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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, 2022
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, 2022 was 48,829,793.

AMPHASTAR PHARMACEUTICALS, INC.
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FORM 10-Q FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2022

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;
- our business and operations in general, including: uncertainty regarding the magnitude, duration and geographic reach of the COVID-19 pandemic and its impact on our business, financial condition, operations, cash flows and liquidity and on the economy in general;
- our ability to successfully execute and maintain the activities and efforts related to the measures we have taken or may take in response to the COVID-19 pandemic and associated costs therewith;
- our ability to attract, hire, and retain highly skilled personnel;
- 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 ongoing COVID-19 pandemic;
- global, national and local economic and market conditions, specifically with respect to geopolitical uncertainty, and the ongoing 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;
- costs and delays resulting from the extensive pharmaceutical regulations to which we are subject or delays in governmental processing time due to travel and work restrictions caused by the COVID-19 pandemic;
- 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, Amphastar Nanjing Pharmaceuticals, Ltd., or ANP;
- the potential for adverse application of environmental, health and safety and other laws and regulations on our operations;
- our expectations for market acceptance of our new products and proprietary drug delivery technologies, as well as those of our active pharmaceutical ingredient, or API, customers;
- the effects of reforms in healthcare regulations and reductions in pharmaceutical pricing, reimbursement and coverage;
- 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;
- variations in intellectual property laws, 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;
- our ability to successfully bid for suitable acquisition targets or licensing opportunities, or to consummate and integrate 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, 2021, 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, 2022 (unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 172,627	$ 126,353
Restricted cash	235	235
Short-term investments	14,383	10,320
Restricted short-term investments	2,200	2,200
Accounts receivable, net	73,166	78,804
Inventories	95,147	92,807
Income tax refunds and deposits	223	126
Prepaid expenses and other assets	6,434	7,274
Total current assets	364,415	318,119
Property, plant, and equipment, net	243,248	244,244
Finance lease right-of-use assets	278	353
Operating lease right-of-use assets	27,843	26,894
Investment in unconsolidated affiliate	3,318	3,985
Goodwill and intangible assets, net	38,436	38,870
Other assets	16,301	16,665
Deferred tax assets	22,399	22,399
Total assets	$ 716,238	$ 671,529
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 95,810	$ 89,545
Income taxes payable	13,116	9,081
Current portion of long-term debt	2,159	2,202
Current portion of operating lease liabilities	3,279	2,982
Total current liabilities	114,364	103,810
Long-term reserve for income tax liabilities	6,531	6,531
Long-term debt, net of current portion and unamortized debt issuance costs	74,348	74,776
Long-term operating lease liabilities, net of current portion	25,489	24,703
Deferred tax liabilities	487	534
Other long-term liabilities	15,494	15,653
Total liabilities	236,713	226,007
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; 57,495,402 and 48,752,175 shares issued and outstanding as of March 31, 2022 and 56,440,202 and 47,714,912 shares issued and outstanding as of December 31, 2021, respectively	6	6
Additional paid-in capital	433,454	422,423
Retained earnings	204,590	180,337
Accumulated other comprehensive loss	(7,245)	(6,765)
Treasury stock	(151,280)	(150,479)
Total equity	479,525	445,522
Total liabilities and stockholders' equity	$ 716,238	$ 671,529

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,	
	2022	2021
Net revenues	$ 120,368	$ 103,020
Cost of revenues	64,542	58,074
Gross profit	55,826	44,946
Operating expenses:		
Selling, distribution, and marketing	5,519	4,537
General and administrative	12,470	15,338
Research and development	16,223	14,765
Total operating expenses	34,212	34,640
Income from operations	21,614	10,306
Non-operating income (expenses):		
Interest income	181	161
Interest expense	(355)	(104)
Other income (expenses), net	7,593	(5,249)
Total non-operating income (expenses), net	7,419	(5,192)
Income before income taxes	29,033	5,114
Income tax provision	4,077	1,155
Income before equity in losses of unconsolidated affiliate	24,956	3,959
Equity in losses of unconsolidated affiliate	(703)	—
Net income	$ 24,253	$ 3,959
Net loss attributable to non-controlling interests	$ —	$ (1,082)
Net income attributable to Amphastar Pharmaceuticals, Inc.	$ 24,253	$ 5,041
Net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders:		
Basic	$ 0.50	$ 0.11
Diluted	$ 0.47	$ 0.10
Weighted-average shares used to compute net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders:		
Basic	48,138	47,520
Diluted	51,979	49,518

See Accompanying Notes to Condensed Consolidated Financial Statements.

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

	Three Months Ended March 31,	
	2022	2021
Net income attributable to Amphastar Pharmaceuticals, Inc.	$ 24,253	$ 5,041
Other comprehensive loss attributable to Amphastar Pharmaceuticals, Inc., net of income taxes		
Foreign currency translation adjustment	(480)	(1,921)
Total other comprehensive loss attributable to Amphastar Pharmaceuticals, Inc.	(480)	(1,921)
Total comprehensive income attributable to Amphastar Pharmaceuticals, Inc.	$ 23,773	$ 3,120

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, 2021	56,440,202	$ 6	$ 422,423	$ 180,337	$ (6,765)	(8,725,290)	$ (150,479)	$ 445,522	$ —	$ 445,522
Net income attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	24,253	—	—	—	24,253	—	24,253
Other comprehensive loss attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	—	(480)	—	—	(480)	—	(480)
Purchase of treasury stock	—	—	—	—	—	(51,168)	(1,229)	(1,229)	—	(1,229)
Issuance of treasury stock in connection with the Company's equity plans	—	—	(428)	—	—	33,231	428	—	—	—
Issuance of common stock in connection with the Company's equity plans	1,055,200	—	6,437	—	—	—	—	6,437	—	6,437
Share-based compensation expense	—	—	5,022	—	—	—	—	5,022	—	5,022
Balance as of March 31, 2022	57,495,402	$ 6	$ 433,454	$ 204,590	$ (7,245)	(8,743,227)	$ (151,280)	$ 479,525	$ —	$ 479,525

