Table of Contents

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, 2024
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 1, 2024 was 48,081,433.

AMPHASTAR PHARMACEUTICALS, INC.
TABLE OF CONTENTS
FORM 10-Q FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2024

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 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: adverse impacts of the Russia-Ukraine and Middle East conflicts and challenging 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, pandemics, wars, terrorist attacks or other events;
- global, national and local economic and market conditions, specifically with respect to geopolitical uncertainty, including the Russia-Ukraine and Middle East conflicts, inflation and high 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, 2023, 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, 2024 (unaudited)	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 192,116	$ 144,296
Restricted cash	235	235
Short-term investments	58,375	112,510
Restricted short-term investments	2,200	2,200
Accounts receivable, net	139,635	114,943
Inventories	130,316	105,833
Income tax refunds and deposits	5,349	526
Prepaid expenses and other assets	17,723	9,057
Total current assets	545,949	489,600
Property, plant, and equipment, net	295,384	282,746
Finance lease right-of-use assets	426	564
Operating lease right-of-use assets	31,708	32,333
Investment in unconsolidated affiliate	—	527
Goodwill and intangible assets, net	594,796	613,295
Long-term investments	—	14,685
Other assets	23,663	25,910
Deferred tax assets	53,252	53,252
Total assets	$ 1,545,178	$ 1,512,912
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 153,268	$ 93,366
Accrued payments for BAQSIMI® (see Note 3)	—	126,090
Income taxes payable	1,281	1,609
Current portion of long-term debt	252	436
Current portion of operating lease liabilities	4,209	3,906
Total current liabilities	159,010	225,407
Long-term reserve for income tax liabilities	6,066	6,066
Long-term debt, net of current portion and unamortized debt issuance costs	596,446	589,579
Long-term operating lease liabilities, net of current portion	28,941	29,721
Other long-term liabilities	27,037	22,718
Total liabilities	817,500	873,491
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; 60,690,076 and 48,372,997 shares issued and outstanding, respectively, as of September 30, 2024 and 59,390,194 and 48,068,881 shares issued and outstanding, respectively, as of December 31, 2023	6	6
Additional paid-in capital	496,427	486,056
Retained earnings	530,823	409,268
Accumulated other comprehensive loss	(8,821)	(8,478)
Treasury stock	(290,757)	(247,431)
Total equity	727,678	639,421
Total liabilities and stockholders' equity	$ 1,545,178	$ 1,512,912

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,	
	2024	2023	2024	2023
Net revenues:				
Product revenues, net	$ 188,819	$ 151,855	$ 525,836	$ 437,589
Other revenues	2,395	28,701	19,608	28,701
Total net revenues	191,214	180,556	545,444	466,290
Cost of revenues	89,273	72,153	258,237	211,309
Gross profit	101,941	108,403	287,207	254,981
Operating expenses:				
Selling, distribution, and marketing	8,995	6,407	27,378	20,234
General and administrative	14,821	12,654	43,782	38,418
Research and development	21,077	16,664	55,772	53,322
Total operating expenses	44,893	35,725	126,932	111,974
Income from operations	57,048	72,678	160,275	143,007
Non-operating income (expenses):				
Interest income	2,427	1,202	8,320	3,156
Interest expense	(6,698)	(13,702)	(23,918)	(17,702)
Other income (expenses), net	(5,094)	3,459	1,125	1,553
Total non-operating income (expenses), net	(9,365)	(9,041)	(14,473)	(12,993)
Income before income taxes	47,683	63,637	145,802	130,014
Income tax provision	7,254	14,025	23,674	27,160
Income before equity in losses of unconsolidated affiliate	40,429	49,612	122,128	102,854
Equity in losses of unconsolidated affiliate	—	(390)	(573)	(1,476)
Net income	$ 40,429	$ 49,222	$ 121,555	$ 101,378
Net income per share:				
Basic	$ 0.83	$ 1.01	$ 2.50	$ 2.10
Diluted	$ 0.78	$ 0.91	$ 2.32	$ 1.91
Weighted-average shares used to compute net income per share:				
Basic	48,621	48,701	48,580	48,368
Diluted	51,862	53,921	52,307	52,997

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,	
	2024	2023	2024	2023
Net income	$ 40,429	$ 49,222	$ 121,555	$ 101,378
Other comprehensive income (loss), net of income taxes				
Foreign currency translation adjustment	5	(87)	(343)	213
Total other comprehensive income (loss)	5	(87)	(343)	213
Total comprehensive income	$ 40,434	$ 49,135	$ 121,212	$ 101,591

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 Income (loss)	Treasury Stock		Total
	Shares	Amount				Shares	Amount	
Balance as of December 31, 2023	59,390,194	$ 6	$ 486,056	$ 409,268	$ (8,478)	(11,321,313)	$ (247,431)	$ 639,421
Net income	—	—	—	43,177	—	—	—	43,177
Other comprehensive loss	—	—	—	—	(291)	—	—	(291)
Issuance of treasury stock in connection with the Company's equity plans	—	—	(33)	—	—	2,197	33	—
Issuance of common stock in connection with the Company's equity plans	770,265	—	(17,311)	—	—	—	—	(17,311)
Share-based compensation expense	—	—	7,360	—	—	—	—	7,360
Balance as of March 31, 2024	60,160,459	$ 6	$ 476,072	$ 452,445	$ (8,769)	(11,319,116)	$ (247,398)	$ 672,356
Net income	—	—	—	37,949	—	—	—	37,949
Other comprehensive loss	—	—	—	—	(57)	—	—	(57)
Purchase of treasury stock	—	—	—	—	—	(207,288)	(8,498)	(8,498)
Issuance of treasury stock in connection with the Company's equity plans	—	—	(97)	—	—	6,363	97	—
Issuance of common stock in connection with the Company's equity plans	321,996	—	5,816	—	—	—	—	5,816
Share-based compensation expense	—	—	5,780	—	—	—	—	5,780
Balance as of June 30, 2024	60,482,455	$ 6	$ 487,571	$ 490,394	$ (8,826)	(11,520,041)	$ (255,799)	$ 713,346
Net income	—	—	—	40,429	—	—	—	40,429
Other comprehensive income	—	—	—	—	5	—	—	5
Purchase of treasury stock	—	—	—	—	—	(797,038)	(34,958)	(34,958)
Issuance of common stock in connection with the Company's equity plans	207,621	—	3,260	—	—	—	—	3,260
Share-based compensation expense	—	—	5,596	—	—	—	—	5,596
Balance as of September 30, 2024	60,690,076	$ 6	$ 496,427	$ 530,823	$ (8,821)	(12,317,079)	$ (290,757)	$ 727,678

	Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (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

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,	
	2024	**2023**
Cash Flows From Operating Activities:		
Net income	$ 121,555	$ 101,378
Reconciliation to net cash provided by operating activities:		
Loss on disposal of assets	110	474
Impairment of long-lived assets	—	2,700
Loss (gain) on interest rate swaps and foreign currency transactions, net	1,496	(1,019)
Depreciation of property, plant, and equipment	20,992	18,559
Amortization of product rights, trademarks, and patents	18,539	6,651
Operating lease right-of-use asset amortization	3,010	2,778
Amortization of discounts, premiums, and debt issuance costs	5,308	8,486
Equity in losses of unconsolidated affiliate	573	1,476
Share-based compensation expense	18,736	15,620
Changes in operating assets and liabilities:		
Accounts receivable, net	(24,577)	(30,175)
Inventories	(24,329)	(6,537)
Prepaid expenses and other assets	(10,489)	105
Income tax refunds, deposits, and payable, net	(5,147)	25,185
Operating lease liabilities	(2,866)	(2,667)
Accounts payable and accrued liabilities	61,451	16,625
Net cash provided by operating activities	184,362	159,639
Cash Flows From Investing Activities:		
BAQSIMI® acquisition (see Note 3)	(129,000)	(506,406)
Purchases and construction of property, plant, and equipment	(28,630)	(28,724)
Purchase of investments	(47,507)	(52,802)
Maturity of investments	118,538	38,801
Deposits and other assets	(2,653)	3,064
Net cash used in investing activities	(89,252)	(546,067)
Cash Flows From Financing Activities:		
Proceeds from equity plans, net of withholding tax payments	(8,234)	7,414
Purchase of treasury stock	(43,456)	(58,144)
Debt issuance costs	(838)	(24,589)
Proceeds from borrowing under lines of credit	13,565	—
Proceeds from issuance of long-term debt	—	845,000
Principal payments on long-term debt	(8,148)	(268,506)
Net cash provided by (used in) financing activities	(47,111)	501,176
Effect of exchange rate changes on cash	(179)	(44)
Net increase in cash, cash equivalents, and restricted cash	47,820	114,704
Cash, cash equivalents, and restricted cash at beginning of period	144,531	156,333
Cash, cash equivalents, and restricted cash at end of period	$ 192,351	$ 271,037
Noncash Investing and Financing Activities:		
Deferred payment for BAQSIMI® acquisition	$ —	$ 121,699
Capital expenditures included in accounts payable	$ 5,120	$ 4,496
Operating lease right-of-use assets in exchange for operating lease liabilities	$ 2,386	$ 9,890
Supplemental Disclosures of Cash Flow Information:		
Interest paid, net of capitalized interest	$ 22,389	$ 12,098
Income taxes paid	$ 29,000	$ 2,136

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, 2023 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, 2023. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with accounting principles generally accepted in the United States of America, 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 presentation of the Company's consolidated financial position, results of operations, comprehensive income, 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 and cash flows for the interim periods are not necessarily indicative of the results of operations and cash flows that it may achieve in future periods.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited condensed consolidated financial statements include the accounts of the Company and its subsidiaries, and are prepared in accordance with GAAP. All intercompany activity has been eliminated in the preparation of the condensed consolidated financial statements. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, which are of a normal recurring nature, necessary to present fairly the consolidated financial position, results of operations, and cash flows of the Company.

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

Investment 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. 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 condensed consolidated statements of operations. Investments accounted for using the equity method may be reported on a lag of up to three months if financial statements of the investee are not available in sufficient time for the investor to apply the equity method as of the current reporting date.

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

The carrying value of equity method investments is reported as "Investment in unconsolidated affiliate" in the accompanying condensed 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.

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, 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, 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 books of record in euros. AUK's subsidiary, IMS UK, maintains its books 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 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 $1.4 million gain and a $0.4 million gain for the three and nine months ended September 30, 2024, respectively. For the three and nine months ended September 30, 2023, 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, respectively.

Comprehensive Income

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

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.

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

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, 2024, advertising expenses were $2.5 million and $7.8 million, respectively. For the three and nine months ended September 30, 2023, advertising expenses were $1.9 million and $8.1 million, respectively.

Financial Instruments

The Company's accompanying condensed consolidated balance sheets include the following financial instruments: cash and cash equivalents, restricted cash, accounts receivable, accounts payable, accrued expenses, short-term borrowings, and long-term obligations. The Company considers the carrying amounts of current assets and liabilities on the condensed consolidated balance sheets to approximate the fair value of these financial instruments due to the short maturity of these items. The carrying value of the Company's long-term obligations, with the exception of the convertible debt (see Note 14), approximates their fair value, as the stated borrowing rates are comparable to rates currently offered to the Company for instruments with similar maturities. Investments and short-term investments are recorded at fair value based on quoted prices from recognized security exchanges and other methods (see Note 9). 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.

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

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, 2024 and December 31, 2023 consisted of certificates of deposit and investment grade corporate, agency and municipal bonds with original maturity dates between three and fifteen months.

Restricted Cash

Restricted cash is collateral required for the Company to guarantee certain vendor payments in France. As of September 30, 2024 and December 31, 2023, the restricted cash balance was $0.2 million.

Restricted Short-Term Investments

Restricted short-term investments consist of certificates of deposit that are collateral for standby letters of credit to qualify for workers' compensation self-insurance. The certificates of deposit have original maturities greater than three months, but less than one year. As of September 30, 2024 and December 31, 2023, 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.

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 Accounting Standards Codification, or ASC, 815-15, *Derivatives and Hedging* and the Company did not issue its convertible debt instruments at a substantial premium. The Company records debt issuance costs as contra-liabilities in its condensed 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 Accounting Standards Update, or 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

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

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 debt instruments are accounted for as a single liability measured at its amortized cost as long as no other features require separation and recognition as derivatives.

Litigation, Commitments and Contingencies

Litigation, commitments and contingencies are accrued when management, after considering the facts and circumstances of each matter as then known to management, has determined it is probable a liability will be found to have been incurred and the amount of the loss can be reasonably estimated. When only a range of amounts is reasonably estimable and no amount within the range is more likely than another, the low end of the range is recorded. Legal fees are expensed as incurred. Due to the inherent uncertainties surrounding gain contingencies, the Company generally does not recognize potential gains until they are realized.

Recent Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* which is intended to improve reportable segment disclosure requirements, primarily through additional disclosures about significant segment expenses. The standard is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The amendments should be applied retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the disclosure requirements related to the new standard.

In December 2023, the FASB issued Accounting Standard Update 2023-09, *Income taxes (Topic 740): Improvements to Income Tax Disclosures* which requires entities to disclose disaggregated information about their effective tax rate reconciliation as well as expanded information on income taxes paid by jurisdiction. The disclosure requirements will be applied on a prospective basis, with the option to apply them retrospectively. The standard is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the disclosure requirements related to the new standard.

Note 3. BAQSIMI® Asset 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.

The Company accounted for the BAQSIMI® acquisition as an asset acquisition in accordance with ASC 805, *Business Combination*s, as substantially all the fair value of the assets acquired was 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.

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

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

	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 amortizes the acquired intangible asset to cost of revenues on a straight line basis over its estimated useful life of 24 years (see Note 10 for additional information).

A portion of the consideration for the asset acquisition was a deferred cash payment. The fair value of the deferred cash payment was accreted to its full $129.0 million amount over a one-year period from the date of acquisition through interest expense. During the nine months ended September 30, 2024, the Company recognized $3.6 million of interest expense related to accretion of the deferred cash payment. During the three and nine months ended September 30, 2023, $1.8 million of interest expense was recognized related to the accretion of the deferred cash payment. The Company made the $129.0 million deferred cash payment in June 2024.

The Company may also be required to pay additional contingent consideration of up to an aggregate of $575.0 million in cash as part of the BAQSIMI® acquisition, based on the achievement of certain net sales milestones. Through September 30, 2024, the Company has not triggered any milestones and therefore no amounts have been recognized or paid.

Manufacturing Services Agreement

In connection with the closing of the acquisition, 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 of the acquisition, the Company also 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 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.

Throughout 2024, the Company assumed distribution responsibilities, from Lilly, to its customers in the United States, and certain other countries. As a result, the Company has recorded the sales and related cost of BAQSIMI® in these countries as product revenue, net and cost of revenues, respectively. The Company will continue to assume distribution of BAQSIMI® for the remaining territories on a country by country basis throughout 2024.

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

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 to which the Company expects to be entitled includes a stated list price, less various forms of variable consideration including provision for chargebacks and rebates, accrual for product returns, prompt pay discounts, distributor fees, patient co-pay assistance, and other related deductions. These deductions to product sales are referred to as gross-to-net deductions and are estimated and recorded in the period in which the related product sales occur. Payment terms offered to customers generally range from 30 to 75 days; however, payment terms differ by jurisdiction, by customer and, in some instances, by type of product. Revenues from product sales, net of gross-to-net deductions, are recorded only to the extent a significant reversal in the amount of cumulative revenue recognized is not probable of occurring when the uncertainty associated with gross-to-net deductions is subsequently resolved. Taxes assessed by governmental authorities and collected from customers are excluded from product sales. If the Company expects, at contract inception, that the period between the transfer of control and corresponding payment from the customer will be one year or less, the amount of consideration is not adjusted for the effects of a financing component. Shipping and handling activities are considered to be fulfillment activities rather than a separate performance obligation and are recorded within selling, distribution and marketing expenses in the accompanying condensed consolidated statements of operations.

