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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, 2023
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, 2023 was 48,274,042.

AMPHASTAR PHARMACEUTICALS, INC.
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FORM 10-Q FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2023

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 the proposed acquisition of BAQSIMI®, including with respect to our ability to increase our revenues and derive certain benefits as a result of the acquisition of BAQSIMI®.;
- our ability to successfully acquire and integrate assets, including our ability to integrate BAQSIMI®;
- 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 ongoing COVID-19 pandemic, adverse impacts of the Russia-Ukraine conflict and related macroeconomic conditions on our business, financial condition, operations, cash flows and liquidity;
- 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 and the Russia-Ukraine conflict;
- global, national and local economic and market conditions, specifically with respect to geopolitical uncertainty, including the Russia-Ukraine conflict, the ongoing COVID-19 pandemic, inflation and rising interest rates;
- 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;
- cost 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 of 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;
- 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 Acts 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 ongoing impact on our business and the impacts of the ongoing Russia-Ukraine conflict, will depend on several factors, including the severity, duration and extent of the pandemic and the conflict, 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, 2022, 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, 2023 (unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 176,615	$ 156,098
Restricted cash	235	235
Short-term investments	16,277	19,664
Restricted short-term investments	2,200	2,200
Accounts receivable, net	100,638	88,804
Inventories	103,647	103,584
Income tax refunds and deposits	731	171
Prepaid expenses and other assets	7,327	7,563
Total current assets	407,670	378,319
Property, plant, and equipment, net	243,479	238,266
Finance lease right-of-use assets	706	753
Operating lease right-of-use assets	25,801	25,554
Investment in unconsolidated affiliate	1,758	2,414
Goodwill and intangible assets, net	37,179	37,298
Other assets	18,536	20,856
Deferred tax assets	38,527	38,527
Total assets	$ 773,656	$ 741,987
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 88,886	$ 84,242
Income taxes payable	11,590	4,571
Current portion of long-term debt	2,168	3,046
Current portion of operating lease liabilities	2,991	3,003
Total current liabilities	105,635	94,862
Long-term reserve for income tax liabilities	7,225	7,225
Long-term debt, net of current portion and unamortized debt issuance costs	72,872	72,839
Long-term operating lease liabilities, net of current portion	23,994	23,694
Deferred tax liabilities	178	144
Other long-term liabilities	15,175	14,565
Total liabilities	225,079	213,329
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; 58,440,531 and 48,179,238 shares issued and outstanding as of March 31, 2023 and 58,110,231 and 48,112,069 shares issued and outstanding as of December 31, 2022, respectively	6	6
Additional paid-in capital	456,623	455,077
Retained earnings	297,755	271,723
Accumulated other comprehensive loss	(8,268)	(8,624)
Treasury stock	(197,539)	(189,524)
Total equity	548,577	528,658
Total liabilities and stockholders' equity	$ 773,656	$ 741,987

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,	
	2023	2022
Net revenues	$ 140,022	$ 120,368
Cost of revenues	66,182	64,542
Gross profit	73,840	55,826
Operating expenses:		
Selling, distribution, and marketing	7,109	5,519
General and administrative	13,483	12,470
Research and development	19,815	16,223
Total operating expenses	40,407	34,212
Income from operations	33,433	21,614
Non-operating income (expenses):		
Interest income	924	181
Interest expense	(398)	(355)
Other income (expenses), net	(390)	7,593
Total non-operating income (expenses), net	136	7,419
Income before income taxes	33,569	29,033
Income tax provision	6,752	4,077
Income before equity in losses of unconsolidated affiliate	26,817	24,956
Equity in losses of unconsolidated affiliate	(785)	(703)
Net income	$ 26,032	$ 24,253
Net income per share:		
Basic	$ 0.54	$ 0.50
Diluted	$ 0.50	$ 0.47
Weighted-average shares used to compute net income per share:		
Basic	48,000	48,138
Diluted	51,970	51,979

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,	
	2023	2022
Net income	$ 26,032	$ 24,253
Other comprehensive income (loss), net of income taxes		
Foreign currency translation adjustment	356	(480)
Total other comprehensive income (loss)	356	(480)
Total comprehensive income	$ 26,388	$ 23,773

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					Treasury Stock		
	Shares	Amount	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive loss	Shares	Amount	Total
Balance as of December 31, 2022	58,110,231	$ 6	$ 455,077	$ 271,723	$ (8,624)	(9,998,162)	$ (189,524)	$ 528,658
Net income	—	—	—	26,032	—	—	—	26,032
Other comprehensive income	—	—	—	—	356	—	—	356
Purchase of treasury stock	—	—	—	—	—	(263,131)	(8,015)	(8,015)
Issuance of common stock in connection with the Company's equity plans	330,300	—	(4,565)	—	—	—	—	(4,565)
Share-based compensation expense	—	—	6,111	—	—	—	—	6,111
Balance as of March 31, 2023	58,440,531	$ 6	$ 456,623	$ 297,755	$ (8,268)	(10,261,293)	$ (197,539)	$ 548,577

	Common Stock					Treasury Stock		
	Shares	Amount	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive loss	Shares	Amount	Total
Balance as of December 31, 2021	56,440,202	$ 6	$ 422,423	$ 180,337	$ (6,765)	(8,725,290)	$ (150,479)	$ 445,522
Net income	—	—	—	24,253	—	—	—	24,253
Other comprehensive loss	—	—	—	—	(480)	—	—	(480)
Purchase of treasury stock	—	—	—	—	—	(51,168)	(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
Share-based compensation expense	—	—	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

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,	
	2023	**2022**
Cash Flows From Operating Activities:		
Net income	$ 26,032	$ 24,253
Reconciliation to net cash provided by operating activities:		
Loss on disposal of assets	2	1
Loss (gain) on interest rate swaps and foreign currency transactions, net	195	(3,013)
Depreciation of property, plant, and equipment	6,252	5,615
Amortization of product rights, trademarks, and patents	241	352
Operating lease right-of-use asset amortization	903	828
Equity in losses of unconsolidated affiliate	785	703
Share-based compensation expense	6,111	5,022
Changes in operating assets and liabilities:		
Accounts receivable, net	(11,796)	5,598
Inventories	268	(2,687)
Prepaid expenses and other assets	219	1,420
Income tax refunds, deposits, and payable, net	6,459	3,926
Operating lease liabilities	(862)	(695)
Accounts payable and accrued liabilities	5,573	9,442
Net cash provided by operating activities	40,382	50,765
Cash Flows From Investing Activities:		
Purchases and construction of property, plant, and equipment	(9,477)	(6,139)
Purchase of investments	(10,574)	(5,317)
Maturity of investments	14,064	2,535
Payment of deposits and other assets	(346)	(189)
Net cash used in investing activities	(6,333)	(9,110)
Cash Flows From Financing Activities:		
Proceeds from equity plans, net of withholding tax payments	(4,565)	6,437
Purchase of treasury stock	(8,015)	(1,229)
Debt issuance costs	—	(22)
Principal payments on long-term debt	(968)	(538)
Net cash used in financing activities	(13,548)	4,648
Effect of exchange rate changes on cash	16	(29)
Net increase in cash, cash equivalents, and restricted cash	20,517	46,274
Cash, cash equivalents, and restricted cash at beginning of period	156,333	126,588
Cash, cash equivalents, and restricted cash at end of period	$ 176,850	$ 172,862
Noncash Investing and Financing Activities:		
Capital expenditure included in accounts payable	$ 4,802	$ 6,709
Operating lease right-of-use assets in exchange for operating lease liabilities	$ 1,150	$ 1,777
Supplemental Disclosures of Cash Flow Information:		
Interest paid, net of capitalized interest	$ 1,245	$ 579
Income taxes paid	$ 336	$ 183

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 focuses primarily on developing, manufacturing, marketing, and selling technically challenging 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, 2022 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, 2022. 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. 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.

Investments in Unconsolidated Affiliate

The Company applies the equity method of accounting for investments when it has significant influence, but not controlling interest in the investee. Judgment regarding the level of influence over each equity method investment includes key factors such as ownership interest, representation on the board of directors, participation in policy-making decisions and material intercompany transactions. The Company's proportionate share of the earnings or losses resulting from these investments is reported as "Equity in losses of unconsolidated affiliate" in the accompanying consolidated statements of operations. Investments accounted for using the equity method may be reported on a lag of up to three months if financial statements of the investee are not available in sufficient time for the investor to apply the equity

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

method as of the current reporting date. The determination of whether an investee's results are recorded on a lag is made on an investment-by-investment basis.

The carrying value of equity method investments is reported as "Investment in unconsolidated affiliate" in the accompanying consolidated balance sheets. The Company's equity method investments are reported at cost and adjusted each period for the Company's share of the investee's earnings or losses and dividends paid, if any.

The Company assesses equity method investments for impairment whenever events or changes in circumstances indicate that the carrying value of an investment may not be recoverable. If the decline in value is considered to be other than temporary, the investment is written down to its estimated fair value, which establishes a new cost basis in the investment. No such impairment was identified for any of the periods presented.

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 value, 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 of USD using the current or historical exchange rates. The resulting currency remeasurement adjustments and other transactional foreign currency exchange gains and losses are reflected in the Company's 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. Activities in the statements of operations are 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, 2023 and 2022 were $0.6 million gain and $0.6 million loss, respectively.

Comprehensive Income

The Company's comprehensive income includes its foreign currency translation gains and losses as well as its share of other comprehensive income from its equity method investments.