	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

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,	
	2022	2021
Cash Flows From Operating Activities:		
Net income	$ 24,253	$ 3,959
Reconciliation to net cash provided by operating activities:		
Loss on disposal of assets	1	6
Gain on interest rate swaps	(3,013)	(179)
Depreciation of property, plant, and equipment	5,615	5,686
Amortization of product rights, trademarks, and patents	352	276
Operating lease right-of-use asset amortization	828	863
Equity in losses of unconsolidated affiliate	703	—
Share-based compensation expense	5,022	4,834
Changes in operating assets and liabilities:		
Accounts receivable, net	5,598	(12,078)
Inventories	(2,687)	(1,144)
Prepaid expenses and other assets	1,420	1,119
Income tax refunds, deposits, and payable, net	3,926	1,182
Operating lease liabilities	(695)	(754)
Accounts payable and accrued liabilities	9,442	19,055
Net cash provided by operating activities	50,765	22,825
Cash Flows From Investing Activities:		
Purchases and construction of property, plant, and equipment	(6,139)	(7,618)
Purchase of investments	(5,317)	(4,501)
Maturity of investments	2,535	3,944
Payment of deposits and other assets	(189)	(520)
Net cash used in investing activities	(9,110)	(8,695)
Cash Flows From Financing Activities:		
Proceeds from equity plans, net of withholding tax payments	6,437	(854)
Purchase of treasury stock	(1,229)	(3,783)
Debt issuance costs	(22)	—
Principal payments on long-term debt	(538)	(2,002)
Net cash provided by (used in) financing activities	4,648	(6,639)
Effect of exchange rate changes on cash	(29)	(162)
Net increase in cash, cash equivalents, and restricted cash	46,274	7,329
Cash, cash equivalents, and restricted cash at beginning of period	126,588	94,507
Cash, cash equivalents, and restricted cash at end of period	$ 172,862	$ 101,836
Noncash Investing and Financing Activities:		
Capital expenditure included in accounts payable	$ 6,709	$ 6,238
Operating lease right-of-use assets in exchange for operating lease liabilities	$ 1,777	$ 103
Equipment acquired under finance leases	$ —	$ 74
Supplemental Disclosures of Cash Flow Information:		
Interest paid, net of capitalized interest	$ 579	$ 508
Income taxes paid	$ 183	$ 30

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, 2021 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, 2021. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with United States 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 GAAP. Certain prior period amounts have been reclassified within the operating activities of the condensed consolidated statements 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) Amphastar France Pharmaceuticals, S.A.S., or AFP, (5) Amphastar UK Ltd., or AUK, and (6) International Medication Systems (UK) Limited, or IMS UK.

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, 2022.

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. Recent increases in COVID-19 cases in Shanghai, China, have led to shutdowns and delays at the ports in Shanghai, which could have an impact on the Company's operations. However, the extent of the impact of this shutdown and delay is highly uncertain and difficult to predict.

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, fair value of financial instruments, allowance for discounts, provision for chargebacks and rebates, provision for product returns, adjustment of inventory to its net realizable values, impairment of investments, long-lived and intangible assets and goodwill, accrual for workers' compensation liabilities, litigation reserves, stock price volatility for share-based compensation expense, valuation allowances for deferred tax assets, and liabilities for uncertain income tax positions.

Foreign Currency

The functional currency of the Company, its domestic subsidiaries, its Chinese subsidiary, ANP, and its U.K. subsidiary, AUK, is the U.S. Dollar, or USD. ANP maintains its books of record in Chinese yuan. These books are remeasured into the functional currency, USD, using the current or historical exchange rates. The resulting currency remeasurement adjustments and other transactional foreign currency exchange gains and losses are reflected in the Company's condensed consolidated statements of operations.

The Company's French subsidiary, AFP, maintains its book of record in euros. 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. Activity in the statement of operations is translated to 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, 2022 and 2021 were $0.6 million loss and $1.5 million loss, respectively.

Comprehensive Income

For the three months ended March 31, 2022 and 2021, the Company included its foreign currency translation gain or loss as part of its comprehensive income.

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, 2022 and 2021, advertising expenses were $2.4 million and $2.2 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. 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.

Investments

Investments as of March 31, 2022 and December 31, 2021 consisted of certificates of deposit and investment grade corporate and municipal bonds with original maturity dates between three and fifteen months.

Restricted Cash

Restricted cash is collateral required for the Company to guarantee certain vendor payments in France. As of each of March 31, 2022 and December 31, 2021, the restricted cash balance was $0.2 million.

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, 2022 and December 31, 2021, 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.

Litigation, Commitments and Contingencies

Litigation, commitments and contingencies are accrued when management, after considering the facts and circumstances of each matter as then known to management, has determined it is probable a liability will be found to have been incurred and the amount of the loss can be reasonably estimated. When only a range of amounts is reasonably estimable and no amount within the range is more likely than another, the low end of the range is recorded. Legal fees are expensed

as incurred. Due to the inherent uncertainties surrounding gain contingencies, the Company generally does not recognize potential gains until realized.

Recent Accounting Pronouncements

The Company does not believe that any recently issued effective pronouncements, or pronouncements issued but not yet effective, if adopted, would have a material effect on the accompanying condensed consolidated financial statements.

Note 3. ANP Restructuring

As a result of the ANP restructuring that was completed during the third quarter of 2021, and subsequent investments by other equity holders of Hanxin, the Company has a 14% noncontrolling investment in Hanxin that is accounted for as an equity method investment.

In addition to the retained noncontrolling investment in Hanxin, the Company maintains a seat on Hanxin's board of directors, and Henry Zhang, a relative of Dr. Jack Zhang and Dr. Mary Luo, is an equity holder, general manager, and chairman of the board of directors of Hanxin. As a result, it was determined that the Company has significant influence over Hanxin and the retained noncontrolling investment in Hanxin is accounted for as an equity method investment.

Hanxin continues to be a related party after the deconsolidation.

Note 4. 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.

Service revenues derived from research and development contracts is recognized over time based on progress toward satisfaction of the performance obligation. For each performance obligation satisfied over time, the Company assesses the proper method to be used for revenue recognition, either an input method to measure progress toward the satisfaction of services or an output method of determining the progress of completion of performance obligation. For the three months ended March 31, 2022, and 2021, revenues from research and development services at ANP were $0.6 million and $0.3 million, respectively.