Provision for Chargebacks and Rebates: The provision for chargebacks and rebates is a significant estimate used in the recognition of revenue. Wholesaler chargebacks relate to sales terms under which the Company agrees to reimburse wholesalers for differences between the gross sales prices at which the Company sells its products to wholesalers and the actual prices of such products that wholesalers resell under the Company's various contractual arrangements with third parties such as hospitals and group purchasing organizations in the United States. Rebates include primarily amounts paid to retailers, payers, and providers in the United States, including those paid to state Medicaid programs, and are based on contractual arrangements or statutory requirements. The Company estimates chargebacks and rebates using the expected value method at the time of sale to wholesalers based on wholesaler inventory stocking levels, historical chargeback and rebate rates, and current contract pricing.

The provision for chargebacks and rebates is reflected as a component of product revenues, net. The following table is an analysis of the chargeback and rebate provision:

	Nine Months Ended September 30,	
	2024	2023
	(in thousands)	
Beginning balance	$ 27,920	$ 26,606
Provision for chargebacks and rebates	218,312	200,317
Credits and payments issued to third parties	(181,216)	(201,650)
Ending balance	$ 65,016	$ 25,273

Changes in the chargeback provision from period to period are primarily dependent on the Company's sales to its wholesalers, the level of inventory held by wholesalers, and the wholesalers' customer mix. Changes in the rebate provision from period to period are primarily dependent on retailers' and other indirect customers' purchases. The approach that the Company uses to estimate chargebacks and rebates has been consistently applied for all periods

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

presented. Variations in estimates have been historically small. The Company continually monitors the provision for chargebacks and rebates and makes adjustments when it believes that the actual chargebacks and rebates may differ from the estimates. The settlement of chargebacks and rebates generally occurs within 20 days to 60 days after the sale to wholesalers. Accounts receivable and/or accounts payable and accrued liabilities are reduced and/or increased by the chargebacks and rebate amounts depending on whether the Company has the right to offset with the customer.

The provision for chargebacks and rebates is included in the following balance sheet accounts:

	September 30, 2024	December 31, 2023
	(in thousands)	
Reduction to accounts receivable, net	$ 21,355	$ 21,861
Accounts payable and accrued liabilities	43,661	6,059
Total	$ 65,016	$ 27,920

Accrual for Product Returns: The Company offers certain 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.

Prompt Pay Discounts: The Company provides its customers with a percentage discount on their invoice if the customers pay within the agreed upon timeframe. The Company expects that its customers will earn prompt pay discounts. The Company estimates the probability of customers paying promptly based on the percentage of discount outlined in the purchase agreement between the two parties, and deducts the full amount of these discounts from gross product sales and accounts receivable at the time revenue is recognized.

Distributor Fees: The Company engages with wholesalers to distribute its products to end customers. The Company pays the wholesalers a fee for services such as: inventory management, chargeback administration, and service level commitments. The Company estimates the amount of distribution services fees to be paid and adjusts the transaction price with the amount of such estimate at the time of sale to the customer. An accrued liability is recorded for unpaid distribution service fees.

Patient Co-Pay Assistance: Co-pay assistance represents financial assistance to qualified patients, assisting them with prescription drug co-payments required by insurance. The accrual for co-pay is based on an estimate of claims and the cost per claim that the Company expects to receive associated with inventory that exists in the distribution channel at period end.

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.

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

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

nine months ended September 30, 2024, revenues from research and development services were $0.1 million and $2.0 million, respectively. For the three and nine months ended September 30, 2023, revenues from research and development services were $0.8 million and $2.1 million, respectively.

Other revenues

Revenues related to sales of BAQSIMI®, which was supplied and sold by Lilly under the TSA during the three and nine months ended September 30, 2024 and 2023, or BAQSIMI® NEB, were recorded on a net basis, similar to a royalty arrangement. This includes revenues in the United States and certain other countries for a portion of the period.

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 and shares issuable under the Company's Employee Stock Purchase Plan, or ESPP, and potential shares of common stock issuable upon conversion of Convertible Notes of the Company, due March 2029, or the 2029 Convertible Notes.

For the three and nine months ended September 30, 2024, options to purchase 619,847 shares of stock with a weighted-average exercise price of $46.63 per share, were excluded in the computation of diluted net income per share because their 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 months ended September 30, 2023, none of the Company's options were excluded from the computation of diluted net income per share. 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 from the computation of diluted net income per share because their 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.

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,	
	2024	2023	2024	2023
	(in thousands, except per share data)			
Basic and dilutive numerator:				
Net income	$ 40,429	$ 49,222	$ 121,555	$ 101,378
Denominator:				
Weighted-average shares outstanding — basic	48,621	48,701	48,580	48,368
Net effect of dilutive securities:				
Incremental shares from equity awards	3,241	5,220	3,727	4,629
Weighted-average shares outstanding — diluted	51,862	53,921	52,307	52,997
Net income per share — basic	$ 0.83	$ 1.01	$ 2.50	$ 2.10
Net income per share — diluted	$ 0.78	$ 0.91	$ 2.32	$ 1.91

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

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 BAQSIMI®, 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 includes the portion of BAQSIMI® sales by Lilly on the Company's behalf under the TSA and is accounted for as a component of the finished pharmaceutical product segment.

Selected financial information by reporting segment is presented below:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(in thousands)			
Net revenues:				
Finished pharmaceutical products	$ 189,752	$ 176,366	$ 538,755	$ 455,242
API	1,462	4,190	6,689	11,048
Total net revenues	191,214	180,556	545,444	466,290
Gross profit (loss):				
Finished pharmaceutical products	105,544	109,499	302,322	262,742
API	(3,603)	(1,096)	(15,115)	(7,761)
Total gross profit	101,941	108,403	287,207	254,981
Operating expenses	44,893	35,725	126,932	111,974
Income from operations	57,048	72,678	160,275	143,007
Non-operating (expenses) income	(9,365)	(9,041)	(14,473)	(12,993)
Income before income taxes	$ 47,683	$ 63,637	$ 145,802	$ 130,014

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.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(in thousands)			
Finished pharmaceutical products segment net revenues:				
BAQSIMI®	$ 40,409	$ —	$ 85,106	$ —
Glucagon	26,792	29,514	82,700	82,486
Epinephrine	21,341	20,199	75,392	57,004
Primatene MIST®	26,055	24,834	73,077	64,837
Lidocaine	15,884	15,522	41,457	43,174
Phytonadione	11,721	7,449	31,998	33,017
Enoxaparin	5,615	7,702	17,984	25,441
Naloxone	4,037	4,715	12,124	14,774
Other finished pharmaceutical products	35,503	37,730	99,309	105,808
Total finished pharmaceutical products net revenues	187,357	147,665	519,147	426,541
BAQSIMI® NEB	2,395	28,701	19,608	28,701
Total finished pharmaceutical products segment net revenues	$ 189,752	$ 176,366	$ 538,755	$ 455,242

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,	
	2024	2023	2024	2023
	(in thousands)			
Depreciation and amortization expense				
Finished pharmaceutical products	$ 8,755	$ 8,616	$ 26,086	$ 13,143
API	1,038	1,003	3,045	2,938
Total depreciation and amortization expense	$ 9,793	$ 9,619	$ 29,131	$ 16,081

Net revenues and carrying values of long-lived assets, which includes property, plant and equipment, as well as finance and operating lease right-of-use assets, by geographic regions, based on where the Company conducts its operations are as follows:

	Net Revenues				Long-Lived Assets	
	Three Months Ended September 30,		Nine Months Ended September 30,		September 30,	December 31,
	2024	2023	2024	2023	2024	2023
	(in thousands)					
United States[1]	$ 186,514	$ 178,056	$ 532,591	$ 459,909	$ 187,410	$ 186,083
China	178	833	2,145	2,142	103,009	91,913
France	4,522	1,667	10,708	4,239	37,099	37,647
Total	$ 191,214	$ 180,556	$ 545,444	$ 466,290	$ 327,518	$ 315,643

(1) Includes Other revenues from the sales of BAQSIMI®.

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

Note 7. Customer and Supplier Concentration

Customer Concentrations

Three large wholesale drug distributors, Cencora Inc., formally AmerisourceBergen, or Cencora, Cardinal Health, Inc., or Cardinal, and McKesson Corporation, or McKesson, are all distributors of the Company's products, as well as suppliers of a broad range of health care products. Lilly currently manufactures and sells BAQSIMI® on the Company's behalf pursuant to the terms of the TSA in certain jurisdictions (see Note 3 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, 2024 and 2023, and accounts receivable as of September 30, 2024 and December 31, 2023, respectively. The following table provides accounts receivable and net revenue information for these major customers:

	% of Total Accounts Receivable		% of Net Revenues			
			Three Months Ended September 30,		Nine Months Ended September 30,	
	September 30, 2024	December 31, 2023	2024	2023	2024	2023
McKesson	29 %	26 %	26 %	22 %	25 %	25 %
Cencora	28 %	16 %	21 %	17 %	20 %	20 %
Cardinal Health	17 %	13 %	20 %	15 %	20 %	16 %
Lilly	2 %	20 %	1 %	16 %	4 %	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.

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

As of September 30, 2024 and December 31, 2023, cash equivalents include money market accounts and corporate and municipal bonds with original maturities of less than three months. Investments consist of certificates of deposit as well as investment-grade corporate, agency and municipal bonds with original maturity dates between three and 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. The fair value of such bonds is disclosed in Note 9 and was 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 values of the Company's financial assets and liabilities measured on a recurring basis as of September 30, 2024 and December 31, 2023, are as follows:

	Total	(Level 1)	(Level 2)	(Level 3)
		(in thousands)		
Cash equivalents	$ 143,637	$ 143,637	$ —	$ —
Restricted cash	235	235	—	—
Short-term investments	26,322	—	26,322	—
Restricted short-term investments	2,200	—	2,200	—
Interest rate swaps related to variable rate loans	(6,881)	—	(6,881)	—
Total assets and liabilities measured at fair value as of September 30, 2024	$ 165,513	$ 143,872	$ 21,641	$ —

	Total	(Level 1)	(Level 2)	(Level 3)
		(in thousands)		
Cash equivalents	$ 116,441	$ 116,441	$ —	$ —
Restricted cash	235	235	—	—
Short-term investments	37,142	—	37,142	—
Restricted short-term investments	2,200	—	2,200	—
Interest rate swaps related to variable rate loans	(5,243)	—	(5,243)	—
Total assets and liabilities measured at fair value as of December 31, 2023	$ 150,775	$ 116,676	$ 34,099	$ —

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, 2024, and December 31, 2023, 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.

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

Note 9. Investments

The following is a summary of the Company's investments that are classified as held-to-maturity:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
Corporate and agency bonds (due within 1 year)	$ 31,903	$ 67	$ (2)	$ 31,968
Total investments as of September 30, 2024	$ 31,903	$ 67	$ (2)	$ 31,968
Corporate and agency bonds (due within 1 year)	$ 73,815	$ 7	$ (21)	$ 73,801
Corporate and agency bonds (due within 1 to 3 years)	14,621	56	(1)	14,676
Municipal bonds (due within 1 year)	1,081	1	—	1,082
Total investments as of December 31, 2023	$ 89,517	$ 64	$ (22)	$ 89,559

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.

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	$ 30,799	$ 560,539
Patents	15	193	92	101
Land-use rights	39	2,540	865	1,675
Subtotal	24	594,071	31,756	562,315
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill - Finished pharmaceutical products	*	3,256	—	3,256
Subtotal	*	32,481	—	32,481
As of September 30, 2024	*	$ 626,552	$ 31,756	$ 594,796

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

	Weighted-Average Life (Years)	Original Cost	Accumulated Amortization	Net Book Value
		(in thousands)		
Definite-lived intangible assets				
BAQSIMI® product rights[1]	24	$ 591,338	$ 12,319	$ 579,019
Patents	12	486	376	110
Land-use rights	39	2,540	815	1,725
Subtotal	24	594,364	13,510	580,854
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill - Finished pharmaceutical products	*	3,216	—	3,216
Subtotal	*	32,441	—	32,441
As of December 31, 2023	*	$ 626,805	$ 13,510	$ 613,295

* Intangible assets with indefinite lives have an indeterminable average life.
(1) See Note 3.

Goodwill

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

	September 30, 2024	December 31, 2023
	(in thousands)	
Beginning balance	$ 3,216	$ 3,126
Currency translation	40	90
Ending balance	$ 3,256	$ 3,216

Note 11. Inventories

Inventories consist of the following:

	September 30, 2024	December 31, 2023
	(in thousands)	
Raw materials and supplies	$ 60,536	$ 50,082
Work in process	36,016	30,822
Finished goods	33,764	24,929
Total inventories	$ 130,316	$ 105,833

Charges of $0.9 million and $10.1 million were included in the cost of revenues in the Company's condensed consolidated statements of operations for the three and nine months ended September 30, 2024, respectively, to adjust the Company's inventory and related firm purchase commitments to its net realizable value. For the three months ended September 30, 2023, the Company had an immaterial amount that was included in cost of revenues to adjust the Company's inventory and related firm purchase commitments to its net realizable value. For the nine months ended September 30, 2023, charges of $9.6 million were included in the cost of revenues to adjust the Company's inventory and related firm purchase commitments to its net realizable value.

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

Note 12. Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

	September 30, 2024	December 31, 2023
	(in thousands)	
Buildings	$ 170,203	$ 168,771
Leasehold improvements	42,012	41,686
Land	7,499	7,484
Machinery and equipment	278,200	259,484
Furniture, fixtures, and automobiles	34,795	31,943
Construction in progress	28,864	18,676
Total property, plant, and equipment	561,573	528,044
Less accumulated depreciation	(266,189)	(245,298)
Total property, plant, and equipment, net	$ 295,384	$ 282,746

Note 13. Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consisted of the following:

	September 30, 2024	December 31, 2023
	(in thousands)	
Accrued customer fees and rebates	$ 59,949	$ 16,702
Accrued payroll and related benefits	29,207	25,203
Accrued product returns, current portion	13,480	12,263
Accrued loss on firm purchase commitments	812	918
Other accrued liabilities	15,732	12,842
Total accrued liabilities	119,180	67,928
Accounts payable	34,088	25,438
Total accounts payable and accrued liabilities	$ 153,268	$ 93,366

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

Note 14. Debt

Debt consists of the following:

	September 30, 2024	December 31, 2023
	(in thousands)	
Convertible Debt		
2029 Convertible Notes	$ 345,000	$ 345,000
Term Loan		
Wells Fargo Term Loan due June 2028	250,000	250,000
Mortgage Loans		
Mortgage payable with East West Bank paid off June 2024	—	8,016
Other Loans and Payment Obligations		
French government loans due December 2026	168	158
Line of Credit Facilities		
Line of credit facility with China Merchant Bank due October 2026	—	—
Wells Fargo Revolving line of credit facility due June 2028	—	—
Line of credit facility with ICBC Bank due November 2033	13,565	—
Equipment under Finance Leases	485	616
Total debt	609,218	603,790
Less current portion of long-term debt	252	436
Less: Loan issuance costs	12,520	13,775
Long-term debt, net of current portion and unamortized debt issuance costs	$ 596,446	$ 589,579

Credit Agreement

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 $8.8 million as of September 30, 2024. The fair value of the 2029 Convertible Notes was approximately $365.4 million as of September 30, 2024 based on level 2 inputs.
The 2029 Convertible Notes are general senior, unsecured obligations and bear an interest rate of 2.0% per year. The

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

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 is payable semi-annually in arrears on March 15 and September 15 of each year. 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.

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

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

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 Line of Credit Facility with ICBC Bank – Due November 2033

In January 2024, the Company entered into a credit agreement with Industrial and Commercial Bank of China Limited, or ICBC Bank, acting as a lender and as agent for other lenders. The credit agreement allows the Company to borrow up to $40.0 million secured by equipment and buildings at ANP. The interest rate and other terms will be determined at the time of the borrowing, depending on the type of loan requested. The credit agreement expires in November 2033.

