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

# FORM 10-Q

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

**FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 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 November 2, 2023 was 47,907,411.

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**FORM 10-Q FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 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 our newly acquired product, BAQSIMI®, including with respect to our ability to increase our revenues and derive certain benefits as a result of our 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: any resurgence of the 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 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 any resurgence of the 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 Israel-Hamas war, 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;
- 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;
- 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. 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)

| | September 30, 2023 (unaudited) | December 31, 2022 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 266,778 | $ 156,098 |
| Restricted cash | 4,259 | 235 |
| Short-term investments | 33,098 | 19,664 |
| Restricted short-term investments | 2,200 | 2,200 |
| Accounts receivable, net | 118,990 | 88,804 |
| Inventories | 109,978 | 103,584 |
| Income tax refunds and deposits | 1,506 | 171 |
| Prepaid expenses and other assets | 6,196 | 7,563 |
| Total current assets | 543,005 | 378,319 |
| Property, plant, and equipment, net | 280,836 | 238,266 |
| Finance lease right-of-use assets | 610 | 753 |
| Operating lease right-of-use assets | 32,666 | 25,554 |
| Investment in unconsolidated affiliate | 1,026 | 2,414 |
| Goodwill and intangible assets, net | 619,351 | 37,298 |
| Long-term investments | 972 | — |
| Other assets | 25,299 | 20,856 |
| Deferred tax assets | 40,868 | 38,527 |
| Total assets | $ 1,544,633 | $ 741,987 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable and accrued liabilities | $ 222,719 | $ 84,242 |
| Income taxes payable | 31,092 | 4,571 |
| Current portion of long-term debt | 433 | 3,046 |
| Current portion of operating lease liabilities | 3,719 | 3,003 |
| Total current liabilities | 257,963 | 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 | 638,206 | 72,839 |
| Long-term operating lease liabilities, net of current portion | 30,199 | 23,694 |
| Deferred tax liabilities | 201 | 144 |
| Other long-term liabilities | 15,699 | 14,565 |
| Total liabilities | 949,493 | 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; 59,220,178 and 47,898,466 shares issued and outstanding as of September 30, 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 | 477,880 | 455,077 |
| Retained earnings | 373,102 | 271,723 |
| Accumulated other comprehensive loss | (8,411) | (8,624) |
| Treasury stock | (247,437) | (189,524) |
| Total equity | 595,140 | 528,658 |
| Total liabilities and stockholders' equity | $ 1,544,633 | $ 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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| Net revenues: | | | | |
| Product revenues, net | $ 151,855 | $ 120,129 | $ 437,589 | $ 363,964 |
| Other revenues | 28,701 | — | 28,701 | — |
| Total net revenues | 180,556 | 120,129 | 466,290 | 363,964 |
| Cost of revenues | 72,153 | 61,619 | 211,309 | 186,272 |
| Gross profit | 108,403 | 58,510 | 254,981 | 177,692 |
| Operating expenses: | | | | |
| Selling, distribution, and marketing | 6,407 | 4,784 | 20,234 | 16,059 |
| General and administrative | 12,654 | 11,984 | 38,418 | 34,433 |
| Research and development | 16,664 | 18,514 | 53,322 | 57,535 |
| Total operating expenses | 35,725 | 35,282 | 111,974 | 108,027 |
| Income from operations | 72,678 | 23,228 | 143,007 | 69,665 |
| Non-operating income (expenses): | | | | |
| Interest income | 1,202 | 331 | 3,156 | 741 |
| Interest expense | (13,702) | (566) | (17,702) | (1,318) |
| Other income (expenses), net | 3,459 | (397) | 1,553 | 5,692 |
| Total non-operating income (expenses), net | (9,041) | (632) | (12,993) | 5,115 |
| Income before income taxes | 63,637 | 22,596 | 130,014 | 74,780 |
| Income tax provision | 14,025 | 6,559 | 27,160 | 16,187 |
| Income before equity in losses of unconsolidated affiliate | 49,612 | 16,037 | 102,854 | 58,593 |
| Equity in losses of unconsolidated affiliate | (390) | (163) | (1,476) | (1,120) |
| Net income | $ 49,222 | $ 15,874 | $ 101,378 | $ 57,473 |
| Net income per share: | | | | |
| Basic | $ 1.01 | $ 0.32 | $ 2.10 | $ 1.18 |
| Diluted | $ 0.91 | $ 0.30 | $ 1.91 | $ 1.09 |
| Weighted-average shares used to compute net income per share: | | | | |
| Basic | 48,701 | 48,904 | 48,368 | 48,635 |
| Diluted | 53,921 | 52,788 | 52,997 | 52,665 |

*See Accompanying Notes to Condensed Consolidated Financial Statements.*

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| Net income | $ 49,222 | $ 15,874 | $ 101,378 | $ 57,473 |
| Other comprehensive income (loss), net of income taxes | | | | |
| Foreign currency translation adjustment | (87) | (1,222) | 213 | (3,166) |
| Total other comprehensive income (loss) | (87) | (1,222) | 213 | (3,166) |
| Total comprehensive income | $ 49,135 | $ 14,652 | $ 101,591 | $ 54,307 |

*See Accompanying Notes to Condensed Consolidated Financial Statements.*

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

| | Common Stock | | Additional Paid-in Capital | Retained Earnings | Accumulated Other Comprehensive loss | Treasury Stock | | Total |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | | | | Shares | Amount | |
| 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 |
| Net income | — | — | — | 26,124 | — | — | — | 26,124 |
| Other comprehensive loss | — | — | — | — | (56) | — | — | (56) |
| Purchase of treasury stock | — | — | — | — | — | (3,585) | (129) | (129) |
| Issuance of treasury stock in connection with the Company's equity plans | — | — | (231) | — | — | 15,207 | 231 | — |
| Issuance of common stock in connection with the Company's equity plans | 627,946 | — | 9,853 | — | — | — | — | 9,853 |
| Share-based compensation expense | — | — | 4,865 | — | — | — | — | 4,865 |
| Balance as of June 30, 2023 | 59,068,477 | $ 6 | $ 471,110 | $ 323,880 | $ (8,324) | (10,249,671) | $ (197,437) | $ 589,235 |
| Net income | — | — | — | 49,222 | — | — | — | 49,222 |
| Other comprehensive loss | — | — | — | — | (87) | — | — | (87) |
| Purchase of treasury stock | — | — | — | — | — | (1,072,041) | (50,000) | (50,000) |
| Issuance of common stock in connection with the Company's equity plans | 151,701 | — | 2,126 | — | — | — | — | 2,126 |
| Share-based compensation expense | — | — | 4,644 | — | — | — | — | 4,644 |
| Balance as of September 30, 2023 | 59,220,178 | $ 6 | $ 477,880 | $ 373,102 | $ (8,411) | (11,321,712) | $ (247,437) | $ 595,140 |

| | Common Stock | | Additional Paid-in Capital | Retained Earnings | Accumulated Other Comprehensive loss | Treasury Stock | | Total |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | | | | Shares | Amount | |
| Balance as of December 31, 2021 | 56,440,202 | $ 6 | $ 422,423 | $ 180,337 | $ (6,765) | (8,725,290) | $ (150,479) | $ 445,522 |
| 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 |
| Net income | — | — | — | 17,346 | — | — | — | 17,346 |
| Other comprehensive loss | — | — | — | — | (1,464) | — | — | (1,464) |
| Purchase of treasury stock | — | — | — | — | — | (189,840) | (6,118) | (6,118) |
| Issuance of treasury stock in connection with the Company's equity plans | — | — | (430) | — | — | 29,019 | 430 | — |
| Issuance of common stock in connection with the Company's equity plans | 400,935 | — | 5,783 | — | — | — | — | 5,783 |
| Share-based compensation expense | — | — | 4,235 | — | — | — | — | 4,235 |
| Balance as of June 30, 2022 | 57,896,337 | $ 6 | $ 443,042 | $ 221,936 | $ (8,709) | (8,904,048) | $ (156,968) | $ 499,307 |
| Net income | — | — | — | 15,874 | — | — | — | 15,874 |
| Other comprehensive loss | — | — | — | — | (1,222) | — | — | (1,222) |
| Purchase of treasury stock | — | — | — | — | — | (478,255) | (14,493) | (14,493) |
| Issuance of common stock in connection with the Company's equity plans | 98,511 | — | 1,400 | — | — | — | — | 1,400 |
| Share-based compensation expense | — | — | 4,299 | — | — | — | — | 4,299 |
| Balance as of September 30, 2022 | 57,994,848 | $ 6 | $ 448,741 | $ 237,810 | $ (9,931) | (9,382,303) | $ (171,461) | $ 505,165 |

*See Accompanying Notes to Condensed Consolidated Financial Statements.*

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

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2023** | **2022** |
| **Cash Flows From Operating Activities:** | | |
| Net income | $ 101,378 | $ 57,473 |
| Reconciliation to net cash provided by operating activities: | | |
| Loss (gain) on disposal of assets | 474 | (52) |
| Impairment of long-lived assets | 2,700 | — |
| Gain on interest rate swaps and foreign currency transactions, net | (1,019) | (1,124) |
| Depreciation of property, plant, and equipment | 18,559 | 17,615 |
| Amortization of product rights, trademarks, and patents | 6,651 | 730 |
| Operating lease right-of-use asset amortization | 2,778 | 2,604 |
| Amortization of discounts, premiums, and debt issuance costs | 8,486 | 436 |
| Equity in losses of unconsolidated affiliate | 1,476 | 1,120 |
| Share-based compensation expense | 15,620 | 13,556 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, net | (30,175) | 1,423 |
| Inventories | (6,537) | (12,922) |
| Prepaid expenses and other assets | 105 | 1,342 |
| Income tax refunds, deposits, and payable, net | 25,185 | (18,789) |
| Operating lease liabilities | (2,667) | (2,303) |
| Accounts payable and accrued liabilities | 16,625 | 12,846 |
| Net cash provided by operating activities | 159,639 | 73,955 |
| **Cash Flows From Investing Activities:** | | |
| BAQSIMI® acquisition | (506,406) | — |
| Purchases and construction of property, plant, and equipment | (28,724) | (17,724) |
| Proceeds from the sale of property, plant and equipment | — | 421 |
| Purchase of investments | (52,802) | (30,568) |
| Maturity of investments | 38,801 | 15,465 |
| Deposits and other assets | 3,064 | (142) |
| Net cash used in investing activities | (546,067) | (32,548) |
| **Cash Flows From Financing Activities:** | | |
| Proceeds from equity plans, net of withholding tax payments | 7,414 | 13,620 |
| Purchase of treasury stock | (58,144) | (21,840) |
| Debt issuance costs | (24,589) | (404) |
| Proceeds from issuance of long-term debt | 845,000 | — |
| Principal payments on long-term debt | (268,506) | (1,653) |
| Net cash provided by (used in) financing activities | 501,176 | (10,277) |
| Effect of exchange rate changes on cash | (44) | (239) |
| Net increase in cash, cash equivalents, and restricted cash | 114,704 | 30,891 |
| Cash, cash equivalents, and restricted cash at beginning of period | 156,333 | 126,588 |
| Cash, cash equivalents, and restricted cash at end of period | $ 271,037 | $ 157,479 |
| **Noncash Investing and Financing Activities:** | | |
| Deferred payment for BAQSIMI® acquisition | $ 121,699 | $ — |
| Capital expenditures included in accounts payable | $ 4,496 | $ 3,431 |
| Operating lease right-of-use assets in exchange for operating lease liabilities | $ 9,890 | $ 2,166 |
| Equipment acquired under finance leases | $ — | $ 453 |
| **Supplemental Disclosures of Cash Flow Information:** | | |
| Interest paid, net of capitalized interest | $ 12,098 | $ 1,960 |
| Income taxes paid | $ 2,136 | $ 35,166 |

*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. Certain prior period amounts have been reclassified within the operating activities of the condensed consolidated statements of cash flows to conform to the current period presentation. All intercompany activity has been eliminated in the preparation of the condensed consolidated financial statements. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, which are of a normal recurring nature, necessary to present fairly the consolidated financial position, results of operations, and cash flows of the Company.

