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

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2022
or

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

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

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

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

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

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

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

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

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

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	AMPH	The NASDAQ Stock Market LLC

The number of shares outstanding of the registrant's only class of common stock as of November 1, 2022 was 48,331,186.

AMPHASTAR PHARMACEUTICALS, INC.
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SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or Quarterly Report, contains "forward-looking statements" that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the following words: "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these identifying words. Forward-looking statements relate to future events or future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by the forward-looking statements. These forward-looking statements include, but are not limited to, statements about:

- our expectations regarding the sales and marketing of our products;
- our expectations regarding our manufacturing and production and the integrity of our supply chain for our products, including the risks associated with our single source suppliers;
- our business and operations in general, including: uncertainty regarding the magnitude, duration and geographic reach of the ongoing COVID-19 pandemic, adverse impacts of the Russia-Ukraine conflict and related macroeconomic conditions on our business, financial condition, operations, cash flows and liquidity;
- our ability to successfully execute and maintain the activities and efforts related to the measures we have taken or may take in response to the COVID-19 pandemic and associated costs therewith;
- our ability to attract, hire, and retain highly skilled personnel;
- interruptions to our manufacturing and production as a result of natural catastrophic events or other causes beyond our control such as power disruptions or widespread disease outbreaks, such as the ongoing COVID-19 pandemic and the Russia-Ukraine conflict;
- global, national and local economic and market conditions, specifically with respect to geopolitical uncertainty, including the Russia-Ukraine conflict, the ongoing COVID-19 pandemic, inflation and rising interest rates;
- the timing and likelihood of U.S. Food and Drug Administration, or FDA, approvals and regulatory actions on our product candidates, manufacturing activities and product marketing activities;
- our ability to advance product candidates in our platforms into successful and completed clinical trials and our subsequent ability to successfully commercialize our product candidates;
- cost and delays resulting from the extensive pharmaceutical regulations to which we are subject or delays in governmental processing time due to travel and work restrictions caused by the COVID-19 pandemic;
- our ability to compete in the development and marketing of our products and product candidates;
- our expectations regarding the business of our Chinese subsidiary, Amphastar Nanjing Pharmaceuticals, Ltd., or ANP;
- the potential for adverse application of environmental, health and safety and other laws and regulations on our operations;
- our expectations for market acceptance of our new products and proprietary drug delivery technologies, as well as those of our active pharmaceutical ingredient, or API, customers;
- the effects of reforms in healthcare regulations and reductions in pharmaceutical pricing, reimbursement and coverage;
- our expectations in obtaining insurance coverage and adequate reimbursement for our products from third-party payers;
- the amount of price concessions or exclusion of suppliers adversely affecting our business;
- variations in intellectual property laws, our ability to establish and maintain intellectual property protection for our products and our ability to successfully defend our intellectual property in cases of alleged infringement;
- the implementation of our business strategies, product development strategies and technology utilization;
- the potential for exposure to product liability claims;
- our ability to successfully bid for suitable acquisition targets or licensing opportunities, or to consummate and integrate acquisitions, divestitures or investments, including the anticipated benefits of such acquisitions, divestitures or investments;
- our ability to expand internationally;
- economic and industry trends and trend analysis;
- our ability to remain in compliance with laws and regulations that currently apply or become applicable to our business both in the United States and internationally;
- the impact of trade tariffs, export or import restrictions, or other trade barriers;
- the impact of Patient Protection and Affordable Care Act (as amended) and other legislative and regulatory healthcare reforms in the countries in which we operate including the potential for drug price controls;
- the timing for completion and the validation of the new construction at our ANP and Amphastar facilities;
- the timing and extent of share buybacks; and
- our financial performance expectations, including our expectations regarding our backlog, revenue, cost of revenue, gross profit or gross margin, operating expenses, including changes in research and development, sales and marketing and general and administrative expenses, and our ability to achieve and maintain future profitability.

You should read this Quarterly Report and the documents that we reference elsewhere in this Quarterly Report completely and with the understanding that our actual results may differ materially from what we expect as expressed or implied by our forward-looking statements. In light of the significant risks and uncertainties to which our forward-looking statements are subject, you should not place undue reliance on or regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all. In particular, the extent of COVID-19's ongoing impact on our business and the impacts of the ongoing Russia-Ukraine conflict, will depend on several factors, including the severity, duration and extent of the pandemic and the conflict, all of which continue to evolve and remain uncertain at this time. We discuss many of these risks and uncertainties in greater detail in this Quarterly Report and in our Annual Report on Form 10-K for the year ended December 31, 2021, particularly in Item 1A. "Risk Factors." These forward-looking statements represent our estimates and assumptions only as of the date of this Quarterly Report regardless of the time of delivery of this Quarterly Report, and such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this Quarterly Report.

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

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2022 (unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 157,244	$ 126,353
Restricted cash	235	235
Short-term investments	26,843	10,320
Restricted short-term investments	2,200	2,200
Accounts receivable, net	77,099	78,804
Inventories	103,250	92,807
Income tax refunds and deposits	11,365	126
Prepaid expenses and other assets	5,986	7,274
Total current assets	384,222	318,119
Property, plant, and equipment, net	232,741	244,244
Finance lease right-of-use assets	601	353
Operating lease right-of-use assets	26,456	26,894
Investment in unconsolidated affiliate	2,690	3,985
Goodwill and intangible assets, net	37,037	38,870
Other assets	20,549	16,665
Deferred tax assets	22,399	22,399
Total assets	$ 726,695	$ 671,529
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 95,796	$ 89,545
Income taxes payable	1,531	9,081
Current portion of long-term debt	1,680	2,202
Current portion of operating lease liabilities	3,183	2,982
Total current liabilities	102,190	103,810
Long-term reserve for income tax liabilities	6,531	6,531
Long-term debt, net of current portion and unamortized debt issuance costs	74,011	74,776
Long-term operating lease liabilities, net of current portion	24,366	24,703
Deferred tax liabilities	242	534
Other long-term liabilities	14,190	15,653
Total liabilities	221,530	226,007
Commitments and contingencies		
Stockholders' equity:		
Preferred stock: par value $0.0001; 20,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock: par value $0.0001; 300,000,000 shares authorized; 57,994,848 and 48,612,545 shares issued and outstanding as of September 30, 2022 and 56,440,202 and 47,714,912 shares issued and outstanding as of December 31, 2021, respectively	6	6
Additional paid-in capital	448,741	422,423
Retained earnings	237,810	180,337
Accumulated other comprehensive loss	(9,931)	(6,765)
Treasury stock	(171,461)	(150,479)
Total equity	505,165	445,522
Total liabilities and stockholders' equity	$ 726,695	$ 671,529

See Accompanying Notes to Condensed Consolidated Financial Statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net revenues	$ 120,129	$ 112,198	$ 363,964	$ 316,881
Cost of revenues	61,619	61,015	186,272	173,376
Gross profit	58,510	51,183	177,692	143,505
Operating expenses:				
Selling, distribution, and marketing	4,784	4,745	16,059	13,411
General and administrative	11,984	10,910	34,433	40,813
Research and development	18,514	10,759	57,535	43,646
Total operating expenses	35,282	26,414	108,027	97,870
Income from operations	23,228	24,769	69,665	45,635
Non-operating income (expenses):				
Interest income	331	141	741	444
Interest expense	(566)	(527)	(1,318)	(717)
Other income (expenses), net	(397)	13,263	5,692	11,615
Total non-operating income (expenses), net	(632)	12,877	5,115	11,342
Income before income taxes	22,596	37,646	74,780	56,977
Income tax provision	6,559	6,686	16,187	13,436
Income before equity in losses of unconsolidated affiliate	16,037	30,960	58,593	43,541
Equity in losses of unconsolidated affiliate	(163)	—	(1,120)	—
Net income	$ 15,874	$ 30,960	$ 57,473	$ 43,541
Net income attributable to non-controlling interests	$ —	$ 1,412	$ —	$ 1,185
Net income attributable to Amphastar Pharmaceuticals, Inc.	$ 15,874	$ 29,548	$ 57,473	$ 42,356
Net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders:				
Basic	$ 0.32	$ 0.62	$ 1.18	$ 0.89
Diluted	$ 0.30	$ 0.59	$ 1.09	$ 0.85
Weighted-average shares used to compute net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders:				
Basic	48,904	48,022	48,635	47,758
Diluted	52,788	50,009	52,665	49,693

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,	
	2022	2021	2022	2021
Net income attributable to Amphastar Pharmaceuticals, Inc.	$ 15,874	$ 29,548	$ 57,473	$ 42,356
Other comprehensive income (loss) attributable to Amphastar Pharmaceuticals, Inc., net of income taxes				
Reclassification of adjustment for amounts included in net income	—	(362)	—	(362)
Foreign currency translation adjustment	(1,222)	(984)	(3,166)	(2,194)
Total other comprehensive income (loss) attributable to Amphastar Pharmaceuticals, Inc.	(1,222)	(1,346)	(3,166)	(2,556)
Total comprehensive income attributable to Amphastar Pharmaceuticals, Inc.	$ 14,652	$ 28,202	$ 54,307	$ 39,800

See Accompanying Notes to Condensed Consolidated Financial Statements.

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

	Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive loss	Treasury Stock		Total Amphastar Stockholders' Equity	Non-controlling Interest	Total
	Shares	Amount				Shares	Amount			
Balance as of December 31, 2021	56,440,202	$ 6	$ 422,423	$ 180,337	$ (6,765)	(8,725,290)	$ (150,479)	$ 445,522	$ —	$ 445,522
Net income attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	24,253	—	—	—	24,253	—	24,253
Other comprehensive loss attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	—	(480)	—	—	(480)	—	(480)
Purchase of treasury stock	—	—	—	—	—	(51,168)	(1,229)	(1,229)	—	(1,229)
Issuance of treasury stock in connection with the Company's equity plans	—	—	(428)	—	—	33,231	428	—	—	—
Issuance of common stock in connection with the Company's equity plans	1,055,200	—	6,437	—	—	—	—	6,437	—	6,437
Share-based compensation expense	—	—	5,022	—	—	—	—	5,022	—	5,022
Balance as of March 31, 2022	57,495,402	$ 6	$ 433,454	$ 204,590	$ (7,245)	(8,743,227)	$ (151,280)	$ 479,525	$ —	$ 479,525
Net income attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	17,346	—	—	—	17,346	—	17,346
Other comprehensive loss attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	—	(1,464)	—	—	(1,464)	—	(1,464)
Purchase of treasury stock	—	—	—	—	—	(189,840)	(6,118)	(6,118)	—	(6,118)
Issuance of treasury stock in connection with the Company's equity plans	—	—	(430)	—	—	29,019	430	—	—	—
Issuance of common stock in connection with the Company's equity plans	400,935	—	5,783	—	—	—	—	5,783	—	5,783
Share-based compensation expense	—	—	4,235	—	—	—	—	4,235	—	4,235
Balance as of June 30, 2022	57,896,337	$ 6	$ 443,042	$ 221,936	$ (8,709)	(8,904,048)	$ (156,968)	$ 499,307	$ —	$ 499,307
Net income attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	15,874	—	—	—	15,874	—	15,874
Other comprehensive loss attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	—	(1,222)	—	—	(1,222)	—	(1,222)
Purchase of treasury stock	—	—	—	—	—	(478,255)	(14,493)	(14,493)	—	(14,493)
Issuance of common stock in connection with the Company's equity plans	98,511	—	1,400	—	—	—	—	1,400	—	1,400
Share-based compensation expense	—	—	4,299	—	—	—	—	4,299	—	4,299
Balance as of September 30, 2022	57,994,848	$ 6	$ 448,741	$ 237,810	$ (9,931)	(9,382,303)	$ (171,461)	$ 505,165	$ —	$ 505,165

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

	Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive loss	Treasury Stock		Total Amphastar Stockholders' Equity	Non-controlling Interest	Total
	Shares	Amount				Shares	Amount			
Balance as of December 31, 2020	54,760,922	$ 5	$ 410,061	$ 117,773	$ (3,721)	(7,265,483)	$ (121,812)	$ 402,306	$ 46,417	$ 448,723
Net income attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	5,041	—	—	—	5,041	—	5,041
Other comprehensive loss attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	—	(1,921)	—	—	(1,921)	—	(1,921)
Net loss attributable to non-controlling interest	—	—	—	—	—	—	—	—	(1,082)	(1,082)
Purchase of treasury stock	—	—	—	—	—	(204,698)	(3,783)	(3,783)	—	(3,783)
Issuance of treasury stock in connection with the Company's equity plans	—	—	(49)	—	—	4,184	49	—	—	—
Issuance of common stock in connection with the Company's equity plans	423,078	1	(853)	—	—	—	—	(852)	—	(852)
Share-based compensation expense	—	—	4,767	—	—	—	—	4,767	67	4,834
Balance as of March 31, 2021	55,184,000	$ 6	$ 413,926	$ 122,814	$ (5,642)	(7,465,997)	$ (125,546)	$ 405,558	$ 45,402	$ 450,960
Net income attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	7,767	—	—	—	7,767	—	7,767
Other comprehensive income attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	—	711	—	—	711	—	711
Net income attributable to non-controlling interest	—	—	—	—	—	—	—	—	855	855
Purchase of treasury stock	—	—	—	—	—	(298,727)	(5,560)	(5,560)	—	(5,560)
Issuance of treasury stock in connection with the Company's equity plans	—	—	(142)	—	—	12,064	142	—	—	—
Issuance of common stock in connection with the Company's equity plans	552,209	—	7,247	—	—	—	—	7,247	—	7,247
Share-based compensation expense	—	—	6,270	—	—	—	—	6,270	(1,027)	5,243
Balance as of June 30, 2021	55,736,209	$ 6	$ 427,301	$ 130,581	$ (4,931)	(7,752,660)	$ (130,964)	$ 421,993	$ 45,230	$ 467,223
Net income attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	29,548	—	—	—	29,548	—	29,548
Other comprehensive loss attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	—	(984)	—	—	(984)	—	(984)
ANP restructuring (see Note 3)	—	—	(22,162)	448	(362)	—	—	(22,076)	(46,642)	(68,718)
Net income attributable to non-controlling interest	—	—	—	—	—	—	—	—	1,412	1,412
Purchase of treasury stock	—	—	—	—	—	(317,212)	(6,094)	(6,094)	—	(6,094)
Issuance of treasury stock in connection with the Company's equity plans	—	—	(11)	—	—	900	11	—	—	—
Issuance of common stock in connection with the Company's equity plans	315,413	—	3,869	—	—	—	—	3,869	—	3,869
Share-based compensation expense	—	—	3,920	—	—	—	—	3,920	—	3,920
Balance as of September 30, 2021	56,051,622	$ 6	$ 412,917	$ 160,577	$ (6,277)	(8,068,972)	$ (137,047)	$ 430,176	$ —	$ 430,176

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,	
	2022	2021
Cash Flows From Operating Activities:		
Net income	$ 57,473	$ 43,541
Reconciliation to net cash provided by operating activities:		
(Gain) loss on disposal of assets	(52)	338
Gain on deconsolidation of subsidiary	—	(13,587)
(Gain) loss on interest rate swaps and foreign currency transactions, net	(1,124)	800
Depreciation of property, plant, and equipment	17,615	16,800
Amortization of product rights, trademarks, and patents	1,088	930
Operating lease right-of-use asset amortization	2,604	2,471
Equity in losses of unconsolidated affiliate	1,120	—
Share-based compensation expense	13,556	14,837
Changes in deferred taxes, net	—	5,170
Changes in operating assets and liabilities:		
Accounts receivable, net	1,423	(14,166)
Inventories	(12,922)	(5,768)
Prepaid expenses and other assets	1,342	1,174
Income tax refunds, deposits, and payable, net	(18,789)	2,832
Operating lease liabilities	(2,303)	(2,529)
Accounts payable and accrued liabilities	12,924	4,710
Net cash provided by operating activities	73,955	57,553
Cash Flows From Investing Activities:		
Purchases and construction of property, plant, and equipment	(17,724)	(20,578)
Proceeds from the sale of property, plant and equipment	421	—
Purchase of investments	(30,568)	(12,459)
Maturity of investments	15,465	17,423
Payment of deposits and other assets	(142)	(1,104)
Net cash used in investing activities	(32,548)	(16,718)
Cash Flows From Financing Activities:		
ANP restructuring (see Note 3)	—	(53,592)
Proceeds from equity plans, net of withholding tax payments	13,620	10,264
Purchase of treasury stock	(21,840)	(15,437)
Settlement of ANP equity awards	—	(839)
Debt issuance costs	(404)	(1,430)
Repayments under lines of credit	—	(1,161)
Proceeds from issuance of long-term debt	—	70,000
Principal payments on long-term debt	(1,653)	(36,127)
Net cash used in financing activities	(10,277)	(28,322)
Effect of exchange rate changes on cash	(239)	(175)
Net increase in cash, cash equivalents, and restricted cash	30,891	12,338
Cash, cash equivalents, and restricted cash at beginning of period	126,588	94,507
Cash, cash equivalents, and restricted cash at end of period	$ 157,479	$ 106,845
Noncash Investing and Financing Activities:		
Capital expenditure included in accounts payable	$ 3,431	$ 6,246
Operating lease right-of-use assets in exchange for operating lease liabilities	$ 2,166	$ 11,015
Equipment acquired under finance leases	$ 453	$ 107
Supplemental Disclosures of Cash Flow Information:		
Interest paid, net of capitalized interest	$ 1,960	$ 1,868
Income taxes paid	$ 35,166	$ 5,480

See Accompanying Notes to Condensed Consolidated Financial Statements.