As of September 30, 2024, the Company borrowed approximately $13.6 million under the credit agreement. The loan bears interest at the prime rate as published by The People's Bank of China minus 0.2%. Interest payments are due quarterly and repayment of the principal amount is biannual and begins in May 2026. As of September 30, 2024, the Company had $13.6 million of principal outstanding under this loan, which is recorded net of loan issuance costs of $0.8 million.

Interest Rate Swap Contract

As of September 30, 2024, the fair value of the loans listed above approximated their carrying amount based on Level 2 inputs, with the exception of the 2029 Convertible Notes. For the Wells Fargo Term Loan, the Company has entered into a fixed interest rate swap contract to exchange the variable interest rates for fixed interest rates. The interest rate swap contract is 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 $7.4 million loss and $1.6 million loss for the three and nine months ended September 30, 2024, respectively. 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.

Covenants

At September 30, 2024 and December 31, 2023, the Company was in compliance with all of its debt covenants.

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

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,	
	2024	2023	2024	2023
	(in thousands)			
Income before taxes	$ 47,683	$ 63,637	$ 145,802	$ 130,014
Income tax provision	7,254	14,025	23,674	27,160
Income before equity in losses of unconsolidated affiliate	$ 40,429	$ 49,612	$ 122,128	$ 102,854
Income tax provision as a percentage of income before income taxes	15.2 %	22.0 %	16.2 %	20.9 %

Valuation Allowance

In assessing the need for a valuation allowance, management considers whether it is more likely than not that some portion or all of the deferred income tax assets will be realized. Ultimately, realization depends on the existence of future taxable income. Management considers sources of taxable income such as income in prior carryback periods, future reversal of existing deferred taxable temporary differences, tax-planning strategies, and projected future taxable income.

The Company continues to record a full valuation allowance on the net deferred income tax assets of its France subsidiary, AFP, and its U.K. subsidiaries, AUK and IMS UK. The Company will continue to do so until the subsidiaries generate sufficient taxable income to realize their respective deferred income tax assets.

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

Note 16. Stockholders' Equity

Share Buyback Program

Pursuant to the Company's existing share buyback program, the Company purchased 797,038 and 1,004,326 shares of its common stock, during the three and nine months ended September 30, 2024, for total consideration of $35.0 million and $43.5 million, respectively. 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's Board of Directors authorized a $50.0 million increase to the Company's share buyback program in June 2024, and an additional $50.0 million increase in November 2024, which is expected to continue for an indefinite period of time. Since the inception of the program, the Company's Board of Directors has authorized a total of $385.0 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.

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

Amended and Restated 2015 Equity Incentive Plan

In February 2024, the Board of Directors approved the Company's amended and restated 2015 Equity Incentive Plan, or the Amended 2015 Plan, which was subsequently approved by the Company's stockholders, and accordingly, adopted by the Company in June 2024. The Amended 2015 Plan extends the terms of the 2015 Equity Incentive Plan, or the Original 2015 Plan, and makes certain other changes. The term of the Amended 2015 Plan will be extended indefinitely, however, the Company's ability to grant incentive stock options thereunder will continue through February 2034.

As of September 30, 2024, the Company reserved an aggregate of 7,817,319 shares of common stock for future issuance under the Amended 2015 Plan.

2014 Employee Stock Purchase Plan

As of September 30, 2024, the Company has issued 1,246,323 shares of common stock under the ESPP and 753,677 shares of its common stock remain available for issuance under the ESPP.

In May 2024, the Company issued 54,189 shares at a purchase price of $35.98 per share under the ESPP. For the three and nine months ended September 30, 2024, the Company recorded ESPP expense of $0.2 million and $0.9 million, respectively. For the three and nine months ended September 30, 2023, the Company recorded ESPP expense of $0.2 million and $0.8 million, respectively.

Share-Based Award Activity and Balances

The Company accounts for share-based compensation payments in accordance with ASC 718, which requires measurement and recognition of compensation expense at fair value for all share-based payment awards made to employees and directors. Under these standards, the fair value of option awards and the option components of the ESPP awards are estimated at the grant date using the Black-Scholes option-pricing model. The fair value of RSUs is estimated at the grant date using the Company's common share price. Compensation cost for all share-based payments granted with service-based graded vesting schedules is recognized using the straight-line method over the requisite service period.

The weighted-averages for key assumptions used in determining the fair value of options granted are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Average volatility	— %	40.2 %	41.3 %	41.4 %
Average risk-free interest rate	— %	4.4 %	4.2 %	4.1 %
Weighted-average expected life in years	—	6.3	6.2	6.2
Dividend yield rate	— %	— %	— %	— %

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

A summary of option activity under all plans for the nine months ended September 30, 2024, 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, 2023	7,762,298	$ 19.70		
Options granted	642,985	46.27		
Options exercised	(1,611,117)	13.66		
Options forfeited	(21,138)	35.10		
Options expired	—	—		
Outstanding as of September 30, 2024	6,773,028	$ 23.61	5.12	$ 168,760
Exercisable as of September 30, 2024	4,968,365	19.02	3.97	$ 146,600
Vested and expected to vest as of September 30, 2024	6,617,113	23.24	5.04	$ 167,346

(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, 2024.

For the three and nine months ended September 30, 2024, the Company recorded expense of $2.7 million and $9.0 million, respectively, related to stock options granted under all plans. 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.

Information relating to option grants and exercises is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(in thousands, except per share data)			
Weighted-average grant date fair value per share	$ —	$ 21.49	$ 21.89	$ 16.76
Intrinsic value of options exercised	6,218	5,628	48,381	24,544
Cash received from options exercised	3,332	2,277	9,154	12,015
Total fair value of the options vested during the period	111	167	9,815	8,887

A summary of the status of the Company's non-vested options as of September 30, 2024, and changes during the nine months ended September 30, 2024, are presented below:

	Options	Weighted-Average Grant Date Fair Value
Non-vested as of December 31, 2023	2,076,355	$ 12.68
Options granted	642,985	21.89
Options vested	(893,539)	10.98
Options forfeited	(21,138)	16.19
Non-vested as of September 30, 2024	1,804,663	16.76

As of September 30 2024, there was $21.3 million of total unrecognized compensation cost, net of forfeitures, related to non-vested stock option based compensation arrangements granted under all plans. The cost is expected to be recognized over a weighted-average period of 2.6 years and will be adjusted for future changes in estimated forfeitures.

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

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 four 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, 2024, the Company recorded total expenses of $2.7 million and $8.8 million, respectively, related to RSU awards granted under all plans. For the three and nine months ended September 30, 2023, the Company recorded expenses of $2.2 million and $7.3 million, respectively, related to RSU awards granted under all plans.

As of September 30, 2024, there was $22.6 million of total unrecognized compensation cost, net of forfeitures, related to non-vested RSU-based compensation arrangements granted under all plans. The cost is expected to be recognized over a weighted-average period of 2.6 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, 2023	920,376	
RSUs granted	303,788	$ 14,060
RSUs forfeited	(9,620)	
RSUs vested[2]	(388,668)	
RSUs outstanding at September 30, 2024	825,876	

(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, 147,959 shares of common stock were surrendered to fulfill tax withholding obligations.

Share-based Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(in thousands)			
Cost of revenues	$ 1,133	$ 1,004	$ 4,583	$ 3,868
Operating expenses:				
Selling, distribution, and marketing	249	213	777	649
General and administrative	3,710	2,975	11,239	9,323
Research and development	504	452	2,137	1,780
Total share-based compensation	$ 5,596	$ 4,644	$ 18,736	$ 15,620

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

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, 2024 were approximately $0.6 million and $2.0 million, respectively, compared to the prior year expense of $0.5 million and $1.7 million for the three and nine months ended September 30, 2023, 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 3.25% as of September 30, 2024 and December 31, 2023. 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 $2.8 million and $2.6 million at September 30, 2024 and December 31, 2023, respectively. The Company recorded an immaterial amount of expense under the plan for each of the three and nine months ended September 30, 2024 and 2023.

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 $9.4 million and $6.8 million as of September 30, 2024 and December 31, 2023, respectively. The plan liabilities were valued at approximately $9.8 million and $7.1 million as of September 30, 2024, and December 31, 2023, 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, 2024, the Company has entered into commitments to purchase equipment and raw materials for an aggregate amount of approximately $95.9 million.

Note 19. Related Party Transactions

Investment in Hanxin Pharmaceutical Technology, Co., Ltd.

The Company has an 11.5% ownership in Hanxin Pharmaceutical Technology Co., Ltd, or 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

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

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

The Company, has various contract manufacturing agreements with Hanxin and its subsidiaries, whereby Hanxin will develop several active pharmaceutical ingredients and finished products for the Chinese market and will engage the Company to manufacture the products on a cost-plus basis.

During the three and nine months ended September 30, 2024, the Company recognized $0.1 million and $0.5 million, respectively, of revenue from manufacturing services provided to Hanxin. 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, 2024, the Company had $0.4 million 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. Hanxin will also perform scale-up manufacturing process development using the RCBs for the Company.

During the three months ended September 30, 2024, the Company did not have any payments under the amended agreement and during the nine months ended September 30 2024, the Company paid $0.2 million under the amended agreement. During the three and nine months ended September 30, 2023, the Company paid $0.4 million and $1.0 million, respectively, under the amended agreement. As of September 30, 2024, the Company had an immaterial amount payable to Hanxin.

Supply Agreement with Letop

In November 2022, the Company, entered into a supply agreement with Nanjing Letop Biotechnology Co., Ltd., or Letop, which is considered a related-party due to an ownership stake of Henry Zhang. Under the terms of the supply agreement Letop will manufacture and deliver chemical intermediates to the Company on a cost-plus basis. The agreement is effective for three years and the total cost of the agreement shall not exceed $1.5 million, with payments adjusted based on the then current exchange rates.

During the three and nine months ended September 30, 2024, the Company paid an immaterial amount under this agreement. During the three months ended September 30, 2023, the Company did not have any payments under this agreement. During the nine months ended September 30, 2023, the Company paid $0.7 million, under this agreement. As of September 30, 2024, the Company did not have any amounts payable to Letop.

Primatene MIST® Distribution agreement with Hong Kong Genreach Limited

In August 2024, the Company entered into a distribution agreement with Hong Kong Genreach Limited, or Genreach, a wholly owned subsidiary of Hanxin, a related party. Per the terms of the agreement, the Company has appointed Genrearch as the exclusive distributor to market and sell Primatene MIST® in Mainland China, Taiwan, Hong Kong, and Macau in the Greater China region. Genreach will be responsible for obtaining any and all regulatory approvals in the region for Primatene MIST®.

The term of the agreement is ten years, with both parties having termination rights without cause after the completion of the second contract year.

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

Note 20. Litigation

Employment Litigation

On April 15, 2024, a former employee ("Plaintiff") initiated an employment litigation against Amphastar and IMS by filing a complaint, as amended, having individual and class action claims for alleged violations of the California Labor Code pertaining to wage and hour, and other state laws. This complaint was filed in the Superior Court of California for the County of Los Angeles. In the complaint, the Plaintiff is seeking damages and related remedies under California Law, as well as various penalty payments under the California Labor Code. The Company intends to vigorously defend itself against the class action complaint.

On June 20, 2024, a former employee ("Plaintiff") initiated an employment litigation against Amphastar, IMS and Roth Staffing Companies L.P. by filing a complaint having individual and class action claims for alleged violations of the California Labor Code pertaining to wage and hour, and other state laws. This complaint was filed in the Superior Court of California for the County of Los Angeles. In the complaint, the Plaintiff is seeking damages and related remedies under California Law, as well as various penalty payments under the California Labor Code. The Company intends to vigorously defend itself against the complaint.

Albuterol sulfate Inhalation Aerosol Patent Litigation

On July 25, 2024, Teva Branded Pharmaceutical Products R&D, Inc. ("Teva Branded"), Norton (Waterford) Ltd. ("Norton"), and Teva Pharmaceuticals USA, Inc. ("Teva USA"), collectively referred to as ("Plaintiff") filed a Complaint in the United States District Court for the District of Delaware ("Delaware Court") against the Company for infringement of U.S. Patent No. 9,463,289, with regard to Amphastar's ANDA No. 212447, for approval to manufacture and sell generic version of ProAir® HFA (albuterol sulfate) Inhalation Aerosol. On October 21, 2024, Plaintiff amended its complaint against the Company to include additional claims for infringement of U.S. Patent No. 9,808,587 and 10,561,808, with regard to Amphastar's ANDA No. 212447, for approval to manufacture and sell generic version of ProAir® HFA (albuterol sulfate) Inhalation Aerosol. The Company intends to vigorously defend this patent lawsuit.

Other litigation

The Company is subject to various 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. Currently, the Company is subject to a lawsuit for a property and casualty claim, for which it has recorded an estimated liability of $6.0 million within accounts payable and other accrued liabilities on the condensed balance sheet as of September 30, 2024. This estimated liability is fully covered by the Company's insurance policies. The $6.0 million insurance recovery related to this claim is recorded within prepaid expenses and other current assets on the condensed consolidated balance sheet as of September 30, 2024.

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

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following is a discussion and analysis of the consolidated operating results, financial condition, liquidity and cash flows of our company as of and for the periods presented below. The following discussion and analysis should be read in conjunction with the "Condensed Consolidated Financial Statements" and the related notes thereto included in this Quarterly Report on Form 10-Q, or Quarterly Report. This discussion contains forward-looking statements that are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Actual results could differ materially from those discussed in or implied by forward-looking statements. These risks, uncertainties, and other factors include, among others, those identified under the "Special Note About Forward-Looking Statements," above and described in greater detail elsewhere in this Quarterly Report and in our Annual Report on Form 10-K for the year ended December 31, 2023, 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 25 products.

Our largest products by net revenues currently include BAQSIMI®, Primatene MIST®, glucagon, epinephrine, lidocaine, enoxaparin sodium, and phytonadione.

We are currently developing a portfolio of generic abbreviated new drug applications, or ANDAs, biosimilar insulin product candidates and proprietary product candidates, which are in various stages of development and target a variety of indications. Four of the ANDAs 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 injectable, inhalation, and intra-nasal 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

Recent uncertain macroeconomic conditions and worldwide events, including extended periods of heightened inflation, fluctuating interest rates and instability in the financial systems, ongoing geopolitical conflicts such as the Russia-Ukraine and Middle East conflicts, as well as rising healthcare costs continue to pose challenges to our business.

See the section titled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023, for further discussion of the potential adverse impact of unfavorable global and geopolitical economic conditions on our business, results of operations and financial conditions.

Recent Developments

BAQSIMI® Acquisition

In connection with the acquisition of BAQSIMI® in June 2023, we entered into a Transition Service Agreement, or the TSA, with Eli Lilly & Company, or Lilly, pursuant to which Lilly agreed, for a period of time not to exceed 18 months to provide certain services to us to support the transition of the BAQSIMI® operations, including with respect to the conduct of certain clinical, regulatory, medical affairs, and commercial sales channel activities. Revenues from the sales of BAQSIMI® under the TSA with Lilly during the transition period 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®.

Throughout 2024, we assumed distribution responsibilities from Lilly to our customers in the United States, which comprises approximately 80% of BAQSIMI® worldwide revenues, as well as certain other countries. As a result, we started recognizing gross revenues and cost of revenues from the sales of BAQSIMI® in these countries, which is classified as product revenue, net and cost of revenue, respectively on the condensed consolidated statement of operations. The assumption of distribution in countries outside the United States will occur on a country-by-country basis once the marketing authorizations for each territory have been transferred to us, we have set up distribution agreements, and we have obtained sufficient inventory.