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,	
	2022	2021
	(in thousands)	
Beginning balance	$ 20,167	$ 20,380
Provision for chargebacks and rebates	46,779	47,031
Credits and payments issued to third parties	(48,394)	(46,881)
Ending balance	$ 18,552	$ 20,530

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 20 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, 2022 and December 31, 2021, $14.1 million and $15.6 million were included as a reduction to accounts receivable, net, on the condensed consolidated balance sheets, respectively. The remaining provision as of March 31, 2022 and December 31, 2021 of $4.5 million and $4.6 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 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,	
	2022	2021
	(in thousands)	
Beginning balance	$ 21,677	$ 14,204
Provision for product returns	1,192	3,233
Credits issued to third parties	(1,480)	(2,517)
Ending balance	$ 21,389	$ 14,920

Of the provision of product returns as of March 31, 2022 and December 31, 2021, $15.9 million and $16.0 million were included in accounts payable and accrued liabilities on the condensed consolidated balance sheets, respectively. The remaining provision as of March 31, 2022 and December 31, 2021 of $5.5 million and $5.7 million, respectively, were included in other long-term liabilities. For the three months ended March 31, 2022 and 2021, the Company's aggregate product return rates were 1.6% and 1.4% of qualified sales, respectively.

Note 5. 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.

For the three months ended March 31, 2022, options to purchase 706,740 shares of stock with a weighted-average exercise price of $34.74 per share 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, 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 loss 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,	
	2022	2021
	(in thousands, except per share data)	
Basic and dilutive numerator:		
Net income attributable to Amphastar Pharmaceuticals, Inc.	$ 24,253	$ 5,041
Denominator:		
Weighted-average shares outstanding — basic	48,138	47,520
Net effect of dilutive securities:		
Incremental shares from equity awards	3,841	1,998
Weighted-average shares outstanding — diluted	51,979	49,518
Net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders — basic	$ 0.50	$ 0.11
Net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders — diluted	$ 0.47	$ 0.10

Note 6. 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
- APIs

The finished pharmaceutical products segment manufactures, markets and distributes Primatene Mist®, glucagon, enoxaparin, naloxone, phytonadione, lidocaine, epinephrine, various critical and non-critical care drugs, as well as certain contract manufacturing and contract research revenues. 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,	
	2022	2021
	(in thousands)	
Net revenues:		
Finished pharmaceutical products	$ 116,546	$ 97,882
API	3,822	5,138
Total net revenues	120,368	103,020
Gross profit (loss):		
Finished pharmaceutical products	56,939	45,286
API	(1,113)	(340)
Total gross profit	55,826	44,946
Operating expenses	34,212	34,640
Income from operations	21,614	10,306
Non-operating income (expenses)	7,419	(5,192)
Income before income taxes	$ 29,033	$ 5,114

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,	
	2022	2021
	(in thousands)	
Finished pharmaceutical products net revenues:		
Primatene Mist®	$ 24,697	$ 18,383
Epinephrine	15,156	15,578
Glucagon	10,984	7,984
Lidocaine	10,590	9,071
Phytonadione	10,475	9,565
Enoxaparin	10,124	10,658
Naloxone	7,413	6,341
Other finished pharmaceutical products	27,107	20,302
Total finished pharmaceutical products net revenues	$ 116,546	$ 97,882

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

	Three Months Ended March 31,	
	2022	2021
	(in thousands)	
Depreciation and amortization expense		
Finished pharmaceutical products	$ 1,794	$ 1,435
API	948	1,048
Total depreciation and amortization expense	$ 2,742	$ 2,483

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,
	2022	2021	2022	2021
	(in thousands)			
United States	$ 117,114	$ 99,170	$ 137,423	$ 134,731
China	933	1,121	90,770	91,876
France	2,321	2,729	43,176	44,884
Total	$ 120,368	$ 103,020	$ 271,369	$ 271,491

Note 7. Customer and Supplier Concentration

Customer Concentrations

Three large wholesale drug distributors, AmerisourceBergen Corporation, or AmerisourceBergen, Cardinal Health, Inc., or Cardinal, and McKesson Corporation, or McKesson, are all distributors of the Company's products, as well as suppliers of a broad range of health care products. 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, 2022 and 2021 and accounts receivable as of March 31, 2022 and December 31, 2021, 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, 2022	December 31, 2021	2022	2021
AmerisourceBergen	13 %	13 %	22 %	25 %
McKesson	23 %	30 %	18 %	20 %
Cardinal Health	22 %	20 %	16 %	15 %

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 8. 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, 2022, cash equivalents include money market accounts. Investments consist of certificates of deposit as well as investment-grade municipal bonds with original maturity dates between three and fifteen 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 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, 2022 and December 31, 2021, are as follows:

	Total	(Level 1)	(Level 2)	(Level 3)
		(in thousands)		
Cash equivalents - money market	$ 140,991	$ 140,991	$ —	$ —
Restricted cash - money market	235	235	—	—
Short-term investments - certificates of deposit	4,600	—	4,600	—
Restricted short-term investments - certificates of deposit	2,200	—	2,200	—
Corporate and municipal bonds	9,676	—	9,676	—
Interest rate swap related to variable rate loans	3,609	—	3,609	—
Fair value measurement as of March 31, 2022	$ 161,311	$ 141,226	$ 20,085	$ —
Cash equivalents - money market	$ 102,863	$ 102,863	$ —	$ —
Restricted cash - money market	235	235	—	—
Short-term investments - certificates of deposit	5,103	—	5,103	—
Restricted short-term investments - certificates of deposit	2,200	—	2,200	—
Corporate and municipal bonds	6,984	—	6,984	—
Interest rate swap related to variable rate loans	596	—	596	—
Fair value measurement as of December 31, 2021	$ 117,981	$ 103,098	$ 14,883	$ —

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 investments in unconsolidated affiliates, long-lived assets, goodwill, and intangible assets for which the fair value is determined as part of the related impairment test. As of March 31, 2022 and December 31, 2021, there were no significant adjustments to fair value for nonfinancial assets or liabilities.

The deferred compensation plan assets are valued using the cash surrender value of the life insurance policies and are not included in the table above.

Note 9. 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 (due within 1 year)	$ 5,557	$ —	$ (30)	$ 5,527
Municipal bonds (due within 1 year)	4,162	—	(13)	4,149
Total investments as of March 31, 2022	$ 9,719	$ —	$ (43)	$ 9,676
Corporate bonds (due within 1 year)	$ 2,481	$ —	$ (3)	$ 2,478
Corporate bonds (due within 1 to 3 years)	1,248	—	(3)	1,245
Municipal bonds (due within 1 year)	3,263	—	(2)	3,261
Total investments as of December 31, 2021	$ 6,992	$ —	$ (8)	$ 6,984

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**.**

Investment in unconsolidated affiliate

The Company accounts for its share of the earnings or losses of its unconsolidated affiliate (Hanxin) with a reporting lag of three months, as the financial statements of Hanxin are not completed on a basis that is sufficient for the Company to apply the equity method on a current basis. The Company's share of Hanxin's losses for the three months ended March 31, 2022 was $0.7 million, which was recorded in the "Equity in losses of unconsolidated affiliate" line on the consolidated statement of operations.