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

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 statements of operations. For the three months ended March 31, 2023 and 2022, advertising expenses were $3.3 million and $2.4 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 interest rate swap contracts to manage its exposure to interest rate changes and its overall cost of long-term debt. The Company's interest rate swap contracts exchange the variable interest rates for fixed interest rates.

From time to time, the Company may enter into forward currency contracts to lock in currency exchange rates to manage its foreign currency exchange rate exposure. The Company's interest rate swaps and forward currency contracts have not been designated as hedging instruments and, therefore are recorded at their fair values at the end of each reporting period with changes in fair value recorded in other income (expenses) on the condensed consolidated statements of operations. As of March 31, 2023, the Company did not have any unsettled forward currency contracts to purchase foreign currency. As of December 31, 2022, the Company had an unsettled forward currency contract to purchase foreign currency with a fair value of approximately $0.2 million, based on Level 2 inputs, which was recorded as a liability in the accounts payable and accrued liabilities line in the condensed consolidated balance sheets.

Cash and Cash Equivalents

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

Investments

Investments as of March 31, 2023 and December 31, 2022 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, 2023 and December 31, 2022, 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, 2023 and December 31, 2022, the balance of restricted short-term investments was $2.2 million.

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

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 they are 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. 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, the Company 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.

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.

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

Service revenues derived from research and development contracts are 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, 2023 and 2022, revenues from research and development services at ANP were $0.1 million and $0.6 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,	
	2023	2022
	(in thousands)	
Beginning balance	$ 26,606	$ 20,167
Provision for chargebacks and rebates	69,027	46,779
Credits and payments issued to third parties	(67,289)	(48,394)
Ending balance	$ 28,344	$ 18,552

Changes in the provision for chargebacks 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 provision for rebates 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. The provision for chargebacks and rebates is recorded within accounts receivable and/or accounts payable and accrued liabilities depending on whether the Company has the right to offset with the customer.

Of the provision for chargebacks and rebates as of March 31, 2023 and December 31, 2022, $21.9 million and $20.5 million were included as a reduction to accounts receivable, net, on the condensed consolidated balance sheets, respectively. The remaining provision as of March 31, 2023 and December 31, 2022 of $6.4 million and $6.1 million, respectively, which were included in accounts payable and accrued liabilities in the condensed consolidated balance sheets.

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

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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,	
	2023	2022
	(in thousands)	
Beginning balance	$ 19,451	$ 21,677
Provision for product returns	614	1,192
Credits issued to third parties	(1,226)	(1,480)
Ending balance	$ 18,839	$ 21,389

Of the provision for product returns as of March 31, 2023 and December 31, 2022, $14.1 million and $14.9 million were included in accounts payable and accrued liabilities on the condensed consolidated balance sheets, respectively. The remaining provision as of March 31, 2023 and December 31, 2022 of $4.7 million and $4.6 million, were included in other long-term liabilities, respectively. For the three months ended March 31, 2023 and 2022, the Company's aggregate product return rate was 1.3% and 1.6% of qualified sales, respectively.

Note 4. Net Income per Share

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

For the three months ended March 31, 2023, options to purchase 1,403,859 shares of stock with a weighted-average exercise price of $34.96 per share were excluded from the computation of diluted net income per share because their effect would be anti-dilutive.

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 from the computation of diluted net income per share because their effect would be anti-dilutive.

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The following table provides the calculation of basic and diluted net income per share for each of the periods presented:

	Three Months Ended March 31,	
	2023	2022
	(in thousands, except per share data)	
Basic and dilutive numerator:		
Net income	$ 26,032	$ 24,253
Denominator:		
Weighted-average shares outstanding — basic	48,000	48,138
Net effect of dilutive securities:		
Incremental shares from equity awards	3,970	3,841
Weighted-average shares outstanding — diluted	51,970	51,979
Net income per share — basic	$ 0.54	$ 0.50
Net income per share — diluted	$ 0.50	$ 0.47

Note 5. Segment Reporting

The Company's business is the development, manufacture, and marketing of pharmaceutical products. The Company has identified two reporting segments that each report to the Chief Operating Decision Maker, or CODM, as defined in ASC 280, *Segment Reporting*. The Company's performance is assessed and resources are allocated by the CODM based on the following two reportable segments:

- Finished pharmaceutical products
- 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.

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Selected financial information by reporting segment is presented below:

	Three Months Ended March 31,	
	2023	2022
	(in thousands)	
Net revenues:		
Finished pharmaceutical products	$ 136,010	$ 116,546
API	4,012	3,822
Total net revenues	140,022	120,368
Gross profit (loss):		
Finished pharmaceutical products	76,176	56,939
API	(2,336)	(1,113)
Total gross profit	73,840	55,826
Operating expenses	40,407	34,212
Income from operations	33,433	21,614
Non-operating income	136	7,419
Income before income taxes	$ 33,569	$ 29,033

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,	
	2023	2022
	(in thousands)	
Finished pharmaceutical products net revenues:		
Glucagon	$ 25,696	$ 10,984
Primatene MIST®	23,483	24,697
Epinephrine	20,091	15,156
Lidocaine	13,646	10,590
Enoxaparin	9,867	10,124
Phytonadione	7,713	10,475
Naloxone	4,957	7,413
Other finished pharmaceutical products	30,557	27,107
Total finished pharmaceutical products net revenues	$ 136,010	$ 116,546

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

	Three Months Ended March 31,	
	2023	2022
	(in thousands)	
Depreciation and amortization expense		
Finished pharmaceutical products	$ 2,446	$ 1,794
API	953	948
Total depreciation and amortization expense	$ 3,399	$ 2,742

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,
	2023	2022	2023	2022
	(in thousands)			
United States	$ 137,958	$ 117,114	$ 141,384	$ 136,328
China	127	933	89,171	88,647
France	1,937	2,321	39,431	39,598
Total	$ 140,022	$ 120,368	$ 269,986	$ 264,573

Note 6. Customer and Supplier Concentration

Customer Concentrations

Three large wholesale drug distributors, AmerisourceBergen Corporation, or AmerisourceBergen, Cardinal Health, Inc., or Cardinal, and McKesson Corporation, or McKesson, are all distributors of the Company's products, as well as suppliers of a broad range of health care products. The Company considers these three customers to be its major customers, as each individually, and these customers collectively, represented a significant percentage of the Company's net revenue for the three months ended March 31, 2023 and 2022 and accounts receivable as of March 31, 2023 and December 31, 2022, 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, 2023	December 31, 2022	2023	2022
AmerisourceBergen	16 %	16 %	24 %	22 %
McKesson	31 %	32 %	23 %	18 %
Cardinal Health	21 %	19 %	16 %	16 %

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

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and market its products, it could have a materially adverse effect on the Company's business, financial condition, and results of operations.

Note 7. Fair Value Measurements

GAAP defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the principal or most advantageous market for the asset or liability at the measurement date (an exit price). These standards also establish a hierarchy that prioritizes observable and unobservable inputs used in measuring fair value of an asset or liability, as described below:

- *Level 1* – Inputs to measure fair value are based on quoted prices (unadjusted) in active markets on identical assets or liabilities;
- *Level 2* – Inputs to measure fair value are based on the following: a) quoted prices in active markets on similar assets or liabilities, b) quoted prices for identical or similar instruments in inactive markets, or c) observable (other than quoted prices) or collaborated observable market data used in a pricing model from which the fair value is derived; and
- *Level 3* – Inputs to measure fair value are unobservable and the assets or liabilities have little, if any, market activity; these inputs reflect the Company's own assumptions about the assumptions that market participants would use in pricing the assets or liabilities based on best information available in the circumstances.

As of March 31, 2023, cash equivalents include money market accounts and corporate and municipal bonds with original maturities of less than three months. Investments consist of certificates of deposit as well as investment-grade corporate, agency and municipal bonds with original maturity dates between three and twelve months. The certificates of deposit are carried at amortized cost in the Company's condensed consolidated balance sheets, which approximates their fair value determined based on Level 2 inputs. The corporate, agency 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 an immaterial 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, 2023 and December 31, 2022, are as follows:

	Total	(Level 1)	(Level 2)	(Level 3)
		(in thousands)		
Cash equivalents	$ 123,064	$ 123,064	$ —	$ —
Restricted cash	235	235	—	—
Short-term investments	4,600	—	4,600	—
Restricted short-term investments	2,200	—	2,200	—
Corporate, agency and municipal bonds	11,603	—	11,603	—
Interest rate swaps related to variable rate loans	5,084	—	5,084	—
Fair value measurement as of March 31, 2023	$ 146,786	$ 123,299	$ 23,487	$ —
Cash equivalents	$ 130,199	$ 130,199	$ —	$ —
Restricted cash	235	235	—	—
Short-term investments	4,600	—	4,600	—
Restricted short-term investments	2,200	—	2,200	—
Corporate, agency and municipal bonds	14,931	—	14,931	—
Interest rate swaps related to variable rate loans	6,048	—	6,048	—
Fair value measurement as of December 31, 2022	$ 158,213	$ 130,434	$ 27,779	$ —

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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, 2023 and December 31, 2022, 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 8. Investments

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(in thousands)		
Corporate and agency bonds (due within 1 year)	$ 19,101	$ —	$ (29)	$ 19,072
Municipal bonds (due within 1 year)	878	—	—	878
Total investments as of March 31, 2023	$ 19,979	$ —	$ (29)	$ 19,950
Corporate and agency bonds (due within 1 year)	$ 21,612	$ —	$ (60)	$ 21,552
Municipal bonds (due within 1 year)	1,903	—	(2)	1,901
Total investments as of December 31, 2022	$ 23,515	$ —	$ (62)	$ 23,453

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, identifying 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, 2023 and 2022 was $0.8 million and $0.7 million, respectively, which was recorded in the "Equity in losses of unconsolidated affiliate" line on the condensed consolidated statement of operations.