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 September 30, 2024, our performance is assessed and resources are allocated based on the following two reportable segments: (1) finished pharmaceutical products and (2) Active Pharmaceutical Ingredient, or API, products. The finished pharmaceutical products segment manufactures, markets and distributes BAQSIMI®, Primatene MIST®, epinephrine, glucagon, phytonadione, lidocaine, enoxaparin, naloxone, as well as various other critical and non-critical care drugs. The API segment manufactures and distributes Recombinant Human Insulin, or 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, 2024 Compared to Three Months Ended September 30, 2023

Net revenues

	Three Months Ended September 30,		Change	
	2024	2023	Dollars	%
		(in thousands)		
Net revenues				
Finished pharmaceutical products	$ 187,357	$ 147,665	$ 39,692	27 %
API	1,462	4,190	(2,728)	(65)%
Total product revenues, net	188,819	151,855	36,964	24 %
Other revenues	2,395	28,701	(26,306)	(92)%
Total net revenues	$ 191,214	$ 180,556	$ 10,658	6 %
Cost of revenues				
Finished pharmaceutical products	$ 84,208	$ 66,867	$ 17,341	26 %
API	5,065	5,286	(221)	(4)%
Total cost of revenues	$ 89,273	$ 72,153	$ 17,120	24 %
Gross profit	$ 101,941	$ 108,403	$ (6,462)	(6)%
as % of net revenues	*53 %*	*60 %*		

The increase in net revenues of the finished pharmaceutical products for the three months ended September 30, 2024 was due to the following changes:

	Three Months Ended September 30,		Change	
	2024	2023	Dollars	%
	(in thousands)			
Finished pharmaceutical products net revenues				
BAQSIMI®	$ 40,409	$ —	$ 40,409	N/A
Glucagon	26,792	29,514	(2,722)	(9)%
Primatene MIST®	26,055	24,834	1,221	5 %
Epinephrine	21,341	20,199	1,142	6 %
Lidocaine	15,884	15,522	362	2 %
Phytonadione	11,721	7,449	4,272	57 %
Enoxaparin	5,615	7,702	(2,087)	(27)%
Naloxone	4,037	4,715	(678)	(14)%
Other finished pharmaceutical products	35,503	37,730	(2,227)	(6)%
Total finished pharmaceutical products net revenues	$ 187,357	$ 147,665	$ 39,692	27 %

Product Revenues, net

Throughout 2024, we assumed distribution responsibilities for BAQSIMI® from Lilly to our customers in the United States, and certain other countries. As a result, $40.4 million of our third quarter BAQSIMI® sales were recognized separate from the cost of revenues, similar to our other products. During the third quarter of 2024, while the Company was transitioning from Lilly labeled product to Amphastar labeled product, our supplier was unable to supply Amphastar labeled product in 14 European countries on a timely basis, which limited sales by approximately $2.0 million to $3.0 million.

For more information, see “Part I – Item 1. Financial Statements – Notes to the Condensed Consolidated Financial Statements – Note 4. Revenue Recognition.”

Primatene MIST® sales increased primarily due to an increase in unit volumes. The increase in sales of epinephrine was primarily due to sales of epinephrine pre-filled syringes in Canada, which we began this quarter. The increase in sales of phytonadione was primarily driven by an increase in unit volume, as a result of an increase in demand. The decrease in sales of glucagon was due to a decrease in unit volumes as a result of a move to ready to use glucagon products such as BAQSIMI®, as well as a decrease in average selling price. The decrease in sales of enoxaparin and naloxone was primarily due to a decrease in unit volumes. The decrease in other finished pharmaceutical products was primarily due to lower unit sales of atropine and calcium chloride, as a result of other suppliers returning to their historical distribution levels. This decrease was partially offset by higher unit volumes of sodium bicarbonate due to an increase in capacity at our subsidiary, International Medication Systems, Limited, as well as the launch of albuterol in August 2024. Between $2.0 million and $4.0 million in sales expected to be recognized in the third quarter were not recognized due to delayed shipments caused by the aftermath of Hurricane Helene. Revenues for these shipments are expected to be recognized in the fourth quarter.

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

Sales of API primarily depend on the timing of customer purchases, and will be lower for the next two years because MannKind, our largest RHI customer, is in the process of qualifying our upgraded RHI, which uses our internally produced inclusion bodies made at AFP. Until they complete this process, we anticipate sales of RHI will be at levels lower than historical.

Other Revenues

Other revenues include the portion of BAQSIMI® sales made by Lilly on our behalf under the TSA which amounted to $2.4 million and $28.7 million during the three months ended September 30, 2024 and 2023, respectively, based on total BAQSIMI® sales of $6.4 million and $48.7 million, respectively, as reported to us by Lilly, which was recognized on a net basis, similar to a royalty arrangement. The BAQSIMI® sales made by Lilly on our behalf under the TSA have decreased throughout 2024, due to our assumption of distribution responsibilities for BAQSIMI® from Lilly to our customers in the United States, and certain other countries. We recognized these sales within product net revenues.

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, 2024, 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 decrease in gross margins during the three months ended September 30, 2024, is primarily due to an increase in labor costs and certain component costs, as well as charges included in cost of revenues to adjust our inventory and related purchase commitments to their net realizable value. As a result of the TSA with Lilly, the portion of revenues relating to BAQSIMI® sales made by Lilly on our behalf are reported on a net basis, similar to a royalty arrangement with no amount reported as cost of revenues. Therefore, in the prior year, BAQSIMI® sales did not have any associated cost of revenues, which increased the gross margins.

The decrease in gross margins was partially offset by an increase in sales of Primatene MIST® and epinephrine, which are higher-margin products.

We are currently experiencing increased costs for labor as well as certain APIs and purchased components. However, we believe that this trend will be offset longer term by increased sales of our higher-margin products, including BAQSIMI®, Primatene MIST®, vasopressin, ganirelix, and albuterol, and new products we anticipate launching.

Selling, distribution and marketing, and general and administrative

	Three Months Ended September 30,		Change	
	2024	2023	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	$ 8,995	$ 6,407	$ 2,588	40 %
General and administrative	$ 14,821	$ 12,654	$ 2,167	17 %

The increase in selling, distribution and marketing expenses was primarily due to expenses related to the expansion of our sales and marketing efforts related to BAQSIMI®. The increase in general and administrative expense was primarily due to an increase in salary and personnel-related expenses and expenses related to BAQSIMI®.

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

Research and development

	Three Months Ended September 30,		Change	
	2024	2023	Dollars	%
	(in thousands)			
Salaries and personnel-related expenses	$ 7,768	$ 7,007	$ 761	11 %
Pre-launch inventory	222	460	(238)	(52)%
Clinical trials	9	673	(664)	(99)%
FDA fees	34	45	(11)	(24)%
Materials and supplies	5,852	3,664	2,188	60 %
Depreciation	3,278	2,452	826	34 %
Other expenses	3,914	2,363	1,551	66 %
Total research and development expenses	$ 21,077	$ 16,664	$ 4,413	26 %

The increase in research and development expenses is primarily due to an increase in expenditure on raw materials and components for our insulin pipeline products, as well as an increase in salary and personnel-related expenses. This was partially offset by a decrease in clinical trial expense, due to the timing of clinical trials.

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.

Non-operating income (expenses), net

	Three Months Ended September 30,		Change	
	2024	2023	Dollars	%
	(in thousands)			
Non-operating income (expenses)				
Interest income	$ 2,427	$ 1,202	$ 1,225	102 %
Interest expense	(6,698)	(13,702)	7,004	(51)%
Other income (expenses), net	(5,094)	3,459	(8,553)	(247)%
Total non-operating income (expenses), net	$ (9,365)	$ (9,041)	$ (324)	4 %

The change in non-operating income (expenses), net is primarily a result of:

- An increase in interest income resulting from an increase in cash and investments.
- A decrease in interest expense was primarily due to the $250.0 million repayment of the principal balance of the Wells Fargo Term Loan in September 2023, along with the write-off of the associated unamortized debt issuance costs related to the Term Loan in 2023.
- A change to Other income (expenses), net primarily as a result of foreign currency fluctuation, as well as mark-to-market adjustments relating to our interest rate swap contracts during the three months ended September 30, 2024.

Income tax provision

	Three Months Ended September 30,		Change	
	2024	2023	Dollars	%
	(in thousands)			
Income tax provision	$ 7,254	$ 14,025	$ (6,771)	(48)%
Effective tax rate	*15 %*	*22 %*		

Our effective tax rate for the three months ended September 30, 2024 decreased in comparison to the three months ended September 30, 2023, 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."

Beginning in 2024, many countries are implementing some or all of the Organization for Economic Co-operation and Development's Inclusive Framework on Base Erosion and Profit Shifting Two-Pillar in response to tax challenges arising from the digitalization of the global economy. While we continue to evaluate those countries' implementations, we do not expect those implementations to have a material impact on our consolidated financial statements in 2024.

Nine Months Ended September 30, 2024 Compared to Nine Months Ended September 30, 2023

Net revenues

	Nine Months Ended September 30,		Change	
	2024	2023	Dollars	%
	(in thousands)			
Net revenues				
Finished pharmaceutical products	$ 519,147	$ 426,541	$ 92,606	22 %
API	6,689	11,048	(4,359)	(39)%
Total product revenues, net	525,836	437,589	88,247	20 %
Other revenues	19,608	28,701	(9,093)	(32)%
Total net revenues	$ 545,444	$ 466,290	$ 79,154	17 %
Cost of revenues				
Finished pharmaceutical products	$ 236,433	$ 192,500	$ 43,933	23 %
API	21,804	18,809	2,995	16 %
Total cost of revenues	$ 258,237	$ 211,309	$ 46,928	22 %
Gross profit	$ 287,207	$ 254,981	$ 32,226	13 %
as % of net revenues	*53 %*	*55 %*		

The increase in net revenues of the finished pharmaceutical products for the nine months ended September 30, 2024, was due to the following changes:

	Nine Months Ended September 30,		Change	
	2024	2023	Dollars	%
		(in thousands)		
Finished pharmaceutical products net revenues				
BAQSIMI®	$ 85,106	$ —	$ 85,106	N/A
Glucagon	82,700	82,486	214	0 %
Epinephrine	75,392	57,004	18,388	32 %
Primatene MIST®	73,077	64,837	8,240	13 %
Lidocaine	41,457	43,174	(1,717)	(4)%
Phytonadione	31,998	33,017	(1,019)	(3)%
Enoxaparin	17,984	25,441	(7,457)	(29)%
Naloxone	12,124	14,774	(2,650)	(18)%
Other finished pharmaceutical products	99,309	105,808	(6,499)	(6)%
Total finished pharmaceutical products net revenues	$ 519,147	$ 426,541	$ 92,606	22 %

Product Revenues, net

Throughout 2024, we assumed distribution responsibilities for BAQSIMI ® from Lilly to our customers in the United States, and certain other countries. As a result, $85.1 million of our BAQSIMI® sales for the nine months ended September 30, 2024, are recognized separate from the cost of revenues, similar to our other products.

For more information, see “Part I – Item 1. Financial Statements – Notes to the Condensed Consolidated Financial Statements – Note 4. Revenue Recognition.”

The increase in sales of epinephrine was primarily due to an increase in unit volumes, as a result of an increase in demand caused by other supplier shortages. Primatene MIST® sales increased primarily due to an increase in unit volumes. The decrease in sales of enoxaparin and naloxone was primarily due to a decrease in unit volumes. The decrease in other finished pharmaceutical products was primarily due to lower unit sales of atropine and calcium chloride, as a result of other suppliers returning to their historical distribution levels, as well as lower unit sales of medroxyprogesterone, as our API supplier discontinued making the active ingredient, which resulted in a halt of sales of medroxyprogesterone after the third quarter of 2023. Subsequently, we qualified our subsidiary, ANP, to manufacture this API, and in September 2024, we re-launched the product. This decrease was partially offset by higher unit volumes of dextrose and sodium bicarbonate due to an increase in demand caused by other supplier shortages, as well as the launch of albuterol in August 2024.

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

Sales of API primarily depend on the timing of customer purchases, and will be lower for the next two years because MannKind, our largest RHI customer, is in the process of qualifying our upgraded Recombinant Human Insulin, or RHI, which uses our internally produced inclusion bodies made at AFP. Until they complete this process, we anticipate sales of RHI will be at levels lower than historical.

Other Revenues

Other revenues include the portion of BAQSIMI® sales made by Lilly on our behalf under the TSA which amounted to $19.6 million and $28.7 million during the nine months ended September 30, 2024 and 2023, respectively, based on total BAQSIMI® sales of $38.6 million and $48.7 million, respectively, as reported to us by Lilly, which was recognized on a net basis, similar to a royalty arrangement. The BAQSIMI® sales made by Lilly on our behalf under the TSA have

decreased throughout 2024, due to our assumption of distribution responsibilities for BAQSIMI® from Lilly to our customers in the United States, and certain other countries. We recognized these sales within product net revenues.

Gross margins

The decrease in gross margins during the nine months ended September 30, 2024, is primarily due to an increase in depreciation and amortization expenses related to the acquired BAQSIMI® assets, an increase in labor costs and certain component costs, as well as charges included in cost of revenues to adjust our inventory and related purchase commitments to their net realizable value. As a result of the TSA with Lilly, the portion of revenues relating to BAQSIMI® sales made by Lilly on our behalf are reported on a net basis, similar to a royalty arrangement with no amount reported as cost of revenues. Therefore, in the prior year, BAQSIMI® sales did not have any associated cost of revenues, which increased the gross margins.

The decrease in gross margins was partially offset by the increase in sales of Primatene MIST® and epinephrine, which are higher-margin products.

We are currently experiencing increased costs for labor as well as certain APIs and purchased components. However, we believe that this trend will be offset longer term by increased sales of our higher-margin products, including BAQSIMI®, Primatene MIST®, vasopressin, ganirelix, albuterol, and new products we anticipate launching.

Selling, distribution and marketing, and general and administrative

	Nine Months Ended September 30,		Change	
	2024	2023	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	$ 27,378	$ 20,234	$ 7,144	35 %
General and administrative	$ 43,782	$ 38,418	$ 5,364	14 %

The increase in selling, distribution and marketing expenses was primarily due to expenses related to the expansion of our sales and marketing efforts related to BAQSIMI®. The increase in general and administrative expense was primarily due to an increase in salary and personnel-related expenses and expenses related to BAQSIMI®.

We expect that selling, distribution and marketing expenses will continue to increase due to the increase in marketing expenditures for BAQSIMI® and 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	
	2024	2023	Dollars	%
	(in thousands)			
Salaries and personnel-related expenses	$ 23,898	$ 21,653	$ 2,245	10 %
Pre-launch inventory	222	460	(238)	(52)%
Clinical trials	292	3,430	(3,138)	(91)%
FDA fees	1,333	142	1,191	NM
Materials and supplies	12,334	13,556	(1,222)	(9)%
Depreciation	9,206	7,282	1,924	26 %
Other expenses	8,487	6,799	1,688	25 %
Total research and development expenses	$ 55,772	$ 53,322	$ 2,450	5 %

The increase in research and development expenses is primarily due to an increase in salary and personnel-related expenses, as well as an increase in FDA filing fees as we filed the ANDA for AMP-018 in the second quarter of 2024.

This was partially offset by a decrease in clinical trials expense, as well as a decrease in materials and supply expense, as a result of a ramp-up of expenses in 2023 for our insulin and inhalation pipeline products.

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.