Note 10. 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	$ 9,182	$ 5,203	$ 3,979
Patents	12	486	350	136
Land-use rights	39	2,540	700	1,840
Subtotal	12	12,208	6,253	5,955
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill - Finished pharmaceutical products	*	3,256	—	3,256
Subtotal	*	32,481	—	32,481
As of March 31, 2022	*	$ 44,689	$ 6,253	$ 38,436

	Weighted-Average Life (Years)	Original Cost	Accumulated Amortization	Net Book Value
		(in thousands)		
Definite-lived intangible assets				
IMS (UK) international product rights	10	$ 9,445	$ 5,116	$ 4,329
Patents	12	486	340	146
Land-use rights	39	2,540	683	1,857
Subtotal	12	12,471	6,139	6,332
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill - Finished pharmaceutical products	*	3,313	—	3,313
Subtotal	*	32,538	—	32,538
As of December 31, 2021	*	$ 45,009	$ 6,139	$ 38,870

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

Goodwill

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

	March 31, 2022	December 31, 2021
	(in thousands)	
Beginning balance	$ 3,313	$ 3,940
ANP restructuring	—	(374)
Currency translation	(57)	(253)
Ending balance	$ 3,256	$ 3,313

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, 2022.

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 11. Inventories

Inventories consist of the following:

	March 31, 2022	December 31, 2021
	(in thousands)	
Raw materials and supplies	$ 40,358	$ 41,853
Work in process	40,264	33,298
Finished goods	14,525	17,656
Total inventories	$ 95,147	$ 92,807

Charges of $8.0 million and $9.5 million were included in the cost of revenues in the Company's condensed consolidated statements of operations for the three months ended March 31, 2022 and 2021, 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 $6.4 million and $8.2 million as of March 31, 2022 and 2021, respectively.

Note 12. Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

	March 31, 2022	December 31, 2021
	(in thousands)	
Buildings	$ 130,364	$ 130,582
Leasehold improvements	29,221	29,221
Land	7,592	7,615
Machinery and equipment	207,006	207,883
Furniture, fixtures, and automobiles	27,635	27,376
Construction in progress	44,685	41,186
Total property, plant, and equipment	446,503	443,863
Less accumulated depreciation	(203,255)	(199,619)
Total property, plant, and equipment, net	$ 243,248	$ 244,244

Note 13. Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consisted of the following:

	March 31, 2022	December 31, 2021
	(in thousands)	
Accrued customer fees and rebates	$ 12,903	$ 12,121
Accrued payroll and related benefits	24,178	23,256
Accrued product returns, current portion	15,898	16,028
Accrued loss on firm purchase commitments	9,779	7,133
Other accrued liabilities	9,209	8,793
Total accrued liabilities	71,967	67,331
Accounts payable	23,843	22,214
Total accounts payable and accrued liabilities	$ 95,810	$ 89,545

Note 14. Debt

Debt consists of the following:

	March 31, 2022	December 31, 2021
	(in thousands)	
Line of Credit Facilities		
Line of credit facility with China Merchant Bank	$ —	$ —
Revolving line of credit facility with Capital One N.A. due August 2026	—	—
Term Loan		
Term loan with Capital One N.A. due August 2026	69,125	69,563
Mortgage Loans		
Mortgage payable with East West Bank due June 2027	8,313	8,353
Other Loans and Payment Obligations		
French government loans due December 2026	267	269
Equipment under Finance Leases	337	398
Total debt	78,042	78,583
Less current portion of long-term debt	2,159	2,202
Less: Loan issuance costs	1,535	1,605
Long-term debt, net of current portion and unamortized debt issuance costs	$ 74,348	$ 74,776

As of March 31, 2022, 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 the mortgage loan with East West Bank, as well as the term loan with Capital One N.A., the Company has entered into fixed interest rate swap contracts to exchange the variable interest rates for a fixed interest rates.

Covenants

At March 31, 2022 and December 31, 2021, the Company was in compliance with all of its debt covenants.

Note 15. Income Taxes

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

	Three Months Ended March 31,	
	2022	2021
	(in thousands)	
Income before taxes	$ 29,033	$ 5,114
Income tax provision	4,077	1,155
Income before equity in losses of unconsolidated affiliate	$ 24,956	$ 3,959
Income tax provision as a percentage of income before income taxes	14.0 %	22.6 %

The change in the Company's effective tax rate for the three months ended March 31, 2022 was 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 AFP's net deferred income tax assets and will continue to do so until AFP generates sufficient taxable income to realize its 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 an immaterial amount during the three months ended March 31, 2022 and 2021.

Note 16. Stockholders' Equity

Share Buyback Program

Pursuant to the Company's existing share buyback program, the Company purchased 51,168 and 204,698 shares of its common stock during the three months ended March 31, 2022 and 2021, totaling $1.2 million and $3.8 million, respectively.

In May 2022, the Company's Board of Directors authorized a $25.0 million increase to the Company's share buyback program, which is expected to continue for an indefinite period of time. Since the inception of the program, the Company's Board of Directors have authorized an aggregate of $185.0 million to the Company's share buyback program. 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, 2022, the Company reserved an aggregate of 6,462,223 shares of common stock for future issuance under the Amended and Restated 2015 Equity Incentive Plan, or the 2015 Plan, including 1,192,873 shares, which were reserved in January 2022 pursuant to the evergreen provision in the 2015 Plan.

2014 Employee Stock Purchase Plan

As of March 31, 2022, the Company has issued 954,456 shares of common stock under the ESPP and 1,045,544 shares of its common stock remain available for issuance under the ESPP.

For the three months ended March 31, 2022 and 2021, the Company recorded ESPP expenses of $0.2 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 ESPP awards are estimated at the grant date using the Black-Scholes option-pricing model. The fair value of RSUs is estimated at the grant date using the Company's common share price. Compensation cost for all share-based payments granted with service-based graded vesting schedules is recognized using the straight-line method over the requisite service period.