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Note 9. Goodwill and Intangible Assets

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

	Weighted-Average Life (Years)	Original Cost	Accumulated Amortization	Net Book Value
		(in thousands)		
Definite-lived intangible assets				
IMS (UK) international product rights	10	$ 8,655	$ 5,770	$ 2,885
Patents	12	486	366	120
Land-use rights	39	2,540	766	1,774
Subtotal	11	11,681	6,902	4,779
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill - Finished pharmaceutical products	*	3,175	—	3,175
Subtotal	*	32,400	—	32,400
As of March 31, 2023	*	$ 44,081	$ 6,902	$ 37,179

	Weighted-Average Life (Years)	Original Cost	Accumulated Amortization	Net Book Value
		(in thousands)		
Definite-lived intangible assets				
IMS (UK) international product rights	10	$ 8,462	$ 5,430	$ 3,032
Patents	12	486	362	124
Land-use rights	39	2,540	749	1,791
Subtotal	11	11,488	6,541	4,947
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill - Finished pharmaceutical products	*	3,126	—	3,126
Subtotal	*	32,351	—	32,351
As of December 31, 2022	*	$ 43,839	$ 6,541	$ 37,298

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

Goodwill

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

	March 31, 2023	December 31, 2022
	(in thousands)	
Beginning balance	$ 3,126	$ 3,313
Currency translation	49	(187)
Ending balance	$ 3,175	$ 3,126

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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, 2023.

The trademark was determined to have an indefinite life. In determining its indefinite life, the Company considered the following: the expected use of the intangible; the longevity of the brand; the legal, regulatory and contractual provisions that affect their maximum useful life; the Company's ability to renew or extend the asset's legal or contractual life without substantial costs; effects of the regulatory environment; expected changes in distribution channels; maintenance expenditures required to obtain the expected future cash flows from the asset; and considerations for obsolescence, demand, competition and other economic factors.

Note 10. Inventories

Inventories consist of the following:

	March 31, 2023	December 31, 2022
	(in thousands)	
Raw materials and supplies	$ 47,919	$ 47,607
Work in process	30,873	37,090
Finished goods	24,855	18,887
Total inventories	$ 103,647	$ 103,584

Charges of $1.9 million and $8.0 million were included in the cost of revenues in the Company's condensed consolidated statements of operations for the three months ended March 31, 2023 and 2022, 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 as of March 31, 2023 and December 31, 2022 were $1.3 million and $2.7 million, respectively, which are recorded in cost of revenues in the Company's condensed consolidated statement of operations.

Note 11. Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

	March 31, 2023	December 31, 2022
	(in thousands)	
Buildings	$ 131,193	$ 130,726
Leasehold improvements	31,535	31,535
Land	7,469	7,451
Machinery and equipment	216,742	208,068
Furniture, fixtures, and automobiles	30,273	29,674
Construction in progress	52,851	50,842
Total property, plant, and equipment	470,063	458,296
Less accumulated depreciation	(226,584)	(220,030)
Total property, plant, and equipment, net	$ 243,479	$ 238,266

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Note 12. Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consisted of the following:

	March 31, 2023	December 31, 2022
	(in thousands)	
Accrued customer fees and rebates	$ 17,030	$ 14,198
Accrued payroll and related benefits	23,940	22,847
Accrued product returns, current portion	14,148	14,867
Accrued loss on firm purchase commitments	3,075	2,686
Other accrued liabilities	8,714	9,143
Total accrued liabilities	66,907	63,741
Accounts payable	21,979	20,501
Total accounts payable and accrued liabilities	$ 88,886	$ 84,242

Note 13. Debt

Debt consists of the following:

	March 31, 2023	December 31, 2022
	(in thousands)	
Term Loan		
Term loan with Capital One N.A. due August 2026	$ 67,375	$ 68,250
Mortgage Loans		
Mortgage payable with East West Bank due June 2027	8,146	8,188
Other Loans and Payment Obligations		
French government loans due December 2026	210	204
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	—	—
Equipment under Finance Leases	739	790
Total debt	76,470	77,432
Less current portion of long-term debt	2,168	3,046
Less: Loan issuance costs	1,430	1,547
Long-term debt, net of current portion and unamortized debt issuance costs	$ 72,872	$ 72,839

Interest Rate Swap Contracts

As of March 31, 2023, 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

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variable interest rates for fixed interest rates. The interest rate swap contracts are recorded at fair value in the other assets line in the condensed consolidated balance sheets. Changes in the fair values of interest rate swaps were $1.0 million loss and $3.0 million gain for the three months ended March 31, 2023 and 2022, respectively.

Covenants

At March 31, 2023 and December 31, 2022, the Company was in compliance with all of its debt covenants.

Note 14. Income Taxes

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

	Three Months Ended March 31,	
	2023	2022
	(in thousands)	
Income before taxes	$ 33,569	$ 29,033
Income tax provision	6,752	4,077
Income before equity in losses of unconsolidated affiliate	$ 26,817	$ 24,956
Income tax provision as a percentage of income before income taxes	20.1 %	14.0 %

The change in the Company's effective tax rate for the three months ended March 31, 2023 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.

The Company records a valuation allowance on net deferred income tax assets in states where it files separately and will continue to do so until sufficient taxable income is generated to realize these state deferred income tax assets.

Note 15. Stockholders' Equity

Share Buyback Program

Pursuant to the Company's existing share buyback program, the Company purchased 263,131 and 51,168 shares of its common stock during the three months ended March 31, 2023 and 2022, totaling $8.0 million and $1.2 million, respectively.

In November 2022, the Company's Board of Directors authorized a $50.0 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 a total of $235.0 million in the share buyback program. The primary goal of the program is to offset dilution created by the Company's equity compensation programs.

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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, 2023, the Company reserved an aggregate of 6,833,188 shares of common stock for future issuance under the Amended and Restated 2015 Equity Incentive Plan, or the 2015 Plan, including 1,202,802 shares, which were reserved in January 2023 pursuant to the evergreen provision in the 2015 Plan.

2014 Employee Stock Purchase Plan

As of March 31, 2023, the Company has issued 1,089,545 shares of common stock under the ESPP and 910,455 shares of its common stock remain available for issuance under the ESPP.

For the three months ended March 31, 2023 and 2022, the Company recorded ESPP expense of $0.3 million and $0.2 million, respectively.

Share-Based Award Activity and Balances

The Company accounts for share-based compensation payments in accordance with ASC 718, which requires measurement and recognition of compensation expense at fair value for all share-based payment awards made to employees and directors. Under these standards, the fair value of option awards and the option components of the 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, 2023 and 2022, are as follows:

	Three Months Ended March 31,	
	2023	2022
Average volatility	41.5 %	41.1 %
Average risk-free interest rate	4.2 %	2.2 %
Weighted-average expected life in years	6.3	6.3
Dividend yield rate	— %	— %

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A summary of option activity under all plans for the three months ended March 31, 2023, 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, 2022	7,929,150	$ 17.66		
Options granted	700,601	35.13		
Options exercised	(102,024)	13.61		
Options forfeited	(1,601)	31.21		
Options expired	—	—		
Outstanding as of March 31, 2023	8,526,126	$ 19.15	5.15	156,491
Exercisable as of March 31, 2023	6,376,523	$ 16.25	3.94	135,510
Vested and expected to vest as of March 31, 2023	8,270,035	$ 18.83	5.03	154,400

(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 stock for those awards that have an exercise price below the estimated fair value at March 31, 2023.

For the three months ended March 31, 2023 and 2022, the Company recorded expense of $3.0 million and $2.5 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,	
	2023	2022
	(in thousands, except per share data)	
Weighted-average grant date fair value per option share	$ 16.67	$ 15.06
Intrinsic value of options exercised	2,341	12,200
Cash received from options exercised	1,388	12,450
Total fair value of the options vested during the period	7,584	6,987

A summary of the status of the Company's non-vested options as of March 31, 2023, and changes during the three months ended March 31, 2023, are presented below:

	Options	Weighted-Average Grant Date Fair Value
Non-vested as of December 31, 2022	2,378,453	$ 9.48
Options granted	700,601	16.67
Options vested	(927,850)	8.17
Options forfeited	(1,601)	13.96
Non-vested as of March 31, 2023	2,149,603	12.39

As of March 31, 2023, there was $21.4 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

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RSU awarded. The RSUs may not be sold or otherwise transferred until vested. 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. For the three months ended March 31, 2023 and 2022, the Company recorded expenses of $2.9 million and $2.4 million, respectively, related to RSU awards granted under all plans.

As of March 31, 2023, there was $22.6 million of total unrecognized compensation cost, net of forfeitures, related to non-vested RSU based compensation arrangements granted under all plans. The cost is expected to be recognized over a weighted-average period of 3.1 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, 2022	1,007,052	
RSUs granted	332,247	$ 11,672
RSUs forfeited	(705)	
RSUs vested[2]	(389,250)	
RSUs outstanding at March 31, 2023	949,344	

(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, 160,974 shares of common stock were surrendered to fulfil tax withholding obligations.

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,	
	2023	2022
	(in thousands)	
Cost of revenues	$ 1,706	$ 1,385
Operating expenses:		
Selling, distribution, and marketing	209	168
General and administrative	3,357	2,861
Research and development	839	608
Total share-based compensation	$ 6,111	$ 5,022

Note 16. Employee Benefits

401(k) Plan

The Company has a defined contribution 401(k) plan, or the Plan, whereby eligible employees voluntarily contribute up to a defined percentage of their annual compensation. The Company matches contributions at a rate of 50% on the first 6% of employee contributions, and pays the administrative costs of the Plan. Total employer contributions for the three months ended March 31, 2023 and 2022, were approximately $0.6 million.

