used in operating, investing, and financing activities for the three months ended March 31, 2021 and 2020:

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Statement of Cash Flow Data:		
Net cash provided by (used in)		
Operating activities	$ 22,825	$ 1,477
Investing activities	(8,695)	(8,722)
Financing activities	(6,639)	(11,449)
Effect of exchange rate changes on cash	(162)	(146)
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ 7,329	$ (18,840)

Sources and Use of Cash

Operating Activities

Net cash provided by operating activities was $22.8 million for the three months ended March 31, 2021, which included net income of $4.0 million. Non-cash items comprised primarily of $6.0 million of depreciation and amortization, and $4.8 million of share-based compensation expense.

Additionally, for the three months ended March 31, 2021, there was a net cash inflow from changes in operating assets and liabilities of $7.2 million, which resulted from an increase in accounts payable and accrued liabilities which was partially offset by an increase in accounts receivable. Accounts payable and accrued liabilities increased primarily due to the timing of payments. The increase in accounts receivable was due to both increases in sales and the timing of sales.

Net cash provided by operating activities was $1.5 million for the three months ended March 31, 2020, which included net income of $3.5 million. Non-cash items were primarily comprised of $5.0 million of depreciation and amortization, and $5.3 million of share-based compensation expense. Additionally, there was a net cash outflow from changes in operating assets and liabilities of $14.8 million, which resulted from an increase in accounts receivable and a decrease in accounts payable and accrued liabilities, which was partially offset by a decrease in inventory. The increase in accounts receivable was due to the timing of sales, including the increase in sales of Primatene Mist® towards the end of the quarter as a result of the COVID-19 pandemic. Accounts payable and accrued liabilities decreased primarily due to the timing of payments.

Investing Activities

Net cash used in investing activities was $8.7 million for the three months ended March 31, 2021, primarily as a result of $7.6 million in purchases of property, plant, and equipment, which included $2.6 million incurred in the United States, $0.1 million in France, and $4.9 million in China.

Net cash used in investing activities was $8.7 million for the three months ended March 31, 2020, primarily as a result of $8.0 million in purchases of property, plant, and equipment, which included $1.5 million incurred in the United States, $1.1 million in France, and $5.4 million in China.

Financing Activities

Net cash used in financing activities was $6.6 million for the three months ended March 31, 2021, primarily as a result of $3.8 million used to purchase treasury stock and $0.9 million in net proceeds used to settle share-based compensation awards under our equity plans. Additionally, we also made $2.0 million in principal payments on our long-term.

Net cash used in financing activities was $11.4 million for the three months ended March 31, 2020, primarily as a result of $11.0 million used to purchase treasury stock, and $1.2 million in net proceeds used to settle share-based compensation awards under our equity plans. Additionally, we received $3.1 million from borrowings on an equipment line of credit that converted into an equipment loan during the quarter and made $2.3 million in principal payments on our long-term debt.

Indebtedness

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

Contractual Obligations

There have been no material changes outside the ordinary course of our business in the contractual obligations disclosed in our Annual Report on Form 10-K for the year ended December 31, 2020, except that our outstanding debt obligations have changed as follows:

	March 31, 2021	December 31, 2020	Change
		(in thousands)	
Short-term debt and current portion of long-term debt	$ 12,173	$ 12,263	$ (90)
Long-term debt	32,334	34,186	(1,852)
Total debt	$ 44,507	$ 46,449	$ (1,942)

As of March 31, 2021, we had $56.0 million in unused borrowing capacity under revolving lines of credit and equipment lines of credit with Cathay Bank, East West Bank, and China Merchant 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, 2020.

Recent Accounting Pronouncements

For information regarding recent accounting pronouncements, see “Part I – Item 1. Financial Statements – Notes to Condensed Consolidated Financial Statements – 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

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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Except for the broad, ongoing effects of the COVID-19 pandemic as a result of its negative impact on the global economy and financial markets, there have been no material changes in market risk from the information provided in our Annual Report on Form 10-K for the year ended December 31, 2020. We are exposed to market risk in the ordinary course of business. 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).

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 March 31, 2021, 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 Condensed 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, 2020, filed with the Securities and Exchange Commission on March 15, 2021.

Our business may be adversely affected by the ongoing COVID-19 pandemic or other epidemics.

In March 2020, the World Health Organization declared the outbreak of a novel coronavirus, or COVID-19, as a pandemic, which continues to spread throughout the world, including locations where we operate, such as the United States, China and France. We have been actively monitoring the COVID-19 pandemic and its impact globally. In late January 2020, China implemented extensive curfews and travel restrictions to control the outbreak, and started easing these restrictions in March. In March 2020, France also implemented a stay-at-home order limiting movement and restricting travel. In March 2020, the Governors of the States of California and Massachusetts declared a health emergency and issued orders to close all nonessential businesses. As a bio-pharmaceutical company we are deemed to be an essential business. Since then, the governments in the United States, China and France, have re-opened and re-imposed restrictions on travel and business as the pandemic recedes and grows.