The weighted-averages for key assumptions used in determining the fair value of options granted during the three months ended March 31, 2022 and 2021, are as follows:

	Three Months Ended March 31,	
	2022	2021
Average volatility	41.1 %	42.2 %
Average risk-free interest rate	2.2 %	1.3 %
Weighted-average expected life in years	6.3	6.3
Dividend yield rate	— %	— %

A summary of option activity for the three months ended March 31, 2022, 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, 2021	8,455,721	$ 15.67		
Options granted	706,740	34.74		
Options exercised	(795,795)	14.43		
Options cancelled	(7,646)	17.19		
Options expired	(3,914)	13.35		
Outstanding as of March 31, 2022	8,355,106	$ 17.40	5.58	$ 154,559
Exercisable as of March 31, 2022	5,816,368	$ 15.53	4.23	$ 118,506
Vested and expected to vest as of March 31, 2022	8,071,696	$ 17.20	5.46	$ 150,955

(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, 2022.

For the three months ended March 31, 2022 and 2021, the Company recorded an expense of $2.5 million and $2.4 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,	
	2022	2021
	(in thousands, except per share data)	
Weighted-average grant date fair value per option share	$ 15.06	$ 7.66
Intrinsic value of options exercised	12,200	1,029
Cash received from options exercised	12,450	2,169
Total fair value of the options vested during the period	6,987	6,772

A summary of the status of the Company's non-vested options as of March 31, 2022, and changes during the three months ended March 31, 2022, is presented below:

	Options	Weighted-Average Grant Date Fair Value
Non-vested as of December 31, 2021	2,848,934	$ 6.95
Options granted	706,740	15.06
Options vested	(1,009,290)	6.92
Options forfeited	(7,646)	7.34
Non-vested as of March 31, 2022	2,538,738	9.22

As of March 31, 2022, there was $18.8 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 3.1 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, 2022 and 2021, the Company recorded expenses of $2.4 million and $2.2 million, respectively, related to RSU awards granted under all plans.

As of March 31, 2022, there was $20.0 million of total unrecognized compensation cost, net of forfeitures, related to non-vested RSU stock-based compensation arrangements granted under all plans. The cost is expected to be recognized over a weighted-average period of 3.1 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[1]
		(in thousands)
RSUs outstanding at December 31, 2021	1,184,842	
RSUs granted	306,080	$ 10,633
RSUs forfeited	(3,259)	
RSUs vested[2]	(417,007)	
RSUs outstanding at March 31, 2022	1,070,656	

(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, 174,982 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 was set to expire in December 2023. The 2018 Plan permitted the grant of stock options and other equity awards in ANP shares to ANP employees.

During the second quarter of 2021, in connection with the ANP restructuring, the 2018 Plan was terminated.

Prior to the termination of the 2018 Plan, during the three months ended March 31, 2021, the Company recorded expense of $0.1 million related to stock options issued by ANP under the 2018 Plan.

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,	
	2022	2021
	(in thousands)	
Cost of revenues	$ 1,385	$ 1,146
Operating expenses:		
Selling, distribution, and marketing	168	127
General and administrative	2,861	2,968
Research and development	608	593
Total share-based compensation	$ 5,022	$ 4,834

Note 17. 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, 2022 and 2021, were approximately $0.6 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 1.00% as of March 31, 2022 and December 31, 2021. The liability is included in other long-term liabilities in the accompanying condensed consolidated balance sheets. The plan is currently unfunded, and the benefit obligation under the plan was $2.7 million at March 31, 2022 and December 31, 2021. The Company recorded an immaterial amount of expense under the plan for the three months ended March 31, 2022 and 2021.

Non-qualified Deferred Compensation Plan

In December 2019, the Company established a non-qualified deferred compensation plan. The 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. The plan assets were valued at approximately $3.5 million and $3.4 million as of March 31, 2022 and December 31, 2021, respectively. The plan liabilities were valued at approximately $3.6 million and $3.5 million as of March 31, 2022 and December 31, 2021, respectively. The plan assets and liabilities are included in other long-term assets and other long-term liabilities, respectively, on the Company's condensed consolidated balance sheets.

Note 18. Commitments and Contingencies

Purchase Commitments

As of March 31, 2022, the Company has entered into commitments to purchase equipment and raw materials for an aggregate amount of approximately $72.9 million. The Company anticipates that most of these commitments with a remaining term in excess of one year will be fulfilled by 2023.

Note 19. Litigation

Hatch-Waxman Litigations

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. The Company's 30-month FDA stay expires August 10, 2022. On January 26, 2022, the Company and Astellas-Gilead reached an agreement to resolve the lawsuit. The parties submitted, and the Court granted on January 27, 2022, a Motion to Dismiss Without Prejudice for Astellas-Gilead's complaint of infringement against IMS. Under the terms of the agreement, the Company received $5.4 million from Astellas constituting saved litigation expenses. The Company recorded the settlement amount as other income (expenses), in its condensed consolidated statement of operations for the three months ended March 31, 2022.

Other Litigation

The Company is also subject to various other claims, arbitrations, investigations, and lawsuits from time to time arising in the ordinary course of business. In addition, third parties may, from time to time, assert claims against the Company in the forms of letters and other communications.

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 20. Subsequent Event

In April 2022, the Company's Chinese subsidiary, ANP, entered into a contract manufacturing agreement with Hanxin, which is a related party, whereby Hanxin will develop several active pharmaceutical ingredients and finished products for the Chinese market and will engage ANP to manufacture the products on a cost-plus basis. Hanxin will commit to purchase certain quantities from ANP subject to the terms and conditions set forth in the agreement, including Hanxin filing for and obtaining any required marketing authorizations.

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, 2021, 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 generic abbreviated new drug applications, or ANDAs, biosimilar insulin product candidates and proprietary product candidates, which are in various stages of development and target a variety of indications. Four of the ANDAs and one new drug application, or NDA, are currently on file with the FDA. Additionally, we have one product with tentative FDA approval, Vasopressin, which we plan to launch in the third quarter of 2022, subject to a confidential settlement agreement with the product's innovator.

Our largest products by net revenues currently include Primatene Mist®, epinephrine, glucagon, phytonadione, lidocaine, and enoxaparin sodium injection. In April 2022, the FDA granted approval of our ganirelix acetate injection, 250mg/0.5mL prefilled syringe, which we plan to launch in the second quarter of 2022.

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.