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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 3.75% as of March 31, 2023 and December 31, 2022. 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 $2.3 million and $2.2 million at March 31, 2023 and December 31, 2022. The Company recorded an immaterial amount of expense under the plan for each of the three months ended March 31, 2023 and 2022.

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 $4.9 million and $4.5 million as of March 31, 2023 and December 31, 2022, respectively. The plan liabilities were valued at approximately $5.0 million and $4.6 million as of March 31, 2023 and December 31, 2022, 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 17. Commitments and Contingencies

Purchase Commitments

As of March 31, 2023, the Company has entered into commitments to purchase equipment and raw materials for an aggregate amount of approximately $60.1 million.

Note 18. Related Party Transactions

Investment in Hanxin

The Company has a 14% ownership in Hanxin that is accounted for as an equity method investment. The Company maintains a seat on Hanxin's board of directors, and Henry Zhang, the son of Dr. Jack Zhang is an equity holder, the general manager, and the chairman of the board of directors of Hanxin. Additionally, Dr. Mary Luo and Dr. Jack Zhang, have an ownership interest in Hanxin through an affiliated entity. As a result, Hanxin is a related party.

Contract manufacturing agreement with Hanxin

In April 2022, ANP, entered into a contract manufacturing agreement with Hanxin, whereby Hanxin will develop several active pharmaceutical ingredients and finished products for the Chinese market and will engage ANP to manufacture the

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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.

During the three months ended March 31, 2023, the Company recognized an immaterial amount of revenue from manufacturing services provided to Hanxin. As of March 31, 2023, the Company had an immaterial amount of receivables from Hanxin.

Contract Research Agreement with Hanxin

In July 2022, the Company entered into a three-year contract research agreement with Hanxin, a related party, whereby Hanxin will develop Recombinant Human Insulin Research Cell Banks, or RCBs, for the Company and license the RCBs to the Company subject to a fully paid, exclusive, perpetual, transferable, sub-licensable worldwide license. The RCBs will be used by the Company to make Master Cell Banks for one of its product candidates. Per the terms of the agreement with Hanxin, all title to the RCBs developed, prepared and produced by Hanxin in conducting research and development will belong to the Company. The Company will also own any confidential and proprietary information, technology regarding development and manufacturing of the RCBs, which shall include engineering, scientific and practical information and formula, research data, design, and procedures and others to develop and manufacture the RCBs, in use or developed by Hanxin. The total cost of the agreement to the Company shall not exceed approximately $2.2 million, with payments adjusted based on the then current exchange rates. Any additional work or changes to the scope of work requested by the Company will be charged by Hanxin to the Company on a cost-plus basis, plus any applicable taxes.

In March 2023, the Company amended the agreement with Hanxin, whereby Hanxin will perform scale-up manufacturing process development using the RCBs for the Company. Per the terms of the amended agreement the Company will own any confidential and proprietary information and technology produced during the scale-up manufacturing, which shall include engineering, scientific and practical information and formula, research data design and procedures and others to develop and manufacture the RCBs. The amendment agreement will remain in full force and effect until July 5, 2025. The total cost of the amended agreement to the Company shall not exceed approximately $0.5 million in additional payments beyond the $2.2 million in payments under the contract research agreement, with payments adjusted based on actual currency exchange rates. Any additional work or changes to the scope of work requested by the Company will be charged by Hanxin to the Company on a cost-plus basis, plus any applicable taxes.

During the three months ended March 31, 2023, the Company paid $0.6 million under this amended agreement and has accrued an additional $0.2 million payable to Hanxin as of March 31, 2023.

Supply Agreement with Letop

In November 2022, ANP, entered in to a supply agreement with Nanjing Letop Biotechnology Co., Ltd., or Letop, a subsidiary of Hanxin, whereby Letop will manufacture and deliver chemical intermediates for ANP on a cost-plus basis. The agreement is effective for three years and the total cost of the agreement shall not exceed approximately $1.5 million, with payments adjusted based on the then current exchange rates.

During the three months ended Mar 31, 2023, ANP paid $0.7 million under this agreement. As of March 31, 2023, the Company did not have any amounts payable to Letop.

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Note 19. Litigation

Hatch-Waxman Litigation

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 January 26, 2022, the Company and Astellas-Gilead reached an agreement to resolve the lawsuit. Under the terms of the agreement, the Company received $5.4 million from Astellas constituting saved litigation expenses. The Company recorded the settlement amount in the other income (expenses) line 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 Events

BAQSIMI® Acquisition

On April 20, 2023, the Company entered into an Asset Purchase Agreement, or the Purchase Agreement, with Eli Lilly & Company, or Lilly, and Amphastar Medication Co., LLC, or Amphastar Medication, a wholly-owned subsidiary of the Company, to acquire Lilly's BAQSIMI® glucagon nasal powder, or BAQSIMI®, and certain related assets and assume certain liabilities, or the Acquisition, for a purchase price of $500.0 million in cash payable at the consummation of the transactions contemplated by the Purchase Agreement, or Closing. In addition, the Company will pay Lilly a $125.0 million guaranteed payment on the first anniversary after the Closing. The Company may also be required to pay additional contingent consideration of up to $450.0 million to Lilly based on the achievement of certain milestones. The Company has agreed to guarantee all obligations of Amphastar Medication under the Purchase Agreement. In addition, the Assumed Liabilities will include an assumption of certain earnout obligations of Lilly, which would require the Company to pay up to an aggregate of $125.0 million based on the achievement of annual net sales milestones of $350.0 million, $400.0 million and $600.0 million.

The Purchase Agreement contains certain customary termination rights, including a right to terminate the Purchase Agreement if the Acquisition is not consummated by October 21, 2023. If the Purchase Agreement is terminated under certain circumstances involving a failure to obtain certain regulatory approvals for the Acquisition, the Company will be obligated to pay Lilly a termination fee equal to $5.0 million in cash.

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The Board of Directors of the Company has approved the Purchase Agreement and the transactions contemplated thereby. During the three months ended March 31, 2023, the Company incurred $1.3 million in cost associated with the acquisition.

In connection with the Purchase Agreement, the Company has entered into a debt commitment letter effective April 21, 2023, or the Commitment Letter, with certain lenders have committed to provide a senior secured term loan facility in an aggregate principal amount of $500.0 million and a senior secured revolving credit facility in an aggregate principal amount of $150.0 million, or collectively, the Debt Financing. The Debt Financing is available (i) to finance the transaction contemplated by the Acquisition, (ii) to refinance certain of the Company's existing third-party indebtedness, and (iii) to pay fees and expenses incurred in connection therewith. The funding of the Debt Financing provided for in the Commitment Letter is contingent on the satisfaction of customary conditions, including, among other things, (i) the execution and delivery of definitive documentation in accordance with the terms sets forth in the Commitment Letter and (ii) the consummation of the Acquisition in accordance with the terms of the Purchase Agreement. The definitive documentation governing the Debt Financing has not been finalized, and, accordingly, the actual terms may differ from the description of such terms in the Commitment Letter.

The Purchase Agreement provides that the contingent consideration that may become payable to Lilly would be achieved as follows: (i) a one-time payment of $100.0 million if the Company achieves annual net sales of $175.0 million or more of BAQSIMI® and certain related products, or the Milestone Products, in any one year during the first five years after the Closing; (ii) up to two payments of $100 million each if the Company achieves annual net sales of $200.0 million or more of Milestone Products in any one year during the first five years after the Closing; and (iii) a one-time payment of $150.0 million if the Company achieves total cumulative net sales of $950.0 million or more of the Milestone Products for the first five years after the Closing.

The Closing is subject to customary conditions, including, among other things, the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and other closing conditions, such as the accuracy of representations and warranties (subject to certain materiality qualifiers), material performance of covenants and no occurrence of a material adverse effect. The Purchase Agreement contains indemnification rights for each of the Company and Lilly for breaches of representations, warranties, and covenants, as well as certain other matters, subject to customary deductibles, caps and other limitations.

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, 2022, particularly in Item 1A. "Risk Factors".

Overview

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

Our largest products by net revenues currently include Primatene MIST®, glucagon, epinephrine, lidocaine, enoxaparin sodium, and phytonadione. In April 2022, the FDA approved our ganirelix acetate injection 250mg/0.5mL prefilled syringe, which we launched in June 2022. In July 2022, the FDA approved our vasopressin injection, USP 20 Units/mL, 1 mL single-dose vial, which we launched in August 2022. In May 2022, the FDA approved our regadenoson injection, 0.08mg/mL, 5mL, single-dose prefilled syringe, which we launched in April 2023.

In March 2023, the FDA approved our naloxone hydrochloride nasal spray 4mg, which we plan to launch in the third quarter of 2023.

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. Three of the ANDAs are currently on file with the FDA.

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.

Macroeconomic Trends and Uncertainties

The Russia-Ukraine conflict and resulting sanctions and other actions against Russia have led to uncertainty and disruption in the global economy. Although the conflict has not had a direct material adverse impact on our revenues or other financial results, one of our insulin API customers in Western Europe, that previously bought our product and resold it into Russia, did not purchase API from us in 2022 and 2023. We are closely monitoring the events of the Russia-Ukraine conflict and its impact on Europe and throughout the rest of the world. It is not clear at this time how long the conflict will endure, or if it will escalate further, which could further compound the adverse impact to the global economy and consequently affect our results of operations.