Non-operating income (expenses), net

	Nine Months Ended September 30,		Change	
	2024	2023	Dollars	%
	(in thousands)			
Non-operating income (expenses)				
Interest income	$ 8,320	$ 3,156	$ 5,164	164 %
Interest expense	(23,918)	(17,702)	(6,216)	35 %
Other income (expenses), net	1,125	1,553	(428)	(28)%
Total non-operating income (expense), net	$ (14,473)	$ (12,993)	$ (1,480)	11 %

The change in non-operating income (expenses), net is primarily a result of:

- An increase in interest income resulting from an increase in cash and investments.
- An increase in interest expense resulting from the Term Loan used to finance the acquisition of BAQSIMI®, as well as the 2029 Convertible Notes, which we entered into in the second half of 2023. For more information regarding our debt, see "Part I – Item 1. Financial Statements – Notes to Condensed Consolidated Financial Statements – Note 14. Debt."
- A change to Other income (expenses), net primarily as a result of foreign currency fluctuation, as well as mark-to-market adjustments relating to our interest rate swap contracts during the nine months ended September 30, 2024.

Income tax provision

	Nine Months Ended September 30,		Change	
	2024	2023	Dollars	%
	(in thousands)			
Income tax provision	$ 23,674	$ 27,160	$ (3,486)	(13)%
Effective tax rate	*16 %*	*21 %*		

Our effective tax rate for the nine months ended September 30, 2024 decreased in comparison to the nine months ended September 30, 2023, primarily due to the timing of discrete tax items partially offset by differences in pre-tax income positions. 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 primarily with cash flows from operations. We may also become subject to cash obligations of up to an aggregate of $575.0 million that are contingent upon certain net sales milestones related to the BAQSIMI® acquisition. No milestone payments have been made through the date of this filing. 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, 2024, our foreign subsidiaries collectively held $9.5 million in cash and cash equivalents. Cash or cash equivalents held at foreign subsidiaries are not available to fund the parent company's operations in the United States. We believe that our cash reserves, operating cash flows, and borrowing availability under our credit facilities will be sufficient to fund our operations for at least the next 12 months from the date of filing of this Quarterly Report on Form 10-Q. We expect additional cash flows to be generated in the longer term from future product introductions, although there can be no assurance as to the receipt of regulatory approval for any product candidates that we are developing or the timing of any product introductions, which could be lengthy or ultimately unsuccessful.

Working capital increased $122.7 million to $386.9 million at September 30, 2024, compared to $264.2 million at December 31, 2023.

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, 2024 and 2023:

	Nine Months Ended September 30,	
	2024	2023
	(in thousands)	
Statement of Cash Flow Data:		
Net cash provided by (used in)		
Operating activities	$ 184,362	$ 159,639
Investing activities	(89,252)	(546,067)
Financing activities	(47,111)	501,176
Effect of exchange rate changes on cash	(179)	(44)
Net increase in cash, cash equivalents, and restricted cash	$ 47,820	$ 114,704

Sources and Use of Cash

Operating Activities

Net cash provided by operating activities was $184.4 million for the nine months ended September 30, 2024, which included net income of $121.6 million. Non-cash items comprised primarily of $47.8 million of depreciation and amortization, which includes $21.0 million related to depreciation of property, plant and equipment; $18.5 million related to amortization of product rights, trademarks and patents; $3.0 million related to amortization of operating lease right-of-use assets; $5.3 million related to amortization of discounts, premiums, and debt issuance costs; and share-based compensation expense of $18.7 million.

Additionally, for the nine months ended September 30, 2024, there was a net cash outflow from changes in operating assets and liabilities of $6.0 million, which resulted primarily from an increase in accounts receivables, an increase in inventories, as well as an increase in prepaid expenses and other assets, which was partially offset by an increase in accounts payable and accrued liabilities. The increase in accounts receivables was primarily due to the increase in sales. The increase in inventories was primarily due to the increased purchases of certain raw materials and components. Accounts payable and accrued liabilities increased primarily due to the increase in accrued customer fees and rebates associated with BAQSIMI® sales, as we continue to assume distribution responsibilities for BAQSIMI® from Lilly to our customers in the United States and certain other countries.

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.

Investing Activities

Net cash used in investing activities was $89.3 million for the nine months ended September 30, 2024, primarily due to the payment of $129.0 million relating to the BAQSIMI® acquisition, $28.6 million in purchases of property, plant, and equipment, which included $10.2 million incurred in the United States, $2.4 million in France, and $15.9 million in China. This was partially offset by a net cash inflow of $71.0 million from sales and purchases of investments during the period.

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.

Financing Activities

Net cash used in financing activities was $47.1 million for the nine months ended September 30, 2024, primarily as a result of $43.5 million used to purchase treasury stock and $8.2 million used to settle share-based compensation awards under our equity plan and for tax payments related to the net share settlement of options exercised. Additionally, we made $8.1 million in principal payments on our long-term debt, primarily as a result of paying off the mortgage loan with East West Bank. This was partially offset by $13.6 million of net proceeds from borrowings on our line of credit in China.

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.

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, 2023. 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, 2023.

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 20 through March 1, 2024, our Amphastar facility in Rancho Cucamonga, California was subject to pre-approval and cGMP inspection by the FDA. The inspection included a review of compliance with FDA regulations to support one of our pending applications as well as to compliance with Good Manufacturing Practices. The inspection resulted in several 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.

From July 15 through July 19, 2024, our Armstrong facility in Canton, Massachusetts was subject to a pre-approval inspection by the FDA. The inspection included review of compliance of our analytical laboratory with FDA regulations to support one of our pending applications. The inspection resulted in several 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, 2023. 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 (the "Exchange Act"), 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, 2024, 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, 2023, filed with the SEC on February 29, 2024.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

The facilities we use for our headquarters, laboratory and research and development activities are located in earthquake-prone areas of California. A significant percentage of the facilities we use for our manufacturing, packaging, warehousing, distribution and administration offices are also located in these areas. Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. Additionally, we currently rely on third parties whose operations may be disrupted by natural disasters. For example, the aftermath of Hurricane Helene caused us to experience delays in shipments of certain products.

If a natural disaster, power outage or other event occurred that prevented us or the third parties upon whom we depend from using all or a significant portion of our facilities, that damaged critical infrastructure, such as our or third parties' manufacturing facilities, or that otherwise disrupted operations of ours or those of third parties, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans.

Jack Y. Zhang and Mary Z. Luo have each pledged shares of our common stock to secure funds borrowed under existing credit lines from three financial institutions. Each of the lenders has varying rights as a lender, including one which has the right to conduct a forced sale at its sole discretion. An action by one of the lenders could include a sale of certain shares of our common stock pledged as collateral, the sale of which could cause the price of our common stock to decline. An action to cure and cover indebtedness by any one of the lenders could also have other negative impacts on our business.

Since September 2015, UBS Bank USA, or UBS, has made extensions of credit up to the amount of $8.0 million to Applied Physics & Chemistry Laboratories, Inc., or APCL, which is controlled by Jack Y. Zhang and Mary Z. Luo. In May 2019, the credit amount was increased to $11.0 million. Since February 2017, UBS Group AG, or UBS AG, has also provided an extension of credit up to the amount of $8.0 million to APCL. In 2021, the outstanding UBS AG credit line was transferred to UBS's Utah location due to an organizational change and in June 2024, the credit line with UBS was increased to $11.9 million. As of September 30, 2024, the total outstanding UBS combined credit lines were $11.9 million. The UBS credit lines are secured by a pledge of 400,000 shares of our common stock currently held by APCL. Interest on the loans accrues at market rates. UBS has an unlimited and unilateral right to call each of the credit lines for any reason whatsoever.

In October 2017, East West Bank, or East West, entered into an agreement with Drs. Zhang and Luo whereby East West would loan them up to $5.0 million. In March 2023, East West amended the loan to increase the loan amount to $8.0 million. As of September 30, 2024, the loan is secured by a pledge of 500,000 shares of our common stock held by Dr. Zhang. Interest on the loan accrues at market rates. East West has acceleration rights to protect itself in the event of a default.

In June 2024, Cathay Bank entered into an agreement with APCL and Dr. Luo, whereby Cathay Bank would loan them up to $20.0 million. As of September 30, 2024, the loan is secured by a pledge of 1,000,000 shares of our common stock held by APCL and Dr. Luo. Interest on the loan accrues at market rates. Cathay Bank has acceleration rights to protect itself in the event of a default.

We are not a party to these loans, which are full recourse against APCL and each of Drs. Zhang and Luo, respectively, and are secured by pledges of a portion of the shares of our common stock currently held by APCL and each of Drs. Zhang and Luo.

In 2021, we created a pledging policy to restrict the pledging of shares by our executive officers and directors. The policy prohibits our executive officers and directors from entering into any transaction whereby the executive officer or director, directly or indirectly, pledges, hypothecates, or otherwise encumbers more than twenty (20) percent of shares of common stock held by the individual or more than five (5) percent of our total outstanding shares of common stock as of the date of the transaction, whichever is lower, as collateral for indebtedness. This restriction extends to any hedging or similar transaction designed to decrease the risks associated with holding our securities. For already existing pledges made by executive officers and directors, those existing pledges must be reduced to no more than twenty (20) percent of the shares of our common stock held by such individual as collateral for indebtedness within three (3) years of December 31, 2021. As a result of this policy, Drs. Zhang and Luo reduced their total number of pledged shares to 1,900,000 in June 2024 from 2,350,000 in May 2022, 3,182,898 in February 2022, and 8,582,898 in February 2021.

If the price of our common stock declines, Drs. Zhang and Luo may be forced by these financial institutions to provide additional collateral for the loans or to sell shares of our common stock held by them in order to remain within the margin limitations imposed under the terms of their loans. Furthermore, the pledged shares of our common stock may be acquired and sold by the lenders. These factors may limit Drs. Zhang and Luo's ability to either pledge additional shares of our common stock or sell shares of our common stock held by them as a means to avoid or satisfy a margin call with respect to their pledged shares of our common stock in the event of a decline in our stock price that is large enough to trigger a margin call. Any significant sales of shares of our common stock by one or more of these three lenders could cause the price of our common stock to decline further.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(c) Issuer Purchases of Equity Securities

The table below provides information with respect to repurchases of our common stock.

Period	Total Number of Shares Purchased [1]	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
July 1 - July 31, 2024	277,955	$ 39.55	277,955	—
August 1 - August 31, 2024	247,158	44.48	247,158	—
September 1 - September 30, 2024	271,925	47.64	271,925	—

(1) On June 3, 2024, we announced that our Board of Directors authorized an increase of $50.0 million to our share buyback program. As of September 30, 2024, $42.0 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
10.1*	Distribution Agreement by and between Armstrong Pharmaceuticals, Inc. and Hong Kong Genreach Limited, dated August 28, 2024
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.

* Certain confidential information contained in this exhibit was omitted by means of marking such portions with brackets because the identified confidential information (i) is not material and (ii) is of the type that the registrant treats as private or confidential. In addition, certain schedules (or similar attachments) have been omitted from this exhibit pursuant to Item 601(a)(5) of Regulation S-K.

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 7, 2024

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

Date: November 7, 2024

Exhibit 10.1

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS ([***]), HAS BEEN OMITTED PURSUANT TO ITEM 601(B)(10)(IV) OF REGULATION S-K, BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) IS THE TYPE THAT THE COMPANY TREATS AS PRIVATE OR CONFIDENTIAL. IN ADDITION, CERTAIN SCHEDULES (OR SIMILAR ATTACHMENTS) HAVE BEEN OMITTED FROM THIS EXHIBIT PURSUANT TO ITEM 601(A)(5) OF REGULATION S-K.

Distribution Agreement

经销协议

This DISTRIBUTION AGREEMENT (this "**Agreement**") is entered into on August 28, 2024 (the "**Effective Date**") by and between the following parties:

本经销协议（以下简称"**本协议**"）由以下双方于2024年_8_月__28_日（以下简称"**生效日期**"）签订：

(1) Armstrong Pharmaceuticals, Inc., a company incorporated under the laws of the State of Delaware, with its principal place of business located at 25 John Road, Canton, Massachusetts ("**ARMSTRONG**"); and

Armstrong Pharmaceuticals, Inc.，一家根据特拉华州法律注册成立的公司，主要营业地址为马萨诸塞州坎顿约翰路25号（以下简称"**ARMSTRONG**"）；及

(2) Hong Kong Genreach Limited, a company incorporated under the laws of Hong Kong, with its registered place located at RM 1007B,10/F.,HO KING COMMERCIAL CTR.,NO.2-16 FA YUEN STREET, MONGKOK HONG KONG, China ("**GENREACH**" or "**Distributor**").

香港金瑞驰有限公司，一家根据中华人民共和国（以下简称"**中国**"）法律注册成立的公司，注册地址为香港旺角发源街2-16号豪景商业大厦10楼1007B室（以下简称"**GENREACH**"或"**经销商**"）。

ARMSTRONG and GENREACH are hereinafter collectively referred to as the "**Parties**", and each as a "**Party**".

ARMSTRONG和GENREACH以下统称为"双方"，各自称为"一方"。

THE PARTIES AGREE AS FOLLOWS:

双方同意如下：

1 Definition

定义

1.1 Affiliate means, in this Agreement means, with respect to any specified entity, any other entity that directly, or indirectly through one or more intermediaries, Controls, is Controlled by, or is under common Control with, such specified person.

关联方是指，在本协议中，就任何特定实体而言，直接或通过一个或多个中间人间接控制该实体、受其控制或与该实体共同控制的任何其他实体。

1.2 Control of a person (including the terms "Controlled by" and "under common Control with") means, (i) ownership of more than 50% of the shares or economic interests of such person; (ii) the power, directly or indirectly and whether exercised or not, to direct the management or policies of such person, whether through the ownership of more than 50% of the voting power of such person, through the power to appoint a majority of the members of the board of directors or similar governing body of such person, through contractual arrangements or otherwise, or (iii) ownership of the largest amount of shares of such person.

对实体的控制（包括"受控于"和"与他人共同控制"）是指，(i) 拥有该实体50%以上的股份或经济利益；(ii) 无论行使与否，拥有直接或间接影响该实体管理层或政策制定的权力，无论该权力的取得是通过拥有该实体50%以上的投票权，还是通过任命该实体的董事会或类似管理机构大多数人的权力，还是通过合同安排或其他方式，或(iii) 是该实体所有股东中持股最多的股东。

1.3 Collaboration Region means Mainland China, Taiwan, Hong Kong, and Macau in the Greater China region.

合作区域是指大中华地区，包括中国大陆，中国台湾，中国香港，中国澳门。

1.4 Contract Year means each consecutive twelve (12) month period during the Term, the first of which shall commence on the Effective Date and shall end on the first anniversary thereof.

合同年是指有效期内的每一连续十二（12）个月，第一个合同年从生效日期开始至其第一个周年之日结束。

1.5 Intellectual Property means any design, patent (including invention, utility model and design patent; including patent application, reissue, division, continuation and extension thereof), copyright, trade marks, trade names, service marks, business names, trade secret, mask work right, idea, algorithm, concept, structure, logic, know-how, invention, discovery, improvement, document, product, system, practice, rule, tool, method, ingredient, process, device, procedure, software, drawing and sketch, specification, technical description, and all other intellectual property or similar proprietary rights of whatever nature, whether registered, filed, patented or not, which may now or in the future subsist anywhere in the world.

知识产权是指任何设计、专利（包括发明、实用新型和外观设计；包括专利申请、再颁专利、分案、续案和延伸等）、版权、商标、商品名称、服务标识、企业名称、商业秘密、制模样品权、想法、算法、概念、结构、逻辑、专有技术、发明、发现、改进、文件、产品、系统、实践、规则、工具、方法、成分、过程、设备、程序、软件、图纸和草图、规格、技术说明，以及现在或将来在世界任何地方存在的所有其他知识产权或类似的专有权利，无论其性质如何，也无论其是否注册、备案、获得专利。

1.6 Product P means Primatene Mist owned by ARMSTRONG, an OTC medication approved by the FDA in the United States, which comes in a 160-spray device, with each spray containing 0.125mg of epinephrine, and is used for the temporary relief of mild symptoms of intermittent asthma.