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

Note 1. General

Amphastar Pharmaceuticals, Inc., a Delaware corporation (together with its subsidiaries, hereinafter referred to as the "Company") is a bio-pharmaceutical company that develops, manufactures, markets, and sells generic and proprietary injectable, inhalation, and intranasal products, including products with high technical barriers to market entry. Additionally, the Company sells insulin active pharmaceutical ingredient, or API, products. Most of the Company's products are used in hospital or urgent care clinical settings and are primarily contracted and distributed through group purchasing organizations and drug wholesalers. The Company's insulin API products are sold to other pharmaceutical companies for use in their own products and are being used by the Company in the development of injectable finished pharmaceutical products. The Company's inhalation product, Primatene Mist®, is primarily distributed through drug retailers.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements of the Company for the year ended December 31, 2021 and the notes thereto as filed with the Securities and Exchange Commission, or SEC, in the Company's Annual Report on Form 10-K for the year ended December 31, 2021. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with United States generally accepted accounting principles, or GAAP, have been condensed or omitted from the accompanying condensed consolidated financial statements. The accompanying year-end condensed consolidated balance sheet was derived from the audited financial statements. The accompanying interim financial statements are unaudited, but reflect all adjustments which are, in the opinion of management, necessary for a fair statement of the Company's consolidated financial position, results of operations, comprehensive income (loss), stockholders' equity, and cash flows for the periods presented. Unless otherwise noted, all such adjustments are of a normal, recurring nature. The Company's results of operations, comprehensive income (loss) and cash flows for the interim periods are not necessarily indicative of the results of operations and cash flows that it may achieve in future periods.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

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

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

Use of Estimates

The preparation of condensed consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results could differ from those estimates. The principal accounting estimates include: determination of allowances for credit losses, fair value of financial instruments, allowance for discounts, provision for chargebacks and rebates, provision for product returns, adjustment of inventory to its net realizable values, impairment

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of investments, long-lived and intangible assets and goodwill, accrual for workers' compensation liabilities, litigation reserves, stock price volatility for share-based compensation expense, valuation allowances for deferred tax assets, and liabilities for uncertain income tax positions.

Foreign Currency

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

The Company's French subsidiary, AFP, maintains its book of record in euros. AUK's subsidiary, IMS UK, maintains its book of record in British pounds. These local currencies have been determined to be the subsidiaries' respective functional currencies. Activities in the statements of operations are translated to USD using average exchange rates during the period. Assets and liabilities are translated at the rate of exchange prevailing on the balance sheet date. Equity is translated at the prevailing rate of exchange at the date of the equity transactions. Translation adjustments are reflected in stockholders' equity and are included as a component of other accumulated comprehensive income (loss). The unrealized gains or losses of intercompany foreign currency transactions that are of a long-term investment nature are reported in other accumulated comprehensive income (loss).

The unrealized gains and losses of intercompany foreign currency transactions that are of a long-term investment nature were a $2.0 million loss and a $4.7 million loss for the three and nine months ended September 30, 2022, respectively. For the three and nine months ended September 30, 2021, 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 $1.9 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 investment.

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, 2022, advertising expenses were $1.6 million and $6.5 million, respectively. For the three and nine months ended September 30, 2021, advertising expenses were $2.3 million and $6.4 million, respectively.

Financial Instruments

The carrying amounts of cash and cash equivalents, short-term investments, restricted cash and short-term investments, accounts receivable, accounts payable, accrued expenses, and short-term borrowings approximate fair value due to the short maturity of these items. The majority of the Company's long-term obligations consist of variable rate debt, and their carrying value approximates fair value as the stated borrowing rates are comparable to rates currently offered to the Company for instruments with similar maturities. The Company at times enters into interest rate swap contracts to manage its exposure to interest rate changes and its overall cost of long-term debt. The Company's interest rate swap contracts exchange the variable interest rates for fixed interest rates. The Company's interest rate swaps have not been

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designated as hedging instruments and, therefore are recorded at their fair values at the end of each reporting period with changes in fair value recorded in other income (expenses) on the condensed consolidated statements of operations.

Cash and Cash Equivalents

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

Investments

Investments as of September 30, 2022 and December 31, 2021 consisted of certificates of deposit and investment grade corporate and municipal bonds with original maturity dates between three and fifteen months.

Restricted Cash

Restricted cash is collateral required for the Company to guarantee certain vendor payments in France. As of September 30, 2022 and December 31, 2021, the restricted cash balances were $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, 2022 and December 31, 2021, the balance of restricted short-term investments was $2.2 million.

Deferred Income Taxes

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

Litigation, Commitments and Contingencies

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

Recent Accounting Pronouncements

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

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Note 3. ANP Restructuring

As a result of the ANP restructuring that was completed during the third quarter of 2021, and subsequent investments by other equity holders of Hanxin, the Company had a 14% noncontrolling investment in Hanxin as of September 30, 2022 that is accounted for as an equity method investment.

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

Hanxin continues to be a related party after the restructuring.

Note 4. Revenue Recognition

In accordance with Accounting Standard Codification, or ASC, 606 *Revenue from Contracts with Customers*, revenue is recognized at the time that the Company's customers obtain control of the promised goods.

Generally, revenue is recognized at the time of product delivery to the Company's customers. In some cases, revenue is recognized at the time of shipment when stipulated by the terms of the sale agreements.

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

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

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

Revenues derived from contract manufacturing services are recognized when third-party products are shipped to customers, and after the customer has accepted test samples of the products to be shipped.

The Company's accounting policy is to review each agreement involving contract development and manufacturing services to determine if there are multiple revenue-generating activities that constitute more than one unit of accounting. Revenues are recognized for each unit of accounting based on revenue recognition criteria relevant to that unit. The Company does not have any revenue arrangements with multiple performance obligations.

Service revenues derived from research and development contracts is recognized over time based on progress toward satisfaction of the performance obligation. For each performance obligation satisfied over time, the Company assesses the proper method to be used for revenue recognition, either an input method to measure progress toward the satisfaction of services or an output method of determining the progress of completion of performance obligation. For the three and nine months ended September 30, 2022, revenues from research and development services at ANP were $0.8 million and $2.1 million, respectively. For the three and nine months ended September 30, 2021, revenues from research and development services at ANP were $2.6 million and $3.9 million, respectively.

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Provision for Chargebacks and Rebates

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

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

	Nine Months Ended September 30,	
	2022	2021
	(in thousands)	
Beginning balance	$ 20,167	$ 20,380
Provision for chargebacks and rebates	147,899	151,174
Credits and payments issued to third parties	(144,233)	(154,143)
Ending balance	$ 23,833	$ 17,411

Changes in the chargeback provision from period to period are primarily dependent on the Company's sales to its wholesalers, the level of inventory held by wholesalers, and the wholesalers' customer mix. Changes in the rebate provision from period to period are primarily dependent on retailer's and other indirect customers' purchases. The approach that the Company uses to estimate chargebacks has been consistently applied for all periods presented. Variations in estimates have been historically small. The Company continually monitors the provision for chargebacks and rebates and makes adjustments when it believes that the actual chargebacks and rebates may differ from the estimates. The settlement of chargebacks and rebates generally occurs within 20 days to 60 days after the sale to wholesalers. Accounts receivable and/or accounts payable and accrued liabilities are reduced and/or increased by the chargebacks and rebate amounts depending on whether the Company has the right to offset with the customer.

Of the provision for chargebacks and rebates as of September 30, 2022 and December 31, 2021, $18.4 million and $15.6 million were included as a reduction to accounts receivable, net, on the condensed consolidated balance sheets, respectively. The remaining provision as of September 30, 2022 and December 31, 2021 of $5.4 million and $4.6 million, respectively, were included in accounts payable and accrued liabilities.

Accrual for Product Returns

The Company offers most customers the right to return qualified excess or expired inventory for partial credit; however, API product sales are generally non-returnable. The Company's product returns primarily consist of the returns of expired products from sales made in prior periods. Returned products cannot be resold. At the time product revenue is recognized, the Company records an accrual for product returns estimated using the expected value method. The accrual is based, in part, upon the historical relationship of product returns to sales and customer contract terms. The Company also assesses other factors that could affect product returns including market conditions, product obsolescence, and new competition. Although these factors do not normally give the Company's customers the right to return products outside of the regular return policy, the Company realizes that such factors could ultimately lead to increased returns. The

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Company analyzes these situations on a case-by-case basis and makes adjustments to the product return reserve as appropriate.

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

	Nine Months Ended September 30,	
	2022	2021
	(in thousands)	
Beginning balance	$ 21,677	$ 14,204
Provision for product returns	3,086	11,714
Credits issued to third parties	(5,019)	(6,183)
Ending balance	$ 19,744	$ 19,735

Of the provision for product returns as of September 30, 2022 and December 31, 2021, $14.9 million and $16.0 million, were included in accounts payable and accrued liabilities on the condensed consolidated balance sheets, respectively. The remaining provision as of September 30, 2022 and December 31, 2021 of $4.8 million and $5.7 million, were included in other long-term liabilities, respectively. For the nine months ended September 30, 2022 and 2021, the Company's aggregate product return rate was 1.4% and 1.7% of qualified sales, respectively.

Note 5. Income per Share Attributable to Amphastar Pharmaceuticals, Inc. Stockholders

Basic net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders is calculated based upon the weighted-average number of shares outstanding during the period. Diluted net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders gives effect to all 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.

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

For the three and nine months ended September 30, 2021, options to purchase 1,885,093 and 2,045,878 shares of stock, with a weighted-average exercise price of $20.86 per share and $20.74 per share, respectively, were excluded in the computation of diluted net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders because the effect would be anti-dilutive.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(in thousands, except per share data)			
Basic and dilutive numerator:				
Net income attributable to Amphastar Pharmaceuticals, Inc.	$ 15,874	$ 29,548	$ 57,473	$ 42,356
Denominator:				
Weighted-average shares outstanding — basic	48,904	48,022	48,635	47,758
Net effect of dilutive securities:				
Incremental shares from equity awards	3,884	1,987	4,030	1,935
Weighted-average shares outstanding — diluted	52,788	50,009	52,665	49,693
Net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders — basic	$ 0.32	$ 0.62	$ 1.18	$ 0.89
Net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders — diluted	$ 0.30	$ 0.59	$ 1.09	$ 0.85

Note 6. Segment Reporting

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

- Finished pharmaceutical products
- APIs

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

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Selected financial information by reporting segment is presented below:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(in thousands)			
Net revenues:				
Finished pharmaceutical products	$ 117,120	$ 108,990	$ 353,789	$ 301,594
API	3,009	3,208	10,175	15,287
Total net revenues	120,129	112,198	363,964	316,881
Gross profit (loss):				
Finished pharmaceutical products	61,439	54,602	185,462	149,502
API	(2,929)	(3,419)	(7,770)	(5,997)
Total gross profit	58,510	51,183	177,692	143,505
Operating expenses	35,282	26,414	108,027	97,870
Income from operations	23,228	24,769	69,665	45,635
Non-operating income (expenses)	(632)	12,877	5,115	11,342
Income before income taxes	$ 22,596	$ 37,646	$ 74,780	$ 56,977

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(in thousands)			
Finished pharmaceutical products net revenues:				
Primatene Mist®	$ 18,359	$ 16,561	$ 62,030	$ 51,624
Epinephrine	19,502	13,892	52,777	38,662
Lidocaine	12,621	11,649	39,253	32,314
Phytonadione	13,978	11,591	37,834	31,577
Glucagon	14,224	12,189	37,003	32,304
Enoxaparin	7,983	8,034	27,138	28,020
Naloxone	6,818	8,028	21,424	20,994
Other finished pharmaceutical products	23,635	27,046	76,330	66,099
Total finished pharmaceutical products net revenues	$ 117,120	$ 108,990	$ 353,789	$ 301,594

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(in thousands)			
Depreciation and amortization expense				
Finished pharmaceutical products	$ 2,517	$ 1,534	$ 6,370	$ 4,429
API	904	970	2,789	3,197
Total depreciation and amortization expense	$ 3,421	$ 2,504	$ 9,159	$ 7,626

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

	Net Revenue				Long-Lived Assets	
	Three Months Ended September 30,		Nine Months Ended September 30,		September 30,	December 31,
	2022	2021	2022	2021	2022	2021
	(in thousands)					
United States	$ 117,780	$ 107,829	$ 355,680	$ 302,192	$ 134,847	$ 134,731
China	719	2,554	2,418	4,801	88,422	91,876
France	1,630	1,815	5,866	9,888	36,529	44,884
Total	$ 120,129	$ 112,198	$ 363,964	$ 316,881	$ 259,798	$ 271,491

Note 7. Customer and Supplier Concentration

Customer Concentrations

Three large wholesale drug distributors, AmerisourceBergen Corporation, or AmerisourceBergen, Cardinal Health, Inc., or Cardinal, and McKesson Corporation, or McKesson, are all distributors of the Company's products, as well as suppliers of a broad range of health care products. The Company considers these three customers to be its major customers, as each individually, and these customers collectively, represented a significant percentage of the Company's net revenue for the three and nine months ended September 30, 2022 and 2021, and accounts receivable as of September 30, 2022 and December 31, 2021, respectively. The following table provides accounts receivable and net revenue information for these major customers:

	% of Total Accounts Receivable		% of Net Revenue			
			Three Months Ended September 30,		Nine Months Ended September 30,	
	September 30, 2022	December 31, 2021	2022	2021	2022	2021
AmerisourceBergen	14 %	13 %	23 %	25 %	23 %	24 %
McKesson	29 %	30 %	23 %	21 %	21 %	20 %
Cardinal Health	24 %	20 %	17 %	18 %	16 %	16 %

Supplier Concentrations

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

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

Note 8. Fair Value Measurements

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

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

As of September 30, 2022, cash equivalents include money market accounts and municipal bonds with original maturities of less than three months. Investments consist of certificates of deposit as well as investment-grade corporate and municipal bonds with original maturity dates between three and twelve months. The certificates of deposit are carried at amortized cost in the Company's condensed consolidated balance sheets, which approximates their fair value determined based on Level 2 inputs. The corporate and municipal bonds are classified as held-to-maturity and are carried at amortized cost net of allowance for credit losses, which approximates their fair value determined based on Level 2 inputs. The restrictions on restricted cash and investments have an immaterial effect on the fair value of these financial assets.

The fair value of the Company's financial assets and liabilities measured on a recurring basis as of September 30, 2022 and December 31, 2021, are as follows:

	Total	(Level 1)	(Level 2)	(Level 3)
		(in thousands)		
Cash equivalents	$ 130,130	$ 130,130	$ —	$ —
Restricted cash	235	235	—	—
Short-term investments	4,600	—	4,600	—
Restricted short-term investments	2,200	—	2,200	—
Corporate and municipal bonds	23,089	—	23,089	—
Interest rate swap related to variable rate loans	6,508	—	6,508	—
Fair value measurement as of September 30, 2022	$ 166,762	$ 130,365	$ 36,397	$ —
Cash equivalents	$ 102,863	$ 102,863	$ —	$ —
Restricted cash	235	235	—	—
Short-term investments	5,103	—	5,103	—
Restricted short-term investments	2,200	—	2,200	—
Corporate and municipal bonds	6,984	—	6,984	—
Interest rate swap related to variable rate loans	596	—	596	—
Fair value measurement as of December 31, 2021	$ 117,981	$ 103,098	$ 14,883	$ —

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The Company does not hold any Level 3 instruments that are measured at fair value on a recurring basis.

Nonfinancial assets and liabilities are not measured at fair value on a recurring basis but are subject to fair value adjustments in certain circumstances. These items primarily include investments in unconsolidated affiliates, long-lived assets, goodwill, and intangible assets for which the fair value is determined as part of the related impairment test. As of September 30, 2022, and December 31, 2021, there were no significant adjustments to fair value for nonfinancial assets or liabilities.

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

Note 9. Investments

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(in thousands)		
Corporate bonds (due within 1 year)	$ 20,978	$ —	$ (77)	$ 20,901
Municipal bonds (due within 1 year)	2,194	—	(6)	2,188
Total investments as of September 30, 2022	$ 23,172	$ —	$ (83)	$ 23,089
Corporate bonds (due within 1 year)	$ 2,481	$ —	$ (3)	$ 2,478
Corporate bonds (due within 1 to 3 years)	1,248	—	(3)	1,245
Municipal bonds (due within 1 year)	3,263	—	(2)	3,261
Total investments as of December 31, 2021	$ 6,992	$ —	$ (8)	$ 6,984

At each reporting period, the Company evaluates securities for impairment when the fair value of the investment is less than its amortized cost. The Company evaluated the underlying credit quality and credit ratings of the issuers, noting neither a significant deterioration since purchase nor any other factors that would indicate a material credit loss.

The Company measures expected credit losses on held-to-maturity investments on a collective basis. All the Company's held-to-maturity investments were considered to be one pool. The estimate for credit losses considers historical loss information that is adjusted for current conditions and reasonable and supportable forecasts. Expected credit losses on held-to-maturity investments were not material to the condensed consolidated financial statements.

Investment in unconsolidated affiliate

The Company accounts for its share of the earnings or losses of its unconsolidated affiliate (Hanxin) with a reporting lag of three months, as the financial statements of Hanxin are not completed on a basis that is sufficient for the Company to apply the equity method on a current basis. The Company's share of Hanxin's losses for the three and nine months ended September 30, 2022 was $0.2 million and $1.1 million, respectively, which was recorded in the "Equity in losses of unconsolidated affiliate" line on the condensed consolidated statements of operations.

In the second quarter of 2022, Hanxin entered into an agreement with certain of its shareholders, including certain shareholders who are related parties of the Company, to allow for the conversion of outstanding loans with those shareholders to equity. The conversion rate had not been set and none of the loans had been converted to equity as of September 30, 2022. Conversion of such loans would result in dilution of the Company's direct ownership interest in Hanxin.

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Note 10. Goodwill and Intangible Assets

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

	Weighted-Average Life (Years)	Original Cost	Accumulated Amortization	Net Book Value
		(in thousands)		
Definite-lived intangible assets				
IMS (UK) international product rights	10	$ 7,806	$ 4,814	$ 2,992
Patents	12	486	359	127
Land-use rights	39	2,540	733	1,807
Subtotal	10	10,832	5,906	4,926
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill - Finished pharmaceutical products	*	2,886	—	2,886
Subtotal	*	32,111	—	32,111
As of September 30, 2022	*	$ 42,943	$ 5,906	$ 37,037

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

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

Goodwill

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

	September 30, 2022	December 31, 2021
	(in thousands)	
Beginning balance	$ 3,313	$ 3,940
ANP restructuring	—	(374)
Currency translation	(427)	(253)
Ending balance	$ 2,886	$ 3,313

Primatene® Trademark

In January 2009, the Company acquired the exclusive rights to the trademark, domain name, website and domestic marketing, distribution and selling rights related to Primatene Mist®, an over-the-counter bronchodilator product,

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recorded at the allocated fair value of $29.2 million, which is its carrying value as of September 30, 2022.

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

Note 11. Inventories

Inventories consist of the following:

	September 30, 2022	December 31, 2021
	(in thousands)	
Raw materials and supplies	$ 47,082	$ 41,853
Work in process	38,560	33,298
Finished goods	17,608	17,656
Total inventories	$ 103,250	$ 92,807

Charges of $5.5 million and $14.1 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, 2022, respectively, to adjust the Company's inventory and related firm purchase commitments to their net realizable value. For the three and nine months ended September 30, 2021, charges of $6.1 million and $17.0 million were included in the cost of revenues, respectively, to adjust the Company's inventory and related firm purchase commitments to their net realizable value.