Certain other worldwide events and macroeconomic factors, such as international trade relations, new legislation and regulations, taxation or monetary policy changes, political and civil unrest, supply chain disruptions, inflationary pressures, and rising interest rates, among other factors, also increase volatility in the global economy. For example, the United States has recently experienced historically high levels of inflation. The existence of inflation in the United States, and global economy has and may continue to result in higher interest rates and capital costs, increased costs of labor, weakening exchange rates and other similar effects.

See the "Risk Factors" section for further discussion of the possible impact of the Russia-Ukraine conflict and other macroeconomic factors on our business.

COVID-19 Pandemic

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 governments imposed travel restrictions. Some clinical trials experienced increased expenses due to new protocols to protect participants from COVID-19. Additionally participants are now more apprehensive to participate in trials as they believe it will increase exposure to COVID-19, particularly specific populations such as the elderly or those with breathing conditions that could worsen if exposed to COVID-19.

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.

We cannot anticipate all of the ways in which health epidemics such as COVID-19 could adversely impact our business. See Item 1A, "Risk Factors" for further discussion of the possible impact of the COVID-19 pandemic on our business.

Business Segments

As of March 31, 2023, 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 – Note 5. Segment Reporting."

Recent Developments

BAQSIMI® Acquisition

On April 20, 2023, we entered into an Asset Purchase Agreement, or the Purchase Agreement, under which we and our wholly-owned subsidiary agreed to acquire Eli Lilly & Company's, or Lilly's, BAQSIMI® glucagon nasal powder, or BAQSIMI®, and related assets, and assume certain liabilities for a purchase price of $500.0 million in cash, or the Acquisition, payable at the consummation of the transactions contemplated by the Purchase Agreement, or Closing. In addition, the Company will pay Lilly a $125.0 million guaranteed payment on the first anniversary after the Closing. We may also be required to pay additional contingent consideration of up to $450.0 million to Lilly based on the achievement of certain milestones. The Board of Directors has approved the Purchase Agreement and the transactions contemplated thereby.

In connection with the Purchase Agreement, we entered into a debt commitment letter, effective April 21, 2023, or the Commitment Letter, with certain lenders who have committed to provide a senior secured term loan facility in an aggregate principal amount of $500.0 million and a senior secured revolving credit facility in an aggregate principal amount of $150.0 million, or, collectively, the Debt Financing. The Debt Financing is available (i) to finance the transactions contemplated by the Purchase Agreement, or the Acquisition, (ii) to refinance certain of the Company's existing third-party indebtedness, and (iii) to pay fees and expenses incurred in connection therewith.

For more information regarding our acquisition of BAQSIMI®, see "Part I – Item 1. Financial Statements – Notes to Condensed Consolidated Financial Statements – Note 20. Subsequent Events."

Results of Operations

Three Months Ended March 31, 2023 Compared to Three Months Ended March 31, 2022

Net revenues

	Three Months Ended March 31,		Change	
	2023	2022	Dollars	%
	(in thousands)			
Net revenues				
Finished pharmaceutical products	$ 136,010	$ 116,546	$ 19,464	17 %
API	4,012	3,822	190	5 %
Total net revenues	$ 140,022	$ 120,368	$ 19,654	16 %
Cost of revenues				
Finished pharmaceutical products	$ 59,834	$ 59,607	$ 227	0 %
API	6,348	4,935	1,413	29 %
Total cost of revenues	$ 66,182	$ 64,542	$ 1,640	3 %
Gross profit	$ 73,840	$ 55,826	$ 18,014	32 %
as % of net revenues	*53 %*	*46 %*		

The increase in net revenues of the finished pharmaceutical products for the three months ended March 31, 2023, was due to the following changes:

	Three Months Ended March 31,		Change	
	2023	2022	Dollars	%
	(in thousands)			
Finished pharmaceutical products net revenues				
Glucagon	$ 25,696	$ 10,984	$ 14,712	134 %
Primatene MIST®	23,483	24,697	(1,214)	(5)%
Epinephrine	20,091	15,156	4,935	33 %
Lidocaine	13,646	10,590	3,056	29 %
Enoxaparin	9,867	10,124	(257)	(3)%
Phytonadione	7,713	10,475	(2,762)	(26)%
Naloxone	4,957	7,413	(2,456)	(33)%
Other finished pharmaceutical products	30,557	27,107	3,450	13 %
Total finished pharmaceutical products net revenues	$ 136,010	$ 116,546	$ 19,464	17 %

The increase is sales of glucagon was primarily due to an increase in unit volumes. Primatene MIST® sales decreased $3.6 million due to reduced unit volume, which was partially offset by an increase in average selling price contributing $2.4 million. The increase in sales of epinephrine was primarily due to an increase in unit volumes, due to an increase in demand caused by shortages at other suppliers. The increase in sales of lidocaine was primarily due to an increase in unit volumes. The decrease in sales of phytonadione was due to lower unit volumes, as a new supplier commenced sales. The decrease in sales of naloxone was primarily due to a decrease in average selling price. The increase in other finished pharmaceutical products was primarily due to higher unit volumes of dextrose, due to increased demand caused by shortages at other suppliers, as well as the launch of ganirelix and vasopressin in June 2022 and August 2022, respectively.

We anticipate that sales of naloxone and enoxaparin will continue to fluctuate in the future due to competitive dynamics. We also anticipate that sales of epinephrine and other finished pharmaceutical products will continue to fluctuate depending on the ability of our competitors to supply market demands.

Sales of API primarily depend on the timing of customer purchases.

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, as of March 31, 2023, we experienced a backlog of approximately $4.9 million for various products, partially as a result of competitor shortages and supplier constraints. We are currently working on resolving backlog related issues and have reduced the overall backlog by $2.1 million in the first quarter of 2023. We believe that we will be able to further 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 glucagon and epinephrine, which are higher-margin products, as well as the sales of ganirelix and vasopressin, both of which we launched last year, helped increase our gross margins for the three months ended March 31, 2023. These increases in gross margins were partially offset by an overall increase in labor, material and overhead costs.

We are experiencing increased costs for labor and certain purchased components. Additionally, the cost of heparin may fluctuate, which could put 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, vasopressin, ganirelix and new products we anticipate launching in 2023.

Selling, distribution and marketing, and general and administrative

	Three Months Ended March 31,		Change	
	2023	2022	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	$ 7,109	$ 5,519	$ 1,590	29 %
General and administrative	$ 13,483	$ 12,470	$ 1,013	8 %

The increase in selling, distribution and marketing expenses was primarily due to an increase in advertising spending for Primatene MIST®. The increase in general and administrative expense was primarily due to an increase in legal expenses related to the planned purchase of BAQSIMI®, as well as salary and personnel-related expenses.

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	
	2023	2022	Dollars	%
	(in thousands)			
Salaries and personnel-related expenses	$ 7,728	$ 6,484	$ 1,244	19 %
Clinical trials	1,274	105	1,169	1,113 %
FDA fees	25	29	(4)	(14)%
Materials and supplies	6,157	5,401	756	14 %
Depreciation	2,442	2,626	(184)	(7)%
Other expenses	2,189	1,578	611	39 %
Total research and development expenses	$ 19,815	$ 16,223	$ 3,592	22 %

The increase in research and development expenses is primarily due to an increase in salary and personnel-related expenses, as well as, an increase in clinical trial expense as we continue to work on external studies related to our insulin and inhalation product pipeline. Additionally, materials and supply expense increased as a result of an increase in expenditures on raw materials and components for our insulin products.

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 insulin 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 trial sites changed their operating protocols to protect participants from COVID-19. Additionally participants are now more apprehensive to participate in trials as they believe it will increase exposure to COVID-19. This is particularly difficult for specific populations such as elderly or those with breathing conditions. These conditions may continue to increase the costs of clinical trials and also delay spending and results of these trials.

Other income (expense), net

	Three Months Ended March 31,		Change	
	2023	2022	Dollars	%
	(in thousands)			
Other income (expenses), net	$ (390)	$ 7,593	$ (7,983)	NM

In January 2022, we received a settlement of $5.4 million in connection with the Regadenoson patent litigation. For more information regarding our litigation matters, see “Part I – Item 1. Financial Statements – Notes to Condensed Consolidated Financial Statements – Note 19. Litigation”.

Income tax provision

	Three Months Ended March 31,		Change	
	2023	2022	Dollars	%
	(in thousands)			
Income tax provision	$ 6,752	$ 4,077	$ 2,675	66 %
Effective tax rate	*20 %*	*14 %*		

Our effective tax rate for the three months ended March 31, 2023 increased in comparison to the three months ended March 31, 2022, primarily due to differences in pre-tax income positions and timing of discrete tax items. For more information regarding our income taxes, see "Part I – Item 1. Financial Statements – Notes to Condensed Consolidated Financial Statements – Note 14. Income Taxes".

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 over the next few years. 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, 2023, our foreign subsidiaries collectively held $15.2 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 $18.5 million to $302.0 million at March 31, 2023, compared to $283.5 million at December 31, 2022.

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, 2023 and 2022:

	Three Months Ended March 31,	
	2023	2022
	(in thousands)	
Statement of Cash Flow Data:		
Net cash provided by (used in)		
Operating activities	$ 40,382	$ 50,765
Investing activities	(6,333)	(9,110)
Financing activities	(13,548)	4,648
Effect of exchange rate changes on cash	16	(29)
Net increase in cash, cash equivalents, and restricted cash	$ 20,517	$ 46,274

Sources and Use of Cash

Operating Activities

Net cash provided by operating activities was $40.4 million for the three months ended March 31, 2023, which included net income of $26.0 million. Non-cash items comprised primarily of $7.4 million of depreciation and amortization and $6.1 million of share-based compensation expense.