产品P是指ARMSTRONG持有的Primatene mist，一款在美国获得FDA批准的非处方药品，其规格为160支装，每支含0.125毫克肾上腺素，用于间歇性哮喘轻微症状的暂时缓解。

1.7 NMPA means National Medical Products Administration of the PRC.

NMPA是指中国国家药品监督管理局。

2 Distribution

经销

2.1 Appointment of Distributor. ARMSTRONG hereby appoints the Distributor, and the Distributor hereby agrees to accept the appointment, to act for ARMSTRONG as its exclusive distributor to market and sell Product P within the Collaboration Region subject to the Distributor's compliance with the terms and conditions of this Agreement.

经销商的任命。ARMSTRONG特此任命经销商，经销商特此同意接受任命，在经销商遵守本协议条款和条件的前提下，作为ARMSTRONG的独家经销商，在合作区域内推广和销售产品P。

For avoidance of doubt, the Distributor shall be responsible to ensure that Product P that are shipped to it is only being marketed and distributed in the Collaboration Region, and not being distributed in the United States and/or any other country or region outside the Collaboration Region.

为免疑义，经销商应负责确保其接收的产品P仅在合作区域内进行市场推广和销售，并且不得在美国或合作区域以外的任何其他国家或地区进行销售。

2.2 Other Obligations of Distributor. The Distributor hereby agrees to:

经销商的其他义务。经销商同意：

(1) exercise its best efforts to obtain and promote the sale of Product P in the Collaboration Region;

尽其最大努力在合作区域获得和促进产品P的销售；

(2) maintain adequate staff at all times, including but not limited to adequate sales staff;

始终保持充足的员工，包括但不限于充足的销售人员；

(3) abide by each of ARMSTRONG's policies, procedures or other rules, and applicable laws and regulations regarding the purchase and sale and distribution of Product P, and storage and transport of Product P;

遵守ARMSTRONG有关购买、销售、经销、储存和运输产品P的各项政策、程序或其他规定以及适用的法律法规；

(4) conduct its business in a manner that is favorable to and promotional of ARMSTRONG and Product P and to not disparage, tarnish, or imply poor favor of the name, reputation or goodwill of ARMSTRONG;

以有利于和促进ARMSTRONG和产品P的方式开展业务，不诋毁、玷污或对ARMSTRONG的名称、声誉或商誉作出不利的暗示；

(5) accept reasonable advices from ARMSTRONG on the sales and distribution of Product P;

接受ARMSTRONG对于销售和经销产品P的合理建议；

(6) promptly notify ARMSTRONG upon becoming aware of any breach of its obligations under this Agreement, or any circumstances or matters that are reasonably likely to give rise to any such breach;

在意识到任何违反其在本协议项下义务的行为，或合理可能导致任何此类违约的任何情况或事项时，立即通知ARMSTRONG；

(7) not sell or distribute any products that infringe on any ARMSTRONG Intellectual Property, promptly notify ARMSTRONG upon becoming aware of any such products or infringement on any ARMSTRONG Intellectual Property and, upon ARMSTRONG's request, promptly provide all necessary information, cooperation and assistance for defense of infringement; and

不销售和经销任何侵犯ARMSTRONG知识产权的产品，在意识到任何此类产品或对ARMSTRONG知识产权的侵权时，立即通知ARMSTRONG，并经ARMSTRONG的要求立即提供所有侵权辩护的必要信息、合作和协助；及

(8) cooperate fully with and provide any necessary assistance and information to ARMSTRONG in implementing any recall, withdrawal, seizure or destruction of Product P initiated by ARMSTRONG.

与ARMSTRONG充分合作，并向ARMSTRONG提供任何必要的协助和信息，以实施ARMSTRONG发起的任何产品P的召回、撤回、扣押或销毁。

(9) Comply with Safety Data Exchange Agreement (SDEA) as set forth in Appendix A.

遵守本协议附件A所列示的《安全数据交换协议》(SDEA)。

(10) Comply with Quality Agreement (Quality Agreement) as set forth in Appendix B.

遵守本协议附件B所列示的《质量协议》(Quality Agreement)。

3 No Employment or Representation

非雇佣或代理

3.1 Nothing in this Agreement shall be construed as to create an employment relationship between ARMSTRONG and the Distributor. The Distributor has no authority or power to bind ARMSTRONG or contract in the name of ARMSTRONG.

本协议的任何内容均不得解释为在ARMSTRONG与经销商之间建立雇佣关系。经销商没有授权或权利约束ARMSTRONG或以ARMSTRONG的名义订立合同。

3.2 The Distributor, its employees and its representatives must refrain from any act that might create the false impression that they are employees or agents or representatives of ARMSTRONG. Whenever the Distributor describes its

relationship with ARMSTRONG it shall make it clear that it is an independent distributor and not an agent, representative or person having the authority to enter into contracts on behalf of ARMSTRONG or incur obligations binding on ARMSTRONG.

经销商及其员工和代表必须避免任何可能造成他们是ARMSTRONG员工、代理或代表的错误印象的行为。当经销商描述其与ARMSTRONG的关系时，应明确说明其为独立经销商，而非代理、代表或有权代表ARMSTRONG订立合同或为ARMSTRONG设置有约束力的义务的人士。

4 Development Plan

开发计划

4.1 The Parties hereby agree that the development plan of registration, sales and distribution of Product P is as follows ("**Development Plan**"):

双方同意，注册、销售和经销产品P的开发计划如下（以下简称"**开发计划**"）：

4.1.1 Step One. The Distributor shall assist in filing the fast-track market launch and sales application of Product P in the pilot zone of Hainan free trade port according to applicable law. The Distributor shall be responsible for completing relevant permit, certificate, registration, approval, filing or other relevant procedure ("**Regulatory Approval**"), including but not limited to finding proper local medical institution as applicant, signing relevant cooperation contract with the aforesaid medical institution and taking any other necessary actions, provided that any procedure concerning the ownership of Product P (if any) shall be completed under the name of GENREACH or its designated affiliate. The Distributor shall have exclusive distribution rights of Product P within the permitted sales area in Hainan free trade port during such period.

第一步。经销商应根据适用法律协助在海南自由贸易港先行区进行快速上市销售申请。经销商应负责完成相关许可、证书、注册、批准、备案或其他相关程序（以下简称"**监管批准**"），包括但不限于寻找适格的当地医疗机构作为申请人、与前述医疗机构签署相关合作协议以及采取任何其他必要行动，但前提是，任何有关P产品所有权的程序（如有）应以GENREACH或其指定关联方的名义完成。在此期间，经销商在海南自由贸易港的被允许销售的范围内拥有产品P的独家经销权。

4.1.2 Step Two. The Distributor or its designated affiliate shall file the drug registration application of Product P as imported drug in Hong Kong according to applicable law. The drug registration certificate of Product P in Hong Kong and relevant permits, files and materials shall be solely owned by the Distributor or its designated affiliate, and the Distributor or its designated affiliate shall have exclusive distribution rights of Product P within the permitted sales area, including Hong Kong, Macau and certain cities in Guangdong Province, as applicable law permits during such period. The Distributor or its designated affiliate shall be

responsible for import-relevant procedures in Hong Kong and such permitted sales area.

第二步。经销商或其指定关联方应根据适用法律在中国香港进行产品P作为进口药品的药品注册申请。产品P在中国香港的药品注册证书以及相关许可、文件和材料应由经销商或其指定关联方单独所有，在此期间，在适用法律允许的范围内，经销商或其指定关联方在被允许销售的范围内（包括中国香港、中国澳门和广东省的特定城市）拥有产品P的独家经销权。经销商或其指定关联方负责办理香港及被允许销售地区进口相关的程序。

The Distributor shall have exclusive general distribution rights of Product P within the Collaboration Region after the achievement of all necessary Regulatory Approval.

在获得所有必要的监管批准后，经销商在合作区域内拥有产品P的独家总经销权。

Under such exclusive distribution rights in the above steps, the Distributor shall be entitled to appoint, at its sole discretion, sub-distributors and/or agents or representatives (the "**Sub-Distributor**") for the sale, resale and/or retail of Product P under such terms and conditions as the Distributor may, in its sole judgment, consider appropriate; provided, however, that (i) the Distributor's appointment shall not exceed the Term of this Agreement or otherwise violate any terms or conditions thereof, (ii) the Sub-Distributors shall distribute Product P only within the Collaboration Region, which means each Sub-Distributor shall, and shall cause its downstream resellers and retailers to be prohibited from selling or otherwise transferring, directly or indirectly, Product P to any party outside of the Collaboration Region, and vice versa, (iii) the Distributor shall sign written agreements with all of its Sub-Distributors incorporating the terms and conditions in respect of distribution provided under this Agreement.

根据上述步骤中的独家经销权，经销商有权自行决定任命次级分销商和/或代理或代表（以下简称"**次级分销商**"），次级分销商根据经销商自行决定合适的条款和条件进行产品P的销售、转售和/或零售；但需符合下列条件，包括(i) 经销商的任命不得超过本协议的有效期或以其他方式违反本协议的任何条款或条件；(ii) 次级分销商应在合作区域内进行产品P的分销，因此每一次级分销商均不得、且应禁止其下游分销商和零售商直接或间接向任何合作区域以外的主体销售或以任何其他方式转售产品P，反之亦然；(iii) 经销商应与所有次级分销商签订书面协议，将本协议规定的经销条款和条件纳入相关书面协议中。

4.2 The Distributor shall be responsible to ensure that all necessary Regulatory Approval required for the Development Plan have been achieved and completed in accordance with applicable laws and regulations before any sales or distribution of Product P.

经销商应负责确保在销售或经销产品P之前，开发计划所需的所有必要的监管批准已经根据适用的法律法规取得并完成。

4.3 The Distributor shall be responsible for all the costs and fees of the confirmatory clinical trials of Product P and any other necessary procedures in the Development Plan, and ARMSTRONG shall have the right (but not obligation) to review all clinical data and other relevant materials. For avoidance of doubt, ARMSTRONG is not obligated to perform any clinical or other studies for the drug registration of Product P in the Development Plan.

经销商应承担产品P验证性临床试验以及其他开发计划中的必要程序的所有成本和费用，ARMSTRONG有权（但无义务）审查所有临床数据和其他相关材料。为免疑义，ARMSTRONG无义务为开发计划中产品P的药品注册开展任何临床或其他研究。

4.4 ARMSTRONG shall provide the Distributor with the necessary documentation for the import drug registration as aforementioned, including but not limited to CMC (Chemistry, Manufacturing, and Controls) data and clinical data, to the legally permissible extent and as long as ARMSTRONG has the requested documents.

ARMSTRONG在法律允许的范围内，且ARMSTRONG拥有所要求的文件的前提下，向经销商提供进口药注册所需的资料，包括但不限于CMC资料、临床资料。

4.5 The development plan regarding Product P shall be subject to this Agreement, and any changes shall be subject to a separate written agreement after consultation between GENREACH and ARMSTRONG.

关于产品P的开发计划以本协议为准，如需变更，经GENREACH和ARMSTRONG双方协商后，另行签订书面协议。

5 Sales Forecasts and Minimum Purchase Amount

销售预测和最低购买量

5.1 Sale Forecasts. The parties agree that the sale forecasts of Product P during the term of this Agreement are as follows:

销售预测。双方同意，在本协议有效期内，产品P的销售预测如下：

Year 年度	Contract Year Sale (Units) 合同年销售量（支）
Contract Year 1/第一个合同年	[***]
Contract Year 2/第二个合同年	[***]
Contract Year 3 and Contract Year 4/第三至第四个合同年	[***]
Contract Year 5 and after/第五个合同年及之后	[***]

5.2 Minimum Purchase Amount. During the term of this Agreement, the purchase amount of Product P of the Distributor from ARMSTRONG shall be no less than one (1) batch (approximately [***] units) per Contract Year ("**Minimum Purchase Amount**"). In case the aggregate amount of actual purchase by the Distributor of Product P from ARMSTRONG in a Contract Year falls below the Minimum Purchase Amount, the Distributor shall be deemed to have materially breached this Agreement and ARMSTRONG is entitled to terminate this Agreement in accordance with Section 11.2.

最低购买量。在本协议有效期内，经销商从ARMSTRONG购买产品P的每一合同年购买量应不少于一（1）个生产批次（大约[***]支）（以下简称"**最低购买量**"）。如果经销商从ARMSTRONG购买产品P的某一合同年购买总量低于最低购买量，经销商应被视为实质违反本协议，ARMSTRONG有权根据第11.2条终止本协议。

6 Supply and Delivery

供应和交付

6.1 Delivery Terms. EXW rules (facility of ARMSTRONG in the United States) shall apply to the delivery of Product P. The Distributor shall assume all applicable risks immediately after being provided the requested Product P at ARMSTRONG's facility, whether onto a conveyor/transport system or otherwise.

交付条款。产品P的交付应适用EXW规则（ARMSTRONG在美国的工厂）。经销商在ARMSTRONG工厂收到经要求的产品P后应承担立即出现的所有适用风险，无论是通过承运方/运输系统还是其他方式。

For purposes of this Agreement, trade terms (e.g., EXW) used to describe the rights and obligations of the Parties shall have the meanings assigned to them by Incoterms 2020 published by the International Chamber of Commerce.

为本协议之目的，本协议中使用的描述双方权利与义务的贸易术语（如EXW）应具有国际商会出版的《国际贸易术语解释通则（2020）》赋予它们的含义。

6.2 Supply Price. The supply price of Product P from ARMSTRONG to the Distributor is EXW price USD [***] per unit ("**Supply Price**"). For avoidance of doubt, all transport costs and customs clearance costs shall be borne by the Distributor.

供应价格。ARMSTRONG向经销商供应产品P的价格为十[***]美元/支（EXW价格，以下简称"**供应价格**"）。为免疑义，所有运输费用和海关清关费用应由经销商承担。

Notwithstanding aforesaid, ARMSTRONG reserves the right to increase the Supply Price of no more than one (1) time per Contract Year. Such increase of the Supply Price shall be no more than five percent (5%) on an annual basis except in the circumstance that ARMSTRONG's standard costs of Product P has increased by more than five percent (5%).

尽管有上述规定，ARMSTRONG保留每一合同年最多一（1）次上调供应价格的权利。除非ARMSTRONG对产品P的标准成本增加了百分之五（5%）以上，否则供应价格的年增长率不得超过百分之五（5%）。

6.3 Purchase Order. The Distributor shall issue purchase orders to ARMSTRONG. The purchase order shall specify the quantity, expected delivery date and other matters mutually agreed by the Parties. The Parties hereby agree that the Distributor shall provide ARMSTRONG with a delivery period of no less than ninety (90) days.

采购订单。经销商应向ARMSTRONG发出采购订单。采购订单应明确采购数量、预期交付日期和双方共同商定的其他事项。双方特此同意，经销商应向ARMSTRONG提供不少于九十（90）天的交付期。

6.4 Payment. The Distributor shall pay for Product P within thirty (30) days from the date of invoice provided by ARMSTRONG to the Distributor.

付款。经销商应于ARMSTRONG向其提供发票之日起三十（30）天之内支付产品P的价款。

6.5 Supply Shortage. If, at any time, ARMSTRONG's supply of Product P is insufficient to meet total requirements of the Distributor ("**Supply Shortage**"), ARMSTRONG is entitled to cancel or postpone the delivery of Product P to the Distributor on its own discretion. In such situation ARMSTRONG shall not be liable to the Distributor for any claims, losses, damages or expenses related to any failure by ARMSTRONG to supply, including without limitation any direct, indirect, special, incidental or consequential claims, losses, damages or expenses (including without limitation any cost of cover or lost revenues or profits), whether or not the possibility or extent of any such damages are foreseen or foreseeable. After such Supply Shortage has occurred, the Parties will meet together as soon as practicable and engage in friendly discussions in order to allow ARMSTRONG to recover such Supply Shortage within a reasonable period of time.