In 2021, we completed the restructuring of our Chinese subsidiary, ANP, resulting in the reduction of ANP's ownership in Hanxin Pharmaceutical Technology Co., Ltd, or Hanxin, and Hanxin's subsidiaries to 14%, see Note 3 to the condensed consolidated financial statements. As a result of the restructuring, we determined that we have significant influence over Hanxin and, as such, the retained non-controlling investment in Hanxin is accounted for as an equity method investment. Hanxin continues to be a related party subsequent to the restructuring.

COVID-19 Pandemic

We are actively monitoring the COVID-19 pandemic, including the Omicron variants, and its impact globally. Currently, our production facilities in all of our locations continue to operate as they had before the COVID-19 pandemic with few changes, other than for enhanced safety measures intended to prevent the spread of the virus.

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, and we are experiencing longer lead time for components. Recent increases in COVID-19 cases in Shanghai, China, have led to shutdowns and delays at the ports in Shanghai, which could have an impact to our operations. However, the extent of the impact of this shutdown and delay is highly uncertain and difficult to predict.

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 effects will depend on future developments, which are highly uncertain and cannot be predicted. Infections may resurge or become more widespread, including due to new variants 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 prolonged for extended periods, all of which would have a negative impact on our business, financial condition, and operating results.

Even after the COVID-19 pandemic has subsided, we may continue to experience an adverse impact on our business due to the continued global economic impact of the COVID-19 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, 2022, 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®, epinephrine, glucagon, phytonadione, lidocaine, enoxaparin, naloxone, 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, 2022 Compared to Three Months Ended March 31, 2021

Net revenues

	Three Months Ended March 31,		Change	
	2022	2021	Dollars	%
		(in thousands)		
Net revenues				
Finished pharmaceutical products	$ 116,546	$ 97,882	$ 18,664	19 %
API	3,822	5,138	(1,316)	(26)%
Total net revenues	$ 120,368	$ 103,020	$ 17,348	17 %
Cost of revenues				
Finished pharmaceutical products	$ 59,607	$ 52,596	$ 7,011	13 %
API	4,935	5,478	(543)	(10)%
Total cost of revenues	$ 64,542	$ 58,074	$ 6,468	11 %
Gross profit	$ 55,826	$ 44,946	$ 10,880	24 %
as % of net revenues	*46 %*	*44 %*		

The increase in net revenues of the finished pharmaceutical products for the three months ended March 31, 2022, was due to the following changes:

	Three Months Ended March 31,		Change	
	2022	2021	Dollars	%
		(in thousands)		
Finished pharmaceutical products net revenues				
Primatene Mist®	$ 24,697	$ 18,383	$ 6,314	34 %
Epinephrine	15,156	15,578	(422)	(3)%
Glucagon	10,984	7,984	3,000	38 %
Lidocaine	10,590	9,071	1,519	17 %
Phytonadione	10,475	9,565	910	10 %
Enoxaparin	10,124	10,658	(534)	(5)%
Naloxone	7,413	6,341	1,072	17 %
Other finished pharmaceutical products	27,107	20,302	6,805	34 %
Total finished pharmaceutical products net revenues	$ 116,546	$ 97,882	$ 18,664	19 %

Primatene Mist® sales continued to grow in the first quarter of 2022, as a result of increased unit volumes, which was primarily a result of the continued success of our advertising campaign. The increase in sales of glucagon was primarily due to an increase in unit volumes as the prior year period did not include a full quarter of sales due to glucagon's launch in the first quarter of 2021. The increase in sales of lidocaine was primarily due to an increase in unit volumes. The increase in sales of phytonadione was primarily due to higher average selling price. Sales of enoxaparin decreased primarily due to a decrease in unit volumes, as a competitor re-entered the market during the second quarter of 2021. The increase in sales of naloxone was primarily due an increase in unit volumes. The increase in other finished pharmaceutical products was primarily due to higher unit volumes of calcium chloride and sodium bicarbonate, which were in high demand due to market shortages.

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. In May 2021, we amended the Supply Agreement with MannKind Corporation, whereby MannKind's aggregate total commitment of RHI API under the Supply Agreement was modified and extended for an additional year through 2027, which timeframe would have previously lapsed after calendar year 2026. MannKind has agreed to pay us an amendment fee of $2.0 million. We received the first payment of the amendment fee of $1.0 million in June 2021 which we recognized in net revenues during the year ended December 31, 2021. The remaining $1.0 million of the amendment fee was received in January 2022 and relates to the amendments to the 2022 supply level and will be recognized ratably to net revenues in 2022. We anticipate that sales of API will continue to fluctuate and may decrease due to the inherent uncertainties related to sales to MannKind 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. However, during the first quarter of 2022, we experienced a backlog of approximately $5.9 million for various products, partially brought on by competitor shortages and supplier constraints. We are currently working on resolving related issues and believe that we will be able to reduce the backlog in the near future. 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® and glucagon, which are higher-margin products, helped increase our gross margins for the three months ended March 31, 2022. These increases in gross margins were partially offset by overall

increase in labor cost, as well as an increase in the cost for heparin raw material, which is used as the starting material for enoxaparin, and a lower average selling price for enoxaparin.

We are experiencing increased costs for labor and certain purchased components. Additionally, the cost of heparin may increase further, putting downward pressure on our gross margins. However, we believe that this trend will be offset by increased sales of our higher-margin products, including Primatene Mist®, glucagon and new products we anticipate launching in 2022.

Selling, distribution and marketing, and general and administrative

	Three Months Ended March 31,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	$ 5,519	$ 4,537	$ 982	22 %
General and administrative	$ 12,470	$ 15,338	$ (2,868)	(19)%

The increase in selling, distribution and marketing expenses was primarily due to increased freight expenses. The decrease in general and administrative expense was primarily due to a decrease in legal expenses and a decrease in expenses in China due to the ANP restructuring.

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

Research and development

	Three Months Ended March 31,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Salaries and personnel-related expenses	$ 6,484	$ 6,979	$ (495)	(7)%
Clinical trials	105	738	(633)	(86)%
FDA fees	29	40	(11)	(28)%
Testing, operating and lab supplies	5,401	2,153	3,248	151 %
Depreciation	2,626	2,938	(312)	(11)%
Other expenses	1,578	1,917	(339)	(18)%
Total research and development expenses	$ 16,223	$ 14,765	$ 1,458	10 %

The increase in research and development expenses is primarily due to an increase in testing, operating and lab supplies as a result of in an increase in expenditures on raw materials and components for our pipeline products. This was partially offset by a decrease in clinical trial expense as a result of a shift in timing on some of our clinical trial studies.