Additionally, for the three months ended March 31, 2023, there was a net cash outflow from changes in operating assets and liabilities of $0.1 million, which resulted from an increase in accounts receivables, which was partially offset by an increase in accounts payable and accrued liabilities. Accounts payable and accrued liabilities increased primarily due to the timing of payments. The increase in accounts receivables was due to both increases in sales and timing of sales.

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.

Investing Activities

Net cash used in investing activities was $6.3 million for the three months ended March 31, 2023, primarily as a result of $9.5 million in purchases of property, plant, and equipment, which included $6.6 million incurred in the United States, $0.1 million in France, and $2.8 million in China. This was partially offset by a net cash inflows from purchases and sales of short-term investments during the period of $3.5 million.

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.

Financing Activities

Net cash used in financing activities was $13.5 million for the three months ended March 31, 2023, primarily as a result of purchases of $8.0 million of treasury stock and $4.5 million used to settle share-based compensation awards under our equity plan. Additionally, we also made $1.0 million in principal payments on our long-term debt.

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.

Indebtedness

For more information regarding our outstanding indebtedness, see “Part I – Item 1. Financial Statements – Notes to Condensed Consolidated Financial Statements – Note 13. 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 condensed consolidated financial statements and 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, 2022. 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, 2022.

Recent Accounting Pronouncements

For information regarding recent accounting pronouncements, see "Part I – Item 1. Financial Statements – Notes to Condensed Consolidated Financial Statements – Note 2. Summary of Significant Accounting Policies".

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.

From February 6 through February 16, 2023, our IMS facility in South El Monte, California was subject to pre-approval inspection by the FDA. The inspection included a review of compliance with FDA regulations to support one of our pending applications. The inspection resulted in two observations on Form 483. We responded to those observations. We believe that our response to the observations will satisfy the requirements of the FDA and that no significant further actions will be necessary.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Except for the broad, ongoing macroeconomic challenges facing 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, 2022. 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 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, 2023, 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 – Note 19. 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, 2022, filed with the Securities and Exchange Commission on March 1, 2023.

Failure to complete the Acquisition in a timely manner, or at all, could negatively impact our stock price and our future business and financial results.

If the Acquisition is not completed, our ongoing business may be adversely affected and we will be subject to a number of risks, including:

- we may be required to pay a termination fee of up to $5.0 million if the Purchase Agreement is terminated under certain circumstances;
- we will be required to pay certain costs relating to the Acquisition, whether or not the Acquisition is completed; and
- matters relating to the Acquisition (including integration planning) may require substantial commitments of time and resources by our management, which could otherwise have been devoted to other opportunities that may have been beneficial to us.

The Acquisition is also subject to a number of other conditions beyond our control that may prevent, delay or otherwise materially adversely affect the completion of the Acquisition, including litigation related to any failure to complete the Acquisition or related to any enforcement proceeding commenced against us to perform our obligations under any of the agreements related to the Acquisition. We cannot predict with certainty whether or when these other conditions will be satisfied. Any delay in completing the Acquisition could cause us not to realize, or delay the realization of, some or all of the benefits expected from the Acquisition.

If the Acquisition is completed, our actual financial and operating results could differ materially from any expectations or guidance provided by us concerning future results with respect to the acquisition.

Although we currently expect to realize increased revenues as a result of our proposed Acquisition, the expectations and guidance we have provided with respect to the potential financial impact of the Acquisition are subject to numerous assumptions including assumptions derived from our diligence efforts concerning the status of and prospects for BAQSIMI® business, which we do not currently control, and assumptions relating to the near-term prospects for glucagon products generally and the markets for BAQSIMI® in particular. Additional assumptions we have made relate to numerous matters, including (without limitation) the following:

- projections of BAQSIMI®'s future revenues;
- the amount of goodwill and intangibles that will result from the Acquisition;
- certain other purchase accounting adjustments that we expect to record in our financial statements in connection with the Acquisition;
- Acquisition costs, including transaction costs payable to our financial, legal, and accounting advisors;
- our ability to maintain, develop, and deepen relationships with BAQSIMI® customers and suppliers; and

- other financial and strategic risks of the Acquisition, including the possible impact of our reduced liquidity resulting from deal-related cash outlays, the credit risk associated from the potential debt facility described below, and continued uncertainty arising from the global economic downturn.

We cannot provide any assurances with respect to the accuracy of our assumptions, including our assumptions with respect to future revenues or revenue growth rates, if any, of BAQSIMI®, and we cannot provide assurances with respect to our ability to realize the cost savings that we currently anticipate. There are a variety of risks and uncertainties, some of which are outside of our control, which could cause our actual financial and operating results to differ materially from any expectations or guidance provided by us, concerning our future results with respect to the Acquisition.

We may fail to realize the projected revenue and other benefits expected from the Acquisition, which could adversely affect the value of our common stock.

Our ability to realize the projected revenue and other benefits from the Acquisition will depend, in part, on our ability to integrate BAQSIMI® into our current business. If we are not able to achieve the projected revenue or other benefits within the anticipated time frame, or at all, or if the projected revenue or other benefits take longer to realize than expected, then the value of our common stock may be adversely affected.

We and the business associated with BAQSIMI® will continue to operate independently until the completion of the Acquisition. It is possible that the integration process following the Acquisition could result in the disruption of our business or ongoing business associated with BAQSIMI®. We may also identify inconsistencies in standards, controls, procedures and policies between the two businesses that could adversely affect our ability to maintain relationships with our customers, suppliers, distributors, creditors, lessors, clinical trial investigators or managers or to achieve the anticipated benefits BAQSIMI®.

Specifically, in order to realize the anticipated benefits of the Acquisition, we will:

- rely on Lilly for manufacturing services and transition services, including for performance of clinical and commercial activities, relating to BAQSIMI® and transfer of the corresponding activities to Amphastar;
- be required to enter into our own arrangements with certain suppliers/manufacturers in the supply chain;
- be required to set up distribution and sales arrangements for BAQSIMI® including payor and other agreements; and
- transfer regulatory approvals relating to BAQSIMI® to us following the Closing of the Acquisition.

Integration efforts between us and the business associated with BAQSIMI® will also divert management attention and resources. In addition, the actual integration of BAQSIMI® may result in additional and unforeseen expenses or liabilities (including those that may be assumed in connection with the Acquisition), and any anticipated benefits of the integration plan may not be realized. If we are not able to adequately address these challenges, we may be unable to successfully integrate BAQSIMI® into our business, or to realize some or any of the anticipated benefits of the Acquisition.

Delays encountered in the integration process could have a material adverse effect on our revenues, expenses, operating results and financial condition. Although we expect significant benefits, such as increased sales revenues, from the Acquisition, there can be no assurance that we will realize these or any other anticipated benefits.

In order to consummate the Acquisition, we will incur material indebtedness of up to $650.0 million and we may also use a portion of our cash resources which will materially increase our indebtedness and will adversely affect our operating results and cash flows.

We will finance the Acquisition in part with the Debt Financing, which will provide funding of up to $650.0 million. A portion of the proceeds from the Debt Financing will be used to repay certain existing debt of the Company in full. The material increase in our indebtedness as a result of the Debt Financing will adversely affect our operating results, cash-flows and our ability to use cash generated from operations as we satisfy our materially increased underlying interest and

principal payment obligations and our operating expenses under the term loan facility and revolving credit facility, as applicable.

Specifically, our materially increased indebtedness could have important consequences to investors in our common stock, including any or all of the following:

- we could be subject to substantial variable interest rate risk because our interest rate under term loans typically vary based on a fixed margin over an indexed rate or an adjusted base rate. If interest rates were to further increase substantially, particularly with respect to our anticipated debt associated with Acquisition, it would have a material adverse effect our operating results and could affect our ability to service the indebtedness;
- our ability to obtain any necessary financing in the future for working capital, capital expenditures, debt service requirements, or other purposes may be limited or financing may be unavailable;
- a substantial portion of our cash flows must be dedicated to the payment of principal and interest on our indebtedness and other obligations and will not be available for use in our business;
- our level of indebtedness could limit our flexibility in planning for, or reacting to, changes in our business and the markets in which we operate; and
- our high degree of indebtedness will make us more vulnerable to changes in general economic conditions and/or a downturn in our business, thereby making it more difficult for us to satisfy our obligations.

Our ability to make scheduled payments of the principal and interest when due, or to refinance our borrowings under the Debt Financing, will depend on our future performance, which is subject to economic, financial, competitive and other factors beyond our control.

Our business may not continue to generate cash flow from operations in the future sufficient to satisfy our obligations under our indebtedness, and any future indebtedness we may incur and to make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as reducing or delaying investments or capital expenditures, selling assets, refinancing or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our existing or future indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on the Debt Financing or future indebtedness.

If we fail to make required debt payments we would be in default under the terms of these agreements. Subject to customary cure rights, any default would permit the holders of the indebtedness to accelerate repayment of this debt and could cause defaults under other indebtedness that we have, any of which could have a material adverse effect on the trading price of our common stock.

Our outstanding loan agreements contain restrictive covenants that may limit our operating flexibility.

Our loan agreements are collateralized by substantially all of our presently existing and subsequently acquired personal property assets and subject us to certain affirmative and negative covenants, including limitations on our ability to transfer or dispose of assets, merge with or acquire other companies, make investments, pay dividends, incur additional indebtedness and liens and conduct transactions with affiliates. For example, the definitive documentation governing the Debt Financing is expected to contain financial and operational covenants that would adversely affect our operational freedom or ability to pursue strategic transactions that we would otherwise consider to be in the best interests of stockholders, including obtaining additional indebtedness to finance such transactions.