The Company's subsidiaries include: (1) International Medication Systems, Limited, or IMS, (2) Armstrong Pharmaceuticals, Inc., or Armstrong, (3) Amphastar Nanjing Pharmaceuticals Inc., or ANP, (4) Amphastar France Pharmaceuticals, S.A.S., or AFP, (5) Amphastar UK Ltd., or AUK, (6) International Medication Systems (UK) Limited, or IMS UK, and (7) Amphastar Medication Co., LLC, or Amphastar Medication.

*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

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

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 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: fair value of acquired assets, 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 were a $0.9 million loss and a $0.4 million loss for the three and nine months ended September 30, 2023, respectively. For the three and nine months ended September 30, 2022, the unrealized gains and losses of intercompany foreign currency transactions that are of a long-term investment nature were a $2.0 million loss and a $4.7 million loss, respectively.

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*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.

*Acquisitions*

The Company evaluates acquisitions and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen is met, the transaction is accounted for as an asset acquisition. If the screen is not met, further determination is required as to whether or not the Company has acquired inputs and substantive processes that have the ability to create outputs, which would meet the definition of a business.

Acquisitions meeting the definition of business combinations are accounted for using the acquisition method of accounting, which requires that the purchase price be allocated to the net assets acquired at their respective fair values. In a business combination, any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

For asset acquisitions, a cost accumulation model is used to determine the cost of an asset acquisition. Direct transaction costs are recognized as part of the cost of an asset acquisition. The cost of an asset acquisition, including transaction costs, is allocated to identifiable assets acquired and liabilities assumed based on a relative fair value basis, with the exception of non-qualifying assets. Goodwill is not recognized in an asset acquisition. When a transaction accounted for as an asset acquisition includes an in-process research and development, or IPR&D, asset, the IPR&D asset is only capitalized if it has an alternative future use other than in a particular research and development project. Asset acquisitions may include contingent consideration arrangements that encompass obligations to make future payments to sellers contingent upon the achievement of future financial targets. Contingent consideration, including assumed contingent considerations, is not recognized until all contingencies are resolved and the consideration is paid or becomes payable (unless contingent considerations meets the definition of a derivative, in which case the amount becomes part of the basis in the asset acquired), at which point the consideration is allocated to the assets acquired based on their relative fair values at the acquisition date, with the exception of non-qualifying assets.

Judgments are used in determining estimates of useful lives of long-lived assets. Useful life estimates are based on, among other factors, estimates of expected future net cash flows, the assessment of each asset's life cycle, and the impact of competitive trends on each asset's life cycle and other factors. These judgments can materially impact the estimates used to allocate purchase consideration to assets acquired and liabilities assumed, and the resulting timing and amounts charged to or recognized in current and future operating results. For these and other reasons, actual results may vary significantly from estimated results.

*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 and nine months ended September 30, 2023, advertising expenses were $1.9 million and $8.1 million, respectively. For the three and nine months ended September 30, 2022, advertising expenses were $1.6 million and $6.5 million, respectively.

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*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 carrying value of the Company's long-term obligations approximates their 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 September 30, 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 September 30, 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 and China. As of September 30, 2023 and December 31, 2022, the restricted cash balance was $4.3 million and $0.2 million, respectively.

*Restricted Short-Term Investments*

Restricted short-term investments consist of certificates of deposit that are collateral for standby letters of credit to qualify for workers' compensation self-insurance. The certificates of deposit have original maturities greater than three months, but less than one year. As of September 30, 2023 and December 31, 2022, the balance of restricted short-term investments was $2.2 million.

*Deferred Income Taxes*

The Company utilizes the liability method of accounting for income taxes, under which deferred taxes are determined based on the temporary differences between the financial statements and the tax basis of assets and liabilities using enacted tax rates. A valuation allowance is recorded when it is more likely than not that the deferred tax assets will not be realized.

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*Debt Issuance Costs*

Debt issuance costs related to non-revolving debt are recognized as a reduction to the related debt balance in the accompanying condensed consolidated balance sheets and amortized to interest expense over the contractual term of the related debt using the effective interest method. Debt issuance costs associated with revolving debt are capitalized within other long-term assets on the condensed consolidated balance sheets and are amortized to interest expense over the term of the related revolving debt.

*Convertible Debt*

The Company accounts for its convertible debt instruments as a single unit of accounting, a liability, because the Company concluded that the conversion features do not require bifurcation as a derivative under ASC 815-15 and the Company did not issue its convertible debt instruments at a substantial premium. The Company records debt issuance costs as contra-liabilities in our consolidated balance sheets at issuance and amortizes them over the contractual term of the convertible debt instrument using the effective interest rate.

In accordance with ASU *2020-06,* Debt—*Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, the Company evaluates convertible debt instruments to determine if the conversion feature is freestanding or embedded. If the conversion feature is embedded, the conversion feature is not bifurcated from the host instrument. If the conversion feature does not require derivative treatment under ASC 815, the instrument is evaluated under ASC 470-20 "Debt with Conversion and Other Options" for consideration of any beneficial conversion features. If no beneficial conversion features exist that require separate recognition, convertible notes are accounted for as a single liability measured at its amortized cost as long as no other features require separation and recognition as derivatives.

*Impairment of Long Lived Assets, including Identifiable Definite-Lived Intangible Assets*

The Company assesses long-term and identifiable definite-lived intangible assets or asset groups for impairment when events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. If the sum of the expected future undiscounted cash flows is less than the carrying amount of the asset or an asset group, further impairment analysis is performed. An impairment loss is measured as the amount by which the carrying amount of the asset or asset groups exceeds the fair value (assets to be held and used) or fair value less cost to sell (assets to be disposed of). The Company also assesses the useful lives of its assets periodically to determine whether events and circumstances warrant a revision to the remaining useful life. Changes in the useful life are adjusted prospectively by revising the remaining period over which the asset is amortized.

*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.

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*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. BAQSIMI® Acquisition**

On June 30, 2023, the Company completed its acquisition of BAQSIMI® glucagon nasal powder, or BAQSIMI® pursuant to an asset purchase agreement, or the Purchase Agreement, with Eli Lilly & Company, or Lilly, dated April 21, 2023. In connection with the closing of the transaction, or the Closing, the Company paid Lilly $500.0 million in cash. In addition, the Company is required to pay Lilly a $125.0 million guaranteed payment on the first anniversary of the closing. The Company is also required to pay Lilly $4.0 million upon the assignment of certain contracts to the Company after the first anniversary of the Closing, but no later than 18 months 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 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.

In addition, the Company assumed certain contingent consideration 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 Company has accounted for the BAQSIMI® acquisition as an asset acquisition in accordance with Accounting Standard Codification, or ASC, 805, *Business Combination*s, as substantially all the fair value of the assets acquired is concentrated in a single identifiable asset, BAQSIMI® product rights. The BAQSIMI® product rights include the license for the BAQSIMI® intellectual property, regulatory documentation, marketing authorizations, and domain names, which are considered a single asset as they are inextricably linked. As an asset acquisition, the cost to acquire the group of assets, including transaction costs, is allocated to the individual assets acquired based on their relative fair values, with the exception of non-qualifying assets.

The relative fair values of identifiable assets from the acquisition of BAQSIMI® are based on estimates of fair value using assumptions that the Company believes are reasonable.

*Manufacturing Services Agreement*

In connection with the Closing, the Company entered into a Manufacturing Services Agreement, or the MSA, with Lilly, pursuant to which Lilly has agreed, for a period of time not to exceed 18 months, to provide certain manufacturing, packaging, labeling and supply services for BAQSIMI® directly or through third-party contractors to the Company in connection with its operation of the development, manufacture, and commercialization of BAQSIMI®. Upon termination of the MSA, the Company will be obligated to purchase all API, components, and finished goods on hand at prices agreed upon in the MSA.

*Transition Services Agreement*

In connection with the Closing, the Company entered into a Transition Services Agreement, or the TSA, with Lilly pursuant to which Lilly has agreed, for a period of time not to exceed 18 months, to provide certain services to the

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Company to support the transition of BAQSIMI® operations to the Company, including with respect to the conduct of certain clinical, regulatory, medical affairs, and commercial sales channel activities.

The following table summarizes the aggregate amount paid for the assets acquired by the Company in connection with the acquisition of BAQSIMI®:

| | Fair Value (in thousands) |
|---|---|
| Cash payment | $ 500,000 |
| Fair value of deferred cash payments | 121,699 |
| Transaction costs | 6,406 |
| Total purchase price | $ 628,105 |

The total purchase price was allocated to the acquired assets based on their relative fair values, as follow:

| | Fair Value (in thousands) |
|---|---|
| Property, plant, and equipment | $ 34,426 |
| BAQSIMI® product rights | 591,338 |
| Deferred tax assets | 2,341 |
| Total assets acquired | $ 628,105 |

The Company is amortizing the acquired intangible asset on a straight line basis over its estimated useful life of 24 years (See Note 10 for additional information).

The fair value of the deferred cash payment is being accreted to the full $129.0 million amount over a one-year period through interest expense. During the three and nine months ended September 30, 2023 $1.8 million of interest expense was recognized related to accretion of the deferred cash payments.

*Credit Agreement*

On June 30, 2023, in conjunction with the Company's acquisition of BAQSIMI®, the Company entered into a $700.0 million syndicated credit agreement, or the Credit Agreement, by and among the Company, certain subsidiaries of the Company, as guarantors, certain lenders, and Wells Fargo Bank, National Association, or Wells Fargo, as Administrative Agent (in such capacity, Agent), Swing line Lender and L/C Issuer.

The Credit Agreement provides for a senior secured term loan, or the Wells Fargo Term Loan in an aggregate principal amount of $500.0 million. The Wells Fargo Term Loan matures on the June 30, 2028.

The Credit Agreement also provides a senior secured revolving credit facility, or the Revolving Credit Facility, in an aggregate principal amount of $200.0 million, with a $15.0 million letter of credit sublimit and a $15.0 million swingline loan sublimit. The Revolving Credit Facility matures on June 30, 2028. As of September 30, 2023, the Company had no borrowings outstanding under the Revolving Credit Facility.

Proceeds from the Term Loan were used to finance the acquisition of BAQSIMI®.

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**Note 4. Revenue Recognition**

*Product revenues, net*

In accordance with 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.

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 and nine months ended September 30, 2023, revenues from research and development services at ANP were $0.8 million and $2.1 million, respectively. For the three and nine months ended September 30, 2022, revenues from research and development services at ANP were $0.8 million and $2.1 million, respectively.

*Other revenues*

Revenues related to sales of BAQSIMI®, which was acquired on June 30, 2023 and was manufactured and sold by Lilly under the TSA during the three months ended September 30, 2023, were recorded on a net basis, similar to a royalty arrangement.