供应短缺。如果在任何时候，ARMSTRONG供应的产品P不足以满足经销商的全部要求（以下简称"**供应短缺**"），ARMSTRONG有权自行决定取消或推迟向经销商交付产品P。在这种情况下，ARMSTRONG不对经销商承担与ARMSTRONG供应失败有关的任何索赔、损失、损害或费用，包括但不限于任何直接、间接、特殊、附带或后果性索赔、损失、损害或费用（包括但不限于任何保险费用或收入或利润损失），无论任何此类损害的可能性或程度是否已预见或

可预见。在供应短缺问题发生后，双方将在可行的情况下尽快会晤并进行友好协商，以便ARMSTRONG在合理的时间内补足供应短缺。

6.6 Profit Sharing. GENREACH shall pay ARMSTRONG Profit Sharing. "**Profit Sharing**" is calculated based on GENREACH Earnings. "**GENREACH Earnings**" is defined as GENREACH's per unit net revenue for Product P during a Calculation Period (i.e. the total revenue during a Calculation Period minus Supply Price and Distribution Costs as defined in Section 7.1 during such Calculation Period, then divided by total sold units amount during such Calculation Period).

The Profit Sharing shall be calculated as follow:

利润分成。GENREACH应向ARMSTRONG支付利润分成，该等"**利润分成**"将根据GENREACH收益进行计算。"**GENREACH收益**"指在一个计算期间内GENREACH单支产品P的净收入（即某一计算期间内GENREACH总收入减去该计算期间内供应价格、以及本协议第7.1条定义的销售成本，再除以该计算期间内总销售数量）。

利润分成具体计算方式如下：

6.6.1 For GENREACH Earnings that is USD [***] to USD [***] per unit of Product P, GENREACH shall pay [***] Profit Sharing regarding the part above USD [***].

For example: if GENREACH Earnings is USD [***] per unit for the sale of 100,000 units in a Calculation Period, then ARMSTRONG shall earn Profit Sharing of (USD [***] – USD [***]) x [***] x 100,000 units = USD [***]

当每一支产品P的GENREACH收益在 [***] 美元至 [***] 美元之间，GENREACH应就超过 [***] 美元的部分支付[***]的利润分成。

例如，如果GENREACH某计算期间共销售100,000支，每一支的GENREACH收益为[***]美元，那么ARMSTRONG应收取的利润分成为：([***]美元-[***]美元) x [***] x 100,000支 = [***]美元。

6.6.2 For GENREACH Earnings that is more than USD [***] per unit of Product P, GENREACH shall pay [***] Profit Sharing regarding the part above USD [***] and below USD [***] and [***] Profit Sharing regarding the part above USD [***].

For example: if GENREACH Earnings is USD [***] per unit with 100,000 units sold in a Calculation Period, then Armstrong shall earn Profit Sharing as follow: (USD [***] – USD [***]) x [***] x 100,000 + (USD [***] – USD [***]) x [***] x 100,000 = USD [***]

当每一支产品P的GENREACH收益高于[***]美元，GENREACH应就超过[***]美元但未超过[***]美元的部分支付[***]的利润分成，以及就超过[***]美元的部分支付[***]的利润分成。

例如，如果GENREACH某计算期间共销售100,000支，每一支的GENREACH收益为[***]美元，那么ARMSTRONG应收取的利润分成为：([***]美元-[***]美元) x [***] x 100,000支 + ([***]美元-[***]美元) x [***] x 100,000支= [***]美元。

6.6.3 There will be no Profit Sharing earned if GENREACH Earnings is USD [***]or less per unit of Product P.

当每一支产品P的GENREACH收益小于或等于[***]美元，则GENREACH无需支付利润分成。

Profit Sharing is calculated and payable every 12 month period (the "**Calculation Period**"). GENREACH shall provide ARMSTRONG with all necessary data and supporting documents to calculate the Profit Sharing amount within twenty (20) days after expiration of each Contract Year. After confirmation of the Profit Sharing amount by ARMSTRONG, GENREACH shall pay the Profit Sharing amount within thirty (30) days from the date of invoice provided by ARMSTRONG to GENREACH. If ARMSTRONG has any query or disagreement with the Profit Sharing amount, ARMSTRONG has the right to request GENREACH to provide additional supporting materials, and to inspect relevant accounting books and other documents of GENREACH.

该等利润分成每12个月（"**计算期间**"）进行计算并支付。GENREACH应在每个合同年度结束后的二十（20）日内向ARMSTRONG提供计算利润分成金额所需的所有必要数据和支持文件。在ARMSTRONG确认利润分成金额后，GENREACH应在ARMSTRONG向其提供的发票日期起三十（30）日内支付利润分成金额。如ARMSTRONG对利润分成金额有疑问或异议，ARMSTRONG有权要求GENREACH提供进一步补充材料，并有权对GENREACH相关会计账簿等文件进行检查。

6.7 Returns. Distributer will not be allowed to make returns of Product P.

退货。经销商不得就产品P进行退货。

6.8 Residual Validity. Product P delivered by Armstrong shall have a residual validity period of not less than 21 months.

有效期。Armstrong交付的产品 P 的剩余有效期不得少于 21 个月。

7 Distribution Costs and Additional Fees

销售成本和额外费用

7.1 Distribution Costs. The Distributor shall itself bear all the distribution costs of Product P ("**Distribution Costs**"), including all the costs and expenses incurred for the purpose of (i) obtaining any Regulatory Approval required for the Development Plan, (ii) marketing and clinical costs of Product P in the Collaboration Region, (iii) warehousing and transportation costs, and (iv) other costs incurred for or in relation to the sales and distribution of Product P. For avoidance of doubt, the Distribution Costs are not included in the Supply Price paid to ARMSTRONG.

销售成本。经销商应自行承担产品P的所有销售成本（以下简称"**销售成本**"），包括为以下目的而产生的所有成本和费用：(i) 获得开发计划所需的任何监管批准；(ii) 在合作区域内产品P的推广和临床成本；(iii) 仓储和运输费用；及(iv) 因销售和分销产品P而发生的或与之相关的其他成本。为免疑义，经销商支付给ARMSTRONG的供应价格中不包含销售成本。

7.2 Additional Fees. In the case the Distributor requires additional supports from ARMSTRONG, such as personnel supports, the Distributor shall pay additional fees to ARMSTRONG, which will be negotiated separately.

额外费用。如果经销商要求ARMSTRONG提供额外的支持，如人员支持，经销商应向ARMSTRONG支付额外费用，额外费用由双方另行协商。

8 Intellectual Property, License and Trademarks

知识产权、许可和商标

8.1 ARMSTRONG Intellectual Property. The Distributor hereby acknowledges that (i) all Intellectual Property in relation to and developed for Product P, and (ii) any Intellectual Property further generated in the context of Product P, including but not limited to those generated or improved during any clinical trials or marketing activities on behalf of the Distributor, and any other peripheral technologies shall solely belong to ARMSTRONG, regardless of whether such Intellectual Property have been registered or not (the "**ARMSTRONG Intellectual Property**").

ARMSTRONG知识产权。经销商确认，(i) 与产品P有关的和为产品P而开发的所有知识产权；及(ii) 在产品P的背景下进一步产生的任何知识产权，包括但不限于经销商在任何临床试验或市场推广活动中产生或改进的知识产权，以及所有周边技术，均应由ARMSTRONG单独所有，无论这些知识产权是否已经注册（以下简称"**ARMSTRONG知识产权**"）。

8.2 License to the Distributor. ARMSTRONG hereby grants to the Distributor and the Distributor hereby accepts a non-exclusive license to use ARMSTRONG Intellectual Property solely in connection with (i) the distribution and promotion of Product P in the Collaboration Region within the term of this Agreement, and (ii) application for necessary Regulatory Approval for the Development Plan, with the right to sublicense to permitted Sub-Distributors to use ARMSTRONG Intellectual Property solely in connection with the distribution and promotion of Product P in the Collaboration Region within the term of this Agreement.

对经销商的许可。ARMSTRONG向经销商授予且经销商接受一项使用ARMSTRONG知识产权的非独占许可。经销商使用ARMSTRONG知识产权仅可用于(i) 在本协议有效期内在合作地区内经销和推广产品P，及(ii) 为开发计划申请必要的监管批准。经销商有权分许可给本协议允许的次级分销商，仅用于在本协议有效期内在合作地区内分销和推广产品P而使用ARMSTRONG知识产权。

8.3 Limitation of Use of ARMSTRONG Intellectual Property. Without the express written consent from ARMSTRONG, the Distributor shall not manufacture, market or sell any product that contains Product P or embodies any of ARMSTRONG's Intellectual Property for purposes other than to perform this Agreement. The Distributor shall not use (other than pursuant to this Agreement) or seek to register or apply for statutory protection any of ARMSTRONG's Intellectual Property, or any Intellectual Property that may impair the protection of ARMSTRONG Intellectual Property. The

Distributor shall immediately notify ARMSTRONG if it becomes aware of a possible infringement of ARMSTRONG's Intellectual Property.

ARMSTRONG知识产权的使用限制。未经ARMSTRONG明确书面同意，经销商不得为履行本协议以外的目的制造、推广或销售任何含有产品P或包含ARMSTRONG的知识产权的产品。经销商不得使用（根据本协议的使用除外）或寻求注册或申请任何ARMSTRONG的知识产权，或可能损害ARMSTRONG知识产权保护的任何知识产权。如果经销商发现ARMSTRONG的知识产权可能受到侵犯，应立即通知ARMSTRONG。

8.4 No Exclusiveness When Breach. Notwithstanding the foregoing, the exclusive license granted under this Agreement is suspended and ARMSTRONG shall retain the right to market and sell the Product P anywhere in the world through third parties in the event that the Distributor is in violation of this Agreement.

违约时无排他性。尽管有上述规定，如果经销商违反本协议，根据本协议授予的排他性许可将被取消，ARMSTRONG应保留通过第三方在世界任何地方推广和销售产品P的权利。

9 Representations, Warranties and Liabilities

声明、保证和责任

9.1 General Representations and Warranties. Each Party respectively represents and warrants to the other Party that: (i) it is a corporation duly incorporated, validly existing, and in good standing under the applicable law; (ii) it has full right, power, and authority to enter into this Agreement and to perform its obligations hereunder; no consent of, approval from, authorization of, designation of, declaration from or filing with any governmental authority is required in connection with the valid execution, delivery and performance of this Agreement; and it has no current legal arrangement with any other party that would conflict with this Agreement; (iii) the representative entrusted by it to execute this Agreement has been duly authorized to do so; (iv) upon execution, this Agreement shall become a lawful, valid, and binding obligation of such Party, enforceable against it in accordance with its terms; and (v) it shall not enter into any agreement or make any commitment or take any other action that would impair its ability to perform its obligations under this Agreement.

一般声明和保证。双方分别向对方声明并保证：(i) 其是根据适用法律正式成立、有效存续且信誉良好的公司；(ii) 其拥有签订本协议并履行其在本协议项下义务的全部权利、权力和权限；本协议的有效签署、交付和履行不需要任何政府机构的同意、认证、授权、指定、声明或备案；其目前与任何其他方没有与本协议相冲突的法律安排；(iii) 其委托签署本协议的代表已获得正式授权；(iv) 签署后，本协议将成为其合法、有效且具有约束力的合同义务，可根据其条款对其强制执行；及(v) 其不会订立任何协议或做出任何承诺或采取任何其他行动以损害其履行本协议项下义务的能力。

9.2 Compliance with Law. The Distributor shall comply with all legislations, rules, regulations and statutory requirements existing from time to time in the jurisdiction where Product P is being sold that are applicable to the sale

and distribution of Product P. The Distributor shall be responsible for obtaining all necessary authorizations, consents, approvals, licenses and permits in relation to the performance by them of their obligations under this Agreement and for making any necessary filling, record or registration of this Agreement and shall, upon request, provide ARMSTRONG satisfactory evidence thereof as reasonably required by ARMSTRONG from time to time. The Distributor shall indemnify ARMSTRONG and its Affiliates and their respective employees, servants and agents and hold them harmless from and against any loss, suit, claim, liability, expense (including and without limitation reasonable attorney's fees), proceeding or damage (on an after-tax basis) to persons or property arising out of or related to warehousing, transportation, distribution, sale, marketing of Product P in the Collaboration Region.

遵守法律。经销商应遵守产品P销售所在司法管辖区内不时存在的适用于产品P的销售和经销的所有立法、规则、条例和法定要求。经销商应负责获得与其履行本协议项下义务有关的所有必要的授权、同意、批准、执照和许可，并负责对本协议进行任何必要的备案、记录或登记，并根据ARMSTRONG不时提出的合理要求，向ARMSTRONG提供令ARMSTRONG满意的证明。经销商应赔偿ARMSTRONG及其关联方及其各自的雇员、职员和代理并为其辩护，使其免受因产品P在合作区域内仓储、运输、经销、销售、市场宣传等而产生的任何损失、诉讼、索赔、责任、费用（包括但不限于合理的律师费）、诉讼或对人身或财产造成的损害（在税后基础上）。

9.3 LIMITED WARRANTIES AND DISCLAIMER. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, ARMSTRONG MAKES NO WARRANTY TO THE DISTRIBUTOR WITH RESPECT TO PRODUCT P AND EXCLUDES ALL OTHER EXPRESS AND IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE, NONINFRINGEMENT, QUIET ENJOYMENT, AND ANY IMPLIED WARRANTY ARISING FROM THE COURSE OF DEALING OR THE COURSE OF PERFORMANCE.

有限保证和免责声明。除本协议明确规定外，ARMSTRONG就产品P对经销商不作任何保证，并且排除所有其他明示和暗示的保证，包括但不限于对适销性、特定用途的适用性、不侵权、平静受益的暗示保证，以及因交易过程或履约过程而产生的任何暗示保证。

10 Indemnification

赔偿

10.1 Indemnity. Each Party (the "**Indemnifying Party**") shall indemnify and defend the other Party and its Affiliates and their respective employees, servants and agents and hold them harmless from and against any loss, suit, claim, liability, expense (including and without limitation reasonable attorney's fees), proceeding or damage (on an after-tax basis) to persons or property arising out of or related to (a) any acts, whether of omission or commission, that may be committed by the Indemnifying Party; and (b) any alleged or actual breach by the Indemnifying Party of its warranties, representations, covenants and obligations under this Agreement. The

provisions of this Section 10.1 shall survive the termination of this Agreement.

赔偿。每一方（以下简称"**赔偿方**"）应赔偿另一方及其关联方及其各自的雇员、职员和代理并为其辩护，使其免受因以下情况产生的任何损失、诉讼、索赔、责任、费用（包括但不限于合理的律师费）、诉讼或对人身或财产造成的损害（在税后基础上）：(a) 赔偿方可能实施的任何行为（无论是作为或不作为）；(b) 赔偿方声称或实际违反其在本协议项下的保证、声明、约定和义务。本第10.1条在本协议终止后继续有效。

11 Term and Termination

有效期和终止

11.1 Term. This Agreement shall be effective upon the Effective Date, and shall be binding upon and inure to the benefit of the Parties and their respective assigns and successors in interest. The term of this Agreement (the "**Term**") shall be ten (10) years commencing on the Effective Date herein. The Parties may negotiate on extension of this Agreement commencing six (6) months prior to the expiration.

有效期。本协议的自生效日期起生效，对双方及其各自的受让人和利益继承人具有约束力并以其为受益人。本协议的有效期（以下简称"**有效期**"）为十（10）年，自生效日期起计算。双方可在本协议到期前六（6）个月就本协议的延期进行谈判为十（10）年，自生效之日起计算。双方可在本协议有效期满前六（6）个月就本协议的延期进行协商。

11.2 Termination. This Agreement may be terminated before the expiration in any of the following events:

终止。在下列任何一种情况下，本协议可在有效期满前终止：

(1) After the completion of Contract Year 2, either party is entitled to terminate this Agreement without cause by giving a six (6) months' prior written notice;

两（2）个合同年后，任何一方有权经提前六（6）个月书面通知无理由终止本协议；

(2) If any party breaches this Agreement, the other party is entitled to terminate this Agreement by giving a two (2) months' prior written notice;

如一方违反本协议，另一方有权经提前两（2）个月书面通知终止本协议；

(3) If the Distributor fails to reach the sales forecasts in Section 5.1 herein for two (2) consecutive Contract Years, ARMSTRONG is entitled to terminate this Agreement immediately; and

如经销商连续两（2）个合同年无法达到第5.1条规定的销售预测，ARMSTRONG有权立即终止本协议；及

(4) If the Distributor fails to purchase [***] units of Product P from ARMSTRONG in any Contract Year, ARMSTRONG is entitled to terminate this Agreement immediately.