We are also subject to certain covenants that require us to maintain certain financial ratios and are required under certain conditions to make mandatory prepayments of outstanding principal. As a result of these covenants and ratios, we have certain limitations on the manner in which we can conduct our business, and we may be restricted from engaging in

favorable business activities or financing future operations or capital needs until our current debt obligations are paid in full or we obtain the consent of our lenders, which we may not be able to obtain. For example, the definitive documentation governing the Debt Financing will contain financial and operational covenants that may adversely affect our ability to engage in certain activities, including certain financing and acquisition transactions, stock repurchases, guarantees, and similar transactions, without obtaining the consent of the lenders, which may or may not be forthcoming. We expect such financial and operational covenants will include compliance with a total net leverage ratio test.

We may not be able to generate sufficient cash flow or revenue to meet the financial covenants or pay the principal and interest on our debt, and in the past we have not been in compliance with certain financial covenants. In addition, upon the occurrence of an event of default, our lenders, among other things, can declare all indebtedness due and payable immediately, which would adversely impact our liquidity and reduce the availability of our cash flows to fund working capital needs, capital expenditures and other general corporate purposes. An event of default includes our failure to pay any amount due and payable under the loan agreements, the occurrence of a material adverse change in our business as defined in the loan agreements, our breach of any covenant in the loan agreements, or an involuntary insolvency proceeding. Additionally, a lender could exercise its lien on substantially all of our assets and our future working capital, borrowings or equity financing may not be available to repay or refinance any such debt.

The Acquisition is subject to the receipt of certain required clearances or approvals from governmental entities that could delay the completion of the Acquisition or impose conditions that could have a material adverse effect on us.

Completion of the Acquisition is conditioned upon the receipt of certain governmental clearances or approvals, including, the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, or HSR Act. Although the parties to the Purchase Agreement have agreed to reasonable best efforts to obtain the requisite governmental approvals to complete the Acquisition, there can be no assurance that these clearances and approvals will be obtained. In addition, the governmental entities from which these clearances and approvals are required may impose conditions on the completion of the Acquisition or require changes to the terms of the Acquisition. If we become subject to any material conditions in order to obtain any clearances or approvals required to complete the Acquisition, the BAQSIMI® business and results of operations of the business may be adversely affected. We may be required to pay a termination fee of up to $5.0 million if the Purchase Agreement is terminated under certain circumstances.

Our business relationships, including customer relationships, and those of the business related to BAQSIMI® may be subject to disruption due to uncertainty associated with the Acquisition.

Suppliers, vendors, and other third parties with whom we or the business related to BAQSIMI®, do business or otherwise have relationships may experience uncertainty associated with the Acquisition, and this uncertainty could materially affect their decisions with respect to existing or future business relationships with us while the Acquisition is pending or with us after the Acquisition is consummated. As a result, we are currently unable to predict the effect of the Acquisition on certain assumed contractual rights and obligations, including intellectual property rights.

Contracts, agreements, licenses, permits, authorizations and other arrangements related to the BAQSIMI® business that contain provisions giving counterparties certain rights (including, in some cases, termination rights) in the event of an "assignment" of such agreement or a "change in control" of Lilly or its subsidiaries. The definitions of "assignment" and "change in control" vary from contract to contract and, in some cases, the "assignment" or "change in control" provisions may be implicated by the Acquisition. If an "assignment" or "change in control" occurs, a counterparty may be permitted to terminate its contract with respect to BAQSIMI®.

We cannot predict the effects, if any, if the Acquisition is deemed to constitute an assignment or change in control under certain of the contracts and other arrangements related to BAQSIMI®, including the extent to which cancellation rights or other rights would be exercised, if at all, or the effect on our financial condition, results of operations or cash flows.

Our business may be adversely affected by the ongoing COVID-19 pandemic and the related challenging macroeconomic conditions globally.

The ongoing COVID-19 pandemic has continued to impact worldwide economic activity and financial markets, and remains a potential 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 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 ongoing COVID-19 pandemic has and could continue to adversely affect economies and financial markets globally and nationally, including inflationary pressures and changes in interest rates, which have and could continue to decrease spending and adversely affect demand for our products and harm our business and results of operations. To the extent macroeconomic uncertainty persists or the COVID-19 pandemic or macroeconomic conditions worsen, we may experience a continuing adverse effect on the demand for some of our products. The degree of impact of the COVID-19 pandemic and the related challenging macroeconomic conditions globally 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 and the challenging macroeconomic conditions globally, 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, have and may continue to 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 prioritized their resources toward the COVID-19 pandemic and governments imposed 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 2022. These delays may have been caused by manufacturing disruptions due to the COVID-19 pandemic. For example, in the first quarter of 2022, increases in COVID-19 cases in Shanghai, China, led to shutdowns and delays at the ports in Shanghai, which led to temporary delays in shipping certain APIs and starting materials. Future shutdowns could have an adverse impact on our operations.

Any of the negative impacts of the ongoing COVID-19 pandemic and the related challenging macroeconomic conditions, including, among others, those described above, alone or in combination with others, may have a material adverse effect on our business and operations, results of operations, financial condition, and cash flows. It is not possible at this time to estimate the complete impact that the COVID-19 pandemic and the related challenging economic conditions could have on our business, as the impact will depend on future developments, which are highly uncertain and cannot be predicted.

Macroeconomic conditions may continue to worsen leading to changes in monetary policy and other responses from governmental bodies, 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 enacted or extended for longer periods of time, each of which alone or in combination with others, 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 and the related challenging macroeconomic conditions 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, including China's policies with respect to COVID-19;
- the imposition of additional tariffs, export controls 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 U.S. and foreign export controls such as U.S. controls preventing the export of a wide-range of items to Russia, new controls impacting the ability to send certain products and technology, specifically related to semi-conductor manufacturing and supercomputing to China without an export license, and the addition of new China-based entities to certain U.S. restricted party lists including the Entity List and Unverified List, trade sanctions and import laws and regulations, 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 such as the war in Ukraine, natural disasters including earthquakes, typhoons, floods, and fires, or outbreaks of health epidemics 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 on our business. 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. For example, in the first quarter of 2022, increases in COVID-19 cases in Shanghai, China, led to shutdowns and delays at the ports in Shanghai. However, the extent of any future shutdown or 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 business may be affected by new sanctions and export controls targeting Russia and other responses to Russia's invasion of Ukraine.

As a result of Russia's invasion of Ukraine, the U.S., the U.K. and the EU governments, among others, have developed coordinated sanctions and export-control measure packages.

Based on the public statements to date, these packages include:

- comprehensive financial sanctions against major Russian banks (including SWIFT cut off);
- designations of individuals and entities involved in Russian military activities;
- additional designations of Russian individuals including but not limited to those with significant business interests and government connections; and
- enhanced export controls and trade sanctions targeting Russia's imports of a wide range of goods as a whole, including potentially tighter controls on exports and reexports of items previously subject to only a low level of control, stricter licensing policy with respect to issuing export licenses, and/or increased use of "end-use" controls to block or impose licensing requirements on exports.

Prior to Russia's invasion of Ukraine, we sold APIs indirectly to Russian customers. The imposition of enhanced export controls and economic sanctions on transactions with Russia and Russian entities by the U.S., the U.K., and/or the EU could prevent us from selling our products to Russian customers. In addition, even if a Russian entity is not formally subject to sanctions, customers of such Russian entity may decide to reevaluate, or cancel projects with such entity, and such actions could have a similar impact on us as if sanctions were applied directly as described above. Depending on the extent and breadth of new sanctions or export controls that may be imposed against Russia, it is possible that our business, results of operations and financial condition could be adversely affected.

The Affordable Care Act and certain legislation and regulatory proposals may increase our costs of compliance and negatively impact our profitability over time.

In March 2010, former President Barack Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, which we refer to collectively as the Affordable Care Act. The Affordable Care Act made extensive changes to the delivery of health care in the United States. We expect that the rebates, discounts, taxes and other costs resulting from the Affordable Care Act over time will have a negative effect on our expenses and profitability in the future. Furthermore, the Independent Payment Advisory Board created by the Affordable Care Act to reduce the per capita rate of growth in Medicare spending could potentially limit access to certain treatments or mandate price controls for our products. Moreover, expanded government investigative authority and increased disclosure obligations may increase the cost of compliance with new regulations and programs.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, or ACA. In June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case without specifically ruling on the constitutionality of the ACA. Accordingly, the ACA remains in effect in its current form. It is unclear how this Supreme Court decision, future litigation, or healthcare measures promulgated by the Biden administration will impact our business, financial condition and results of operations. Complying with any new legislation or changes in healthcare regulation could be time-intensive and expensive, resulting in material adverse effect on our business.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the pharmaceutical industry. For example, in November 2013, Congress passed the Drug Quality and Security Act, or the DQSA. The DQSA establishes federal pedigree tracking standards requiring drugs to be labeled and tracked at the lot level, preempts state drug pedigree requirements, and will eventually require all supply-chain stakeholders to participate in an electronic, interoperable prescription drug track and trace system. The DQSA also establishes new requirements for drug wholesale distributors and third party logistics providers, including licensing requirements in states that had not previously licensed

such entities. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition and results of operations.