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. Over the past year, some of our ongoing clinical trials experienced short term interruptions in the recruitment of patients due to the COVID-19 pandemic, as hospitals prioritized their resources towards the COVID-19 pandemic and government imposed travel restrictions. These conditions may in turn delay spending and delay the results of these trials.

Additionally, some clinical trials experienced increased expenses due to new protocols to protect participants from COVID-19.

Other income (expense), net

	Three Months Ended March 31,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Other income (expense), net	$ 7,593	$ (5,249)	$ 12,842	NM

In January 2022, we received a settlement of $5.4 million in connection with the Regadenoson patent litigation. In the first quarter of 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 19 to the condensed consolidated financial statements.

Income tax provision

	Three Months Ended March 31,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Income tax provision	$ 4,077	$ 1,155	$ 2,922	NM
Effective tax rate	*14 %*	*23 %*		

Our effective tax rate for the three months ended March 31, 2022 decreased in comparison to the three months ended March 31, 2021, primarily due to differences in pre-tax income positions and timing of discrete tax items. For more information regarding our income taxes, see Note 15 to the condensed consolidated financial statements.

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 and China, including a significant increase in capital expenditures in 2022. We plan to fund this facility expansion with cash flows from operations. 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, 2022, our foreign subsidiaries collectively held $19.4 million in cash and cash equivalents. Cash or cash equivalents held at foreign subsidiaries are not available to fund the parent company's operations in the United States. We believe that our 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, debt securities, depositary shares, warrants, subscription rights, purchase contracts, or units. 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 $35.8 million to $250.1 million at March 31, 2022, compared to $214.3 million at December 31, 2021.

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, 2022 and 2021:

	Three Months Ended March 31,	
	2022	2021
	(in thousands)	
Statement of Cash Flow Data:		
Net cash provided by (used in)		
Operating activities	$ 50,765	$ 22,825
Investing activities	(9,110)	(8,695)
Financing activities	4,648	(6,639)
Effect of exchange rate changes on cash	(29)	(162)
Net increase in cash, cash equivalents, and restricted cash	$ 46,274	$ 7,329

Sources and Use of Cash

Operating Activities

Net cash provided by operating activities was $50.8 million for the three months ended March 31, 2022, which included net income of $24.3 million. Non-cash items comprised primarily of $6.8 million of depreciation and amortization and $5.0 million of share-based compensation expense.

Additionally, for the three months ended March 31, 2022, there was a net cash inflow from changes in operating assets and liabilities of $17.0 million, which resulted from an increase in accounts payable and accrued liabilities, as well as a decrease in accounts receivable. Accounts payable and accrued liabilities increased primarily due to the timing of payments. The decrease in accounts receivable was due to the timing of sales in the quarter ended December 31, 2021.

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 $7.4 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.

Investing Activities

Net cash used in investing activities was $9.1 million for the three months ended March 31, 2022, primarily as a result of $6.1 million in purchases of property, plant, and equipment, which included $4.3 million incurred in the United States, $0.3 million in France, and $1.5 million in China.

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.

Financing Activities

Net cash provided by financing activities was $4.6 million for the three months ended March 31, 2022, primarily as a

result of $6.4 million in net proceeds from the settlement of share-based compensation awards under our equity plan, which was partially offset by the use of $1.2 million to purchase treasury stock. Additionally, we also made $0.5 million in principal payments on our long-term debt.

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.

Indebtedness

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

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, 2021. There have been no material changes to our critical accounting policies as compared to the critical accounting policies as described in our Annual Report on Form 10-K for the year ended December 31, 2021.

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, 2021. 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, 2022, 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, 2021, filed with the Securities and Exchange Commission on March 11, 2022.

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

The ongoing COVID-19 pandemic, including the recent Omicron variants, 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 delayed shipments to us in 2021 and 2022. These delays may have been caused by manufacturing disruptions due to the COVID-19 pandemic. Recent increases in COVID-19 cases in Shanghai, China, have led to shutdowns and delays at the ports in Shanghai, which could have an impact to our operations. However, the extent of the impact of this shutdown and delay is highly uncertain and difficult to predict. None of these delays caused delays in our manufacturing, but future delays could cause manufacturing disruptions at our factories.

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 the ongoing 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 ongoing 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. Recent increases in COVID-19 cases in Shanghai, China, have led to shutdowns and delays at the ports in Shanghai, which could have an impact to our operations. However, the extent of the impact of this shutdown and delay is highly uncertain and difficult to predict. 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 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, contains 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 of 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 we launched the product in May 2020.

The FDA granted approval of our products that were previously marketed under the "grandfather" exception, such as atropine sulfate injection 0.1 mg/mL in the 10mL Luer-Jet® prefilled syringe in October 2020, 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 the epinephrine prefilled syringe. For the years ended December 31, 2021, 2020, and 2019, we recorded net revenues of $27.8 million, $13.2 million, and $13.9 million, respectively, for epinephrine prefilled syringes and for the three months ended March 31, 2022 and 2021, we recorded net revenues of $6.2 million, and $9.3 million, respectively, for this product. We filed an NDA for our epinephrine prefilled syringes 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. In 2020, the HHS announced that termination of the FDA Unapproved Drugs Initiative (UDI), citing that the Compliance Policy Guide (CPG) issued with the UDI was "linked to prescription drug price increases and shortages" and announced its withdrawal. However, under the Biden administration, in May 2021, HHS and FDA, each under new leadership, jointly issued a withdrawal-of-the-termination notice, withdrawing the prior HHS notice of termination issued under the Trump administration, citing multiple legal and factual inaccuracies. New guidance from the agency is anticipated in the future. The long-term impact of this policy and other measures promulgated by the Biden administration on our business remains unclear.

Our business and operations have been impacted in the past, and may be impacted in the future, in the event of system breach or failure.

We, our collaborators, third-party providers, distributors, customers and other contractors utilize information technology systems and networks to transmit, store and otherwise process electronic data in connection with our business activities, including our supply chain processes, operations and communications. This includes our clinical data and business proprietary information, Electronic Data Interchange, or EDI, on purchase orders, invoices, chargebacks, etc. We, and others on our behalf, also collect, transmit, store and otherwise process certain data relating to individuals, including

about our personnel, business partners, and others, which may be subject to applicable data protection, security and privacy laws and regulations that require adoption of minimum information security standards. The cost of compliance with applicable data protection, security and privacy laws and regulations have increased and may increase in the future.