*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

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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:

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2023 | 2022 |
| | (in thousands) | |
| Beginning balance | $ 26,606 | $ 20,167 |
| Provision for chargebacks and rebates | 200,317 | 147,899 |
| Credits and payments issued to third parties | (201,650) | (144,233) |
| Ending balance | $ 25,273 | $ 23,833 |

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 September 30, 2023 and December 31, 2022, $18.9 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 September 30, 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 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.

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

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2023 | 2022 |
| | (in thousands) | |
| Beginning balance | $ 19,451 | $ 21,677 |
| Provision for product returns | 2,750 | 3,086 |
| Credits issued to third parties | (4,467) | (5,019) |
| Ending balance | $ 17,734 | $ 19,744 |

Of the provision for product returns as of September 30, 2023 and December 31, 2022, $12.9 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 September 30, 2023 and December 31, 2022 of $4.8 million and $4.6 million, were included in other long-term liabilities, respectively. For the nine months ended September 30, 2023 and 2022, the Company's aggregate product return rate was 1.1% and 1.4% of qualified sales, respectively.

**Note 5. 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 potentially dilutive shares outstanding during the period, such as stock options, non-vested restricted stock units, shares issuable under the Company's Employee Stock Purchase Plan, or ESPP, and potential common shares issued upon the conversion of Convertible Notes of the Company, due March 2029, or the 2029 Convertible Notes.

For the nine months ended September 30, 2023, options to purchase 45,934 shares of stock, with a weighted-average exercise price of $46.01 per share were excluded in the computation of diluted net income per share because the effect would be anti-dilutive. The 2029 Convertible Notes had no impact on the computation of diluted net income per share as the average stock price during the period was less than the conversion price.

For the three and nine months ended September 30, 2022, options to purchase 704,483 shares of stock, with a weighted-average exercise price of $34.79 per share, were excluded in the computation of diluted net income per share because the effect would be anti-dilutive.

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| | (in thousands, except per share data) | | | |
| Basic and dilutive numerator: | | | | |
| Net income | $ 49,222 | $ 15,874 | $ 101,378 | $ 57,473 |
| Denominator: | | | | |
| Weighted-average shares outstanding — basic | 48,701 | 48,904 | 48,368 | 48,635 |
| | | | | |
| Net effect of dilutive securities: | | | | |
| Incremental shares from equity awards | 5,220 | 3,884 | 4,629 | 4,030 |
| Weighted-average shares outstanding — diluted | 53,921 | 52,788 | 52,997 | 52,665 |
| Net income per share — basic | $ 1.01 | $ 0.32 | $ 2.10 | $ 1.18 |
| Net income per share — diluted | $ 0.91 | $ 0.30 | $ 1.91 | $ 1.09 |

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**Note 6. Segment Reporting**

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

- Finished pharmaceutical products
- APIs

The finished pharmaceutical products segment manufactures, markets and distributes Primatene MIST®, glucagon, enoxaparin, naloxone, phytonadione, lidocaine, epinephrine, various critical and non-critical care drugs, as well as certain contract manufacturing and contract research revenues. The API segment manufactures and distributes recombinant human insulin API and porcine insulin API for external customers and internal product development.

Other revenues from the sale of BAQSIMI® are accounted for as a component of the finished pharmaceutical products segment.

Selected financial information by reporting segment is presented below:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| | (in thousands) | | | |
| **Net revenues:** | | | | |
| Finished pharmaceutical products | $ 176,366 | $ 117,120 | $ 455,242 | $ 353,789 |
| API | 4,190 | 3,009 | 11,048 | 10,175 |
| Total net revenues | 180,556 | 120,129 | 466,290 | 363,964 |
| | | | | |
| **Gross profit (loss):** | | | | |
| Finished pharmaceutical products | 109,499 | 61,439 | 262,742 | 185,462 |
| API | (1,096) | (2,929) | (7,761) | (7,770) |
| Total gross profit | 108,403 | 58,510 | 254,981 | 177,692 |
| | | | | |
| Operating expenses | 35,725 | 35,282 | 111,974 | 108,027 |
| | | | | |
| Income from operations | 72,678 | 23,228 | 143,007 | 69,665 |
| Non-operating income | (9,041) | (632) | (12,993) | 5,115 |
| | | | | |
| Income before income taxes | $ 63,637 | $ 22,596 | $ 130,014 | $ 74,780 |

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.

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| | (in thousands) | | | |
| **Finished pharmaceutical products segment net revenues:** | | | | |
| Glucagon | $ 29,514 | $ 14,224 | $ 82,486 | $ 37,003 |
| Primatene MIST® | 24,834 | 18,359 | 64,837 | 62,030 |
| Epinephrine | 20,199 | 19,502 | 57,004 | 52,777 |
| Lidocaine | 15,522 | 12,621 | 43,174 | 39,253 |
| Phytonadione | 7,449 | 13,978 | 33,017 | 37,834 |
| Enoxaparin | 7,702 | 7,983 | 25,441 | 27,138 |
| Naloxone | 4,715 | 6,818 | 14,774 | 21,424 |
| Other finished pharmaceutical products | 37,730 | 23,635 | 105,808 | 76,330 |
| Total finished pharmaceutical products net revenues | 147,665 | 117,120 | 426,541 | 353,789 |
| BAQSIMI® | 28,701 | — | 28,701 | — |
| Total finished pharmaceutical products segment net revenues | $ 176,366 | $ 117,120 | $ 455,242 | $ 353,789 |

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| | (in thousands) | | | |
| **Depreciation and amortization expense** | | | | |
| Finished pharmaceutical products | $ 8,616 | $ 2,517 | $ 13,143 | $ 6,370 |
| API | 1,003 | 904 | 2,938 | 2,789 |
| Total depreciation and amortization expense | $ 9,619 | $ 3,421 | $ 16,081 | $ 9,159 |

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

| | Net Revenue | | | | Long-Lived Assets | |
|---|---|---|---|---|---|---|
| | Three Months Ended September 30, | | Nine Months Ended September 30, | | September 30, | December 31, |
| | 2023 | 2022 | 2023 | 2022 | 2023 | 2022 |
| | (in thousands) | | | | | |
| United States[1] | $ 178,056 | $ 117,780 | $ 459,909 | $ 355,680 | $ 772,066 | $ 136,328 |
| China | 833 | 719 | 2,142 | 2,418 | 89,737 | 88,647 |
| France | 1,667 | 1,630 | 4,239 | 5,866 | 37,488 | 39,598 |
| Total | $ 180,556 | $ 120,129 | $ 466,290 | $ 363,964 | $ 899,291 | $ 264,573 |

(1) Includes revenue from the sales of BAQSIMI®

**Note 7. Customer and Supplier Concentration**

*Customer Concentrations*

Three large wholesale drug distributors, AmerisourceBergen Corporation, or AmerisourceBergen, Cardinal Health, Inc., or Cardinal, and McKesson Corporation, or McKesson, are all distributors of the Company's products, as well as

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suppliers of a broad range of health care products. Lilly currently manufactures and sells BAQSIMI® on the Company's behalf pursuant to the terms of the TSA (See Note 4 for additional information). The Company considers these four customers to be its major customers, as each individually, and these customers collectively, represented a significant percentage of the Company's net revenue for the three and nine months ended September 30, 2023 and 2022, and accounts receivable as of September 30, 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 September 30, | | Nine Months Ended September 30, | |
| | September 30, 2023 | December 31, 2022 | 2023 | 2022 | 2023 | 2022 |
| McKesson | 24 % | 32 % | 22 % | 23 % | 25 % | 21 % |
| AmerisourceBergen | 9 % | 16 % | 17 % | 23 % | 20 % | 23 % |
| Cardinal Health | 17 % | 19 % | 15 % | 17 % | 16 % | 16 % |
| Lilly | 24 % | — | 16 % | — | 6 % | — |

*Supplier Concentrations*

The Company depends on suppliers for raw materials, APIs, and other components that are subject to stringent FDA requirements. Some of these materials may only be available from one or a limited number of sources. Establishing additional or replacement suppliers for these materials may take a substantial period of time, as suppliers must be approved by the FDA. Furthermore, a significant portion of raw materials may only be available from foreign sources. If the Company is unable to secure, on a timely basis, sufficient quantities of the materials it depends on to manufacture and market its products, it could have a materially adverse effect on the Company's business, financial condition, and results of operations.

**Note 8. Fair Value Measurements**

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

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

As of September 30, 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 fifteen 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

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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 September 30, 2023 and December 31, 2022, are as follows:

| | Total | (Level 1) | (Level 2) | (Level 3) |
|---|---|---|---|---|
| | | (in thousands) | | |
| **Assets:** | | | | |
| Cash equivalents | $ 230,668 | $ 230,668 | $ — | $ — |
| Restricted cash | 4,259 | 4,259 | — | — |
| Short-term investments | 6,016 | — | 6,016 | — |
| Restricted short-term investments | 2,200 | — | 2,200 | — |
| Corporate, agency and municipal bonds | 33,632 | — | 33,632 | — |
| Interest rate swaps related to variable rate loans | 3,387 | — | 3,387 | — |
| Total assets measured at fair value as of September 30, 2023 | $ 280,162 | $ 234,927 | $ 45,235 | $ — |

| | Total | (Level 1) | (Level 2) | (Level 3) |
|---|---|---|---|---|
| | | (in thousands) | | |
| **Assets:** | | | | |
| 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 | — |
| Total assets measured at fair value as of December 31, 2022 | $ 158,213 | $ 130,434 | $ 27,779 | $ — |

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 an impairment test. As of September 30, 2023, and December 31, 2022, there were no significant adjustments to fair value for nonfinancial assets or liabilities.

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

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## Note 9. Investments

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

| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|---|---|---|---|
| | | (in thousands) | | |
| Corporate and agency bonds (due within 1 year) | $ 32,313 | $ — | $ (23) | $ 32,290 |
| Corporate bonds (due within 1 to 3 years) | 964 | — | (1) | 963 |
| Municipal bonds (due within 1 year) | 379 | — | — | 379 |
| Total investments as of September 30, 2023 | $ 33,656 | $ — | $ (24) | $ 33,632 |
| | | | | |
| 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 (Nanjing Hanxin Biomedical Testing Service Co., Ltd., or 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 and nine months ended September 30, 2023 was $0.4 million and $1.5 million, respectively, which was recorded in the "Equity in losses of unconsolidated affiliate" line on the condensed consolidated statement of operations. The Company's share of Hanxin's losses for the three and nine months ended September 30, 2022, was $0.2 million and $1.1 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 10. Goodwill and Intangible Assets

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

| | Weighted-Average Life (Years) | Original Cost | Accumulated Amortization | Net Book Value |
|---|---|---|---|---|
| | | (in thousands) | | |
| *Definite-lived intangible assets* | | | | |
| BAQSIMI® product rights[1] | 24 | $ 591,338 | $ 6,159 | $ 585,179 |
| IMS (UK) international product rights[2] | 10 | 8,462 | 8,462 | — |
| Patents | 12 | 486 | 372 | 114 |
| Land-use rights | 39 | 2,540 | 799 | 1,741 |
| Subtotal | 23 | 602,826 | 15,792 | 587,034 |
| *Indefinite-lived intangible assets* | | | | |
| Trademark | * | 29,225 | — | 29,225 |
| Goodwill - Finished pharmaceutical products | * | 3,092 | — | 3,092 |
| Subtotal | * | 32,317 | — | 32,317 |
| As of September 30, 2023 | * | $ 635,143 | $ 15,792 | $ 619,351 |

| | Weighted-Average Life (Years) | Original Cost | Accumulated Amortization | Net Book Value |
|---|---|---|---|---|
| | | (in thousands) | | |
| *Definite-lived intangible assets* | | | | |
| IMS (UK) international product rights[2] | 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.
(1) See Note 3.
(2) In June 2023, the Company recorded an impairment related to its IMS (UK) international product rights in the amount of $2.7 million. The Company recorded the impairment in the cost of revenue line in its condensed consolidated statement of operations for the nine months ended September 30, 2023

*Goodwill*

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

| | September 30, 2023 | December 31, 2022 |
|---|---|---|
| | (in thousands) | |
| Beginning balance | $ 3,126 | $ 3,313 |
| Currency translation | (34) | (187) |
| Ending balance | $ 3,092 | $ 3,126 |

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**Amortization**

As of September 30, 2023, the expected amortization expense for all intangible assets during the next five fiscal years ended December 31 and thereafter is as follows:

| | (in thousands) |
|---|---|
| 2023 | $ 6,180 |
| 2024 | 24,718 |
| 2025 | 24,718 |
| 2026 | 24,718 |
| 2027 | 24,718 |
| Thereafter | 481,982 |
| Total amortizable intangible assets | 587,034 |
| Indefinite-lived intangibles | 32,317 |
| Total intangibles (net of accumulated amortization) | $ 619,351 |

*Primatene® Trademark*

In January 2009, the Company acquired the exclusive rights to the trademark, domain name, website and domestic marketing, distribution and selling rights related to Primatene MIST®, an over-the-counter bronchodilator product, recorded at the allocated fair value of $29.2 million, which is its carrying value as of September 30, 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.