For the three and nine months ended September 30, 2022, the losses on firm purchase commitments related to raw materials on order was $2.8 million and $9.2 million, respectively. Losses on firm purchase commitments related to raw materials on order were $2.3 million and $11.6 million for the three and nine months ended September 30, 2021, respectively.

Note 12. Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

	September 30, 2022	December 31, 2021
	(in thousands)	
Buildings	$ 129,658	$ 130,582
Leasehold improvements	31,548	29,221
Land	7,360	7,615
Machinery and equipment	204,288	207,883
Furniture, fixtures, and automobiles	28,622	27,376
Construction in progress	44,460	41,186
Total property, plant, and equipment	445,936	443,863
Less accumulated depreciation	(213,195)	(199,619)
Total property, plant, and equipment, net	$ 232,741	$ 244,244

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Note 13. Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consisted of the following:

	September 30, 2022	December 31, 2021
	(in thousands)	
Accrued customer fees and rebates	$ 13,972	$ 12,121
Accrued payroll and related benefits	26,872	23,256
Accrued product returns, current portion	14,853	16,028
Accrued loss on firm purchase commitments	7,450	7,133
Other accrued liabilities	12,686	8,793
Total accrued liabilities	75,833	67,331
Accounts payable	19,963	22,214
Total accounts payable and accrued liabilities	$ 95,796	$ 89,545

Note 14. Debt

Debt consists of the following:

	September 30, 2022	December 31, 2021
	(in thousands)	
Term Loan		
Term loan with Capital One N.A. due August 2026	$ 68,250	$ 69,563
Mortgage Loans		
Mortgage payable with East West Bank due June 2027	8,231	8,353
Other Loans and Payment Obligations		
French government loans due December 2026	240	269
Line of Credit Facilities		
Line of credit facility with China Merchant Bank	—	—
Revolving line of credit facility with Capital One N.A. due August 2026	—	—
Equipment under Finance Leases	621	398
Total debt	77,342	78,583
Less current portion of long-term debt	1,680	2,202
Less: Loan issuance costs	1,651	1,605
Long-term debt, net of current portion and unamortized debt issuance costs	$ 74,011	$ 74,776

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As of September 30, 2022, the fair value of the loans listed above approximated their carrying amount. The interest rate used in the fair value estimation was determined to be a Level 2 input. For the mortgage loan with East West Bank, as well as the term loan with Capital One N.A., the Company has entered into fixed interest rate swap contracts to exchange the variable interest rates for a fixed interest rates. The interest rate swap contracts are recorded at fair value in the other assets line in the condensed consolidated balance sheets. Gains from changes in the fair values of interest rate swaps were $2.0 million and $5.9 million for the three and nine months ended September 30, 2022, respectively.

Covenants

At September 30, 2022 and December 31, 2021, the Company was in compliance with all of its debt covenants.

Note 15. Income Taxes

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(in thousands)			
Income before taxes	$ 22,596	$ 37,646	$ 74,780	$ 56,977
Income tax provision	6,559	6,686	16,187	13,436
Income before equity in losses of unconsolidated affiliate	$ 16,037	$ 30,960	$ 58,593	$ 43,541
Income tax provision as a percentage of income before income taxes	29.0 %	17.8 %	21.6 %	23.6 %

The change in the Company's effective tax rate for the three and nine months ended September 30, 2022, was primarily due to differences in pre-tax income positions and timing of discrete tax items.

Valuation Allowance

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

The Company continues to record a full valuation allowance on AFP's net deferred income tax assets and will continue to do so until AFP generates sufficient taxable income to realize its deferred income tax assets.

For purposes of computing its annual effective tax rate, the Company did not benefit from its losses in the states where it files separately. This increased the Company's income tax expense by an immaterial amount for the three and nine months ended September 30, 2022 and 2021.

Note 16. Stockholders' Equity

Share Buyback Program

Pursuant to the Company's existing share buyback program, the Company purchased 478,255 and 719,263 shares of its common stock during the three and nine months ended September 30, 2022, for total consideration of $14.5 million and $21.8 million, respectively. The Company purchased 317,212 and 820,637 shares of its common stock during the three and nine months ended September 30, 2021, for total consideration of $6.1 million and $15.4 million, respectively.

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In May 2022, the Company's Board of Directors authorized a $25.0 million increase to the Company's share buyback program and in November 2022, the Company's Board of Directors authorized a $50.0 million increase to the Company's share buyback program, which is expected to continue for an indefinite period of time. Since the inception of the program, the Company's Board of Directors have authorized an aggregate of $235.0 million to the Company's share buyback program. The primary goal of the program is to offset dilution created by the Company's equity compensation programs.

Purchases are made through open market and private block transactions pursuant to Rule 10b5-1 plans, privately negotiated transactions or other means as determined by the Company's management and in accordance with the requirements of the SEC and applicable laws. The timing and actual number of treasury share purchases will depend on a variety of factors including price, corporate and regulatory requirements, and other conditions. These treasury share purchases are accounted for under the cost method and are included as a component of treasury stock in the Company's condensed consolidated balance sheets.

Amended and Restated 2015 Equity Incentive Plan

As of September 30, 2022, the Company reserved an aggregate of 6,499,678 shares of common stock for future issuance under the Amended and Restated 2015 Equity Incentive Plan, or the 2015 Plan, including 1,192,873 shares, which were reserved in January 2022 pursuant to the evergreen provision in the 2015 Plan.

2014 Employee Stock Purchase Plan

As of September 30, 2022, the Company has issued 1,039,832 shares of common stock under the ESPP, and 960,168 shares of its common stock remain available for issuance under the ESPP.

In May 2022, the Company issued 85,376 shares at a weighted-average purchase price of $16.88 per share under the ESPP. For the three and nine months ended September 30, 2022, the Company recorded ESPP expense of $0.2 million and $0.6 million, respectively. For the three and nine months ended September 30, 2021, the Company recorded ESPP expense of $0.2 million and $0.5 million, respectively.

Share-Based Award Activity and Balances (excluding the ANP Equity Plan)

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

The weighted-averages for key assumptions used in determining the fair value of options granted during the three and nine months ended September 30, 2022 and 2021, are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Average volatility	42.7 %	41.4 %	41.0 %	42.1 %
Average risk-free interest rate	2.9 %	1.1 %	2.3 %	1.2 %
Weighted-average expected life in years	6.3	6.3	6.1	6.1
Dividend yield rate	— %	— %	— %	— %

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A summary of option activity for the nine months ended September 30, 2022, is presented below:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value[1]
				(in thousands)
Outstanding as of December 31, 2021	8,455,721	$ 15.67		
Options granted	792,441	34.35		
Options exercised	(1,156,664)	14.70		
Options cancelled	(91,251)	19.56		
Options expired	(5,614)	13.79		
Outstanding as of September 30, 2022	7,994,633	$ 17.62	5.17	88,639
Exercisable as of September 30, 2022	5,614,323	$ 15.65	3.86	69,885
Vested and expected to vest as of September 30, 2022	7,788,485	$ 17.45	5.07	87,242

(1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the estimated fair value of the Company's common stock for those awards that have an exercise price below the estimated fair value at September 30, 2022.

For the three and nine months ended September 30, 2022, the Company recorded an expense of $2.0 million and $6.5 million, respectively, related to stock options granted under all plans. For the three and nine months ended September 30, 2021, the Company recorded an expense of $1.9 million and $6.2 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,	
	2022	2021	2022	2021
	(in thousands, except per share data)			
Weighted-average grant date fair value per option share	$ 14.40	$ 8.00	$ 14.75	$ 7.62
Intrinsic value of options exercised	1,421	2,176	20,131	5,292
Cash received from options exercised	1,483	3,953	18,402	12,122
Total fair value of the options vested during the period	167	112	8,157	8,162

A summary of the status of the Company's non-vested options as of September 30, 2022, and changes during the nine months ended September 30, 2022, is presented below:

	Options	Weighted-Average Grant Date Fair Value
Non-vested as of December 31, 2021	2,848,934	$ 6.95
Options granted	792,441	14.75
Options vested	(1,169,814)	6.97
Options forfeited	(91,251)	8.41
Non-vested as of September 30, 2022	2,380,310	9.48

As of September 30, 2022, there was $16.1 million of total unrecognized compensation cost, net of forfeitures, related to non-vested stock option based compensation arrangements granted under all plans. The cost is expected to be recognized over a weighted-average period of 2.7 years and will be adjusted for future changes in estimated forfeitures.

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Restricted Stock Units

The Company grants restricted stock units, or RSUs, to certain employees and members of the Board of Directors with a vesting period of up to five years. The grantee receives one share of common stock at a specified future date for each RSU awarded. The RSUs may not be sold or otherwise transferred until certificates of common stock have been issued, recorded, and delivered to the participant. The RSUs do not have any voting or dividend rights prior to the issuance of certificates of the underlying common stock. The share-based expense associated with these grants was based on the Company's common stock fair value at the time of grant and is amortized over the requisite service period, which generally is the vesting period using the straight-line method. During the three and nine months ended September 30, 2022, the Company recorded total expenses of $2.0 million and $6.4 million, respectively, related to RSU awards granted under all plans. During the three and nine months ended September 30, 2021, the Company recorded expenses of $1.9 million and $6.2 million, respectively, related to RSU awards granted under all plans.

As of September 30, 2022, there was $17.1 million of total unrecognized compensation cost, net of forfeitures, related to non-vested RSU-based compensation arrangements granted under all plans. The cost is expected to be recognized over a weighted-average period of 2.7 years and will be adjusted for future changes in estimated forfeitures.

Information relating to RSU grants and deliveries is as follows:

	Total RSUs Issued	Total Fair Market Value of RSUs Issued[1] (in thousands)
RSUs outstanding at December 31, 2021	1,184,842	
RSUs granted	339,397	$ 11,675
RSUs forfeited	(39,119)	
RSUs vested[2]	(477,274)	
RSUs outstanding at September 30, 2022	1,007,846	

(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, 181,271 shares of common stock were surrendered to fulfill tax withholding obligations.

The 2018 ANP Equity Incentive Plan

In December 2018, ANP's board of directors approved the 2018 Plan, which was set to expire in December 2023. The 2018 Plan permitted the grant of stock options and other equity awards in ANP shares to ANP employees.

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

At the time the 2018 Plan was terminated, the number of stock options outstanding under the 2018 Plan was 5,018,880. As part of the termination, ANP cash settled 4,091,080 stock options, of which 1,944,771 stock options were vested and 2,146,309 stock options were unvested, for $0.8 million, which approximated the fair value of these awards at the time of settlement. The cash settlement of these awards was recorded as a reduction in equity.

For the remaining 927,800 stock option awards that were outstanding under the 2018 Plan at the time the 2018 Plan was terminated, of which 56,925 stock options were vested and 870,875 were unvested, the Company cancelled these awards and issued replacement awards under the 2015 Plan. The modified awards vest over periods ranging from 1 to 2 years and have a 10-year contractual term. The cancellation and replacement of the awards was accounted for as a modification in accordance with ASC 718.

As a result of the modification, the cost to the Company was $2.3 million, of which $1.8 million was recorded as share-based compensation within general and administrative expenses in the condensed consolidated statement of operations

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for the nine months ended September 30, 2021, and the remaining $0.5 million is being recognized over the vesting period of the modified awards.

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,	
	2022	2021	2022	2021
	(in thousands)			
Cost of revenues	$ 915	$ 889	$ 3,238	$ 2,967
Operating expenses:				
Selling, distribution, and marketing	178	164	540	438
General and administrative	2,810	2,533	8,389	10,069
Research and development	396	333	1,389	1,363
Total share-based compensation	$ 4,299	$ 3,919	$ 13,556	$ 14,837

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, 2022 were approximately $0.5 million and $1.6 million, respectively, compared to the prior year expense of $0.5 million and $1.5 million for the three and nine months ended September 30, 2021, 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 2.5% and 1.0% as of September 30, 2022 and December 31, 2021, respectively. 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 $2.5 million and $2.6 million at September 30, 2022 and December 31, 2021, respectively. The Company recorded an immaterial amount of expense under the plan for the three and nine months ended September 30, 2022 and 2021.

Non-qualified Deferred Compensation Plan

In December 2019, the Company established a non-qualified deferred compensation plan. The plan allows certain eligible participants to defer a portion of their cash compensation and provides a matching contribution at the discretion of the Company. The plan obligations are payable upon retirement, termination of employment and/or certain other times in a lump-sum distribution or in installments, as elected by the participant in accordance with the plan. Participants can allocate their deferred compensation amongst various investment options with earnings accruing to the participant. The

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Company has established a Rabbi Trust to fund the plan obligations and to hold the plan assets. Eligible participants began contributing to the plan in January 2020. The plan assets were valued at approximately $3.5 million as of September 30, 2022 and December 31, 2021, respectively. The plan liabilities were valued at approximately $3.6 million as of September 30, 2022, and December 31, 2021, respectively. The plan assets and liabilities are included in other long-term assets and other long-term liabilities, respectively, on the Company's condensed consolidated balance sheets.

Note 18. Commitments and Contingencies

Purchase Commitments

As of September 30, 2022, the Company has entered into commitments to purchase equipment and raw materials for an aggregate amount of approximately $70.5 million. The Company anticipates that most of these commitments with a remaining term in excess of one year will be fulfilled in 2023.

Note 19. Related Party Transactions

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

During the three and nine months ended September 30, 2022, the Company recognized $0.3 million of revenue from manufacturing services provided to Hanxin. Receivables from Hanxin as of September 30, 2022 were $0.1 million.

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

During the three and nine months ended September 30, 2022, the Company paid $0.2 million under this agreement and has accrued an additional $0.2 million payable to Hanxin as of September 30, 2022.

Note 20. Litigation

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

On February 25, 2020, Astellas US LLC, Astellas Pharma US, Inc., and Gilead Sciences, Inc. (collectively, "Astellas-Gilead") filed a Complaint in the United States District Court for the District of Delaware against IMS for infringement of U.S. Patent Nos. 8,106,183 (the "'183 patent"), RE47,301 (the "'301 patent"), and 8,524,883 (the "'883 patent") (collectively, "Astellas-Gilead Patents") with regard to IMS's ANDA No. 214,252 for approval to manufacture and sell 0.4 mg/5 mL (0.08 mg/mL) intravenous solution of Regadenoson. On March 4, 2020, IMS filed its Answer and Counterclaims. On March 30, 2020, the Court issued an Order allowing the Company to join pending consolidated

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litigation with five other generic Regadenoson ANDA filers involving similar claims. The Company's 30-month FDA stay expired August 10, 2022. On January 26, 2022, the Company and Astellas-Gilead reached an agreement to resolve the lawsuit. The parties submitted, and the Court granted on January 27, 2022, a Motion to Dismiss Without Prejudice for Astellas-Gilead's complaint of infringement against IMS. Under the terms of the agreement, the Company received $5.4 million from Astellas constituting saved litigation expenses. The Company recorded the settlement amount in the other income (expenses) line in its condensed consolidated statement of operations for the nine months ended September 30, 2022.

Other Litigation

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

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

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

The following is a discussion and analysis of the consolidated operating results, financial condition, liquidity and cash flows of our company as of and for the periods presented below. The following discussion and analysis should be read in conjunction with the "Condensed Consolidated Financial Statements" and the related notes thereto included in this Quarterly Report on Form 10-Q, or Quarterly Report. This discussion contains forward-looking statements that are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Actual results could differ materially from those discussed in or implied by forward-looking statements. These risks, uncertainties, and other factors include, among others, those identified under the "Special Note About Forward-Looking Statements," above and described in greater detail elsewhere in this Quarterly Report and in our Annual Report on Form 10-K for the year ended December 31, 2021, particularly in Item 1A. "Risk Factors".

Overview

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

We are currently developing a portfolio of generic abbreviated new drug applications, or ANDAs, biosimilar insulin product candidates and proprietary product candidates, which are in various stages of development and target a variety of indications. Three of the ANDAs and one new drug application, or NDA, are currently on file with the FDA.

Our largest products by net revenues currently include Primatene Mist®, epinephrine, glucagon, phytonadione, lidocaine, and enoxaparin sodium injection. In April 2022, the FDA granted approval of our ganirelix acetate injection 250mg/0.5mL prefilled syringe, which we launched in June 2022. In July 2022, the FDA granted approval of our vasopressin injection, USP 20 Units/mL, 1 mL single dose vial, which we launched in August 2022. In May 2022, the FDA granted approval of our regadenoson injection, 0.08mg/mL, 5mL, single dose prefilled syringe. The timing of the launch of this product is subject to a confidential settlement agreement with the product's innovator.

To complement our internal growth and expertise, we have made several strategic acquisitions of companies, products and technologies. These acquisitions collectively have strengthened our core injectable and inhalation product technology infrastructure by providing additional manufacturing, marketing, and research and development capabilities, including the ability to manufacture raw materials, API, and other components for our products.

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

COVID-19 Pandemic

The ongoing COVID-19 pandemic and the resulting containment measures that have been in effect from time to time in various countries and territories since early 2020 have had, and are expected to continue to have, a number of substantial negative impacts on businesses around the world and on global, regional, and national economies, including widespread disruptions in supply chains for a wide variety of products and resulting increases in the prices of many goods and services. Currently, our production facilities in all of our locations continue to operate as they had before the COVID-19 pandemic with few changes, other than for enhanced safety measures intended to prevent the spread of the virus.

Some of our ongoing clinical trials experienced short-term interruptions in the recruitment of patients due to the COVID-19 pandemic, as hospitals prioritized their resources towards the COVID-19 pandemic and governments imposed travel restrictions. Some clinical trials experienced increased expenses due to new protocols to protect participants from COVID-19. Additionally, certain suppliers had difficulties meeting their delivery commitments, and we are experiencing

longer lead time for components. For example, in the first quarter of 2022, increases in COVID-19 cases in Shanghai, China, led to shutdowns and delays at the ports in Shanghai, which led to temporary delays in shipping certain APIs and starting materials. Future shutdowns could have an adverse impact on our operations. However, the extent of the impact of any future shutdown or delay is highly uncertain and difficult to predict.

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

Even after the COVID-19 pandemic has subsided, we may continue to experience an adverse impact on our business due to the continued global economic impact of the COVID-19 pandemic. We cannot anticipate all of the ways in which health epidemics such as COVID-19 could adversely impact our business. See the "Risk Factors" section for further discussion of the possible impact of the COVID-19 pandemic on our business.