Despite our implementation of security measures to protect the confidentiality, integrity, and availability of the systems, networks and data within our control from various threats (e.g., cyber-attacks, system breaches, malware, viruses, hacking, fraudulent use, social engineering attacks, phishing attacks, ransomware attacks, credential-stuffing attacks, denial-of-service attacks, unauthorized access, insider threats, accidental disclosures, intellectual property theft and economic espionage, exploitable vulnerabilities, defects or bugs in our or our third-party providers' systems, natural disasters, war, terrorism, telecommunications and electrical outages, breakdowns, damage, interruptions), risks remain, and our systems and networks and the systems and networks of third parties that support us and our services may be breached or disrupted due to these threats. The size and complexity of our systems may make them potentially vulnerable to breakdown or interruption, whether due to computer viruses or other causes, which may result in loss of data or the impairment of production and other supply chain processes, adversely affecting our business.

Techniques used to sabotage or obtain unauthorized access to systems and networks are constantly evolving and, in some instances, are not identified until or after they are launched against a target. We and our third-party providers may be unable to anticipate these techniques, discover threats and react in a timely manner, or implement adequate preventative or mitigating measures. Further, system breaches, malware, ransomware, computer hacking, and insider threats have become more prevalent. For example, companies have experienced an increase in phishing and social engineering attacks from third parties in connection with working remotely as a result of the ongoing COVID-19 pandemic. We and our third-party providers who may be operating in remote work environments may have increased security risks, due to increased use of home Wi-Fi networks and virtual private networks, as well as increased disbursement of physical machines. Also, due to political uncertainty and military actions associated with Russia's invasion of Ukraine, we and our third-party providers are vulnerable to heightened risks of threats and attacks from or affiliated with nation-state actors, including attacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products and services. While we implement security measures designed to reduce these risks, there is no guarantee that these measures will be adequate to safeguard all systems and networks. Any failure to maintain performance, reliability, security and availability of our systems and networks may result in accidental or unlawful destruction, damage, loss, unavailability, alteration, impairment, misuse, unauthorized disclosure of, or unauthorized access to our data, including personal information.

Potential legal, regulatory, contractual, financial, operational, and reputational harm may arise from the accidental or unlawful destruction, damage, loss, unavailability, alteration, impairment, misuse, unauthorized disclosure of, or unauthorized access to our systems, networks or data, including data which is transmitted, stored or otherwise processed by us or by collaborators, third-party providers, distributors and other contractors on our behalf. For example:

- The accidental or unlawful loss, unavailability or alteration of clinical trial data from completed or ongoing clinical trials for any of our product candidates could affect our ability to operate, result in delays in our development and regulatory approval efforts, and significantly increase our costs to recover or reproduce the data.
- Any security incident may require costly response and remediation efforts, trigger notification obligations under breach notification laws or contractual notification requirements, result in litigation or adverse regulatory action arising from or related to such an incident or event, damage our reputation, and result in significant additional expense to implement further data protection measures. Integrating the systems and data of any acquired entity may increase these risks due to unforeseen threats and vulnerabilities.
- Similarly, any security incident experienced by our collaborators, third-party providers, distributors and other contractors may hinder our product development, supply chain, other business operations, or our regulatory and contractual obligations to others and could also give rise to litigation or adverse regulatory action.

We have experienced and may continue to experience cyberattacks of varying degrees from time to time. In the first quarter of 2022, our Chinese subsidiary, ANP, was subject to a security incident that resulted in a temporary disruption to some of their internal computer systems. We are currently working with ANP to improve and add additional security

measures to their systems and networks. We have incurred costs to respond to the ANP incident.

In the second quarter of 2020, we were subject to a security incident that resulted in a temporary disruption to some of our internal computer systems. In response to this incident, we engaged a third-party forensic expert to investigate, and determined that cyber criminals illegally obtained certain personal information of certain current and former employees. We notified affected individuals and regulators, as we deemed was required or appropriate. We have incurred costs to respond to this incident, and we expect to continue to incur costs to support our efforts to enhance our security measures.

There can be no assurance that we will be successful in preventing security incidents nor that we will be successful in mitigating their effects, despite the implementation of security measures for systems, networks and data within our control. Similarly, there can be no assurance that our collaborators, third-party providers, distributors and other contractors will be successful in protecting our data on their systems or in protecting other systems upon which we may rely. Furthermore, breach notification laws are not consistent among jurisdictions, and compliance and other measures in the event of a security incident could result in a substantial cost and diversion of resources and distract management and technical personnel in efforts to investigate or correct the security incident, address and eliminate vulnerabilities and prevent future security incidents, and remediate the security incident, which repairing systems and responding to claims of damages for actual or asserted contract breaches. Any such security incident could have a material adverse effect on our business and prospects.

Although we maintain cyber insurance coverage that may cover certain of our losses in connection with a security incident, we cannot be certain our insurance coverage will be adequate for losses actually incurred, that insurance will continue to be available to us on commercially reasonable terms (if at all) or that any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceed available insurance coverage, the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, or denials of coverage, could have a material adverse effect on our business, including our financial condition, results of operations and reputation.

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, 2022	41,416	$ 23.97	41,416	—
February 1 – February 28, 2022	9,752	24.09	9,752	—
March 1 – March 31, 2022	—	—	—	—

(1) On August 9, 2021, we announced that our Board of Directors authorized an increase of $20 million to our share buyback program. The share buyback program does not have an expiration date. As of March 31, 2022, $7.3 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 pursuant to Rule 13a-14(a) or 15d-14a of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification pursuant to Rule 13a-14(a) or 15d-14a of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1#	Certification of Principal 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 Principal 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 10, 2022

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

Date: May 10, 2022

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14a OF THE SECURITIES EXCHANGE ACT OF 1934 AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002

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

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

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

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

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

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

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

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

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

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

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

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

Date: May 10, 2022

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

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14a OF THE SECURITIES EXCHANGE ACT OF 1934 AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002

I, William J. Peters, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 10, 2022

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

Exhibit 32.1

CERTIFICATIONS OF PRINCIPAL 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, 2022 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and

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

Date: May 10, 2022

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

CERTIFICATIONS OF PRINCIPAL 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, 2022 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and

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

Date: May 10, 2022

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.