*BAQSIMI® Product Rights*

As discussed in Note 3, in June 2023, the Company acquired the BAQSIMI® product rights. BAQSIMI® is an emergency nasal spray used to treat severe hypoglycemia. The BAQSIMI® product rights intangible asset is amortized over its estimated useful life of 24 years.

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

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**Note 11. Inventories**

Inventories consist of the following:

| | September 30, 2023 | December 31, 2022 |
|---|---|---|
| | (in thousands) | |
| Raw materials and supplies | $ 55,180 | $ 47,607 |
| Work in process | 28,293 | 37,090 |
| Finished goods | 26,505 | 18,887 |
| Total inventories | $ 109,978 | $ 103,584 |

Charges of $9.6 million were included in the cost of revenues in the Company's condensed consolidated statements of operations for the nine months ended September 30, 2023, to adjust the Company's inventory and related firm purchase commitments to their net realizable value. For the three and nine months ended September 30, 2022, charges of $5.5 million and $14.1 million were included in the cost of revenues, 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 September 30, 2023 and December 31, 2022 were $0.7 million and $2.7 million, respectively, which are recorded in cost of revenues in the Company's condensed consolidated statement of operations.

**Note 12. Property, Plant, and Equipment**

Property, plant, and equipment consist of the following:

| | September 30, 2023 | December 31, 2022 |
|---|---|---|
| | (in thousands) | |
| Buildings | $ 131,488 | $ 130,726 |
| Leasehold improvements | 41,686 | 31,535 |
| Land | 7,438 | 7,451 |
| Machinery and equipment | 257,295 | 208,068 |
| Furniture, fixtures, and automobiles | 31,141 | 29,674 |
| Construction in progress | 49,540 | 50,842 |
| Total property, plant, and equipment | 518,588 | 458,296 |
| Less accumulated depreciation | (237,752) | (220,030) |
| Total property, plant, and equipment, net | $ 280,836 | $ 238,266 |

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### Note 13. Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consisted of the following:

| | September 30, 2023 | December 31, 2022 |
|---|---|---|
| | (in thousands) | |
| Accrued customer fees and rebates | $ 16,261 | $ 14,198 |
| Accrued payroll and related benefits | 26,681 | 22,847 |
| Accrued product returns, current portion | 12,884 | 14,867 |
| Accrued loss on firm purchase commitments | 701 | 2,686 |
| Accrued payments for BAQSIMI® (see note 3) | 123,894 | — |
| Other accrued liabilities | 10,328 | 9,143 |
| Total accrued liabilities | 190,749 | 63,741 |
| Accounts payable | 31,970 | 20,501 |
| Total accounts payable and accrued liabilities | $ 222,719 | $ 84,242 |

### Note 14. Debt

Debt consists of the following:

| | September 30, 2023 | December 31, 2022 |
|---|---|---|
| | (in thousands) | |
| ***Convertible Debt*** | | |
| 2029 Convertible Notes | $ 345,000 | $ — |
| ***Term Loan*** | | |
| Wells Fargo Term Loan due June 2028 | 300,000 | — |
| Capital One N.A. Term Loan paid off June 2023 | — | 68,250 |
| ***Mortgage Loans*** | | |
| Mortgage payable with East West Bank due June 2027 | 8,060 | 8,188 |
| ***Other Loans and Payment Obligations*** | | |
| French government loans due December 2026 | 209 | 204 |
| ***Line of Credit Facilities*** | | |
| Line of credit facility with China Merchant Bank expired April 2023 | — | — |
| Wells Fargo Revolving line of credit facility due June 2028 | — | — |
| Capital One N.A. Revolving line of credit facility closed in June 2023 | — | — |
| ***Equipment under Finance Leases*** | 660 | 790 |
| Total debt | 653,929 | 77,432 |
| Less current portion of long-term debt | 433 | 3,046 |
| Less: Loan issuance costs | 15,290 | 1,547 |
| Long-term debt, net of current portion and unamortized debt issuance costs | $ 638,206 | $ 72,839 |

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**Credit Agreements**

*2029 Convertible Notes*

In September 2023, the Company issued the 2029 Convertible Notes, in the aggregate principal amount of $345.0 million in a private offering pursuant to Section 4(a)(2) and Rule 144A under the Securities Act of 1933, as amended. The Company used portions of the net proceeds from the 2029 Convertible Notes to (i) repay approximately $200.0 million of the Company's borrowings under the Wells Fargo Term Loan and (ii) repurchase $50.0 million of the Company's common stock.

In connection with the issuance of the 2029 Convertible Notes, the Company incurred approximately $10.8 million of debt issuance costs, which primarily consisted of underwriting, legal and other professional fees. Unamortized debt issuance costs related to the 2029 Convertible Notes were $10.8 million as of September 30, 2023.

The 2029 Convertible Notes are general senior, unsecured obligations and bear an interest rate of 2.0% per year. The 2029 Convertible Notes were issued pursuant to an indenture, dated September 15, 2023, or the Indenture, between the Company and U.S. Bank Trust Company, National Association, as trustee.

The 2029 Convertible Notes will rank senior in right of payment to all of the Company's indebtedness that is expressly subordinated in right of payment to the 2029 Convertible Notes; equal in right of payment to all of the Company's unsecured indebtedness that is not so subordinated; effectively junior to any of the Company's secured indebtedness to the extent of the value of the assets securing such indebtedness, including any amount outstanding under the Company's credit facilities; and structurally junior to all indebtedness and other liabilities of the Company's current or future subsidiaries, including trade payables.

Interest will be payable semi-annually in arrears on March 15 and September 15 of each year, beginning on March 15, 2024. The 2029 Convertible Notes may bear additional interest under specified circumstances relating to the Company's failure to comply with its reporting obligations under the Indenture or if the 2029 Convertible Notes are not freely tradeable as required by the Indenture.

The 2029 Convertible Notes will mature on March 15, 2029, unless earlier converted, repurchased or redeemed.

Conversions of the 2029 Convertible Notes will be settled in cash up to the aggregate principal amount of the 2029 Convertible Notes to be converted, and cash, shares of common stock or a combination of cash and shares of common stock, at the Company's election, with respect to the remainder, if any, of the Company's conversion obligation in excess of the aggregate principal amount.

Holders may convert their 2029 Convertible Notes at their option prior to the close of business on the business day immediately preceding December 15, 2028, in multiples of $1,000 principal amount, only under the following circumstances; (i) during any calendar quarter commencing after the calendar quarter ending on December 31, 2023 (and only during such calendar quarter), if the last reported sale price of the common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price for the 2029 Convertible Notes on each applicable trading day, (ii) during the five business day period after any five consecutive trading day period in which the trading price, as defined in the Indenture, per $1,000 principal amount of the 2029 Convertible Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day, (iii) if the Company calls the 2029 Convertible Notes for redemption, at any time prior to the close of business on the second scheduled trading day immediately preceding the redemption date, and (iv) upon the occurrence of specified corporate events defined in the Indenture.

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On or after December 15, 2028, until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert all or any portion of their 2029 Convertible Notes, in multiples of $1,000 principal amount, at the option of the holder regardless of the foregoing circumstances.

The Company may redeem the 2029 Convertible Notes, at its option, in whole or in part (subject to certain limitations), on or after September 20, 2026 and prior to the 41st scheduled trading day preceding the maturity date, if the last reported sale price of the Company's common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on and including the trading day immediately preceding the date on which the Company provides notice of redemption at a redemption price equal to 100% of the principal amount of the 2029 Convertible Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

The initial conversion rate is 15.8821 shares of the Company's common stock per $1,000 principal amount of the 2029 Convertible Notes, which represents an initial conversion price of approximately $62.96 per share of common stock. The initial conversion price of $62.96 represents a premium of approximately 35.0% over the last reported sale price of the Company's common stock on Nasdaq Global Select Market on September 12, 2023. The conversion rate is subject to adjustment under certain circumstances in accordance with the terms of the Indenture.

If a fundamental change, as defined in the Indenture, occurs at any time prior to the maturity date, then, subject to certain conditions, holders of the 2029 Convertible Notes may require the Company to repurchase for cash all or any portion of their 2029 Convertible Notes at a repurchase price equal to 100% of the principal amount of the 2029 Convertible Notes to be repurchased, plus any accrued and unpaid interest. In addition, following certain specified corporate events or if the Company issues a notice of redemption, the Company will, under certain circumstances, increase the conversion rate for holders who convert their 2029 Convertible Notes in connection with such corporate event or during a redemption period.

*Syndicated Credit Agreement with Wells Fargo Bank, National Association - Due June 2028*

In June 2023, in connection with the BAQSIMI® acquisition, the Company entered into a syndicated credit agreement with Wells Fargo, or the Credit Agreement. Under the terms of the Credit Agreement, the Company borrowed $500.0 million in the form of a term loan, or the Wells Fargo Term Loan. Proceeds from the Wells Fargo Term Loan were used to finance the acquisition of BAQSIMI®, repay certain of the Company's and its subsidiaries' existing third-party indebtedness, and pay fees and expenses incurred in connection with each of the foregoing. Outstanding borrowings with respect to the Wells Fargo Term Loan initially accrue interest, at the Company's option, at a per annum rate equal to either (i) a base rate equal to the highest of (x) the federal funds rate, plus 0.50%, (y) the prime rate then in effect and (z) an adjusted daily one-month Secured Overnight Financing Rate, or SOFR, rate determined on the basis of a one-month interest period plus 1.00%, in each case, plus an applicable margin of 1.25%, or (ii) an adjusted Term SOFR rate, subject to a floor of 0.00%, plus an applicable margin of 2.25%. Following delivery of financial statements for the Company's first fiscal quarter following payment in full of a $125.0 million guaranteed payment owed to Lilly on June 30, 2024, the applicable margin for outstanding borrowings with respect to the Wells Fargo Term Loan will range from 0.50% to 1.50% in the case of base rate loans and 1.50% to 2.50% in the case of Term SOFR rate loans, in each case, depending on the Company's consolidated net leverage ratio as of the most recently ended fiscal quarter. The Wells Fargo Term Loan matures in June 2028.