Trends and Uncertainties

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

Certain other worldwide events and macroeconomic factors, such as international trade relations, new legislation and regulations, taxation or monetary policy changes, political and civil unrest, and inflationary pressures, among other factors, also increase volatility in the global economy. For example, the United States has recently experienced historically high levels of inflation. According to the U.S. Department of Labor, the annual inflation rate for the United States was approximately 7.0% for 2021 and has increased to 8.3% as of September 2022. The existence of inflation in the United States, and global economy has and may continue to result in higher interest rates and capital costs, increased costs of labor, weakening exchange rates and other similar effects.

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

Business Segments

As of September 30, 2022, our performance is assessed and resources are allocated based on the following two reportable segments: (1) finished pharmaceutical products and (2) API products. The finished pharmaceutical products segment manufactures, markets and distributes Primatene Mist®, epinephrine, glucagon, phytonadione, lidocaine, enoxaparin, naloxone, as well as various other critical and non-critical care drugs. The API segment manufactures and distributes RHI API and porcine insulin API for external customers and internal product development. Information reported herein is consistent with how it is reviewed and evaluated by our chief operating decision maker. Factors used to identify our segments include markets, customers and products.

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

Results of Operations

Three Months Ended September 30, 2022 Compared to Three Months Ended September 30, 2021

Net revenues

	Three Months Ended September 30,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Net revenues				
Finished pharmaceutical products	$ 117,120	$ 108,990	$ 8,130	7 %
API	3,009	3,208	(199)	(6)%
Total net revenues	$ 120,129	$ 112,198	$ 7,931	7 %
Cost of revenues				
Finished pharmaceutical products	$ 55,681	$ 54,388	$ 1,293	2 %
API	5,938	6,627	(689)	(10)%
Total cost of revenues	$ 61,619	$ 61,015	$ 604	1 %
Gross profit	$ 58,510	$ 51,183	$ 7,327	14 %
as % of net revenues	*49 %*	*46 %*		

The increase in net revenues of the finished pharmaceutical products for the three months ended September 30, 2022 was due to the following changes:

	Three Months Ended September 30,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Finished pharmaceutical products net revenues				
Epinephrine	$ 19,502	$ 13,892	$ 5,610	40 %
Primatene Mist®	18,359	16,561	1,798	11 %
Glucagon	14,224	12,189	2,035	17 %
Phytonadione	13,978	11,591	2,387	21 %
Lidocaine	12,621	11,649	972	8 %
Enoxaparin	7,983	8,034	(51)	(1)%
Naloxone	6,818	8,028	(1,210)	(15)%
Other finished pharmaceutical products	23,635	27,046	(3,411)	(13)%
Total finished pharmaceutical products net revenues	$ 117,120	$ 108,990	$ 8,130	7 %

Sales of epinephrine in the third quarter of 2022 increased $3.3 million due to an increase in average selling price, with the remainder of the increase due to increased unit volume, resulting from higher demand arising from competitor shortages. With the continued success of our advertising campaign, Primatene Mist® sales continued to grow in the third quarter of 2022, primarily due to increased unit volumes. The increase in sales of phytonadione was due to an increase in unit volumes, contributing $1.4 million to sales, and a higher average selling price, which contributed $1.0 million to the increase in sales. Glucagon sales increased due to an increase in inventory levels which allowed us to fill orders for the back to school season. The increase in lidocaine was primarily due to an increase in units for the injectable version. The decrease in naloxone was primary due to lower average selling price. The decrease in other finished pharmaceutical products was primarily due to lower unit volumes of atropine and calcium chloride, largely due to competitors returning to their normal distribution levels. This was partially offset by an increase in unit volume for dextrose, which was in high demand due to competitor shortages during the quarter, as well as the launch of ganirelix, which we launched in June 2022, and vasopressin, which we launched in August 2022.

We anticipate that sales of naloxone and enoxaparin will continue to fluctuate in the future as a result of changing levels of competition. Sales of epinephrine and other finished pharmaceutical products will fluctuate depending on the ability of our competitors to supply the market.

Sales of API primarily depend on the timing of customer purchases. In May 2021, we amended the Supply Agreement with MannKind Corporation, or MannKind, whereby MannKind's aggregate total commitment of RHI API under the Supply Agreement was modified and extended for an additional year through 2027, which timeframe would have previously lapsed after calendar year 2026. MannKind agreed to pay us an amendment fee of $2.0 million. We received the first payment of the amendment fee of $1.0 million in June 2021 which we recognized in net revenues during the year ended December 31, 2021. The remaining $1.0 million of the amendment fee was received in January 2022 and relates to the amendments to the 2022 supply level and has been and will continue to be recognized ratably to net revenues throughout the remainder of 2022. We anticipate that sales of API will continue to fluctuate and may decrease due to the inherent uncertainties related to sales to MannKind pursuant to our supply agreement with them. In addition, most of our API sales are denominated in euros, and the fluctuation in the value of euros versus the U.S. dollar has had, and may continue to have, an impact on API sales revenues in the near term.

A significant portion of our customer shipments in any period relate to orders received and shipped in the same period, generally resulting in low product backlog relative to total shipments at any time. However, during the third quarter of 2022, we experienced a backlog of approximately $6.5 million for various products, partially as a result of competitor shortages, labor shortages and supplier constraints. We are currently working on resolving backlog related issues and believe that we will be able to reduce the backlog in the near future. Historically, our backlog has not been a meaningful indicator in any given period of our ability to achieve any particular level of overall revenue or financial performance.

Gross margins

The increase in sales of epinephrine, Primatene Mist®, phytonadione and glucagon, as well as the launches of ganirelix and vasopressin this year, which are higher-margin products, helped increase our gross margins for the three months ended September 30, 2022.

These increases in gross margins were partially offset by overall increase in labor cost, as well as an increase in the cost for heparin raw material, which is used as the starting material for enoxaparin.

We are experiencing increased costs for labor and certain purchased components. Additionally, the cost of heparin may fluctuate, which could put downward pressure on our gross margins. However, we believe that this trend will be offset by increased sales of our higher-margin products, including Primatene Mist®, glucagon, ganirelix and vasopressin, as well as planned launches in 2023.

Selling, distribution and marketing, and general and administrative

	Three Months Ended September 30,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	$ 4,784	$ 4,745	$ 39	1 %
General and administrative	$ 11,984	$ 10,910	$ 1,074	10 %

The increase in general and administrative expense was primarily due to an increase in legal and compensation expenses.

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

Research and development

	Three Months Ended September 30,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Salaries and personnel-related expenses	$ 6,217	$ 5,934	$ 283	5 %
Clinical trials	2,726	234	2,492	1,065 %
FDA fees	29	109	(80)	(73)%
Materials and supplies	5,217	205	5,012	2,445 %
Depreciation	2,473	2,546	(73)	(3)%
Other expenses	1,852	1,731	121	7 %
Total research and development expenses	$ 18,514	$ 10,759	$ 7,755	72 %

The increase in research and development expenses is primarily due to an increase expenditures for materials and supplies as a result of in an increase in expenditures on raw materials and components for our AMP-018 and insulin product candidates, as well as an increase in clinical trial expense primarily due to external studies related to our insulin and inhalation product candidate pipeline. This was partially offset by a decrease in expenses in China due to the ANP restructuring in 2021.

Research and development costs consist primarily of costs associated with the research and development of our product candidates including the cost of developing APIs. We expense research and development costs as incurred.

We have made, and expect to continue to make, substantial investments in research and development to expand our product portfolio and grow our business. We expect that research and development expenses will increase on an annual basis due to increased clinical trial costs related to our insulin and inhalation product candidates. These expenditures will include costs of APIs developed internally as well as APIs purchased externally, the cost of purchasing reference listed drugs and the costs of performing the clinical trials. As we undertake new and challenging research and development projects, we anticipate that the associated costs will increase significantly over the next several quarters and years. Over the past year, some of our ongoing clinical trials experienced short term interruptions in the recruitment of patients due to the COVID-19 pandemic, as hospitals prioritized their resources towards the COVID-19 pandemic and government imposed travel restrictions. These conditions may in turn delay spending and delay the results of these trials. Additionally, some clinical trials experienced increased expenses due to new protocols to protect participants from COVID-19.

Other income (expenses), net

	Three Months Ended September 30,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Other income (expenses), net	$ (397)	$ 13,263	$ (13,660)	NM

During the third quarter of 2021, we completed the restructuring of ANP, whereby our ownership interest in ANP increased to 100% and ANP's ownership interest in Hanxin was reduced to approximately 14%. As a result of the loss in control over Hanxin, we deconsolidated Hanxin and recorded a $13.6 million gain on deconsolidation. For more information regarding our ANP restructuring, see Note 3 to the condensed consolidated financial statements.

Income tax provision

	Three Months Ended September 30,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Income tax provision	$ 6,559	$ 6,686	$ (127)	(2)%
Effective tax rate	*29 %*	*18 %*		

Our effective tax rate for the three months ended September 30, 2022 increased in comparison to the three months ended September 30, 2021, primarily due to differences in pre-tax income positions and timing of discrete tax items. For more information regarding our income taxes, see Note 15 to the condensed consolidated financial statements.

Nine Months Ended September 30, 2022 Compared to Nine Months Ended September 30, 2021

Net revenues

	Nine Months Ended September 30,		Change	
	2022	2021	Dollars	%
		(in thousands)		
Net revenues				
Finished pharmaceutical products	$ 353,789	$ 301,594	$ 52,195	17 %
API	10,175	15,287	(5,112)	(33)%
Total net revenues	$ 363,964	$ 316,881	$ 47,083	15 %
Cost of revenues				
Finished pharmaceutical products	$ 168,327	$ 152,092	$ 16,235	11 %
API	17,945	21,284	(3,339)	(16)%
Total cost of revenues	$ 186,272	$ 173,376	$ 12,896	7 %
Gross profit	$ 177,692	$ 143,505	$ 34,187	24 %
as % of net revenues	*49 %*	*45 %*		

The increase in net revenues of the finished pharmaceutical products for the nine months ended September 30, 2022, was due to the following changes:

	Nine Months Ended September 30,		Change	
	2022	2021	Dollars	%
		(in thousands)		
Finished pharmaceutical products net revenues				
Primatene Mist®	$ 62,030	$ 51,624	$ 10,406	20 %
Epinephrine	52,777	38,662	14,115	37 %
Lidocaine	39,253	32,314	6,939	21 %
Phytonadione	37,834	31,577	6,257	20 %
Glucagon	37,003	32,304	4,699	15 %
Enoxaparin	27,138	28,020	(882)	(3)%
Naloxone	21,424	20,994	430	2 %
Other finished pharmaceutical products	76,330	66,099	10,231	15 %
Total finished pharmaceutical products net revenues	$ 353,789	$ 301,594	$ 52,195	17 %

Primatene Mist® sales continued to grow in 2022, as a result of increased unit volumes, which was primarily a result of the continued success of our advertising campaign. The increase in sales of epinephrine and lidocaine was primarily due to an increase in unit volumes, arising from high demand due to competitor shortages. The increase in sales of phytonadione was due to an increase in unit volumes, contributing $2.2 million in sales, and a higher average selling price, which contributed $4.1 million to the increase in sales. The increase in sales of glucagon was primarily due to an increase in unit volumes as the prior year period did not include a full year of sales due to glucagon's launch in the first quarter of 2021. The increase in sales of naloxone was primarily due an increase in unit volumes contributing $2.5 million, which was partially offset by a decrease in average selling price, which caused a decline of $2.1 million. The increase in other finished pharmaceutical products was primarily due to higher unit volumes of calcium chloride, dextrose and sodium bicarbonate, which were in high demand due to competitor shortages, as well as the launch of ganirelix and vasopressin in June 2022 and August 2022, respectively.

We anticipate that sales of naloxone and enoxaparin will continue to fluctuate in the future as a result of changing levels of competition. Sales of epinephrine and other finished pharmaceutical products will fluctuate depending on the ability of our competitors to supply the market.

Sales of API primarily depend on the timing of customer purchases. In May 2021, we amended the Supply Agreement with MannKind Corporation, whereby MannKind's aggregate total commitment of RHI API under the Supply Agreement was modified and extended for an additional year through 2027, which timeframe would have previously lapsed after calendar year 2026. MannKind has agreed to pay us an amendment fee of $2.0 million. We received the first payment of the amendment fee of $1.0 million in June 2021 which we recognized in net revenues during the year ended December 31, 2021. The remaining $1.0 million of the amendment fee was received in January 2022 and relates to the amendments to the 2022 supply level and has been and will continue to be recognized ratably to net revenues throughout the remainder of 2022. We anticipate that sales of API will continue to fluctuate and may decrease due to the inherent uncertainties related to sales to MannKind pursuant to our supply agreement with them. In addition, most of our API sales are denominated in euros, and the fluctuation in the value of euros versus the U.S. dollar has had, and may continue to have, an impact on API sales revenues in the near term.

A significant portion of our customer shipments in any period relate to orders received and shipped in the same period, generally resulting in low product backlog relative to total shipments at any time. However, during the third quarter of 2022, we experienced a backlog of approximately $6.5 million for various products, partially brought on by competitor shortages, labor shortages and supplier constraints. We are currently working on resolving these issues and believe that we will be able to reduce the backlog in the near future. Historically, our backlog has not been a meaningful indicator in any given period of our ability to achieve any particular level of overall revenue or financial performance.

Gross margins

The increase in sales of Primatene Mist®, epinephrine and glucagon, which are higher-margin products, helped increase our gross margins for the nine months ended September 30, 2022. These increases in gross margins were partially offset by overall increase in labor cost, as well as an increase in the cost for heparin raw material, which is used as the starting material for enoxaparin.

We are experiencing increased costs for labor and certain purchased components. Additionally, the cost of heparin may fluctuate, which could put downward pressure on our gross margins. However, we believe that this trend will be offset by increased sales of our higher-margin products, including Primatene Mist®, glucagon, vasopressin and ganirelix.

Selling, distribution and marketing, and general and administrative

	Nine Months Ended September 30,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	$ 16,059	$ 13,411	$ 2,648	20 %
General and administrative	$ 34,433	$ 40,813	$ (6,380)	(16)%

The increase in selling, distribution and marketing expenses was primarily due to increased freight expenses. The decrease in general and administrative expense was primarily due to a decrease in legal expenses and a decrease in expenses in China due to the ANP restructuring in 2021.

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

Research and development

	Nine Months Ended September 30,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Salaries and personnel-related expenses	$ 18,767	$ 20,538	$ (1,771)	(9)%
Clinical trials	3,905	2,575	1,330	52 %
FDA fees	86	189	(103)	(54)%
Materials and supplies	21,747	5,816	15,931	274 %
Depreciation	7,647	8,439	(792)	(9)%
Other expenses	5,383	6,089	(706)	(12)%
Total research and development expenses	$ 57,535	$ 43,646	$ 13,889	32 %

The increase in research and development expenses is primarily due to an increase in materials and supplies as a result of in an increase in expenditures on raw materials and components for our AMP-018 and insulin products. Additionally, clinical trial expense increased due to external studies related to our insulin and inhalation product pipeline.

Research and development costs consist primarily of costs associated with the research and development of our product candidates including the cost of developing APIs. We expense research and development costs as incurred.

We have made, and expect to continue to make, substantial investments in research and development to expand our product portfolio and grow our business. We expect that research and development expenses will increase on an annual basis due to increased clinical trial costs related to our insulin and inhalation product candidates. These expenditures will include costs of APIs developed internally as well as APIs purchased externally, the cost of purchasing reference listed drugs and the costs of performing the clinical trials. As we undertake new and challenging research and development projects, we anticipate that the associated costs will increase significantly over the next several quarters and years. Over the past year, some of our ongoing clinical trials experienced short term interruptions in the recruitment of patients due to the COVID-19 pandemic, as hospitals prioritized their resources towards the COVID-19 pandemic and government imposed travel restrictions. These conditions may in turn delay spending and delay the results of these trials. Additionally, some clinical trials experienced increased expenses due to new protocols to protect participants from COVID-19.

Other income (expenses), net

	Nine Months Ended September 30,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Other income (expenses), net	$ 5,692	$ 11,615	$ (5,923)	NM

In January 2022, we received a settlement of $5.4 million in connection with the Regadenoson patent litigation. For more information regarding our litigation matters, see Note 19 to the condensed consolidated financial statements. In the third quarter of 2021, we completed the restructuring of ANP, whereby our ownership interest in ANP increased to 100% and ANP's ownership interest in Hanxin and its subsidiaries was reduced to approximately 14%. As a result of the loss in control over Hanxin, we deconsolidated Hanxin and recorded a $13.6 million gain on deconsolidation. For more information regarding our ANP restructuring, see Note 3 to the condensed consolidated financial statements.

Income tax provision

	Nine Months Ended September 30,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Income tax provision	$ 16,187	$ 13,436	$ 2,751	20 %
Effective tax rate	*22 %*	*24 %*		

Our effective tax rate for the nine months ended September 30, 2022 decreased in comparison to the nine months ended September 30, 2021, primarily due to differences in pre-tax income positions and timing of discrete tax items. For more information regarding our income taxes, see Note 15 to the condensed consolidated financial statements.

Liquidity and Capital Resources

Cash Requirements and Sources

We need capital resources to maintain and expand our business. We expect our cash requirements to increase significantly in the foreseeable future as we sponsor clinical trials for, seek regulatory approvals of, and develop, manufacture and market our current development-stage product candidates and pursue strategic acquisitions of businesses or assets. Our future capital expenditures include projects to upgrade, expand, and improve our manufacturing facilities in the United States and China, including a significant increase in capital expenditures throughout the remainder of 2022. We plan to fund this facility expansion with cash flows from operations. Our cash obligations include the principal and interest payments due on our existing loans and lease payments, as described below and throughout this Quarterly Report.

As of September 30, 2022, our foreign subsidiaries collectively held $15.3 million in cash and cash equivalents. Cash or cash equivalents held at foreign subsidiaries are not available to fund the parent company's operations in the United States. We believe that our cash reserves, operating cash flows, and borrowing availability under our credit facilities will be sufficient to fund our operations for at least the next 12 months from the date of filing of this Quarterly Report on Form 10-Q. We expect additional cash flows to be generated in the longer term from future product introductions, although there can be no assurance as to the receipt of regulatory approval for any product candidates that we are developing or the timing of any product introductions, which could be lengthy or ultimately unsuccessful.