Over the ensuing year, this contagious disease outbreak has continued to impact worldwide economic activity and financial markets. While three vaccines have received Emergency Use Authorization from the FDA, the COVID-19 pandemic remains a challenge to our business until it is abated. Mass and rapid production of the vaccines, for example, has placed increased pressure on the availability of supplies that are also used in our products, such as glass vials and

needles. The COVID-19 pandemic is imposing additional burdens on our business to comply with regulations imposed by the State of California. The COVID-19 pandemic may also disrupt the operations of our customers, suppliers and partners for an indefinite period of time, including as a result of travel restrictions and/or business shutdowns, all of which could negatively impact our business and results of operations, including cash flows. Disruptions to our manufacturing partners and suppliers could result in disruption to the production of our products and failure to satisfy demand. More generally, the outbreak of COVID-19 could adversely affect economies and financial markets globally and nationally, potentially leading to an economic downturn, which could decrease spending and adversely affect demand for our products and harm our business and results of operations. Even after the COVID-19 pandemic has subsided, we may continue to experience an adverse impact to our business as a result of its global economic impact, including any recession that has occurred or may occur in the future. Specifically, difficult macroeconomic conditions, increased and prolonged unemployment or a decline in business confidence as a result of the COVID-19 pandemic, could have a continuing adverse effect on the demand for some of our products. The degree of impact of the COVID-19 pandemic on our business will depend on several factors, such as the duration and the extent of the pandemic, as well as actions taken by governments, businesses, and consumers in response to the pandemic, all of which continue to evolve and remain uncertain at this time.

As a result of the consequences of the COVID-19 pandemic, FDA has issued various COVID-19 related guidance documents applicable to biopharmaceutical manufacturers and clinical trial sponsors. For example, in March 2020, the FDA issued a guidance, which the FDA subsequently updated, on conducting clinical trials during the pandemic, which describes a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical trial report contingency measures implemented to manage the clinical trial, among others. The FDA also issued a guidance on good manufacturing practice considerations for responding to COVID-19 infection in employees in drug products manufacturing, and a guidance on review timelines for applicant responses to Complete Response Letters when a facility assessment is needed during the COVID-19 public health emergency. These and future guidance documents and regulatory requirements, including future legislation, may require us to develop and implement new policies and procedures, make significant adjustments to our clinical trials, or increase the amount time and resources needed for regulatory compliance, which may impact our clinical development plans and timelines.

Some of our ongoing clinical trials have experienced short term interruptions in the recruitment of patients due to the COVID-19 pandemic, as hospitals prioritize their resources toward the COVID-19 pandemic and governments impose travel restrictions. Additionally, protocols at certain clinical sites have changed which could slow down the pace of clinical trials while also increasing their cost. These conditions may in turn delay spending and delay the results of these trials. Additionally, certain suppliers have delayed shipments to us in 2020 and 2021. These delays may have been caused by manufacturing disruptions due to the COVID-19 pandemic. None of these delays caused delays in our manufacturing to date, but future delays could cause manufacturing disruptions at our factories and could also cause lost sales.

It is not possible at this time to estimate the complete impact that the COVID-19 pandemic could have on our business, as the impact will depend on future developments, which are highly uncertain and cannot be predicted. Infections may resurge or become more widespread and the limitation on our ability to travel and timely sell and distribute our products, as well as any closures or supply disruptions, may be extended for longer periods of time, all of which would have a negative impact on our business, financial condition and operating results. We will continue to monitor the impact of the COVID-19 pandemic on all aspects of our business.

Because a portion of our manufacturing takes place in China, a significant disruption in the construction or operation of our manufacturing facility in China, political unrest in China, tariffs, impact of outbreaks of health epidemics, such as the COVID-19 pandemic, or changes in social, political, trade, health, economic, environmental, or climate-related conditions or in laws, regulations and policies governing foreign trade could materially and adversely affect our business, financial condition and results of operations.