The Wells Fargo Term Loan requires principal payments of $12.5 million for the first year, which increases to $25.0 million during the second year, and $37.5 million during the third, fourth and fifth years, with the remaining balance due at maturity. The loan is secured by substantially all of the Company's and certain of its subsidiaries' assets, subject to certain exceptions and limitations. In the third quarter of 2023, the Company repaid approximately $200.0 million of the borrowings under the Wells Fargo term Loan with the proceeds from the 2029 Convertible Notes, thereby satisfying all

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of the current and future loan amortization payments required by the Wells Fargo Term Loan until maturity.

The Credit Agreement also provides for a $200.0 million Revolving Credit Facility and bears the same interest rate as the Wells Fargo Term Loan.

In conjunction with the Credit Agreement, the Company entered into an interest rate swap agreement with Wells Fargo, with a notional amount of $250.0 million to exchange the variable rate on the Wells Fargo Term Loan for a fixed rate of 4.04%. The interest swap asset had a fair value of $3.2 million as of September 30, 2023.

For lenders that were part of the previous credit agreement with Capital One N.A. as well as the new Credit Agreement, the transaction was accounted for as a modification under ASC 470-50, *Debt Modifications and Extinguishments*, based on a comparison of the present value of the cash flows for each lender under the terms of the debt immediately before and after the transaction, which resulted in a change of less than 10%.

The Company incurred approximately $14.3 million in issuance costs in connection with the Credit Agreement, of which $3.0 million represented debt modification costs and were charged to interest expense in the Company's condensed consolidated statement of operations for nine months ended September 30, 2023.

Debt issuance costs associated with the Credit Agreement (other than its Revolving Credit Facility component) are presented as a reduction to the carrying value of the related debt, while debt issuance costs associated with the Revolving Credit Facility are capitalized within other long-term assets on the condensed consolidated balance sheets. Unamortized debt issuance costs related to the Credit Agreement as of September 30, 2023 were $8.9 million which are being amortized over the term of the Credit Agreement using the effective interest rate method.

As a result of the $200.0 million repayment of the principal balance of the Wells Fargo Term Loan, approximately $3.0 million of unamortized debt issuance costs were written off during the three and nine months ended September 30, 2023.

*Syndicated Credit Agreement with Capital One N.A. – Paid off June 2023*

In August 2021, the Company entered into a $140.0 million credit agreement with Capital One N.A. acting as a lender and as agent for other lenders. Under the terms of the credit agreement, the Company borrowed $70.0 million in the form of a term loan, or the Capital One N.A. Term Loan. Proceeds from the loan were used to pay down certain of the Company's outstanding loans and revolving lines of credit with Cathay Bank and East West Bank. The interest rate on the Capital One N.A. Term Loan was based on a variable interest rate, plus an applicable margin rate ranging between 0.5% and 2.5%, determined based on the Company's net leverage ratio as defined by the terms of the agreement. In June 2023, the Company repaid all amounts outstanding under the Capital One N.A. Term Loan.

**Interest Rate Swap Contracts**

As of September 30, 2023, the fair value of the loans listed above approximated their carrying amount based on Level 2 inputs. For the mortgage loan with East West Bank, as well as the Wells Fargo Term Loan, the Company has entered into fixed interest rate swap contracts to exchange the 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 $4.9 million gain and $2.7 million gain for the three and nine months ended September 30, 2023, respectively. Changes in the fair values of interest rate swaps were $2.0 million gain and $5.9 million gain for the three and nine months ended September 30, 2022, respectively.

**Covenants**

At September 30, 2023 and December 31, 2022, the Company was in compliance with all of its debt covenants.

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**Long-Term Debt Maturities**

As of September 30, 2023, the principal amounts of long-term debt maturities during each of the next five fiscal years ending December 31 are as follows:

| | Long-term Debt |
|---|---|
| | (in thousands) |
| 2023 | $ 229 |
| 2024 | 241 |
| 2025 | 250 |
| 2026 | 7,548 |
| 2027 | — |
| Thereafter | 645,000 |
| | $ 653,268 |

**Note 15. Income Taxes**

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| | (in thousands) | | | |
| Income before taxes | $ 63,637 | $ 22,596 | $ 130,014 | $ 74,780 |
| Income tax provision | 14,025 | 6,559 | 27,160 | 16,187 |
| Income before equity in losses of unconsolidated affiliate | $ 49,612 | $ 16,037 | $ 102,854 | $ 58,593 |
| Income tax provision as a percentage of income before income taxes | 22.0 % | 29.0 % | 20.9 % | 21.6 % |

The change in the Company's effective tax rate for the three and nine months ended September 30, 2023, was primarily due to differences in pre-tax income positions and timing of discrete tax items.

In connection with the purchase accounting for its acquisition of BAQSIMI®, the Company recorded a deferred tax asset of $2.3 million.

*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.

During the nine months ended September 30, 2023, the Company determined its U.K. subsidiaries, AUK and IMS UK, more likely than not would not realize the benefits of their deferred tax assets. Therefore, the Company recorded a valuation allowance expense of an immaterial amount and will discontinue recognizing income tax benefits until sufficient taxable income is generated to realize their deferred tax assets.

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.

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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 16. Stockholders' Equity**

*Share Buyback Program*

Pursuant to the Company's existing share buyback program, the Company purchased 1,072,041 and 1,338,757 shares of its common stock during the three and nine months ended September 30, 2023, for total consideration of $50.0 million and $58.1 million, respectively. The Company purchased 478,255 and 719,263 shares of its common stock during the three and nine months ended September 30, 2022, for total consideration of $14.5 million and $21.8 million, respectively.

In August 2023, 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 $285.0 million in the share buyback program. The primary goal of the program is to offset dilution created by the Company's equity compensation programs.

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 September 30, 2023, the Company reserved an aggregate of 6,776,746 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 September 30, 2023, the Company has issued 1,155,478 shares of common stock under the ESPP and 844,522 shares of its common stock remain available for issuance under the ESPP.

In May 2023, the Company issued 65,933 shares at a purchase price of $25.52 per share under the ESPP. For the three and nine months ended September 30, 2023, the Company recorded ESPP expense of $0.2 million and $0.8 million, respectively. For the three and nine months ended September 30, 2022, the Company recorded ESPP expense of $0.2 million and $0.6 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.

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The weighted-averages for key assumptions used in determining the fair value of options granted during the three and nine months ended September 30, 2023 and 2022, are as follows:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| Average volatility | 40.2 % | 42.7 % | 41.4 % | 41.0 % |
| Average risk-free interest rate | 4.4 % | 2.9 % | 4.1 % | 2.3 % |
| Weighted-average expected life in years | 6.3 | 6.3 | 6.2 | 6.1 |
| Dividend yield rate | — % | — % | — % | — % |

A summary of option activity under all plans for the nine months ended September 30, 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 | 759,820 | 35.84 | | |
| Options exercised | (786,891) | 15.27 | | |
| Options forfeited | (4,526) | 29.60 | | |
| Options expired | (543) | 16.25 | | |
| Outstanding as of September 30, 2023 | 7,897,010 | $ 19.65 | 4.78 | 208,046 |
| Exercisable as of September 30, 2023 | 5,819,517 | $ 16.54 | 3.52 | 171,365 |
| Vested and expected to vest as of September 30, 2023 | 7,703,355 | $ 19.37 | 4.68 | 205,029 |

(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 September 30, 2023.

For the three and nine months ended September 30, 2023, the Company recorded expense of $2.2 million and $7.5 million, respectively, related to stock options granted under all plans. For the three and nine months ended September 30, 2022, the Company recorded expense of $2.0 million and $6.5 million, respectively, related to stock options granted under all plans.

Information relating to option grants and exercises is as follows:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| | (in thousands, except per share data) | | | |
| Weighted-average grant date fair value per share | $ 21.49 | $ 14.40 | $ 16.76 | $ 14.75 |
| Intrinsic value of options exercised | 5,628 | 1,421 | 24,544 | 20,131 |
| Cash received from options exercised | 2,277 | 1,483 | 12,015 | 18,402 |
| Total fair value of the options vested during the period | 167 | 167 | 8,887 | 8,157 |

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A summary of the status of the Company's non-vested options as of September 30, 2023, and changes during the nine months ended September 30, 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 | 759,820 | 16.76 |
| Options vested | (1,056,254) | 8.41 |
| Options forfeited | (4,526) | 13.40 |
| Non-vested as of September 30, 2023 | 2,077,493 | 12.68 |

As of September 30, 2023, there was $18.9 million of total unrecognized compensation cost, net of forfeitures, related to non-vested stock option based compensation arrangements granted under all plans. The cost is expected to be recognized over a weighted-average period of 2.7 years and will be adjusted for future changes in estimated forfeitures.

*Restricted Stock Units*

The Company grants restricted stock units, or RSUs, to certain employees and members of the Board of Directors with a vesting period of up to five years. The grantee receives one share of common stock at a specified future date for each RSU awarded. The RSUs may not be sold or otherwise transferred until vested. The RSUs do not have any voting or dividend rights prior to the issuance 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 and nine months ended September 30, 2023, the Company recorded total expenses of $2.2 million and $7.3 million, respectively, related to RSU awards granted under all plans. For the three and nine months ended September 30, 2022, the Company recorded expenses of $2.0 million and $6.4 million, respectively, related to RSU awards granted under all plans.

As of September 30, 2023, there was $19.9 million of total unrecognized compensation cost, net of forfeitures, related to non-vested RSU-based compensation arrangements granted under all plans. The cost is expected to be recognized over a weighted-average period of 2.7 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 | 356,176 | $ 12,725 |
| RSUs forfeited | (2,017) | |
| RSUs vested[2] | (440,337) | |
| RSUs outstanding at September 30, 2023 | 920,874 | |

(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, 168,007 shares of common stock were surrendered to fulfill tax withholding obligations.

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*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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| | (in thousands) | | | |
| Cost of revenues | $ 1,004 | $ 915 | $ 3,868 | $ 3,238 |
| Operating expenses: | | | | |
| Selling, distribution, and marketing | 213 | 178 | 649 | 540 |
| General and administrative | 2,975 | 2,810 | 9,323 | 8,389 |
| Research and development | 452 | 396 | 1,780 | 1,389 |
| Total share-based compensation | $ 4,644 | $ 4,299 | $ 15,620 | $ 13,556 |

**Note 17. Employee Benefits**

*401(k) Plan*

The Company has a defined contribution 401(k) plan, or the Plan, whereby eligible employees voluntarily contribute up to a defined percentage of their annual compensation. The Company matches contributions at a rate of 50% on the first 6% of employee contributions, and pays the administrative costs of the Plan. Total employer contributions for the three and nine months ended September 30, 2023 were approximately $0.5 million and $1.7 million, respectively, compared to the prior year expense of $0.5 million and $1.6 million for the three and nine months ended September 30, 2022, respectively.

*Defined Benefit Pension Plan*

The Company's subsidiary, AFP, has an obligation associated with a defined-benefit plan for its eligible employees. This plan provides benefits to the employees from the date of retirement and is based on the employee's length of time employed by the Company. The calculation is based on a statistical calculation combining a number of factors that include the employee's age, length of service, and AFP employee turnover rate.

The liability under the plan is based on a discount rate of 3.8% as of September 30, 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 September 30, 2023 and December 31, 2022, respectively. The Company recorded an immaterial amount of expense under the plan for each of the three and nine months ended September 30, 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 $5.5 million and $4.5 million as of September 30, 2023 and December 31, 2022, respectively. The plan liabilities were valued at approximately

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$5.7 million and $4.6 million as of September 30, 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 18. Commitments and Contingencies**

*Purchase Commitments*

As of September 30, 2023, the Company has entered into commitments to purchase equipment and raw materials for an aggregate amount of approximately $72.8 million.