We maintain a shelf registration statement on Form S-3 pursuant to which we may, from time to time, sell up to an aggregate of $250 million of our common stock, preferred stock, debt securities, depositary shares, warrants, subscription rights, purchase contracts, or units. If we require or elect to seek additional capital through debt or equity financing in the future, we may not be able to raise capital on terms acceptable to us or at all. To the extent we raise additional capital through the sale of equity or convertible debt securities, the issuance of such securities will result in dilution to our stockholders. If we are required and unable to raise additional capital when desired, our business, operating results and financial condition may be adversely affected.

Working capital increased by $67.7 million to $282.0 million at September 30, 2022, compared to $214.3 million at December 31, 2021.

Cash Flows from Operations

The following table summarizes our cash flows used in operating, investing, and financing activities for the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,	
	2022	2021
	(in thousands)	
Statement of Cash Flow Data:		
Net cash provided by (used in)		
Operating activities	$ 73,955	$ 57,553
Investing activities	(32,548)	(16,718)
Financing activities	(10,277)	(28,322)
Effect of exchange rate changes on cash	(239)	(175)
Net increase in cash, cash equivalents, and restricted cash	$ 30,891	$ 12,338

Sources and Use of Cash

Operating Activities

Net cash provided by operating activities was $74.0 million for the nine months ended September 30, 2022, which included net income of $57.5 million. Non-cash items comprised primarily of $21.3 million of depreciation and amortization and $13.6 million of share-based compensation expense.

Additionally, for the nine months ended September 30, 2022, there was a net cash outflow from changes in operating assets and liabilities of $18.3 million, which resulted from an increase in inventories, as the company increased purchases of certain raw materials and components, which was partially offset by an increase in accounts payable and accrued liabilities. Accounts payable and accrued liabilities increased primarily due to the timing of payments.

Net cash provided by operating activities was $57.6 million for the nine months ended September 30, 2021, which included net income of $43.5 million. Non-cash items comprised primarily of $20.2 million of depreciation and amortization, and $14.8 million of share-based compensation expense and a $13.6 million gain relating to the deconsolidation of Hanxin and its subsidiaries as result of the ANP restructuring during the third quarter of 2021. Additionally, for the nine months ended September 30, 2021, there was a net cash outflow from changes in operating assets and liabilities of $13.7 million, which resulted from an increase in accounts receivable as well as an increase in inventories, which was partially offset by an increase in accounts payable and accrued liabilities. Accounts payable and accrued liabilities increased primarily due to the timing of payments. The increase in accounts receivable was due to both increases in sales and the timing of sales.

Investing Activities

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

Net cash used in investing activities was $16.7 million for the nine months ended September 30, 2021, primarily as a result of $20.6 million in purchases of property, plant, and equipment, which included $11.0 million incurred in the United States, $0.6 million in France, and $9.0 million in China, offset by, increase in cash of $5.0 million relating to short-term investments.

Financing Activities

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

Net cash used in financing activities was $28.3 million for the nine months ended September 30, 2021, primarily as a result of $54.0 million in payments relating to the purchase of additional ANP ownership interest in connection with the ANP restructuring completed during the third quarter of 2021 (see Note 3 to the condensed consolidated financial statements). We borrowed $70.0 million in connection with a credit agreement with Capital One N.A., which was partially offset by $37.3 million in principle payments of our long-term debt and lines of credit. We used $15.4 million to purchase treasury stock and received $10.3 million in net proceeds from the settlement of share-based compensation awards under our equity plans.

Indebtedness

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

Critical Accounting Policies

The preparation of our condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the notes to the financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions. A summary of our critical accounting policies is presented in Part II, Item 7, of our Annual Report on Form 10-K for the year ended December 31, 2021. There have been no material changes to our critical accounting policies as compared to the critical accounting policies as described in our Annual Report on Form 10-K for the year ended December 31, 2021.

Recent Accounting Pronouncements

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

Off-Balance Sheet Arrangements

We do not have any relationships or financial partnerships with unconsolidated entities, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts.

Government Regulation

Our products and facilities are subject to regulation by a number of federal and state governmental agencies. The FDA, in particular, maintains oversight of the formulation, manufacture, distribution, packaging, and labeling of all of our products. The Drug Enforcement Administration, or DEA, maintains oversight over our products that are considered controlled substances.

From May 17 through May 25, 2022, our IMS facility in South El Monte, California was subject to routine cGMP inspection by the FDA. The inspection included a review of compliance with FDA regulations relating to Good Manufacturing Practices. The inspection resulted in one observation on Form 483. We responded to that observation. We believe that our response to the observation will satisfy the requirements of the FDA and that no significant further actions will be necessary.

From May 17, 2022 to June 30, 2022, five of our clinical trial sites were subject to pre-approval biomonitoring inspections by the FDA. The inspections included a review of the clinical trial data to support one of our pending applications. Each inspection resulted in no Form 483 findings. No further actions will be necessary.

On June 21, 2022, our IMS facility in South El Monte, California was subject to routine inspection by the DEA. The inspection included a review of manufacture, storage and handling of our controlled substances. The inspection resulted in no findings. No further actions will be necessary.

From July 18 through July 21, 2022, our Amphastar facility in Rancho Cucamonga, California was subject to a remote pre-approval inspection by the FDA. The inspection included a review of the analytical clinical trial sample testing data to support one of our pending applications. The inspection resulted in no Form 483 findings. No further actions will be necessary.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Except for the broad, ongoing effects of the COVID-19 pandemic as a result of its negative impact on the global economy and financial markets and the impacts of the ongoing Russian invasion of Ukraine, there have been no material changes in market risk from the information provided in our Annual Report on Form 10-K for the year ended December 31, 2021. We are exposed to market risk in the ordinary course of business. Market risk represents the potential loss arising from adverse changes in the value of financial instruments. The risk of loss is assessed based on the likelihood of adverse changes in fair values, cash flows or future earnings. We are exposed to market risk for changes in the market values of our investments (Investment Risk), the impact of interest rate changes (Interest Rate Risk), and the impact of foreign currency exchange changes (Foreign Currency Exchange Risk).

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, our principal executive and principal financial officers, respectively, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934, as amended, as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that as of such date, our disclosure controls and procedures were effective (a) to ensure that information that we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and (b) to include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2022, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act).

Inherent Limitations of Internal Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management overriding of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

For information regarding legal proceedings, see "Part I – Item 1. Financial Statements – Notes to Condensed Consolidated Financial Statements – Litigation".

ITEM 1A. RISK FACTORS

Except as noted below, there were no material changes from the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission on March 11, 2022.

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

The ongoing COVID-19 pandemic, including the emergence of variants, has continued to impact worldwide economic activity and financial markets. While four vaccines have received regulatory approval or Emergency Use Authorization from the FDA, the COVID-19 pandemic remains a challenge to our business until it is abated. Mass and rapid production of the vaccines, for example, has placed increased pressure on the availability of supplies that are also used in our products, such as glass vials and needles. The COVID-19 pandemic may also disrupt the operations of our customers, suppliers and partners for an indefinite period of time, including as a result of travel restrictions and/or business shutdowns, all of which could negatively impact our business and results of operations, including cash flows. Disruptions to our manufacturing partners and suppliers could result in disruption to the production of our products and failure to satisfy demand. For example, China has adopted and continues to rely upon a "zero-COVID" policy pursuant to which it has declared a number of total and partial lockdowns in cities throughout China adversely affecting supply chains worldwide. While these measures may be relaxed or revised in some areas, there is no guarantee these measures will not be reinstated or resumed due to additional variants of COVID-19 or the inability or ineffectiveness of public health measures to limit the further spread of COVID-19. More generally, the ongoing COVID-19 pandemic could continue to adversely affect economies and financial markets globally and nationally, including inflationary pressures and changes in interest rates, which could decrease spending and adversely affect demand for our products and harm our business and results of operations. To the extent macroeconomic uncertainty persists or the COVID-19 pandemic or macroeconomic conditions worsen, we may experience a continuing adverse effect on the demand for some of our products. The degree of impact of the COVID-19 pandemic and the related challenging macroeconomic conditions globally on our business will depend on several factors, such as the duration and the extent of the pandemic, as well as actions taken by governments, businesses, and consumers in response to the pandemic and the challenging macroeconomic conditions globally, all of which continue to evolve and remain uncertain at this time.

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

Some of our ongoing clinical trials have experienced short term interruptions in the recruitment of patients due to the COVID-19 pandemic, as hospitals prioritized their resources toward the COVID-19 pandemic and governments imposed travel restrictions. Additionally, protocols at certain clinical sites have changed which could slow down the pace of clinical trials while also increasing their cost. These conditions may in turn delay spending and delay the results of these

trials. Additionally, certain suppliers delayed shipments to us in 2021 and throughout 2022. These delays may have been caused by manufacturing disruptions due to the COVID-19 pandemic. For example, in the first quarter of 2022, increases in COVID-19 cases in Shanghai, China, led to shutdowns and delays at the ports in Shanghai, which led to temporary delays in shipping certain APIs and starting materials. Future shutdowns could have an adverse impact on our operations. However, the extent of the impact of any future shutdown or delay is highly uncertain and difficult to predict. Shanghai's delays did not ultimately cause delays in our manufacturing, but future delays could cause manufacturing disruptions at our factories.

Any of the negative impacts of the ongoing COVID-19 pandemic and the related challenging macroeconomic conditions, including, among others, those described above, alone or in combination with others, may have a material adverse effect on our business and operations, results of operations, financial condition, and cash flows. It is not possible at this time to estimate the complete impact that the COVID-19 pandemic and the related challenging economic conditions could have on our business, as the impact will depend on future developments, which are highly uncertain and cannot be predicted. Macroeconomic conditions may continue to worsen leading to changes in monetary policy and other responses from governmental bodies, infections may resurge or become more widespread and the limitation on our ability to travel and timely sell and distribute our products, as well as any closures or supply disruptions, may be enacted or extended for longer periods of time, each of which alone or in combination with others, would have a negative impact on our business, financial condition and operating results. We will continue to monitor the impact of the COVID-19 pandemic and the related challenging macroeconomic conditions on all aspects of our business.

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

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

- disruptions in the construction of the manufacturing facility;
- interruptions to our operations in China or the inability of our manufacturing facility to produce adequate quantities of raw materials or APIs to meet our needs as a result of natural catastrophic events or other causes beyond our control such as power disruptions or widespread disease outbreaks, including the recent outbreaks that impact animal-derived products, such as the importation of pig-derived crude heparin from countries impacted by the African swine flu, and the ongoing COVID-19 pandemic, which has resulted in and may in the future result in, business closures, transportation restrictions, import and export complications, and otherwise cause shortages in the supply of raw materials or cause disruptions in our manufacturing capability;
- product supply disruptions and increased costs as a result of heightened exposure to changes in the policies of the Chinese government, political unrest or unstable economic conditions in China, including China's ongoing commitment to a "zero COVID" policy;
- the imposition of additional tariffs, export controls or other trade barriers as a result of changes in social, political, and economic conditions or in laws, regulations, and policies governing foreign trade, including U.S. and foreign export controls such as new U.S. controls preventing the export of a wide-range of items to Russia and new controls impacting the ability to send certain products and technology including chips and chip-related technology and software to China without an export license and the addition of new China-based entities to certain U.S. restricted party lists such as the Entity List and Unverified List, trade sanctions and import laws and regulations, the tariffs previously implemented and additional tariffs that have been proposed by the U.S. government on various imports from China and by the Chinese government on certain U.S. goods, the scope and duration of which, if implemented, remain uncertain;

- the nationalization or other expropriation of private enterprises or intellectual property by the Chinese government, which could result in the total loss of our investment in China; and
- interruptions to our manufacturing or business operations resulting from geo-political actions, including war and terrorism such as the war in Ukraine, natural disasters including earthquakes, typhoons, floods, and fires, or outbreaks of health epidemics, or outbreaks in livestock or animals that impact or restrict importation, use, or distribution of animal-derived products.

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

We are actively monitoring and assessing the ongoing impact of the COVID-19 pandemic on our business. This includes evaluating the impact on our employees, suppliers, and logistics providers as well as evaluating governmental actions being taken to curtail the spread of the virus. For example, in the first quarter of 2022, increases in COVID-19 cases in Shanghai, China, led to shutdowns and delays at the ports in Shanghai. However, the extent of any future shutdown or delay is highly uncertain and difficult to predict. Any material adverse effect on our employees, suppliers, and logistics providers could have a material adverse effect on our manufacturing operations in China or the supply of raw materials or APIs originating from China.

Our business may be affected by new sanctions and export controls targeting Russia and other responses to Russia's invasion of Ukraine.

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

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

- comprehensive financial sanctions against major Russian banks (including SWIFT cut off);
- additional designations of Russian individuals with significant business interests and government connections;
- designations of individuals and entities involved in Russian military activities; and
- enhanced export controls and trade sanctions targeting Russia's imports of a wide range of goods as a whole, including potentially tighter controls on exports and reexports of items previously subject to only a low level of control, stricter licensing policy with respect to issuing export licenses, and/or increased use of “end-use” controls to block or impose licensing requirements on exports.

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

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

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

others on our behalf, also collect, transmit, store and otherwise process certain data relating to individuals, including about our personnel, business partners, and others, which may be subject to applicable data protection, security and privacy laws and regulations that require adoption of minimum information security standards. The cost of compliance with applicable data protection, security and privacy laws and regulations have increased and may increase in the future.

Despite our implementation of security measures to protect the confidentiality, integrity, and availability of the systems, networks and data within our control from various threats (e.g., cyber-attacks, system breaches, malware, viruses, hacking, fraudulent use, social engineering attacks, phishing attacks, ransomware attacks, credential-stuffing attacks, denial-of-service attacks, unauthorized access, insider threats, accidental disclosures, intellectual property theft and economic espionage, exploitable vulnerabilities, defects or bugs in our or our third-party providers' systems, natural disasters, war, terrorism, telecommunications and electrical outages, breakdowns, damage, interruptions), we have experienced and may continue to experience cyber-attacks of varying degrees from time to time. For example, in the first quarter of 2022, our Chinese subsidiary, ANP, was subject to a security incident that resulted in a temporary disruptions to some of their internal computer systems. We are currently working with ANP to improve and add additional security measures to their systems and networks. We have incurred costs to respond to the ANP incident. In addition, in the second quarter of 2020, we were subject to a security incident that resulted in a temporary disruption to some of our internal computer systems. In response to this incident, we engaged a third-party forensic expert to investigate, and determined that cyber criminals illegally obtained certain personal information of certain current and former employees. We notified affected individuals and regulators, as we deemed was required or appropriate. We have incurred cost to respond to this incident, and we expect to continue to incur cost to support our efforts to enhance our security measures. Our systems and networks and the systems and networks of third parties that support us and our services may be breached or disrupted due to these threats. The size and complexity of our systems may make them potentially vulnerable to breakdown or interruption, whether due to computer viruses or other causes, which may result in loss of data or the impairment of production and other supply chain processes, adversely affecting our business.

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

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

- The accidental or unlawful loss, unavailability or alteration of clinical trial data from completed or ongoing clinical trials for any of our product candidates could affect our ability to operate, result in delays in our development and regulatory approval efforts, and significantly increase our costs to recover or reproduce the data.
- Any security incident may require costly response and remediation efforts, trigger notification obligations under breach notification laws or contractual notification requirements, result in litigation or adverse regulatory action arising from or related to such an incident or event, damage our reputation, and result in significant additional

expense to implement further data protection measures. Integrating the systems and data of any acquired entity may increase these risks due to unforeseen threats and vulnerabilities.

- Similarly, any security incident experienced by our collaborators, third-party providers, distributors and other contractors may hinder our product development, supply chain, other business operations, or our regulatory and contractual obligations to others and could also give rise to litigation or adverse regulatory action.

In an effort to ensure appropriate oversight of cyber security issues and risks, management now updates the Board of Directors on cyber security matters on a quarterly basis, and the Board of Directors has assigned oversight of cyber security to the Audit Committee. Additionally, the Company has a security training and compliance program, which employees with access to information technology, must complete annually or more often, if deemed necessary or appropriate.

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

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

Complying with laws in the U.S., Europe, and other jurisdictions that impose restrictive regulations addressing the collection, use, and other processing of personal information may be expensive, and failure to comply with such laws and regulations could cause substantial harm to our business.

We also must comply with data protection, security and privacy requirements. Compliance with laws, rules and regulations regarding privacy, security and protection of personal information, including about our personnel, business partners, and others, could result in higher compliance and technology costs for us. Significant fines, penalties, damages and harm to our global reputation and our brand could result from actual or perceived non-compliance.

We collect, process, use, store, transmit and transfer personal information from individuals located in the EU in connection with our business. The collection, processing, storage, transmission, transfer and use of personal information in the EU are governed by the provisions of the General Data Protection Regulation ((EU) 2016/679), or the GDPR. This legislation imposes requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside of the European Economic Area, to third countries that have not been found to provide adequate protection to such personal information, including to the U.S., providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal information to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments and record-keeping. The GDPR imposes significant responsibilities and liabilities in relation to personal information that we process, and we may be required to put in place additional mechanisms designed to comply with the GDPR. Failure to comply with the requirements of the GDPR and related national data protection laws of the member states of the EU may result in

investigations, substantial fines up to the greater of €20 million or 4% of annual global turnover, civil claims, and damages being brought against us, which could have a material adverse effect on our business, financial condition and results of operations.

While the GDPR applies uniformly across the EU, each EU member State is permitted to issue nation-specific data protection legislation, which has created inconsistencies on a country-by country basis. Further, the United Kingdom's exit from the EU, often referred to as Brexit, and ongoing developments in the United Kingdom have created further uncertainty with regard to the regulation of data protection and privacy in the United Kingdom. The United Kingdom has implemented legislation that substantially implements the GDPR, and the European Commission and issued an adequacy decision under the GDPR and the Law Enforcement Directive on June 28, 2021, pursuant to which personal information generally may be transferred from the EU to the United Kingdom without restriction; however, this adequacy decision is subject to a four-year "sunset" period, after which the European Commission's adequacy decision may be renewed. During that period, the European Commission will monitor the legal situation in the United Kingdom and may intervene at any time with respect to its adequacy decision. The United Kingdom's adequacy determination therefore is subject to future uncertainty and may be subject to modification or revocation in the future, with the United Kingdom potentially being considered an inadequate third country under the GDPR and transfers of personal information from the European Economic Area to the United Kingdom will require a transfer mechanism. Furthermore, there will be increasing scope for divergence in application, interpretation and enforcement of the data protection law as between the United Kingdom and European Economic Area.