如经销商在任何合同年未能向ARMSTRONG购买[***]支产品P，ARMSTRONG有权立即终止本协议。

11.3 Effect of Termination for Parties. Except as expressly provided herein, no Party shall incur any liability to the other party for terminating this Agreement in accordance with this Section 11, and no such termination shall limit the contemporaneous or subsequent exercise of any other rights and remedies such Party may have. Nothing herein shall be construed to release any Party from any obligation that accrued prior to the date of termination, except as expressly provided in this Agreement. Without limitation, (i) all accrued but unpaid amounts that may be owing from a Party to the other Party shall survive termination and (ii) any claim for breach or damages arising prior to or as a result of the termination shall survive (including an claim for any breach or damages continuing after termination).

终止对双方的效力。除本协议明确规定外，任何一方均不得因根据本协议本第11条的规定终止本协议而对另一方产生任何责任，因此种方式终止本协议也不会限制该方可能同时或随后行使的任何其他权利和补救措施。除本协议明确规定外，此处的任何表述均不得解释为免除任何一方在终止日期之前产生的任何义务。不能限制对方行使的权利和不久措施还包括：(i) 一方欠另一方的所有已产生但尚未支付的款项应在终止后继续支付；及(ii) 在本协议终止之前或因终止而产生的任何违约或损害索赔继续存在（包括对本协议终止后继续存在的任何违约或损害提出索赔）。

Upon termination of this Agreement, ARMSTRONG may, without limiting any other right or remedy:

本协议终止后，ARMSTRONG可在不限制任何其他权利或补救措施的情况下：

(1) suspend the supply of all Product P (including under purchase orders not yet fulfilled) to Distributor;

暂停向经销商供应所有产品P（包括尚未履行完毕的采购订单）；

(2) require Distributor and its Affiliates to promptly return to ARMSTRONG all Product P in the possession, custody or control of Distributor or its Affiliates; and

要求经销商及其关联方立即将其拥有、保管或控制的所有产品P退还给ARMSTRONG；及

(3) sell, or engage a third party distributor to sell, all Product P manufactured under purchase order of Distributor to a third party, and recover from Distributor any costs and expenses reasonably incurred by ARMSTRONG in doing so.

向第三方出售或委托第三方经销商销售根据经销商的采购订单生产的所有产品P，并要求经销商弥补ARMSTRONG因此而合理产生的任何成本和费用。

12 Confidentiality.

保密

12.1 The receiving party shall treat as confidential and secret all information which has been or may hereafter be disclosed by the disclosing party, directly or indirectly, to the receiving party, either orally, in writing or through inspection. The receiving party shall use the Confidential Information received only to the extent necessary to execute the Purpose of this Agreement. The receiving party shall not disclose to anyone any Confidential Information received from the disclosing party, and shall use the same degree of care, but no less than a reasonable degree of care, to prevent the disclosure of the Confidential Information to others as it uses to prevent the disclosure of its own Confidential Information. Upon request from the disclosing party, the receiving party shall promptly return to the disclosing party or destroy all drawings, data, memoranda and information in physical form relating to the Confidential Information.

接收方应将披露方已经或今后可能以口头、书面或检查的方式直接或间接向接收方披露的所有信息视为保密信息。接收方只能为执行本协议目的所必需的范围内使用所收到的保密信息。接收方不得向任何人披露从披露方收到的任何保密信息，并应采用与防止披露其自身保密信息相同的谨慎程度，但不得低于合理的谨慎程度，以防止向他人披露保密信息。应披露方的要求，接收方应及时向披露方归还或销毁与保密信息有关的所有实物形式的图纸、数据、备忘录和信息。

"**Confidential Information**" means technical and business information relating to inventions, proprietary ideas and/or patentable ideas, patent applications, background intellectual property, techniques, scientific knowledge, know-how processes, existing and/or contemplated products and services, software, biological material, schematics, research and development, production, costs, profit and margin information, finances and financial projections, customers, clients, licensees, marketing, and current or future business plans and models, or other subject matters of this Agreement, regardless of whether such information is designated as "Confidential Information" at the time of disclosure. The term "Confidential Information" does not include such information which:

"**保密信息**"是指与发明、专有构思和/或可申请专利的构思、专利申请、背景知识产权、技术、科学知识、专有技术工艺、现有和/或计划中的产品和服务、软件、生物材料、示意图、研发、生产、成本、利润和利润率信息、财务和财务预测、客户、顾客、被许可人、市场推广以及当前或未来的商业计划和模式、或本协议的其他主题有关的技术和商业信息，无论这些信息在披露时是否被指定为保密信息。保密信息不包括以下信息：

(i) is or becomes generally available to the public, other than through the receiving party's disclosure,

未经接收方披露，公众普遍可以获得的信息；

(ii) was within the receiving party's possession prior to it being furnished by or on behalf of the disclosing party, provided that receiving party's source had no obligation of confidentiality to the disclosing party,

在由披露方提供或代表披露方提供之前，接收方已获得的信息，前提是接收方的信息来源对披露方不承担保密义务；

(iii) becomes available to the receiving party on a non-confidential basis from an information provider other than the disclosing party, provided that the information provider did not have a duty of confidentiality to the disclosing party, or

接收方可从信息披露方以外的信息提供方获得的非保密信息，前提是信息提供方对披露方不承担保密义务；或

(iv) is or becomes independently developed the receiving party without access to the Confidential Information and without violating any of the receiving party's obligations under this Agreement, as can be demonstrated by the receiving party's written records.

接收方在未获得保密信息且未违反本协议规定的接收方任何义务的情况下独立开发的信息，并且可以被接收方的书面记录证明。

12.2 Each Party agrees to keep the Confidential Information confidential, which includes (but is not limited to) not disclosing the disclosing party's Confidential Information, or any part thereof (except as otherwise may be provided herein), absent the disclosing party's prior written consent, unless required to do so by Applicable Law, act or a valid order of a court or other governing, regulatory body with authority over the receiving party ("**Required Disclosure**"); provided that the receiving party shall first give reasonable written notice to the disclosing party prior to any Required Disclosure and shall exercise its best efforts to obtain an order or other reliable assurance that the Confidential Information disclosed will be treated at the highest level of confidentiality. Upon receipt of notice from the receiving party of any Required Disclosure, the disclosing party may, at the disclosing party's expense, seek to quash or restrict the disclosure of the disclosing party's Confidential Information and the receiving party shall not oppose or seek to impede the disclosing party's efforts to obtain such relief.

双方同意对保密信息保密，包括（但不限于）未经披露方事先书面同意，不披露披露方的保密信息或其任何部分（本协议另有规定的除外），除非适用法律、法令、或法院或其他对接收方有权管理的监管机构的有效命令要求接收方披露（"**被要求的披露**"）；但接收方应在进行任何被要求的披露之前，首先向披露方发出合理书面通知，并应尽最大努力获得命令或其他可靠保证，确保所披露的保密信息得到最高级别的保密处理。在收到接收方关于任何被要求的披露的通知后，披露方可寻求撤销或限制保密信息的披露，费用由披露方承担，接收方不得反对或阻碍披露方获得此类救济的努力。

13 Notice

通知

13.1 All notices and communications between the parties must be in writing and addressed to the receiving party as follows:

双方之间的所有通知和通信必须采用书面形式，并按以下地址寄给接收方：

If to ARMSTRONG:

ARMSTRONG：

Address:11570 Sixth Street, Rancho Cucamonga, CA 91730, U.S.A.

地址：11570 Sixth Street, Rancho Cucamonga, CA 91730, U.S.A.

Email: [***]

邮箱：[***]

Tel:1-909-980-9484

电话：1-909-980-9484

If to the Distributor:

经销商：GENREACH

Address: RM 1007B,10/F.,HO KING COMMERCIAL CTR.,NO.2-16 FA YUEN STREET, MONGKOK HONG KONG, CHINA

地址：中国香港旺角发源街2-16号豪景商业大厦10楼1007B室

Email: [***]

邮箱：[***]

Tel: [***]

电话：[***]

14 Governing Law and Dispute Resolution

适用法律和争议解决

14.1 Governing Law. This Agreement shall be governed by, and construed in accordance with the laws of Hong Kong, excluding provisions relating to conflict of laws or rules that would require the application of the laws of any other jurisdiction and the Convention on Contracts for the International Sale of Goods.

适用法律。本协议应受香港法律管辖并据其解释，但不包括与法律冲突相关的或要求适用其他任何司法管辖区域的法律和《联合国国际货物销售合同公约》的规定。

14.2 Dispute Resolution. This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) (the "**Disputes**") shall first be resolved through consultation. If the Disputes cannot be resolved through negotiation, the Disputes (including a Dispute in connection with the validity or continuity of this Agreement) shall be submitted to arbitration in Hong Kong International Arbitration Centre (HKIAC) with its then effective arbitration rules. The arbitration tribunal shall be consisted by three (3) members. One (1) arbitrator shall be appointed by the Party initiating the arbitration, one (1) arbitrator shall be appointed by the other Party, and the third arbitrator shall be jointly selected by the two (2) appointed arbitrators. The award of the

arbitration tribunal shall be final and binding upon the Parties, and each Party may apply to a court of competent jurisdiction for enforcement of such award. Except for matters in the Dispute during a Dispute which is being resolved in accordance with this Agreement, the Parties shall continue to perform their obligations hereunder.

争议解决。本协议以及因本协议或其标的物或其订立而产生的或与之相关的任何争议或索赔（包括非合同争议或索赔）（以下简称"**争议**"）应首先通过协商解决。如果争议无法通过协商解决，争议（包括与本协议的有效性或持续性有关的争议）应提交香港国际仲裁中心根据其当时有效的仲裁规则进行仲裁。仲裁庭由三（3）名仲裁员组成。一（1）名仲裁员由提起仲裁的一方指定，一（1）名仲裁员由另一方指定，第三名仲裁员由两（2）名指定的仲裁员共同选定。仲裁庭的裁决应为终局裁决，对双方均有约束力，双方均可向有管辖权的法院申请执行该裁决。除根据本协议解决争议期间的争议事项外，双方应继续履行其在本协议下的义务。

15 General Provisions

一般条款

15.1 Taxes. Each Party shall assume full responsibility for the proper reporting and payment of all national, state or local taxes, value-added or other taxes, contributions and/or special levies imposed or required under income tax and/or other laws or regulations, with respect to its performance under this Agreement.

税收。双方应根据所得税和/或其他法律或法规的规定，各自承担其因履行本协议所需申报和支付的所有国家、州或地方税、增值税或其他税款、缴款和/或特别征税。

15.2 Amendment. This Agreement may be amended only in writing signed by both Parties. Any term or condition in other contracts or agreements between the Parties that conflict in whole or in part with the provisions in this Agreement shall be of no force or effect and the provisions of this Agreement shall prevail in any such circumstance.

修改。本协议只能以双方签署的书面形式进行修改。双方之间的其他合同或协议中的任何条款或条件与本协议条款的全部或部分冲突均无效，在任何此类情况下均应以本协议条款为准。

15.3 Assignment. Each Party's rights and obligations under this Agreement are not transferable and assignable without the prior written consent of the other Party.

转让。未经另一方事先书面同意，一方在本协议项下的权利和义务不得转让。

15.4 Severability. If any term, provision, covenant, or condition of this Agreement is held by a court of competent jurisdiction to be invalid, void or unenforceable, the remainder of the provisions shall remain in full force and effect and shall in no way be affected, impaired or invalidated, provided that the Agreement remains substantially capable of performance without adversely affecting the rights of the Parties.

可分割性。如果本协议的任何条款、规定、约定或条件被具有管辖权的法院裁定为无效或不可执行，则其余规定应保持完全有效，并且不得以任何方式受到影响、损害或无效，前提是本协议实质上仍然能够履行而不会对双方的权利产生不利影响。

15.5 Survival. Sections 10, 11.3, 12, 14 and 15 shall survive the termination of this Agreement.

存续。本协议第10、11.3、12、14和15条应在本协议终止后继续有效。

15.6 Waiver. The failure of a Party to enforce, at any time or for any period of time, any provision of this Agreement shall not be construed as a waiver of such provision or the right of such a Party to enforce such provision thereafter.

放弃。一方未能在任何时间或任何时间段内执行本协议的任何条款，不应解释为放弃该条款或此后执行该条款的权利。

15.7 Force Majeure. A Party shall not be responsible for any default in performing this Agreement due to unforeseen circumstances or causes beyond its reasonable control (the "**Force Majeure**"), including but not limited to earthquake, typhoon, flood, or other acts of nature, pandemic (excluding those related to the COVID-19 pandemic subsisting as at the date of this Agreement which have not materially escalated afterwards), fire, terrorism, war and riots. The Party claiming Force Majeure shall notify the other Party in writing within thirty (30) days after the occurrence of such event, take appropriate means to minimize or remove the effects of Force Majeure and make attempts to resume performance of its obligations affected by the Force Majeure. If the Party claiming Force Majeure is unable to perform all or part of this Agreement for three (3) months after the occurrence of such event, the other Party may terminate this Agreement.

不可抗力。由于不可预见的情况或超出其合理控制范围的原因（以下简称"不可抗力"），包括但不限于地震、台风、洪水或其他自然灾害、流行病（不包括在本协议签署之日存在的COVID-19流行病相关的，且此后没有实质性升级的情况）、火灾、恐怖主义、战争和骚乱，一方不应就其对本协议的违反承担责任。主张不可抗力的一方应在此类事件发生后三十（30）天内以书面形式通知另一方，采取适当的方式尽量减少或消除不可抗力的影响，并努力恢复履行其受不可抗力影响的义务。如果主张不可抗力的一方在该事件发生后三（3）个月内无法履行本协议的全部或部分内容，另一方可终止本协议。

15.8 Execution in Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument. This Agreement shall become binding when any one or more counterparts thereof, individually or taken together, bear the signature of both Parties thereto. For the purposes hereof, a facsimile copy of this Agreement, including the signature pages thereto, shall be deemed an original.

份数。本协议可签署一份或多份，每份均为原件，共同构成同一份协议。当本协议的任何一份或多份（单独或合并）由双方签字时，本协议即具有约束力。为此目的，本协议的传真件，包括其签字页，应被视为原件。

15.9 Language. This Agreement is written in English and Chinese. Should there be any discrepancy between the English version and Chinese version, the English version shall prevail.

语言。本协议以英文和中文书就。如英文版本和中文版本之间有任何分歧，以英文版本为准。

[*The below is intentionally left blank*]

[以下无正文]

IN WITNESS WHEREOF, each of the Parties hereto has caused this Agreement to be executed by their representatives, duly authorized hereunto, on the date first above written.

本协议的每一方都已安排由其正式授权的代表在上述日期签署本协议，以昭信守。

For and on behalf of

谨代表

Armstrong Pharmaceuticals, Inc.:

By/签署:	**/s/Tony Marrs**
Name/姓名:	Tony Marrs
Title/职务:	President

For and on behalf of

谨代表

Hong Kong Genreach Limited:

(香港金瑞驰有限公司) (Seal):

By/签署:	**/s/Xuefeng Yang**
Name/姓名:	Xuefeng Yang
Title/职务:	Legal Representative

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 7, 2024

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 7, 2024

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, 2024 (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 7, 2024

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, 2024 (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 7, 2024

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.