**Note 19. Related Party Transactions**

*Investment in Hanxin*

As of September 30, 2023, the Company has a 11.5% 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 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 and nine months ended September 30, 2023, the Company recognized an immaterial amount of revenue from manufacturing services provided to Hanxin. As of September 30, 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

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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 and nine months ended September 30, 2023, the Company paid $0.4 million and $1.4 million, respectively, under this agreement.

*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 September 30, 2023, ANP did not have any payments under this agreement. During the nine months ended September 30, 2023, ANP paid $0.7 million, under this agreement. As of September 30, 2023, the Company did not have any amounts payable to Letop.

**Note 20. 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 nine months ended September 30, 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.

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**Note 21. Subsequent Events**

On October 27, 2023, the Company made a principal payment of $50.0 million on its Wells Fargo Term Loan, reducing the balance to $250.0 million.

## 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, and intranasal products, as well as insulin API products. We currently manufacture and sell over 20 products.

Our largest products by net revenues currently include BAQSIMI®, 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, REXTOVY®, which we plan to launch in the first quarter of 2024.

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 has not purchased from us in 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, public sector budgetary cycles and funding authorization in the United States, political and civil unrest, global conflicts such as the Israel-Hamas war, 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.

**Recent Developments**

BAQSIMI® Acquisition

On June 30, 2023, we completed our acquisition of BAQSIMI® glucagon nasal powder, or BAQSIMI® pursuant to an Asset Purchase Agreement, or the Purchase Agreement, with Eli Lilly & Company, or Lilly, and Amphastar Medication Co., LLC, a wholly owned subsidiary of Amphastar, dated April 21, 2023. In connection with the closing of the transaction, or the Closing, we paid Lilly $500.0 million in cash. In addition, we are required to pay Lilly a $125.0 million guaranteed payment on the first anniversary of 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.

On June 30, 2023, in conjunction with our acquisition of BAQSIMI®, we entered into a $700.0 million syndicated credit agreement, or the Credit Agreement by and among the Company, certain subsidiaries of the Company, as guarantors, certain lenders, and Wells Fargo Bank, National Association, or Wells Fargo, as Administrative Agent, (in such capacity, Agent), Swing Line Lender and L/C Issuer.

The Credit Agreement provides for a senior secured term loan in an aggregate principal amount of $500.0 million, or the Wells Fargo Term Loan. The Wells Fargo Term Loan matures on June 30, 2028. The Wells Fargo Term Loan was fully funded on June 30, 2023.

The Credit Agreement provides for a senior secured revolving credit facility, or the Revolving Credit Facility, in an aggregate principal amount of $200.0 million, with a $15.0 million letter of credit sublimit and a $15.0 million swingline loan sublimit. The Revolving Credit Facility matures on June 30, 2028. As of September 30, 2023, we had no borrowings outstanding under the Revolving Credit Facility. In September 2023, we repaid $200.0 million of the Wells Fargo Term Loan with the proceeds from the issuance of $345.0 million of the 2.00% Convertible Notes, or 2029 Convertible Notes. We repaid approximately $200.0 million of the borrowings under the Wells Fargo Term Loan with the proceeds from the 2029 Convertible Notes.

Revenues from the sales of BAQSIMI®, under the Transition Services Agreement, or TSA, with Lilly during the three months ended September 30, 2023, were recognized on a net basis similar to a royalty arrangement. The impact of this revenue recognition method resulted in lower reported revenues relative to the revenue that would have been reported had we recognized gross revenues from sales of BAQSIMI®. Once we assume distribution responsibilities to our customers, we will begin recognizing gross revenues and cost of revenues from sales BAQSIMI®, which will be classified as product revenues, net and cost of revenues, respectively.

For more information regarding our acquisition of BAQSIMI®, see “Part I – Item 1. Financial Statements – Notes to Condensed Consolidated Financial Statements – Note 3. BAQSIMI® Acquisition.”

**Business Segments**

As of June 30, 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. Revenues from the sale of BAQSIMI® are also accounted for as a component of the finished pharmaceutical product segment. 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 6. Segment Reporting.”

**Results of Operations**

***Three Months Ended September 30, 2023 Compared to Three Months Ended September 30, 2022***

**Net revenues**

| | Three Months Ended September 30, | | Change | |
|---|---|---|---|---|
| | 2023 | 2022 | Dollars | % |
| | (in thousands) | | | |
| Net revenues | | | | |
| Finished pharmaceutical products | $ 147,665 | $ 117,120 | $ 30,545 | 26 % |
| API | 4,190 | 3,009 | 1,181 | 39 % |
| Total product revenues, net | 151,855 | 120,129 | 31,726 | 26 % |
| Other revenues | 28,701 | — | 28,701 | N/A |
| Total net revenues | $ 180,556 | $ 120,129 | $ 60,427 | 50 % |
| Cost of revenues | | | | |
| Finished pharmaceutical products | $ 66,867 | $ 55,681 | $ 11,186 | 20 % |
| API | 5,286 | 5,938 | (652) | (11)% |
| Total cost of revenues | $ 72,153 | $ 61,619 | $ 10,534 | 17 % |
| Gross profit | $ 108,403 | $ 58,510 | $ 49,893 | 85 % |
| *as % of net revenues* | *60 %* | *49 %* | | |

The increase in net revenues of the finished pharmaceutical products for the three months ended September 30, 2023 was due to the following changes:

| | Three Months Ended September 30, | | Change | |
|---|---|---|---|---|
| | 2023 | 2022 | Dollars | % |
| | (in thousands) | | | |
| Finished pharmaceutical products net revenues | | | | |
| Glucagon | $ 29,514 | $ 14,224 | $ 15,290 | 107 % |
| Primatene MIST® | 24,834 | 18,359 | 6,475 | 35 % |
| Epinephrine | 20,199 | 19,502 | 697 | 4 % |
| Lidocaine | 15,522 | 12,621 | 2,901 | 23 % |
| Enoxaparin | 7,702 | 7,983 | (281) | (4)% |
| Phytonadione | 7,449 | 13,978 | (6,529) | (47)% |
| Naloxone | 4,715 | 6,818 | (2,103) | (31)% |
| Other finished pharmaceutical products | 37,730 | 23,635 | 14,095 | 60 % |
| Total finished pharmaceutical products net revenues | $ 147,665 | $ 117,120 | $ 30,545 | 26 % |

*Product Revenues, net*

The increase in sales of glucagon was primarily due to an increase in unit volumes, as a result of two suppliers discontinuing their glucagon injection products at the end of 2022. Primatene MIST® sales increased due to an increase in unit volumes. The increase in sales of lidocaine was primarily due to an increase in unit volumes, as a result of supplier shortages. The decrease in sales of phytonadione was due to a decrease in unit volumes, as a result of increased competition. The decrease in sales of naloxone was primarily due to a decrease in unit volumes. The increase in other finished pharmaceutical products was primarily due to higher unit volumes of dextrose, atropine, calcium chloride, and sodium bicarbonate, due to increased demand caused by supplier shortages during the quarter, as well as a full quarter of sales for vasopressin, which were launched in August 2022, and the launch of regadenoson in April 2023.

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 medroxyprogesterone have essentially been halted as of August 2023 as our API supplier has discontinued making this product. We are currently in the process of qualifying our subsidiary ANP to make this API. However, we do not know when the Drug Master File, or DMF, to approve this as our new API supply will be approved by the FDA. Therefore, we are not sure when we will be able to return to selling this product. Sales of medroxyprogesterone totaled $0.7 million in the three months ended September 30, 2023 compared to $7.2 million in the three months ended September 30, 2022.

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

*Other Revenues*

Other revenues includes revenues from the sales of BAQSIMI® of $28.7 million during the three months ended September 30, 2023, based on total BAQSIMI® sales of $48.7 million as reported to us by Lilly, which was recognized on a net basis similar to a royalty arrangement. Currently, BAQSIMI® is being sold by Lilly on our behalf under the TSA, whereby Lilly would provide certain services to support the transition of the BAQSIMI® operations to us. The transfer of the BAQSIMI® marketing authorizations to us is anticipated to occur at different points in time depending on the jurisdiction, with the United States being the first that is expected to transfer to us in the first quarter of 2024. Upon the assumption of distribution responsibilities, we will begin to recognize gross revenues and cost of revenues in their respective lines on the consolidated statements of comprehensive income.

*Backlog*

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. As of September 30, 2023, we experienced an immaterial amount of backlog for various products, primarily as a result of competitor shortages and supplier constraints. 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 Primatene MIST®, which are higher-margin products, the sales of ganirelix and vasopressin, both of which we launched last year, as well as the sales of regadenoson, which we launched in April 2023, helped increase our gross margins for the three months ended September 30, 2023. Additionally, as a result of the TSA with Lilly, revenues from sales of BAQSIMI® are reported on a net basis similar to a royalty arrangement with no amount reported as cost of revenues.

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, regadenoson and new products we anticipate launching in 2024.

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

| | Three Months Ended September 30, | | Change | |
|---|---|---|---|---|
| | 2023 | 2022 | Dollars | % |
| | (in thousands) | | | |
| Selling, distribution, and marketing | $ 6,407 | $ 4,784 | $ 1,623 | 34 % |
| General and administrative | $ 12,654 | $ 11,984 | $ 670 | 6 % |

The increase in selling, distribution and marketing expenses was primarily due to expenses related to the expansion of our sales force related to BAQSIMI®, as well as an increase in advertising spending for Primatene MIST®. The increase in general and administrative expense was primarily due to an increase in salary and personnel-related expenses, as well as costs related to the acquisition of BAQSIMI®, which was partially offset by a decrease in legal fees.

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 September 30, | | Change | |
|---|---|---|---|---|
| | 2023 | 2022 | Dollars | % |
| | (in thousands) | | | |
| Salaries and personnel-related expenses | $ 7,007 | $ 6,217 | $ 790 | 13 % |
| Pre-launch inventory | 460 | — | 460 | N/A |
| Clinical trials | 673 | 2,726 | (2,053) | (75)% |
| FDA fees | 45 | 29 | 16 | 55 % |
| Materials and supplies | 3,664 | 5,217 | (1,553) | (30)% |
| Depreciation | 2,452 | 2,473 | (21) | (1)% |
| Other expenses | 2,363 | 1,852 | 511 | 28 % |
| Total research and development expenses | $ 16,664 | $ 18,514 | $ (1,850) | (10)% |

The decrease in research and development expenses is primarily due to the timing of clinical trials. Additionally, materials and supplies expense decreased as a result of a ramp-up of expense in 2022 for AMP-018 and our insulin pipeline products. This was partially offset by an increase in salary and personnel-related expenses.

Research and development expenses 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 trials cost 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.

**Other income (expenses), net**

| | Three Months Ended September 30, | | Change | |
|---|---|---|---|---|
| | 2023 | 2022 | Dollars | % |
| | (in thousands) | | | |
| Other income (expenses), net | $ 3,459 | $ (397) | $ 3,856 | NM |

Other income (expenses), net is primarily a result of foreign currency fluctuation, as well as the mark-to-market adjustments relating to our interest rate swap contracts during the three months ended September 30, 2023.