In addition, U.S. states are adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements related to personal information. For example, California enacted the California Consumer Privacy Act, or the CCPA, on June 28, 2018, which took effect on January 1, 2020 and has been dubbed the first "GDPR-like" law in the United States. The CCPA gives California residents, among other things, expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA also provides for civil penalties for violations, as well as a private right of action for certain data breaches that may increase data breach litigation. The CCPA will be expanded substantially on January 1, 2023 when the California Privacy Rights Act of 2020, or the CPRA, which was approved by California voters in November 2020, becomes fully operative. The CPRA will, among other things, give consumers the ability to limit use of information deemed to be sensitive, establish the California Privacy Protection Agency to implement and enforce the CPRA and impose administrative fines. Aspects of the CCPA and CPRA, and their interpretation and enforcement remain uncertain. The potential effects of the CCPA and CPRA are far-reaching and may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply.

The CCPA and CPRA could mark the beginning of a trend toward more stringent data protection, security and privacy legislation in the U.S. The CCPA has prompted a number of proposals for federal and state privacy legislation. For example, in March 2021, Virginia enacted the Virginia Consumer Data Protection Act, or CDPA, a comprehensive privacy statute that becomes effective on January 1, 2023 and shares similarities with the CCPA and the CPRA, but also imposes security and assessment requirements for businesses. In addition, on July 7, 2021, Colorado enacted the Colorado Privacy Act, or CPA, which closely resembles the CDPA. Also, in March 2022, Utah enacted the Utah Consumer Privacy Act, which becomes effective on December 31, 2023, and in May 2022, Connecticut enacted the Act Concerning Personal Data and Online Monitoring, which becomes effective on July 1, 2023, both of which differ from the CPRA, CDPA and CPA. These new state privacy laws will be enforced by the respective states' Attorney General and/or district attorneys. Similar laws have been proposed in other states and at the federal level, reflecting a trend toward more stringent data protection, security and privacy legislation in the U.S. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging.

We may also publicly post privacy policies and other documentation regarding our collection, use, storage, transmission, transfer and other processing of personal information. Although we endeavor to comply with our public policies and documentation, we may at times fail to do so or be alleged to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees or contractors fail to comply with our published policies and documentation. Such failures can subject us to potential regulatory action if they are found to be deceptive, unfair or misrepresentative of our actual practices.

Additionally, other jurisdictions are considering new or expanded laws or regulations relating to privacy, security and data protection. With these laws, regulations and other obligations relating to privacy, security and data protection imposing new and relatively burdensome obligations, which may be inconsistent between jurisdictions or in conflict with each other due to differing applications and interpretations, and with substantial uncertainty over further interpretation and application of these and other obligations, we may face challenges in addressing their requirements, putting in place additional compliance mechanisms and making necessary changes to our policies, contracts and practices, and may incur significant costs and expenses in an effort to do so. Additionally, if we or third parties we work with, such as our third-party providers, violate applicable laws or regulations or our policies, such violations may also put our data at risk and could in turn have an adverse effect on our business. Any failure or perceived failure by us or our service providers to comply with our applicable policies or notices relating to privacy, security or data protection, our contractual or other obligations to third parties, or any of our other legal obligations relating to privacy, security or data protection, may result in public criticism, governmental investigations or enforcement actions, litigation, claims and other proceedings, and could result in significant fines, penalties, and other liability. Additionally, defending against any claims, litigation, regulatory proceedings, or other proceedings can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions or proceedings that may be brought against us, our business may be impaired, and we may suffer reputational and other harm.

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

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

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

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the pharmaceutical industry. For example, in November 2013, Congress passed the Drug Quality and Security Act, or the DQSA. The DQSA establishes federal pedigree tracking standards requiring drugs to be labeled and tracked at the lot level, preempts state drug pedigree requirements, and will eventually require all supply-chain stakeholders to participate in an electronic, interoperable prescription drug track and trace system. The DQSA also establishes new requirements for drug wholesale distributors and third party logistics providers, including licensing requirements in states that had not previously licensed such entities. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition and results of operations.

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

- reauthorizes the Prescription Drug User Fee Act, which increases the amount of associated user fees, and, for certain types of applications, increases the expected time frame for FDA review of NDAs;

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

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

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

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

considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws.

Additionally, we encounter similar regulatory and legislative issues in most other countries. In the European Union, or EU, and some other international markets, the government provides health care at low cost to consumers and regulates pharmaceutical prices, patient eligibility or reimbursement levels to control costs for the government-sponsored health care system. This international system of price regulations may lead to inconsistent prices.
If significant additional reforms are made to the U.S. health care system, or to the health care systems of other markets in which we operate, those reforms could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

(c) Issuer Purchases of Equity Securities

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

Period	Total Number of Shares Purchased [1]	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
July 1 – July 31, 2022	40,357	$ 35.12	40,357	—
August 1 – August 31, 2022	145,994	32.01	145,994	—
September 1 – September 30, 2022	291,904	28.76	291,904	—

[1] As of September 30, 2022, $11.7 million remained available for repurchase under such program. On November 7, 2022, we announced that our Board of Directors authorized an increase of $50.0 million to our share buyback program. The share buyback program does not have an expiration date.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

Exhibit No.	Description
10.1*	Contract Research Agreement by and between Amphastar Pharmaceuticals, Inc. and Nanjing Hanxin Pharmaceutical Technology Co., Ltd, dated July 5, 2022.
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) would be competitively harmful if publicly disclosed.

SIGNATURES

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

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

Date: November 8, 2022

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

Date: November 8, 2022

Exhibit 10.1

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

CONTRACT RESEARCH AGREEMENT
委托开发协议

This Contract Research Agreement (this "**Agreement**") is entered into by and between the following parties on July 5, 2022 (the "**Effective Date**"):

本委托开发协议（"**本协议**"）由以下双方于2022年 7月 5日（"**生效日**"）签订：

(1) **Nanjing Hanxin Pharmaceutical Technology Co., Ltd.**, a limited liability company duly incorporated and validly existing under the laws of PRC, with the Unified Social Credit Code: [***] ("**HX**"); and

(1) **南京汉欣医药科技有限公司**，一家根据中国法律正式成立并有效存续的有限责任公司，统一社会信用代码为：[***]（"**HX**"）；及

(2) **Amphastar Pharmaceuticals, Inc.**, a company established and existing in accordance with the laws of the State of Delaware, the United States of America (together with its Affiliates, the "**Customer**").

(2) **Amphastar Pharmaceuticals, Inc.**，一家根据美国特拉华州法律成立并存续的公司（与其关联方合称为**"委托方"**）。

HX and the Customer are sometimes referred to herein collectively as the "**Parties**" and individually as a "**Party**".

HX与委托方在本协议中合称为"**双方**"，单称为"**一方**"。

Whereas, the Customer intends to engage HX to research and develop certain active pharmaceutical ingredients based on specifications provided by the Customer, and HX intends to accept such engagement.

鉴于，委托方有意委托HX根据委托方提供的规格研发某些活性药物成分，且HX拟接受该等委托。

Therefore, based on the principle of good faith, the Parties hereby agree as follows:

因此，基于诚实信用的原则，双方特此达成协议如下：

1. General

1. 总则

1.1 Headings or titles of this Agreement are used solely for convenience and shall be given no effect in the construction or interpretation of this Agreement.

1.1 本协议的标题仅为方便查阅而设，不影响对本协议的解读或解释。

1.2 Additional agreements necessary to effectuate this Agreement may be executed between the Parties. In the event of conflicting terms, the terms of this Agreement shall prevail.

1.2 双方可签署为实现本协议所必需的其他协议。如条款有冲突，以本协议的约定为准。

1.3 When used in this Agreement, the following terms shall have the meanings set forth in this section:

1.3 本协议中使用的下列术语应具有本条中规定的含义：

(a) "**Affiliate**" means any person or entity which controls, is controlled by or is under the common control of a Party. As used in this Agreement, "**control**" means (i) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, or (ii) in the case of non-corporate entities, the direct or indirect power to manage, direct or cause the direction of the management and policies of the non-corporate entity.

(a) "**关联方**"指控制一方、受一方控制或共同受一方控制的任何个人或实体。本协议中使用的"**控制**"指(i)就公司实体而言，直接或间接拥有至少百分之五十（50%）的具有选举董事的投票权的股票或股份，或(ii)就非公司实体而言，直接或间接拥有管理、指导或促使他人指导该非公司实体的管理和政策的权力。

(b) "**Applicable Law**" means any international, national, federal, state, provincial, commonwealth, or local government law, statute, rule, requirement, code, regulation, or ordinance that applies to either Party, the Product, services hereunder or this Agreement, where applicable, rules governing distribution practice, manufacturing practice and good laboratory practice, as amended from time-to-time.

(b) “**适用法律**”指适用于任一方、产品、本协议项下的服务或本协议的、经不时修订的任何国际、国家、联邦、州、省、联盟或当地政府的法律、法令、规定、要求、法典、法规或条例，以及销售规范、生产规范和实验室管理规范(如适用)。

(c) “**Business Day**” means any day other than Saturday, Sunday, and other days on which banks, as required or authorized by Applicable Law, are temporarily closed for business in the PRC, United States of America.

(c) “**工作日**”指除了周六、周日以及适用法律要求或银行在中国、美国暂停营业的其他日期以外的任何日期。

(d) “**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, 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:

(d) “**保密信息**”指与发明、专有思想和/或可转化为专利思想、专利申请、背景知识产权、技术、科学知识、专有技术、工艺、现有的和/或预期的产品和服务、软件、生物材料、图表、研究和开发、生产、成本、利润和利润率信息、财务和财务预测、顾客、客户、被许可人、营销以及当前或未来的商业计划和模式的技术和商业信息，无论该等信息在披露时是否被指定为“保密信息”。“**保密信息**”一词不包括下列信息：

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

(i) 并非通过接收方的披露而为公众普遍可获得的信息；

(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,

(ii) 在披露方或其代表提供之前已由接收方掌握的信息，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

(iii) 接收方从除披露方之外的其他信息提供者处以非保密的方式获得的信息，前提是该信息提供者对披露方不承担保密义务；或

(iv) is or becomes independently developed by an employee of 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.

(iv) 由接收方的雇员在未接触保密信息且未违反接收方在本协议项下的任何义务的情况下独立开发获得的信息，且有接收方的书面记录作为证明。

(e) "[***]" mean [***] and Company and/or its Affiliates.

(e) "[***]"指礼来公司及和/或其关联方。

(f) "**Force Majeure**" means an event beyond the reasonable control of a Party including but not limited to, a breakdown of machinery or equipment, fire, flood, sabotage, shipwreck, embargo, strike, explosion, labor trouble, pandemic and related restrictions, accident, riot, act of governmental authority (including without limitation, acts relating to raw material or product allocation, and government drug files), acts of God, acts of war and delays or failures in obtaining materials, supplies, equipment or transportation.

(f) "**不可抗力**"指超出一方合理控制范围的事件，包括但不限于机器或设备故障、火灾、水灾、蓄意破坏、海难、禁运、罢工、爆炸、劳资纠纷、流行病和相关限制、事故、暴动、政府部门的行为（包括但不限于与原材料或产品分配有关的行为以及政府药品备案）、天灾、战争以及材料、供给品、设备或运输的延迟或损坏。

(g) "**Research Cell Bank**" or "**RCB**" shall mean an aliquot of a single pool of genetically engineered E-Coli cells that have been prepared from the selected cell clone under defined conditions, dispensed into multiple containers and able to produce recombinant human insulin, used in the

manufacturing of the finished dose formulation for biosimilar [***], meeting the Specifications, including the Reference Product specifications, conditions for the Manufacture, use or sale of the Products.

(g) "**研究细胞库**"或"**RCB**"指自选定的细胞在规定条件下进行克隆制备的、可分装于多个容器且能够生产重组人胰岛素并用于生产 [***] 的生物仿制药的成品制剂、符合规格（包括参考产品的规格、制造、使用或销售产品的条件）的单个经基因改造的大肠埃希菌细胞池的等分试样。

(h) "**Know-How**" means confidential and proprietary information, technology regarding development and Manufacturing of the RCB, which shall include engineering, scientific and practical information and formula, research data, design, and procedures and others to develop and Manufacture the RCB, in use or developed by HX, in sufficient detail that enables the Customer to Manufacture the Product in its facility.

(h) "**专有技术**"指与RCB的开发和制造有关的保密和专有信息和技术，该等信息和技术应包括由HX使用或开发的用于开发和制造RCB的工程、科学和实用信息、配方、研究数据、设计、程序及其他技术，且该等信息和技术足够详细，使委托方能够在其设施中制造产品。

(i) "**Licensed Technology**" means all present and further intellectual property rights (including but not limited to patents and/or patent applications) held by HX, to practice HX's process, procedures, or plan to the extent necessary or useful to Manufacture, use, promote, market, sell, sub-license or distribute the RCB and/or the Product.

(i) "**许可技术**"指HX持有的、用以实施在制造、使用、推广、营销、销售、再许可或分销RCB和/或产品时所必要或有用的流程、程序或计划的所有现有和进一步的知识产权权利（包括但不限于专利和/或专利申请）。

(j) "**Manufacture**" and "**Manufacturing**" means any steps, processes and activities necessary to produce any product, including without limitation, the manufacturing, processing, quality control testing, release and storage of any product; specifically with respect to the Product, "**Manufacture**" and "**Manufacturing**" shall include any steps, processes and activities necessary to produce any Product from the RCB.

(j) "**制造**"指生产任何产品所需的任何步骤、工序和活动，包括但不限于任何产品的制造、加工、质量监控检测、发布和存储；就产品而言，"**制造**"应包括从RCB开始生产任何产品所需的任何步骤、工序和活动。

(k) "**PRC**" means the People's Republic of China (for the purpose of this Agreement, excluding Hong Kong Special Administrative Region, Macao Special Administrative Region and Taiwan).

(k) "**中国**"指中华人民共和国(为本协议之目的，不包括香港特别行政区、澳门特别行政区和台湾)。

(l) "**Product**" means recombinant human insulin, biosimilar to [***], that meets the Specifications, including the Reference Product specifications, whether in the active pharmaceutical ingredient form or finished pharmaceutical product form.

(l) "**产品**"指符合规格（包括参考产品的规格）的重组人胰岛素，是[***]生产的***的生物仿制药，无论为活性药物成分形式或药物成品形式。

(m) **"Reference Product**" means finished pharmaceutical product as specified by Customer, which the Customer will use as reference for the Product.

(m) "**参考产品**"指委托方指定的药物成品，委托方将使用该药物成品作为产品的参考产品。

(n) "**Scope of Work**" means the work that HX shall perform for the Customer to research and develop the RCB and to Manufacture the Product, as provided in Appendix A.

(n) "**工作范围**"指本协议附件A中规定的、HX应为委托方研发RCB和制造产品而开展的工作。

(o) "**Specifications**" means the specifications set forth in Appendix B hereof. The specifications may be adjusted from time to time by mutual written consent of the Parties.

(o) "**规格**"指本协议附件B中列明的规格，可经由双方共同书面同意不时调整。

(p) "**Technology Transfer Commencement Date**" shall mean the date agreed upon by the Parties, on which HX commences the transfer of technology to Customer. The commencement date shall be no later than nine (9) months after the Effective Date.

(p) "**技术转让起始日**"指双方约定的、HX向委托方开始进行技术转让之日，该起始日应不迟于生效日后九（9）个月。

(q) "**Term**" means the period during which this Agreement is in effect as set forth in section 7.

(q) "**协议期限**"指本协议第7条中所约定的本协议的生效期限。

(r) "**Territory**" means all countries, worldwide, without any restrictions.

(r) "**区域**"指世界范围内的所有国家，不受任何限制。

2. Provision of Services

2. 提供服务

2.1 HX shall provide services to the Customer in accordance with the Scope of Work. HX shall use its professional judgment, ability, skill and due diligence to perform services and relevant obligations under this Agreement and the Scope of Work to the best of its ability with the professionalism not lower than that of professional institutions providing similar services in the industry.

2.1 HX应根据工作范围向委托方提供服务。HX应运用其专业判断、能力、技巧和勤勉，以不低于行业内提供类似服务的专业机构的专业水准，尽其所能地履行本协议和工作范围项下之服务及相关义务。

2.2 HX shall keep the Customer informed of the progress of development and research set forth in the Scope of Work, and shall provide the Customer with written reports at least once per month, within ten (10) Business Days of the start of the succeeding month or at any other time the Customer may direct, unless otherwise expressed in the Scope of Work. Matters to be included in such reports shall be from designated by the Customer from time to time.

2.2 HX应使委托方知悉服务范围内列明的研发进程，并应至少每月、在下一个月开始后十（10）个工作日内或在委托方可能指示的任何其他时间内向委托方提供书面报告，除非工作范围另有规定。该等报告所包含的事项应由委托方不时指定。

2.3 In the event that HX expects or foresees any delay of the schedule in performing its obligations under this Agreement or the Scope of Work, HX shall immediately notify the Customer of such expectation or foreseeing and reasons thereof in writing, and follow the instructions given by the Customer. Delay of part or all of the services for more than sixty (60) Business Days shall be deemed as a material breach of this Agreement.

2.3 如果HX预期或预见其履行本协议或任何工作范围项下义务的时间表将发生任何延迟，HX应立即书面通知委托方该等预期或预见及其原因，并遵循委托方作出的指示。服务的部分或全部延迟超过六十（60）个工作日应视为对本协议的重大违反。

2.4 HX and the Customer agree that any change to the details of the Scope of Work or the assumptions upon which such Scope of Work is based may require changes to budget, estimated timelines, or payment schedule. HX shall perform the change as instructed or requested by the Customer. Any such required changes shall be reflected as a written amendment to the Scope of Work.

2.4 HX和委托方同意，对工作范围的细节或该等工作范围所依据的假设作出的任何变更可能需要对预算、预计时限或付款时间表作出变更。HX应按照委托方的指示或要求执行该等变更。任何该等变更应以对工作范围的书面修订的方式呈现。

3. Technology Transfer

3. 技术转让

3.1 Transfer of the Know-How. All the Know-How researched and developed by HX in conducting any work or providing any service for the Customer hereunder, whether or not patentable, shall be owned and/or controlled exclusively by the Customer and HX shall acquire no rights or interests whatsoever in or to any such Know-How. During the continuance of this Agreement and thereafter, HX shall not take, or permit any other person, firm, corporation or other entity to take, any action that may limit or impair the Customer's sole ownership of all rights, title and interests in and to any or all of the Know-How. HX shall furnish to the Customer in print and electronic format a copy of the Know-How as provided in Appendix C, as of the Technology Transfer Commencement Date and promptly and expeditiously transfer such Know-How to the Customer on such date. HX shall be responsible for obtaining all licenses, permits, authorizations and approvals and making all filings, notifications and reports to all government authorities that are necessary or appropriate for such transfer of the Know-How. For the avoidance of doubt, HX will file the technology exportation filing with the local branch of the PRC Ministry of Commerce.