Former President Barack Obama also signed into law the Food and Drug Administration Safety and Innovation Act. The law and related agreements make several significant changes to the FFDCA and FDA's processes for reviewing marketing applications that could have a significant impact on the pharmaceutical industry, including, among other things, the following:

- reauthorizes the Prescription Drug User Fee Act, which increases the amount of associated user fees, and, for certain types of applications, increases the expected time frame for FDA review of new drug applications, or NDAs;
- permanently reauthorizes and makes some revisions to the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, which provide for pediatric exclusivity and mandated pediatric assessments for certain types of applications, respectively;
- revises certain standards and requirements for FDA inspections of manufacturing facilities and the importation of drug products from foreign countries;
- creates incentives for the development of certain antibiotic drug products;
- modifies the standards for accelerated approval of certain new medical treatments;
- expands the reporting requirements for potential and actual drug shortages;
- requires the FDA to issue a report on, among other things, ensuring the safety of prescription drugs that have the potential for abuse;
- requires the FDA to hold a public meeting regarding the potential rescheduling of drug products containing hydrocodone, which was held in October 2012; and
- requires electronic submission of certain marketing applications following the issuance of final FDA regulations.

The full impact of new laws and regulations and changes to any existing regulations by the Biden administration is uncertain; however, we anticipate that it will have an adverse effect on our results of operations.

There has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at increasing competition for prescription drugs. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. The impact of these legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the Biden administration on us and the

pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our approved products.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, in September 2020, the Governor of California signed legislation that brings California one step closer to establishing its own generic drug label, which could have significant impact on the generic drug industry and generic drug pricing. A number of states are also considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws.

Additionally, we encounter similar regulatory and legislative issues in most other countries. In the European Union, or EU, and some other international markets, the government provides health care at low cost to consumers and regulates pharmaceutical prices, patient eligibility or reimbursement levels to control costs for the government-sponsored health care system. This international system of price regulations may lead to inconsistent prices.

If significant additional reforms are made to the U.S. health care system, or to the health care systems of other markets in which we operate, those reforms could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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, 2023	138,190	$ 28.92	138,190	—
February 1 – February 28, 2023	98,504	31.35	98,504	—
March 1 – March 31, 2023	26,437	34.93	26,437	—

(1) On November 7, 2022, we announced that our Board of Directors authorized an increase of $50.0 million to our share buyback program. As of March 31, 2023, $35.6 million remained available for repurchase under such program. The share buyback program does not have an expiration date.

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
3.1	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on February 23, 2023)
10.1*	Amendment to Contact Research Agreement by and between Amphastar Pharmaceuticals, Inc. and Nanjing Hanxin Pharmaceutical Technology Co., Ltd., dated March 8, 2023
31.1	Certification of the Principal Executive Officer 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 of the Principal Financial Officer 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.

* Certain confidential information contained in this Exhibit was omitted by means of marking such portions with brackets because the identified confidential information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

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 9, 2023

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

Date: May 9, 2023

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS ([***]), HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED

AMENDMENT TO THE CONTRACT RESEARCH AGREEMENT
委托开发协议之修订协议

This Amendment to the Contract Research Agreement (this "**Amendment**") is entered into by and between the following parties on March 8, 2023:
本委托开发协议之修订协议（"**本修订协议**"）由以下双方于2023年3月8日签订：

(1) **Nanjing Hanxin Pharmaceutical Technology Co., Ltd.**, a limited liability company duly incorporated and validly existing under the laws of PRC, with the Unified Social Credit Code: [***] ("**HX**"); and
(1) **南京汉欣医药科技有限公司**，一家根据中国法律正式成立并有效存续的有限责任公司，统一社会信用代码为：[***]（"**HX**"）；及

(2) **Amphastar Pharmaceuticals, Inc.**, a company established and existing in accordance with the laws of the State of Delaware, the United States of America (together with its Affiliates, the "**Customer**").
(2) **Amphastar Pharmaceuticals, Inc.**，一家根据美国特拉华州法律成立并存续的公司（与其关联方合称为"**委托方**"）。

HX and the Customer are sometimes referred to herein collectively as the "**Parties**" and individually as a "**Party**".
HX与委托方在本修订协议中合称为"**双方**"，单称为"**一方**"。

Whereas,
鉴于，

(1) The Parties have entered into the Contract Research Agreement (the "**Original**

Agreement") on July 5, 2022, pursuant to which the Customer has engaged HX to research and develop certain active pharmaceutical ingredients for the Customer;

(1) 双方于2022年7月5日签订了委托开发协议（"**原协议**"），约定了委托方委托HX为其研发某些活性药物成分；

(2) The Parties intend to amend and supplement certain terms of the original Agreement.

(2) 双方拟对原协议中的部分条款进行修改和补充。

Therefore, the Parties enter into this Amendment on the basis of equality and voluntariness and through friendly negotiation as follows:

因此，双方在平等、自愿的基础上，经友好协商，达成本修订协议如下：

1. Unless otherwise stipulated herein, the defined terms in the Original Agreement, when referred to herein, shall have the same meanings as those ascribed to them in the Original Agreement.

1. 除非本修订协议另有约定，原协议中已定义的术语在本修订协议中提及时应当具有与原协议的定义相同的含义。

2. The Parties acknowledge and agree that the supplement scope of work as provided in Appendix I herein (the "**Supplement Scope of Work**") shall be a supplement to the Scope of Work as set forth in the Original Agreement, and all terms and conditions (including without limitation, corresponding obligations of HX with respect to provision of services, the Customer's ownership of Know-How arising out of such services) relating to or applicable to the Scope of Work as set forth in the Original Agreement shall apply to the Supplement Scope of Work.

2. 双方确认和同意，本修订协议附录I所列之补充工作范围（"**补充工作范围**"）为原协议工作范围的补充，原协议中有关或适用于工作范围的条款和条件（包括但不限于HX在提供服务对应的义务，委托方针对相关服务产生的专有技术的所有权）均应适用于补充工作范围。

3. The Parties acknowledge and agree that:

3. 双方确认并同意：

(a) the Customer shall make payments to HX with respect to HX's performance of the Supplement Scope of Works pursuant to Section 5.1(b) of the Original Agreement, the total payment with respect to the Supplement Scope of Work shall be calculated pursuant to Section 5.1(d) of the Original Agreement and shall not exceed [CNY 3,085,400.79] (Payment from Customer to HX will be adjusted from CNY to USD, based on actual currency exchange rate as reported by the Bloomberg Currency Spot Exchange Rate the date of which the invoice is issued by HX).

(a) 就HX对补充工作范围的履行而言，委托方应根据原协议第5.1(b)条向HX支付款项，就补充工作范围相关的付款总额应根据原协议第5.1(d)条计算，不得超过人民币3,085,400.79元（委托方向HX支付的款项将从人民币调整为美元，以HX发票开具之日公布的彭博货币即期汇率的实际货币兑换率计算）。

(b) based on the foregoing, the total payment made from the Customer to HX under the Original Agreement and this Amendment shall not exceed CNY [17,771,910.79] (Payment from Customer to HX will be adjusted from CNY to USD, based on actual currency exchange rate as reported by the Bloomberg Currency Spot Exchange Rate the date of which the invoice is issued by HX).

(b) 基于上述，委托方基于原协议及本修订协议向HX支付的款项总额不得超过人民币17,771,910.79元（委托方向HX支付的款项将从人民币调整为美元，以HX发票开具之日公布的彭博货币即期汇率的实际货币兑换率计算）。

4. This Amendment shall be an integral part of the Original Agreement and constitute the true agreement between the Parties with respect to the arrangements relating to

the entrustment. In the event of any inconsistency between this Amendment and the Original Agreement, this Amendment shall prevail. For any contents that are not expressly amended or supplemented herein, the terms of the Original Agreement shall remain valid.

4. 本修订协议为原协议不可分割的组成部分，共同构成双方之间对于委托相关安排的真实合意。本修订协议与原协议不一致之处，以本修订协议为准。本修订协议未明确约定修改或补充的内容，原协议的约定应仍然有效。

5. This Amendment and any dispute or claim arising out of or in connection with it or its subject matter or formation shall be resolved pursuant to Section 14 of the Original Agreement.

5. 本修订协议以及因本修订协议及其内容或其成立而引起的或与之相关的任何争议或诉请应根据原协议第14条的约定处理。

6. This Amendment shall become effective upon the date of being duly executed by the Parties. This Amendment may be executed in several duplicates, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. For the avoidance of doubt, this Amendment is concluded both in Chinese version and English version. In the event of any inconsistency between the Chinese version and the English version, the English version shall prevail.

6. 本修订协议于双方适当签署之日生效。本修订协议可签署多份副本，每一份副本均应被视为原件，但所有副本应共同构成同一文件。为免疑义，本修订协议以中文和英文双语书就。若中文版本和英文版本之间存在不一致之处，应以英文版本为准。

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In Witness whereof, the Parties have executed this Amendment by their duly authorized representatives.

有鉴于此，本修订协议由双方授权代表正式签署

Amphastar Pharmaceuticals, Inc.		Nanjing Hanxin Pharmaceutical Technology Co., Ltd. 南京汉欣医药科技有限公司	
By/签署:	/s/Rong Zhou	By/签署:	/s/Bob Bao
Name/姓名:	Rong Zhou	Name/姓名:	Bob Bao 鲍海涛
Title/职位:	Sr. EVP Production Center	Title/职位:	Vice General Manager 副总经理
Date/日期:	March 8, 2023	Date/日期:	March 8, 2023

APPENDIX I: SUPPLEMENT SCOPE OF WORK

附录**I**：补充工作范围

As provided in the HX Supplement Proposal dated February 13, 2023.

如[2023年2月13日]的HX补充提案所述。

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 9, 2023

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 9, 2023

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, 2023 (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 9, 2023

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, 2023 (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 9, 2023

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.