**Income tax provision**

| | Three Months Ended September 30, | | Change | |
|---|---|---|---|---|
| | 2023 | 2022 | Dollars | % |
| | (in thousands) | | | |
| Income tax provision | $ 14,025 | $ 6,559 | $ 7,466 | 114 % |
| *Effective tax rate* | *22 %* | *29 %* | | |

Our effective tax rate for the three months ended September 30, 2023 decreased in comparison to the three months ended September 30, 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 15. Income Taxes”.

***Nine Months Ended September 30, 2023 Compared to Nine Months Ended September 30, 2022***

**Net revenues**

| | Nine Months Ended September 30, | | Change | |
|---|---|---|---|---|
| | 2023 | 2022 | Dollars | % |
| | (in thousands) | | | |
| Net revenues | | | | |
| Finished pharmaceutical products | $ 426,541 | $ 353,789 | $ 72,752 | 21 % |
| API | 11,048 | 10,175 | 873 | 9 % |
| Total product revenues, net | 437,589 | 363,964 | 73,625 | 20 % |
| Other revenues | 28,701 | — | 28,701 | N/A |
| Total net revenues | $ 466,290 | $ 363,964 | $ 102,326 | 28 % |
| Cost of revenues | | | | |
| Finished pharmaceutical products | $ 192,500 | $ 168,327 | $ 24,173 | 14 % |
| API | 18,809 | 17,945 | 864 | 5 % |
| Total cost of revenues | $ 211,309 | $ 186,272 | $ 25,037 | 13 % |
| Gross profit | $ 254,981 | $ 177,692 | $ 77,289 | 43 % |
| *as % of net revenues* | *55 %* | *49 %* | | |

The increase in net revenues of the finished pharmaceutical products for the nine months ended September 30, 2023, was due to the following changes:

| | Nine Months Ended September 30, | | Change | |
|---|---|---|---|---|
| | 2023 | 2022 | Dollars | % |
| | (in thousands) | | | |
| Finished pharmaceutical products net revenues | | | | |
| Glucagon | $ 82,486 | $ 37,003 | $ 45,483 | 123 % |
| Primatene MIST® | 64,837 | 62,030 | 2,807 | 5 % |
| Epinephrine | 57,004 | 52,777 | 4,227 | 8 % |
| Lidocaine | 43,174 | 39,253 | 3,921 | 10 % |
| Phytonadione | 33,017 | 37,834 | (4,817) | (13)% |
| Enoxaparin | 25,441 | 27,138 | (1,697) | (6)% |
| Naloxone | 14,774 | 21,424 | (6,650) | (31)% |
| Other finished pharmaceutical products | 105,808 | 76,330 | 29,478 | 39 % |
| Total finished pharmaceutical products net revenues | $ 426,541 | $ 353,789 | $ 72,752 | 21 % |

*Product Revenues, net*

The increase in sales of glucagon was primarily due to an increase in unit volumes, as a result of two suppliers discontinuing their glucagon injection products at the end of 2022. Primatene MIST® sales increased due to an increase in average selling price contributing $3.5 million, which was partially offset by a reduction in unit volume, as a result of inventory drawdowns by retailers, amounting to $0.7 million. The increase in sales of epinephrine and lidocaine was primarily due to an increase in unit volumes, due to an increase in demand caused by supplier shortages. The decrease in sales of phytonadione was due to a decrease in unit volumes, as a result of increased competition. The decrease in sales of enoxaparin was primarily due to a decrease in unit volumes. The decrease in sales of naloxone was due to both a decrease in unit volumes, as well as a lower average selling price. The increase in other finished pharmaceutical products was primarily due to higher unit volumes of dextrose, atropine, calcium chloride, and sodium bicarbonate, due to increased demand caused by supplier shortages, as well as a full period of sales for ganirelix and vasopressin, which were launched in June 2022 and August 2022, respectively, and the launch of regadenoson in April 2023.

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 medroxyprogesterone have essentially been halted as of August 2023 as our API supplier has discontinued making this product. We are currently in the process of qualifying our subsidiary ANP to make this API. However, we do not know when the Drug Master File, or DMF, to approve this as our new API supply will be approved by the FDA. Therefore, we are not sure when we will be able to return to selling this product. Sales of medroxyprogesterone totaled $10.7 million in the nine months ended September 30, 2023, compared to $19.8 million in the nine months ended September 30, 2022.

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

*Other Revenues*

Other revenues includes revenues from the sales of BAQSIMI® of $28.7 million during the nine months ended September 30, 2023, based on total BAQSIMI® sales of $48.7 million as reported to us by Lilly, which was recognized on a net basis similar to a royalty arrangement. Currently, BAQSIMI® is being sold by Lilly on our behalf under the TSA, whereby Lilly would provide certain services to support the transition of the BAQSIMI® operations to us. The transfer of the BAQSIMI® marketing authorizations to us is anticipated to occur at different points in time depending on the jurisdiction, with the United States being the first that is expected to transfer to us in the first quarter of 2024. Upon the assumption of distribution responsibilities, we will begin to recognize gross revenues and cost of revenues in their respective lines on the consolidated statements of comprehensive income.

*Backlog*

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. As of September 30, 2023, we experienced an immaterial amount of backlog for various products, primarily as a result of competitor shortages and supplier constraints. 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, Primatene MIST®, and epinephrine, which are higher-margin products, the sales of ganirelix and vasopressin, both of which we launched last year, as well as the sales of regadenoson, which we launched in April 2023, helped increase our gross margins for the nine months ended September 30, 2023. Additionally, as a result of the TSA with Lilly, the revenues relating to BAQSIMI® is reported on a net basis similar to a royalty arrangement with no amount reported as cost of revenues. These increases in gross margins were partially offset by an impairment charge of $2.7 million in June 2023 relating to the impairment of the IMS (UK) international product rights, as well as charges included in cost of revenue to adjust our inventory and related purchase commitments to their net realizable value.

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 glucagon, vasopressin, ganirelix, regadenoson and new products we anticipate launching in 2023 and 2024.

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

| | Nine Months Ended September 30, | | Change | |
|---|---|---|---|---|
| | 2023 | 2022 | Dollars | % |
| | (in thousands) | | | |
| Selling, distribution, and marketing | $ 20,234 | $ 16,059 | $ 4,175 | 26 % |
| General and administrative | $ 38,418 | $ 34,433 | $ 3,985 | 12 % |

The increase in selling, distribution and marketing expenses was primarily due to expenses related to the expansion of our sales force related to BAQSIMI®, as well as an increase in advertising spending for Primatene MIST®. The increase in general and administrative expense was primarily due to an increase in salary and personnel-related expenses, as well as costs related to the acquisition of BAQSIMI®.

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**

| | Nine Months Ended September 30, | | Change | |
|---|---|---|---|---|
| | 2023 | 2022 | Dollars | % |
| | (in thousands) | | | |
| Salaries and personnel-related expenses | $ 21,653 | $ 18,767 | $ 2,886 | 15 % |
| Pre-launch inventory | 460 | — | 460 | N/A |
| Clinical trials | 3,430 | 3,905 | (475) | (12)% |
| FDA fees | 142 | 86 | 56 | 65 % |
| Materials and supplies | 13,556 | 21,747 | (8,191) | (38)% |
| Depreciation | 7,282 | 7,647 | (365) | (5)% |
| Other expenses | 6,799 | 5,383 | 1,416 | 26 % |
| Total research and development expenses | $ 53,322 | $ 57,535 | $ (4,213) | (7)% |

The decrease in research and development expenses is primarily due to a decrease in materials and supply expense, as a result of a ramp-up of expenses in 2022 for AMP-018 and other insulin pipeline products. This was partially offset by an increase in salary and personnel-related expenses.

Research and development expenses 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 trials 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.

**Other income (expenses), net**

| | Nine Months Ended September 30, | | Change | |
|---|---|---|---|---|
| | 2023 | 2022 | Dollars | % |
| | (in thousands) | | | |
| Other income (expenses), net | $ 1,553 | $ 5,692 | $ (4,139) | NM |

Other income (expenses), net is primarily a result of foreign currency fluctuation, as well as the mark-to-market adjustments relating to our interest rate swap contracts during the nine months ended September 30, 2023. For the nine months ended September 30, 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 20. Litigation”.

**Income tax provision**

| | Nine Months Ended September 30, | | Change | |
|---|---|---|---|---|
| | 2023 | 2022 | Dollars | % |
| | (in thousands) | | | |
| Income tax provision | $ 27,160 | $ 16,187 | $ 10,973 | 68 % |
| *Effective tax rate* | *21 %* | *22 %* | | |

Our effective tax rate for the nine months ended September 30, 2023 decreased in comparison to the nine months ended September 30, 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 15. 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 September 30, 2023, our foreign subsidiaries collectively held $5.8 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, including from sales of BAQSIMI®, 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 by $1.5 million to $285.0 million at September 30, 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 nine months ended September 30, 2023 and 2022:

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2023 | 2022 |
| | (in thousands) | |
| **Statement of Cash Flow Data:** | | |
| Net cash provided by (used in) | | |
| Operating activities | $ 159,639 | $ 73,955 |
| Investing activities | (546,067) | (32,548) |
| Financing activities | 501,176 | (10,277) |
| Effect of exchange rate changes on cash | (44) | (239) |
| Net increase in cash, cash equivalents, and restricted cash | $ 114,704 | $ 30,891 |

*Sources and Use of Cash*

Operating Activities

Net cash provided by operating activities was $159.6 million for the nine months ended September 30, 2023, which included net income of $101.4 million. Non-cash items comprised primarily of $36.5 million of depreciation and amortization, $15.6 million of share-based compensation expense, and an impairment charge of $2.7 million relating to the impairment of the IMS (UK) international product rights.

Additionally, for the nine months ended September 30, 2023, there was a net cash inflow from changes in operating assets and liabilities of $2.5 million, which resulted from an increase in accounts payable and accrued liabilities, which was partially offset by an increase in accounts receivables and inventories. Accounts payable and accrued liabilities increased primarily due to the timing of payments. The increase in accounts receivables was primarily due to the timing of the payment from Lilly for BAQSIMI® during the quarter, which was received subsequent to the quarter end.

Net cash provided by operating activities was $74.0 million for the nine months ended September 30, 2022, which included net income of $57.5 million. Non-cash items comprised primarily of $21.4 million of depreciation and amortization and $13.6 million of share-based compensation expense. Additionally, for the nine months ended September 30, 2022, there was a net cash outflow from changes in operating assets and liabilities of $18.4 million, which resulted from an increase in inventories, due to increased purchases of certain raw materials and components, 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.

Investing Activities

Net cash used in investing activities was $546.1 million for the nine months ended September 30, 2023, primarily as a result of $506.4 million relating to the BAQSIMI® acquisition, $28.7 million in purchases of property, plant, and equipment, which included $19.5 million incurred in the United States, $1.7 million in France, and $7.5 million in China.

Net cash used in investing activities was $32.5 million for the nine months ended September 30, 2022, primarily as a result of $17.7 million in purchases of property, plant, and equipment, which included $11.1 million incurred in the United States, $0.9 million in France, and $5.7 million in China. Additionally, net cash outflows from short-term investing activities during the period was $15.1 million.

Financing Activities

Net cash provided by financing activities was $501.2 million for the nine months ended September 30, 2023, primarily due to our entry into the Credit Agreement with Wells Fargo and the issuance of the 2029 Convertible Notes, which was

partially offset by $268.5 million in principal payments of our long-term debt and $24.6 million in debt issuance cost. Additionally, we received $7.4 million in net proceeds from the settlement of share-based compensation awards under our equity plan, which was partially offset by the $58.4 million used to purchase treasury stock.