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

- disruptions in the construction of the manufacturing facility;
- interruptions to our operations in China or the inability of our manufacturing facility to produce adequate quantities of raw materials or APIs to meet our needs as a result of natural catastrophic events or other causes beyond our control such as power disruptions or widespread disease outbreaks, including the recent outbreaks that impact animal-derived products, such as the importation of pig-derived crude heparin from countries impacted by the African swine flu, and outbreak of the COVID-19 pandemic, which has resulted in and may in the future result in, business closures, transportation restrictions, import and export complications, and otherwise cause shortages in the supply of raw materials or cause disruptions in our manufacturing capability;
- product supply disruptions and increased costs as a result of heightened exposure to changes in the policies of the Chinese government, political unrest or unstable economic conditions in China;
- the imposition of tariffs or other trade barriers as a result of changes in social, political, and economic conditions or in laws, regulations, and policies governing foreign trade, including the tariffs previously implemented and additional tariffs that have been proposed by the U.S. government on various imports from China and by the Chinese government on certain U.S. goods, the scope and duration of which, if implemented, remain uncertain;
- the nationalization or other expropriation of private enterprises or intellectual property by the Chinese government, which could result in the total loss of our investment in China; and
- interruptions to our manufacturing or business operations resulting from geo-political actions, including war and terrorism, natural disasters including earthquakes, typhoons, floods, and fires, or outbreaks of health epidemics such as coronavirus, or outbreaks in livestock or animals that impact or restrict importation, use, or distribution of animal-derived products.

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

We are actively monitoring and assessing the potential impact of the COVID-19 pandemic. This includes evaluating the impact on our employees, suppliers, and logistics providers as well as evaluating governmental actions being taken to curtail the spread of the virus. While the Chinese government has been relaxing work restrictions, at this time, it is unclear if the Chinese government will reinstate restrictions or if further restrictions will be put into place by the government. In addition, many countries have placed significant bans on travel to and from China, with many countries and airlines suspending flights to and from mainland China. Any material adverse effect on our employees, suppliers, and logistics providers could have a material adverse effect on our manufacturing operations in China or the supply of raw materials or APIs originating from China.

Our epinephrine prefilled syringe product is marketed without FDA approval and may be subject to enforcement actions by the FDA.

Our epinephrine prefilled syringe prescription product is marketed without FDA approval. This product, like many other prescription drugs on the market that have not been formally evaluated as being effective by the FDA, contain active ingredients that were first marketed prior to the enactment of the Federal Food, Drug, and Cosmetic Act, or FFDCA. The FDA has assessed this product in a program known as the “Prescription Drug Wrap-Up” and has stated that this drug cannot be lawfully marketed unless they comply with certain “grandfather” exceptions to the definition of “new drug” in the FFDCA. These exceptions have been strictly construed by FDA and by the courts, and the FDA has stated that it is unlikely that any of the unapproved prescription drugs on the market, including our drug, qualify for the exceptions. At any time, the FDA may require that our unapproved prescription drug be submitted for approval and may direct us to recall this product and/or cease marketing the product until they are approved. The FDA may also take enforcement actions based on our marketing of this unapproved product, including but not limited to the issuance of an untitled letter or a warning letter, 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 product, we would be subject to a higher likelihood that the FDA may seek to take action against our unapproved product. 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 help address a national drug shortage, while we prepared and filed applications for approval of the products. Between August and October 2010, we reintroduced our 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. In April 2020, the FDA granted approval of our Epinephrine Injection, USP 30mg/mL Multiple Dose Vial, and launched the product in May 2020.

The FDA granted approval of our Atropine Sulfate Injection 0.1mg/mL in the 10mL Luer-Jet® Prefilled Syringe in October 2020, our Dextrose Injection 50% in the 50mL Luer-Jet® Prefilled Syringe in March 2021 and our Morphine Sulfate Injection USP, 1mg/mL 30mL in April 2021.

Our only unapproved product currently on the market is epinephrine prefilled syringes. For the years ended December 31, 2020, 2019, 2018, we recorded net revenues of $13.2 million, $13.9 million, $10.1 million, respectively, for epinephrine prefilled syringes and for the three months ended March 31, 2021 and 2020, we recorded net revenues of $9.3 million, and $4.0 million, respectively, for this product. We have filed an NDA with respect to our remaining unapproved product in order to mitigate all risk associated with the marketing of unapproved drug products. Prior to the approval of our NDA submission, 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.

Period	Total Number of Shares Purchased [1]	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
January 1 – January 31, 2021	48,705	$ 19.36	48,705	—
February 1 – February 28, 2021	53,328	18.57	53,328	—
March 1 – March 31, 2021	102,665	17.98	102,665	—

(1) During the first quarter of 2021, we repurchased shares of our common stock as part of the share buyback program authorized by our Board of Directors on August 4, 2020. As of March 31, 2021, $13.6 million remained available for repurchase 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
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1#	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2#	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document – The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definitions Linkbase Document
104	Cover Page Interactive File (Formatted as Inline XBRL and contained in Exhibit 101)

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.

SIGNATURES

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

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

Date: May 7, 2021

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

Date: May 7, 2021

Exhibit 31.1

Certification

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

1. I have reviewed this Quarterly Report on Form 10-Q of Amphastar Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2021

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

Exhibit 31.2

Certification

I, William J. Peters, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Amphastar Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2021

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

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 March 31, 2021 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and

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

Date: May 7, 2021

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.

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 March 31, 2021 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and

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

Date: May 7, 2021

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.