3.1 转让专有技术. HX在本协议项下为委托方开展任何工作或提供任何服务的过程中研发的所有专有技术（无论是否可申请专利）均应由委托方独家拥有和/或控制，HX不得取得蕴含于任何该等专有技术之中或针对任何该等专有技术的任何权利或权益。在本协议的存续期间及之后，HX不得采取，或允许任何其他人、企业、公司或其他实体采取任何可能限制或损害委托方对蕴含于任何及所有专有技术之中的或针对任何或所有专有技术的所有权利、所有权和利益的独家所有权的任何行动。HX应于技术转让起始日以书面和电子形式向委托方提供附件C中约定的专有技术副本，并于技术转让起始日立即向委托方转让该等

专有技术。HX应负责获得转让该等专有技术所必需或适宜的所有证照、许可、授权和批准，并完成向政府部门作出转让该等专有技术所必需或适宜的所有备案、通知和报告。为避免疑义，汉欣将向中国商务部的地方分支机构进行技术出口备案。

3.2 Provision of the Research Cell Banks. Title to the Research Cell Banks developed, prepared and produced by HX in conducting research and development pursuant to this Agreement shall reside with the Customer. Immediately after completion of the transfer of the Know-How as set forth herein (or such earlier time agreed to by the Parties), HX shall promptly and expeditiously provide the Customer with the Research Cell Banks in sufficient quantities as provided in Appendix A for the Customer to Manufacture the Product. HX shall be responsible for obtaining all licenses, permits, authorizations and approvals and making all filings, notifications and reports to all government authorities that are necessary or appropriate for such provision of the Research Cell Banks, including but not limited to the approval for border crossing of special goods issued by competent customs.

3.2 提供研究细胞库. HX根据本协议进行研发过程中开发、制备并生产的研究细胞库的所有权应归委托方所有。在紧接本协议约定的专有技术转让完成后（或双方同意的更早期限），HX应及时、迅速地向委托方提供如附件A所示数量充足的研究细胞库，以供委托方制造产品。HX应负责获得就提供该等研究细胞库的所必需或适宜的所有证照、许可、授权和批准，并就向委托方提供该等研究细胞库完成向政府部门所必需或适宜的所有备案、通知和报告，包括但不限于主管海关出具的特殊物品进出境审批。

3.3 License. Subject to the terms and conditions of this Agreement, HX hereby grants to the Customer a fully paid, exclusive, perpetual, transferable, sub-licensable license in the Territory, in and to all Licensed Technology.

3.3 许可. 受限于本协议的条款和条件，HX特此向委托方授予一项对所有许可技术在区域内的对价已完全支付的、排他的、永久的、可转让的、可分许可的许可。

3.4 Improved and Derived Technology. Notwithstanding any contrary provisions herein, all intellectual property rights of inventions, designs, copyrights and any other intellectual property rights derived from or any improvements to the Know-How and the Licensed Technology ("**Improved and Derived Technology**") shall be the exclusive property of Customer. The Customer will have the right to seek protection, including patents, trademarks, trade secret, copyright, or any other protection the Customer deems necessary, in the Customer's sole and exclusive discretion, to

protect the Improved and Derived Technology. The Customer may offer to HX a non-exclusive license to such Improved and Derived Technology for a price to be determined in the future. HX shall take all actions, and shall execute and deliver to the Customer, or file with appropriate government authorities, all documents and other materials, as reasonably requested by the Customer, in order to permit the Customer (or any third party assignee designated by the Customer) to perfect and protect its ownership of all rights, title and interests in and to the Improved and Derived Technology therein. Except as specifically provided in this Agreement, HX shall not, either during the continuance of this Agreement or thereafter, claim or represent to any other person, firm, corporation or other entity, that HX has any right, title or interest in or to any of Improved and Derived Technology therein.

3.4 改进和衍生技术. 尽管本协议有任何相反约定，在专有技术和许可技术的基础上改进或衍生的发明、设计、版权的所有知识产权及任何其他知识产权（“**改进和衍生技术**”）应为委托方的专有财产。委托方有权自行决定寻求保护，包括专利、商标、商业秘密、版权或委托方认为必要的任何其他保护，以保护改进和衍生技术。委托方可向HX提供使用该等改进和衍生技术的非排他许可，价格待日后商定。HX应采取委托方合理要求的一切行动，并签署和向委托方交付或向适宜的政府部门提交委托方合理要求的一切文件及其他资料，以使得委托方（或委托方指定的任何第三方受让方）能够完善和保护其对蕴含于本协议项下改进和衍生技术中的和针对本协议项下改进和衍生技术的所有权利、所有权及利益的所有权。除本协议另有特别约定外，HX不得在本协议存续期内或之后，向任何其他人士、公司、企业或其他实体主张或声称HX拥有任何蕴含于本协议项下改进和衍生技术中的或针对本协议项下改进和衍生技术的任何权利、所有权或利益。

3.5 Non-Enforcement and Covenant Not To Sue. HX agrees not to, and shall cause its Affiliates not to bring any action against the Customer for infringement or misappropriation of any intellectual property rights in connection with this Agreement used by the Customer in accordance with the terms of this Agreement.

3.5 不执行及不起诉承诺. HX同意其不得，并应促使其关联方不得，就侵犯或盗用委托方根据本协议条款使用的与本协议有关的任何知识产权而对委托方提起任何诉讼。

3.6 HX shall not, directly or indirectly, manufacture, use, promote, market, sell, license, sub-license or distribute the RCB and/or the Product in the Territory

3.6 HX不得在区域内直接或间接地制造、使用、推广、营销、销售、许可、再许可或分销

RCB和/或产品。

3.7 HX shall not, without the Customer's prior written consent, use the data or information generated or obtained in the performance of this Agreement or any of the Customer's Confidential Information and intellectual property rights following the completion of service hereunder.

3.7 未经委托方事先书面同意，HX不得在本协议项下的服务完成后使用在履行本协议过程中产生或获得的资料或信息或委托方的任何保密信息和知识产权。

3.8 HX shall ensure that no third party's intellectual property right are infringed on throughout the performance of this Agreement.

3.8 HX应确保在本协议履行过程中不侵犯任何第三方的知识产权。

3.9 The Customer will retain ownership of all its Confidential Information that may be shared with HX during the Term of this Agreement, including retention of any manufacturing and production processes for the Product (and all Know-How of such processes).

3.9 委托方将保留在本协议期限内可能与HX共享的所有保密信息的所有权，包括保留产品的任何制造和生产工艺（及该等工艺的所有专有技术）。

4. Consultation Service

4. 咨询服务

4.1 Consultative Visit by HX Personnel to the Customer's Facility. Upon the Customer's written request, and at a time mutually agreed upon by the Parties, HX shall provide on-site consulting support to the Customer with respect to the Manufacture and validation of the manufacturing process at the Customer's premises or at the Customer's manufacturing site. The Customer shall pay HX a reasonable fee for such consultative visit, as mutually agreed in writing by the Parties prior to the consultative visit.

4.1 HX人员对委托方场地的咨询性访问. 经委托方书面要求且在双方一致同意的时间，HX应在委托方的场所或委托方的生产场地向委托方提供与制造和制造工艺验证相关的现场咨询支持。委托方应向HX支付双方在咨询性访问之前一致书面同意的该等咨询性访问的合理费用。

5. Payment

5. 付款

5.1 The Customer shall make the following payments to HX with respect to HX's performance of the Scope of Works

5.1 就HX对工作范围的履行而言，委托方应向HX支付下列款项：

(a) The Customer shall pay HX CNY 1,400,000 as of the Effective Date;

(a) 委托方应于生效日向HX支付人民币1,400,000元；

(b) HX shall submit to the Customer an invoice and provide the Customer with all evidential documents related to the payment at the end of each calendar quarter, and the Customer shall make payment within thirty (30) days after receipt of such invoice and inspection of all relevant evidential documents; provided however that, if the Customer disagrees with any part of the invoice, the Customer will notify HX in writing, noting its objection to the disputed item(s) with specificity within ten (10) Business Days upon receipt of the invoice and evidential documents, and pay the undisputed portion in accordance with the aforementioned period, and the Parties shall discuss and agree in good faith the remaining unpaid amount as soon as possible. The non-payment of any items disputed in good faith hereunder shall not constitute a breach of this Agreement, and HX shall not suspend the performance of services due to such non-payment.

(b) HX应在每个公历季度末向委托方提交发票，并向委托方提供与付款相关的所有证明文件，委托方应在收悉该等发票并验证所有相关证明文件之日起三十（30）日内付款；如委托方对发票的任何部分有异议，委托方将在收到发票和证明文件后的十（10）个工作日内书面通知HX，指明其对争议事项的具体异议，并根据前述期限支付无争议部分的款项，双方应尽快善意讨论剩余未付金额并就此达成一致。根据本条对于任何善意争议款项的不予支付不应构成委托方对本协议的违反，且HX不得因该等未支付行为而中止提供服务。

(c) Total payment made from the Customer to HX shall not exceed CNY 14,686,510 (Payment from Customer to HX will be adjusted from CNY to USD, based on actual currency

exchange rate as reported by the Bloomberg Currency Spot Exchange Rate the date of which the invoice is issued by HX).

(c) 委托方向HX支付的总金额不得超过人民币14,686,510元（委托方向HX支付的款项将从人民币调整为美元，以HX发票开具之日公布的彭博货币即期汇率的实际货币兑换率计算）。

(d) Any additional work or changes to the Scope of Work that the Customer is requesting from HX will be charged by HX to the Customer in the amount equal to the sum of (i) HX's direct costs for such additional work, plus (ii) **% of the amount of such direct costs plus any applicable taxes. Any additional cost must be provided to Customer for approval prior to the work being performed.

(d) 委托方要求HX进行的任何额外工作或对工作范围的变更将由HX向委托方收取金额相当于如下各项之和的款项：(i)HX开展该等额外工作的直接支出，加上(ii)该等直接支出的**%再加上任何适用的税款。任何额外费用必须在开展工作前提供予委托方供批准。

6. Regulatory Matters

6. 监管事项

6.1 The Customer is responsible for filing and obtaining any marketing authorization that is required for the marketing and sale of the Product. HX shall reasonably cooperate with the Customer in requests related to such activities.

6.1 委托方负责申请并取得上市和销售产品所需的任何上市许可。HX应合理地配合委托方提出的与该等活动相关的要求。

6.2 HX shall obtain, and maintain in full force and effect throughout the Term of this Agreement, all licenses, permits, authorizations and approvals required under all Applicable Laws, regulations and government orders, and shall make all filings, notifications and reports to all government agencies that are necessary or appropriate for the performance by HX of all of its obligations under this Agreement. If any approval, license or permit received by HX is conditioned upon any modification or amendment to this Agreement that is unacceptable to the Customer, the Customer shall have the right to terminate this Agreement with immediate effect without any further obligations whatsoever hereunder to HX. HX shall comply with all applicable industry standards,

including industry regulations, operation specifications and procedures, code of conduct, etc. during the performance of this Agreement. HX shall not, through any form of act or omission, violate any applicable industry standards.

6.2 HX应取得所有适用法律、法规和政府命令项下要求的一切证照、许可、授权和批准，并在本协议期限内保持该等证照、许可、授权和批准始终完全有效，同时应向所有政府部门进行对HX履行其在本协议项下所有义务所必需或适宜的所有备案、通知和报告。如果HX取得的任何批准、证照或许可系以对本协议的变更或修订为前提，且该等变更或修订令委托方无法接受，则委托方有权立即终止本协议，而无须在本协议项下对HX承担任何进一步义务。在履行本协议的期间，HX应遵守所有适用的行业标准，包括行业法规、操作规范和程序、行为准则等。HX不得通过任何形式的作为或不作为违反任何适用的行业标准。

7. Term, Amendment and Termination

7. 协议期限、变更和终止

7.1 This Agreement will remain in full force and effect for a period of three (3) years from the Effective Date.

7.1 本协议将自生效日起三（3）年内保持完全有效。

7.2 During the Term, due to changes in laws and regulations, Specifications, Manufacturing procedures or other substantive conditions, this Agreement may be amended by the mutual written consent of the Parties. Any Amendment to this Agreement and its appendices hereto shall come into force with an instrument in writing signed by the Parties.

7.2 于协议期限内，因法律法规、规格、生产规程或其他实质性条件发生变化，本协议可经双方共同书面同意予以修订。对本协议及其附件的任何修订，须经双方签署书面协议方能生效。

7.3 Unless otherwise provided for herein, either Party (the "**Terminating Party**") may immediately terminate this Agreement by notifying the other Party (the "**Terminated Party**") in writing when one of the following situations occurs:

7.3 除本协议另有规定外，任一方（"**终止方**"）可在出现下述情形之一时书面通知另一方（"**被终止方**"）立即终止本协议：

(a) The Terminated Party breaches this Agreement and (i) does not rectify its default within thirty (30) days on the date of receiving written notice from the Terminating Party requiring for rectification; or (ii) there is no realistic possibility to rectify such default; or (iii) such default has resulted in the inability to achieve the purpose of this Agreement;

(a) 被终止方违反本协议且(i)在收悉终止方书面通知要求其纠正违约行为之日起三十（30）日内未纠正其违约行为的；或(ii)不存在纠正该违约行为的现实可能性；或(iii)该违约导致本协议的目的无法实现；

(b) The Terminated Party suffers a Force Majeure event which makes it impossible to achieve the purpose of this Agreement;

(b) 被终止方遭遇不可抗力事件，致使不能实现本协议的目的；

(c) The Terminated Party expresses clearly or by behavior that it will not perform its obligations hereunder, or delays the performance of its obligations and has not fully performed the obligations after being notified;

(c) 被终止方明确表示或以行为表明其将不履行本协议项下义务，或迟延履行本协议义务且经催告后仍未全面履行的；

(d) The Terminated Party loses the ability to perform its obligations hereunder, including but not limited to, entering bankruptcy proceedings, liquidation proceedings, being dissolved, being winding up, being revoked, or losing appropriate qualifications.

(d) 被终止方丧失履行本协议项下义务的能力，包括但不限于进入破产程序、清算程序、被解散、被注销、被吊销、丧失相应资质。

7.4 This Agreement may be terminated by mutual written consent of the Parties.

7.4 本协议可经双方共同书面同意而终止。

7.5 Termination or expiration of this Agreement shall not relieve either Party of any obligation accruing prior to such termination or expiration, including, without limitation, any breach of such obligation, or from any surviving obligation under this Agreement.

7.5 本协议的终止或到期不得免除任何一方在该等终止或届满前已产生的任何义务，包括但不限于对该等义务的任何违反，或本协议项下的任何存续义务。

7.6 Either Party shall return or destroy all documents and materials in its possession which contain Confidential Information of the other Party within thirty (30) days after termination or expiration of this Agreement. The receiving party may retain one copy of documents and materials which contain the disclosing party's Confidential Information for the purpose of verifying the receiving party's compliance with its obligations under this Agreement but for no other purpose whatsoever.

7.6 任何一方应在本协议终止或到期后三十（30）日内归还或销毁其持有的包含另一方保密信息的所有文件和材料。接收方可以保留包含披露方保密信息的文件和材料的一份副本，以核实接收方是否遵守其在本协议项下的义务，但不得以任何其他目的。

7.7 Unless otherwise provided for herein, after termination or expiration of this Agreement, section 1 (*General*), this section 7 (*Term, Amendment and Termination*), section 8 (*Warranties*), section 9 (*Indemnities*), section 10 (Confidential Information), section 11 (*Force Majeure*), section 12 (*Notices*), section 13 (*Binding Effect*), section 14 (*Governing Law and Dispute Resolution*), section 15 (*Assignment*), section 16 (*Severability*), section 17 (*Entire Agreement*), section 18 (*Waiver*), section 19 (*Publicity*), section 20 (*Appendices*), section 21 (*Limitation of liability*), section 22 (*Counterparts and Language*) shall survive.

7.7 除本协议另有规定外，在本协议终止或到期后，本协议第1条（总则）、本第7条（协议期限、变更和终止）、第8条（保证）、第9条（赔偿）、第10条（保密信息）、第11条（不可抗力）、第12条（通知）、第13条（约束力）、第14条（适用法律和争议解决）、第15条（转让）、第16条（可分割性）、第17条（完整协议）、第18条（弃权）、第19条（宣传）、第20条（附件）、第21条（责任限制）和第22条（副本和语言）应继续有效。

8. Warranties

8. 保证

8.1 HX warrants that the RCB delivered to the Customer and pursuant to this Agreement shall at the time of such delivery not be adulterated or misbranded within the meaning of the Applicable Law, and fully meeting the Specifications. HX represents and warrants that it will comply with all present and future Applicable Laws relating to development, manufacture, and supply of the RCB being provided hereunder, including without limitation, those enforced by the United States Food and Drug Administration.

8.1 HX保证，根据本协议向委托方交付的RCB应在该等交付时不存在适用法律所指的假冒伪

劣，且完全符合规格。HX陈述并保证，其将遵守与本协议项下约定的RCB的开发、生产和供应相关的所有现行和未来的适用法律，包括但不限于美国食品和药物管理局执行的适用法律。

8.2 Each party represents and warrants to the other that it is not under any obligation to any person, contractual or otherwise, that is conflicting or inconsistent in any respect with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder.

8.2 每一方向另一方陈述并保证，该方不对任何人承担任何与本协议条款在任何方面存在冲突或不一致的，或可能妨碍其勤勉、完全地履行其在本协议项下的义务（无论是合同义务还是其他义务）。

8.3 HX represents and warrants that (i) it employs adequate numbers of skilled and experienced research, supervisory, and administrative personnel to perform works hereunder in a safe, competent, and efficient manner; (ii) it will perform works hereunder in a safe, competent, and efficient manner consistent with a high standard of workmanship and good laboratory or plant practices; (iii) it, including its facilities in which works hereunder will be conducted is, and during the Term of this Agreement shall remain, in full compliance with all Applicable Laws and regulations including but not limited to laws and regulations of PRC and of local and regional governments or ministries thereof in respect of environmental, health, safety, labor, import, export, Customs, human genetic resources, etc.; and (iv) all employees, agents, consultants or other personnel who work on the Customer's projects hereunder, have assigned or otherwise provided all of their respective rights in any technology to HX or to the Customer.