Net cash used in financing activities was $10.3 million for the nine months ended September 30, 2022, primarily as a result of purchases of $21.8 million of treasury stock, which was partially offset by $13.6 million in net proceeds from the settlement of share-based compensation awards under our equity plan. Additionally, we also made $1.7 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 14. 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 September 30, 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 20. 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.

***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 acquisition of BASQIMI®, 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 did not control at the time such assumptions were made, 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 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;
- 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 debt facility described below, and continued uncertainty arising from the global economic downturn; and
- the FDA approval process is time-consuming and complicated, and we may not obtain the FDA approval required for a product within the timeline we desire, or at all.

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.

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 of 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.

***Our current and future indebtedness has and may continue to adversely affect our operating results and cash flows.***

The Acquisition was financed with proceeds of the Wells Fargo Term Loan. The material increase in our indebtedness as a result of the Credit Agreement and the 2029 Convertible Notes has and may continue to 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 under the Credit Agreement and the 2029 Convertible Notes, 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 interest rates applicable to certain of our indebtedness are based on a fixed margin over an indexed rate or an adjusted base rate. If interest rates were to further increase substantially it could have a material adverse effect on 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 or place us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital;

- 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; and

- any conversion of the 2029 Convertible Notes could dilute the interests of existing investors in our common stock.

Our ability to make scheduled payments of the principal and interest when due, or to refinance our borrowings under the Credit Agreement and/or the 2029 Convertible Notes, 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 under the Credit Agreement, the 2029 Convertible Notes or future indebtedness.

If we fail to make required payments under our existing or future indebtedness, 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 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 Credit Agreement contains financial and operational covenants that may 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 Credit Agreement contains 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 including without limitation, covenants requiring compliance with a maximum consolidated net leverage ratio test and a minimum consolidated interest coverage 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. 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.

***We may not have sufficient cash to settle conversions of the 2029 Convertible Notes in cash, to repurchase the 2029 Convertible Notes upon a fundamental change, or to repay the principal amount of the 2029 Convertible Notes in cash at their maturity, and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the 2029 Convertible Notes.***

Holders of the 2029 Convertible Notes will have the right to require us to repurchase all or a portion of the 2029 Convertible Notes upon the occurrence of a fundamental change, as defined in the Indenture, before the applicable maturity date at a repurchase price equal to 100% of the principal amount of such 2029 Convertible Notes to be repurchased, plus accrued and unpaid interest or special interest, if any, as described in the Indenture governing the 2029 Convertible Notes. In addition, upon conversion of the 2029 Convertible Notes, we will be required to settle a portion or all of its conversion obligation in respect of the 2029 Convertible Notes being converted in cash, as described in the Indenture. Moreover, we will be required to repay the 2029 Convertible Notes in cash at their maturity unless earlier converted, redeemed or repurchased. However, we may not have enough available cash on hand or be able to obtain financing at the time we are required to make repurchases of the 2029 Convertible Notes surrendered therefor or pay cash with respect to the 2029 Convertible Notes being converted or at their respective maturity.

In addition, our ability to repurchase the 2029 Convertible Notes or to pay cash upon conversions of the 2029 Convertible Notes or at their maturity may be limited by law, regulatory authority or agreements governing our future indebtedness. Our failure to repurchase the 2029 Convertible Notes at a time when the repurchase is required by the indenture governing the 2029 Convertible Notes or to pay cash upon the conversion of the 2029 Convertible Notes or at their maturity as required by the indenture would constitute a default under the indenture. A default under the indenture or the fundamental change itself could also lead to a default under agreements governing our existing and future indebtedness. Moreover, the occurrence of a fundamental change under the indenture could constitute an event of default under any such agreement. If the payment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness, which would have a material adverse effect on our business, results of operations and financial condition.

***The conditional conversion feature of the 2029 Convertible Notes, if triggered, may adversely affect our financial condition and operating results.***

In the event the conditional conversion feature of the 2029 Convertible Notes is triggered, holders of the 2029 Convertible Notes will be entitled under the Indenture to convert the 2029 Convertible Notes at any time during the specified periods at their option. Upon such event, if one or more holders elect to convert their 2029 Convertible Notes, we would be required to settle a portion or all of the conversion obligation in cash, which could adversely affect our liquidity. In addition, even if holders of the 2029 Convertible Notes do not elect to convert their 2029 Convertible Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of such 2029 Convertible Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

***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. 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 resurgence of COVID-19 cases or other public health outbreaks that result in business disruptions or related challenging macroeconomic conditions globally.***

While the U.S. government ended the COVID-19 public health emergency on May 11, 2023, any resurgence of COVID-19 cases or other public health outbreaks or disruptions could continue to impact worldwide economic activity and financial markets and present challenges to our business. 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. Such outbreaks 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, any extended public health outbreaks or emergencies could 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 if a resurgence of COVID-19 cases or macroeconomic conditions worsen, we may experience a continuing adverse effect on the demand for some of our products. The degree of impact of any 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.

During the COVID-19 pandemic, FDA has issued various COVID-19 related guidance documents applicable to biopharmaceutical manufacturers and clinical trial sponsors many of which have expired or were withdrawn with the expiration of the COVID-19 public health emergency declaration in May 2023, although some COVID-19 related guidance documents continue in effect. 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.

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 any ongoing pandemic, including any resurgence of COVID-19 cases, 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, any resurgence of COVID-19 cases, and 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.

***The FDA approval process for changes to existing products (such as change of components or API supplier) is time-consuming and complicated, and we may not obtain the FDA approval required for a such changes within the timeline we desire, or at all.***

The development, testing, manufacturing, marketing and sale of generic and proprietary pharmaceutical products and biological products are subject to extensive federal, state and local regulation in the U.S. and other countries. Satisfaction of all regulatory requirements, which typically takes years for drugs that require regulatory approval in ANDAs, NDAs, biological license applications, or BLAs, or biosimilar applications is dependent upon the type, complexity and novelty of the product candidate and requires the expenditure of substantial resources for research (including qualification of suppliers and their supplied materials), development, in vitro and in vivo (including nonclinical and clinical trials) studies, manufacturing process development and commercial scale up. Some of our products are drug-device combination products that are regulated as drug products by the FDA, with consultation from the FDA's Center for Device and Radiological Health. These combination products require the submission of drug applications to the FDA. All of our products are subject to compliance with the FFDCA and/or the Public Health Service Act, or PHSA, and with the FDA's implementing regulations. Failure to adhere to applicable statutory or regulatory requirements by us or our business partners would have a material adverse effect on our operations and financial condition. In addition, in the event we are successful in developing product candidates for distribution and sale in other countries, we would become subject to regulation in such countries. Such foreign regulations and product approval requirements are expected to be time consuming and expensive as well.

We may encounter delays or agency rejections during any stage of the regulatory review and approval process based upon a variety of factors, including without limitation the failure to provide clinical data demonstrating compliance with the FDA's requirements for safety, efficacy and quality. Those requirements may become more stringent prior to submission of our applications for approval or during the review of our applications due to changes in the law or changes in FDA policy or the adoption of new regulations. After submission of an application, the FDA may refuse to file the application, deny approval of the application or require additional testing or data. The FDA can convene an Advisory Committee to assist the FDA in examining specific issues related to the application. For example, we initially filed an NDA, for our Primatene MIST® product in July 2013, but FDA approval was not granted until November 2018 due to delays caused by the FDA's requirement that we provide additional non-clinical information, label revision and follow-up studies (including label comprehension and behavioral/human factor studies), and that we make packaging and label revisions. Additionally, we received Complete Response Letters, or CRLs, from the FDA asking for more information before they could approve the ANDA for our epinephrine vial product. These CRLs have delayed the approval of this product.

Under various user fee enactments, the FDA has committed to timelines for its review of NDAs, ANDAs, BLAs and biosimilar applications. However, the FDA's timelines described in its guidance on these statutes are flexible and subject to changes based on workload and other potential review issues that may delay the FDA's review of an application. Further, the terms of approval of any applications may be more restrictive than our expectations and could affect the marketability of our products.

The FDA also has the authority to revoke or suspend approvals of previously approved products for cause, to debar companies and individuals from participating in the approval process for ANDAs, to request recalls of allegedly violative products, to seize allegedly violative products, to obtain injunctions that may, among other things, close manufacturing plants that are not operating in conformity with cGMP and stop shipments of potentially violative products and to prosecute companies and individuals for violations of the FFDCA.

We were informed that one of our API suppliers has discontinued manufacturing an API included in one of our commercial products. We are currently in the process of qualifying one of our subsidiaries to supply the necessary API, and are required to obtain FDA approval of our new API supply. In the event the FDA does not grant approval or any additional approvals for the new API supply are delayed, such actions would temporarily force us to stop manufacturing our impacted commercial product, potentially for a considerable period of time. If we are forced to stop manufacturing this commercial product or any of our commercial products in the future, for any length of time, it could have a material effect on our operating results and financial condition.

***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. Various industry stakeholders, including pharmaceutical companies, the U.S. Chamber of Commerce, the National Infusion Center Association, the Global Colon Cancer Association, and the Pharmaceutical Research and Manufactures of America, have initiated lawsuits against the federal government asserting that the price negotiation provision of the Inflation Reduction Act are unconstitutional. The impact of these judicial challenges, legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the government 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, USE OF PROCEEDS, AND ISSUER PURCHASES OF EQUITY SECURITIES

### (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 |
|---|---|---|---|---|
| July 1 – July 31, 2023 | — | $ — | — | — |
| August 1 – August 31, 2023 | — | — | — | — |
| September 1 – September 30, 2023 | 1,072,041 | 46.64 | 1,072,041 | — |

(1) On August 28, 2023, we announced that our Board of Directors authorized an increase of $50.0 million to our share buyback program. As of September 30, 2023, $35.5 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**

*Securities Trading Plans of Directors and Executive Officers*

During our last fiscal quarter, none of our officers or directors, as defined in Rule 16a-1(f), adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement, each as defined in Regulation S-K Item 408.

**ITEM 6. EXHIBITS**

| Exhibit No. | Description |
|---|---|
| 4.1 | Indenture, dated September 15, 2023, between Amphastar Pharmaceuticals, Inc. and U.S. Bank Trust Company, National Association, as trustee (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on September 15, 2023) |
| 4.2 | Form of 2.00% Convertible Notes due 2029 (incorporated by reference to Exhibit 4.2 (included in Exhibit 4.1) of the Company's Current Report on Form 8-K filed with the SEC on September 15, 2023) |
| 10.1 | Purchase Agreement, dated September 12, 2023, among Amphastar Pharmaceuticals, Inc. and Jefferies LLC, J.P. Morgan Securities LLC, Wells Fargo Securities LLC and BofA Securities Inc. (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on September 15, 2023) |
| 31.1 | Certification pursuant to Rule 13a-14(a) or 15d-14a of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 31.2 | Certification of pursuant to Rule 13a-14(a) or 15d-14a of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 32.1# | Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 32.2# | Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 101.INS | XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document. |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document |
| 101.DEF | Inline XBRL Taxonomy Extension Definitions Linkbase Document |
| 104 | Cover Page Interactive File (Formatted as Inline XBRL and contained in Exhibit 101) |

# The information in Exhibits 32.1 and 32.2 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act (including this Report), unless the Registrant specifically incorporates the foregoing information into those documents by reference.

**SIGNATURES**

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

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

Date: November 8, 2023

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

Date: November 8, 2023

**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: November 8, 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: November 8, 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 September 30, 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: November 8, 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 September 30, 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: November 8, 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.