8.3 HX陈述并保证，(i)HX雇佣了足够数量的熟练且经验丰富的研发、监督和管理人员以安全、称职、高效地开展本协议项下的工作；(ii)HX将采取较高的工艺标准以及良好的实验或生产操作规范以安全、称职、高效地开展本协议项下的工作；(iii)HX（包括其开展本协议项下工作所需的设施）目前且在本协议期限内应始终保持符合所有适用法律法规的规定，包括但不限于中国及地方和地区政府或部委关于环境、卫生、安全、劳动、进口、出口、海关、人类遗传资源等方面的法律和法规；及(iv)就本协议项下的委托方项目开展工作的所有雇员、代理人、顾问或其他人员均已将其对任何技术的一切相应权利转让或以其他方式提供予HX或委托方。

9. Indemnities

9. 赔偿

9.1 Unless arising from the willful misconduct of HX, the Customer will defend, indemnify and hold HX and its Affiliates and their respective employees, servants and agents harmless against any liability, judgment, demand, action, suit, loss, damage, cost or other expense (including reasonable attorneys' fees and other costs of defense) resulting from: (i) the Customer's material breach of this Agreement or (ii) the Customer's breach of any warranty made under this Agreement.

9.1 除非因HX故意不当行为引起，当(i)委托方严重违反本协议，或(ii)委托方违反其在本协议项下作出的任何保证，委托方应为HX及HX关联方、HX及其关联方的雇员、服务人员、代理人提供抗辩及赔偿，以使得HX及HX前述主体免受任何责任、判决、要求、行动、诉讼、损失、损害、成本或其他费用支出（包括合理的律师费及其他辩护费用）。

9.2 Unless arising from the willful misconduct of the Customer, HX will defend, indemnify and hold the Customer and its respective employees, servants and agents harmless against any liability, judgment, demand, action, suit, loss, damage, cost or other expense (including reasonable attorneys' fees and other costs of defense) resulting from (i) HX's gross negligence in the research, development, manufacture, storage or delivery of RCB; (ii) HX's material breach of this Agreement; or (iii) HX's breach of any warranty made under this Agreement.

9.2 除非因委托方故意不当行为引起，当(i)HX在研发、生产、存储或运输RCB时存在重大过失；(ii)HX严重违反本协议；或(iii)HX违反其在本协议项下作出的任何保证，HX应为委托方及其雇员、服务人员、代理人提供抗辩及赔偿，以使得委托方及委托方前述主体免受任何责任、判决、要求、行为、诉讼、损失、损害或其他费用支出（包括合理的律师费及其他辩护费用）。

9.3 Each indemnified party agrees to give the indemnifying party prompt written notice of any matter upon which such indemnified party intends to base a claim for indemnification (an "**Indemnity Claim**") under section 9. The indemnifying party will have the right to participate jointly with the indemnified party in the indemnified party's defense, settlement or other disposition of any Indemnity Claim. With respect to any Indemnity Claim relating solely to the payment of money damages and which could not result in the indemnified party's becoming subject to injunctive or other equitable relief or otherwise adversely affect the business of the indemnified party in any manner, and as to which the indemnifying party will have acknowledged in writing the obligation

to indemnify the indemnified party hereunder, the indemnifying party will have the sole right to defend, settle or otherwise dispose of such Indemnity Claim, on such terms as the indemnifying party, in its sole discretion, will deem appropriate, provided that the indemnifying party will provide reasonable evidence of its ability to pay any damages claimed and with respect to any such settlement will have obtained the written release of the indemnified party from the Indemnity Claim. The indemnifying party shall apply for a written release from the indemnified party prior to ceasing to defend, settling or otherwise disposing of any Indemnity Claim. If as a result thereof the indemnified party has been subject to injunctive or other equitable relief or the business of the indemnified party has been adversely affected in any matter, the application for exemption will be rejected.

9.3 受偿方同意立即书面通知赔偿方，其根据本协议第9条拟提起的赔偿主张（“**赔偿主张**”）。赔偿方有权参与受偿方对任何赔偿主张进行的辩护、和解或其他方式处理赔偿主张的活动。对于任何仅与经济赔偿有关且不会导致受偿方受限于禁令或其他衡平法救济，也不会以任何形式对受偿方的业务活动产生不利影响的赔偿主张，同时赔偿方已通过书面形式确认了其在本协议项下对受偿方的赔偿义务，则赔偿方拥有以其自行认为合理的方式辩护、和解或以其他方式处理上述赔偿主张的权利，但前提是赔偿方提供合理的证据证明其有能力支付任何被主张的损害赔偿，并且就任何此类和解已获得受偿方的书面免责声明。赔偿方应在辩护、和解或其他处理方式结束之前，向受偿方申请书面免责声明，若受偿方已获得禁令、衡平法救济或其业务活动已受到不利影响，免责申请将被拒绝。

10. Confidential Information

10. 保密信息

10.1The receiving party will 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 and for the Purpose of this Agreement. The receiving party will not disclose to anyone any Confidential Information received from the disclosing party, and will 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 will promptly return to the disclosing party or destroy all drawings, data, memoranda and information in physical form relating to the Confidential Information.

10.1接收方应将披露方已经或之后向接收方直接或间接地披露的所有信息视为保密信息进行保密，无论该等披露是通过口头、书面或检查的方式进行。接收方应仅在必要的范围内为本协议的目的使用收悉的保密信息。接收方不得向任何人披露其从披露方处收悉的任何保密信息，并将以接收方防止其自身保密信息披露而采取的相同程度的谨慎（但不得低于合理的谨慎程度）防止该等保密信息披露给他人。经披露方要求后，接收方应立即向披露方归还或销毁与保密信息有关的所有图纸、数据、备忘录和实物形式的信息。

10.2Each 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 will first give reasonable written notice to the disclosing party prior to any Required Disclosure and will 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 will not oppose or seek to impede the disclosing party's efforts to obtain such relief.

10.2每一方同意对保密信息予以保密，包括（但不限于）未经披露方事先书面同意，不得披露披露方的保密信息或其任何部分（除非本协议另有规定），除非根据适用法律、法令或对接收方有管辖权的法院或其他管辖、监管机构的有效命令要求披露（"**必要披露**"），但前提是接收方应在任何必要披露前首先向披露方发出合理的书面通知，且需尽其最大努力获得法令或其他可靠保证以确保所披露的保密信息得到最高级别的保密处理。在收悉接收方发出的任何必要披露的通知时，披露方可在自行承担费用的情况下寻求撤销或限制对披露方保密信息的披露，接收方不得反对或阻碍披露方获得该等救济。

10.3This provision of confidentiality is not intended to grant or transfer any rights to the Confidential Information to the receiving party and does not transfer or convey any rights under a patent, trademark, copyright, or other intellectual property right to or in the Confidential Information. All Confidential Information (including all copies thereof) will at all times remain the property of the disclosing party. Further, and unless otherwise provided in this Agreement, the disclosure of Confidential Information to a receiving party does not create, and is not intended to

create, any form or type of agency by and between the disclosing party and the receiving party.

10.3本保密条款无意向接收方授予或转让任何保密信息的任何权利，也无意转让或让与关于保密信息的专利、商标、版权或其他知识产权项下的任何权利。所有保密信息（包括其所有副本）将始终为披露方所有。此外，除非本协议另有规定，向接收方披露保密信息并不构成也不旨在构成披露方和接收方之间的任何形式或类型的代理关系。

10.4The receiving party agrees that its obligations hereunder are necessary and reasonable to protect the disclosing party, and expressly agrees that monetary damages would be inadequate to compensate the disclosing party for any breach of any covenant or agreement set forth herein and that, in addition to any and all other remedies available at law or in equity, the disclosing party will be entitled to seek equitable relief, including injunction and specific performance, as a remedy for any actual or threatened breach of this Agreement, and no bond or other security will be required in connection with any such equitable relief. In the event of litigation relating to this Agreement, if a court of competent jurisdiction determines that a Party has breached this Agreement, then the non-breaching party may seek recovery of its reasonable legal fees, including any appeal, in addition to any other remedies to which the non-breaching party may be entitled.

10.4接收方同意，其在本协议下的义务对于保护披露方而言是必要和合理的，如违反本协议约定，不仅应赔偿披露方经济损失，除法律或衡平法可获得的任何和所有其他救济之外，披露方将有权寻求衡平法救济，包括禁令和特别履行，并且无需对该等衡平法救济提供任何保函或担保。如发生与本协议有关的诉讼，如果有管辖权的法院判定一方违反了本协议，则守约方有权要求获得合理的律师费（含上诉）及采取其他补救措施。

11. Force Majeure

11. 不可抗力

11.1 If the performance by either Party of any obligation under this Agreement is prevented or impaired by a Force Majeure event, such Party will be excused from performance so long as such situation continues to prevent or impair performance, provided the Party claiming such excuse must promptly notify the other Party of the existence, nature, duration and other details of the Force Majeure event and will at all times use reasonable efforts consistent with its normal business practices to resume a complete performance.

11.1 如果任何一方对其在本协议项下任何义务的履行因不可抗力事件受到阻碍或损害，则在该等情况继续阻碍或损害履约期间，该方可免除履行义务，前提是主张免于履约的一方必

须立即通知另一方不可抗力事件的存在、性质、持续时间及其他详情，并且应始终按照其正常商业惯例尽合理的努力恢复协议义务的完全履行。

11.2 In the event of a Force Majeure event, the exempting party will advise the other Party from time to time as to the progress in remedying the situation and as to the time when the exempting party expects to resume its obligations. The exempting party shall promptly inform the other Party of elimination of such Force Majeure event.

11.2 不可抗力免责方应定期告知另一方补救措施的进展以及预计何时恢复履行义务。不可抗力事件结束后，免责方应立即告知另一方。

12. Notices

12. 通知

12.1 All notices hereunder shall be in writing and shall be delivered personally, mailed by overnight delivery, registered or certified mail, postage prepaid, or given by facsimile to the following addresses of the respective Parties:

12.1 本协议项下的所有通知均应为书面形式，通过专人递送、隔夜快递、挂号信、预付邮资或传真方式发送到双方的以下地址：

If to HX:	**Address:** Building C5, No.9 Weidi Road, Xianlin University Town,
HX：	地址：仙林大学城纬地路9号C5栋
	Attn: General Manager
	收件人：总经理
	Post Code: 210033
	邮编：210033
If to the Customer:	**Address:** Amphastar Pharmaceuticals, Inc.
委托方：	11570 Sixth Street
	Rancho Cucamonga, CA 91730
	USA
	地址：Amphastar Pharmaceuticals, Inc.
	11570 Sixth Street
	Rancho Cucamonga, CA 91730
	USA
	Attn: Head of Administration Center

收件人：管理中心主管

13. Binding Effect

13. 约束力

13.1 This Agreement shall be binding upon and inure to the benefit of the Parties and their respective assigns and successors in interest.

13.1 本协议应对双方及其各自的受让人和继任人有约束力并及于其各自之利益。

14. Governing Law and Dispute Resolution

14. 适用法律和争议解决

14.1 The Agreement shall be construed, interpreted and governed by the laws of the State of Delaware, the United States of America.

14.1 本协议应受美国特拉华州法管辖并依其解释。

14.2 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 Dispute (including a Dispute in connection with the validity or continuity of this Agreement) shall be submitted to arbitration. Such arbitration shall be conducted in English and shall take place in New York and shall proceed in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("**AAA**") and the laws of the State of New York without regard to the provisions thereof concerning conflict of laws.

14.2 本协议以及因本协议及其内容或其成立而引起的或与之相关的任何争议或诉请（包括非合同争议或诉请）（"**争议**"）应首先由双方通过协商解决。如不能通过协商解决的，则该争议（包括有关本协议有效性或存续性的争议）应提交仲裁。该等仲裁应以英文在纽约进行，并应根据美国仲裁协会（"**美国仲裁协会**"）的商业仲裁规则及纽约州法律进行仲裁，不适用冲突法原则。

14.3 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.

14.3 仲裁裁决应为终局裁决，对双方均具有约束力，每一方可向有管辖权的法院申请强制执行该等裁决。在按照本协议约定解决争议期间，除争议所涉事项外，双方应继续履行其在本协议项下的义务。

15. Assignment

15. 转让

15.1 Neither Party shall assign or transfer its rights and obligations hereunder to any other party without the prior written consent of the other Party. Notwithstanding the foregoing, this Agreement and the rights and obligations herein may be assigned by the Customer to any of its Affiliate. Any permitted assignee will assume all obligations of its assignor under this Agreement.

15.1 未经另一方事先书面同意，任何一方不得将其在本协议项下的权利和义务让与或转让给任何其他方。尽管有前述规定，委托方可将本协议及本协议项下的权利和义务转让给其任何关联方。任何获准受让人将承担其转让人在本协议项下的所有义务。

15.2 No assignment will relieve any Party of the responsibility for the performance of any obligation hereunder.

15.2 任何转让均不得免除任何一方履行本协议项下任何义务的责任。

16. Severability

16. 可分割性

16.1 In the event that any term or provision of this Agreement is held invalid or unenforceable by a court of competent jurisdiction, the remaining terms shall be valid and enforced to the fullest extent permitted by Applicable Law. If any term or provision of this Agreement is deemed by a court to be unenforceable because such provision is too broad in scope, the provision shall be construed in a limited scope to make it enforceable.

16.1 如果本协议的任何条款或规定被有管辖权的法院认定为无效或不可执行，本协议的其余条款仍应在适用法律允许的最大范围内有效且可执行。如果本协议的任何条款或规定因其范围过于宽泛而被法院认定为不可执行，则应在限定范围内对该条款进行解释以使其可执行。

17. Entire Agreement

17. 完整协议

17.1 This Agreement constitutes the entire agreement between the Parties concerning the subject matter and supersedes all prior agreements or understandings between the Parties.

17.1 本协议构成双方就本协议主题事项达成的完整协议，并取代双方先前达成的所有协议或谅解。

18. Waiver

18. 弃权

18.1 No waiver or modification of any of the terms of this Agreement shall be valid unless in writing and signed by authorized representatives of both Parties. Failure by either Party to enforce any rights under this Agreement shall not be construed a waiver of any rights, nor will a waiver by a Party in one instance be construed as a continuing waiver or a waiver in other instances.

18.1 除非由双方授权代表书面签署，否则对本协议任何条款的放弃或修改均为无效。任何一方未能行使本协议项下的任何权利不应被视为在该情况下或任何其他情况下放弃此类权利。任何一方在某种情况下的弃权也不应被视为持续弃权或视为在其他情况下的弃权。

19. Publicity

19. 宣传

19.1 Other than as required by Applicable Law, in the absence of specific agreement between the Parties, neither Party shall originate any publicity, news release or other public announcement, written or oral, whether to the public press, to stockholders or otherwise relating to this Agreement.

19.1 除适用法律要求外，如双方未达成特别协议，任何一方均不得向公众媒体、股东或与本协议有关的其他方发布任何书面或口头的宣传、新闻发布或其他公告。

20. Appendices

20. 附件

20.1 All appendices referenced herein are made a part of this Agreement.

20.1 本协议中提及的所有附件均为本协议的一部分。

21. Limitation of Liability

21. 责任限制

21.1 In no event, however, to the extent permitted by Applicable Law, shall either Party be liable to the other Party or to any third party, under this Agreement, in contract, tort (including negligence), or other-wise howsoever, and whatever the cause thereof, for lost profits, goodwill, the cost of procurement of substitute goods or for any consequential or indirect damages. This limitation shall apply even where a Party has been advised of the possibility of such damage and notwithstanding the failure of the essential purpose of any limited remedy stated herein.

21.1 在任何情况下，在适用法律允许的范围内，本协议项下一方对于另一方或任何第三方就利润损失、商誉、替代商品的采购成本或任何后续或间接损害均不承担赔偿责任，不论是基于合同、侵权（包括过失）或其他方式，且不论是何种原因造成。即使一方已被告知该等损害的可能性，且本协议规定的任何有限救济的基本目的未能实现，该等限制仍应适用。

22. Counterparts and Language

22. 副本和语言

22.1 This Agreement may be executed in several duplicates, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. For the avoidance of doubt, this Agreement is concluded both in Chinese version and English version. In the event of any discrepancy between the Chinese version and the English version, the English version shall prevail.

22.1 本协议可签署多份副本，每一份副本均应被视为原件，但所有副本应共同构成同一文件。为免疑义，本协议以中文和英文双语书就。若中文版本和英文版本之间存在不一致之处，应以英文版本为准。

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

有鉴于此，本协议由双方授权代表正式签署。

Amphastar Pharmaceuticals, Inc.		Nanjing Hanxin Pharmaceutical Technology Co., Ltd. 南京汉欣医药科技有限公司	
By/签署:	/s/Rong Zhou	By/签署:	/s/Bob Bao
Name/姓名:	Rong Zhou	Name/姓名:	Bob Bao 鲍海涛
Title/职位:	Executive VP of Production	Title/职位:	Vice General Manager 副总经理
Date/日期:	July 6, 2022	Date/日期:	July 5, 2022

APPENDIX A: SCOPE OF WORK

附件A：工作范围

As provided in the HX Proposal dated May 27, 2022

根据[2022年5月27日]的HX提案

Provision of the RCBs – HX will supply the Customer with [***] vials of the RCB. After HX provides the Customer with [***] vials of the RCB, HX will keep [***] vials of the RCB in stock. HX will supply the remaining [***] vials, upon the request of the Customer, at no additional cost. The Customer is responsible for the shipment/transportation costs for provision of all of the RCBs.

RCB的提供 – HX将向委托方提供 [***] 瓶RCB。在HX向委托方提供 [***] 瓶RCB后，HX将储备 [***] 瓶RCB的库存。提供少于 [***] 瓶的 RCB不需要额外费用。委托方应承担提供全部RCB的装运/运输费用。

APPENDIX B: SPECIFICATIONS

附件**B**：规格

Part of the Product development work.

产品开发工作的一部分。

APPENDIX C: LIST OF THE KNOW-HOW

附件C：专有技术清单

1. RHI Research Cell bank (RCB) Research and Characterization and Report

1. 重组人胰岛素研究细胞库（RCB）的研究和表征及报告

2. RHI Process Research and Development and Report

2. 重组人胰岛素工艺的研究和开发及报告

3. RHI Lab-scale Sample Test and Structure Characterization and Report

3. 重组人胰岛素实验室规模样品测试和结构表征及报告

Exhibit 31.1

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

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

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

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

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

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

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

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

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

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

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

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

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

Date: November 8, 2022

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

Exhibit 31.2

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

I, William J. Peters, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 8, 2022

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

Exhibit 32.1

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

The undersigned officer of Amphastar Pharmaceuticals, Inc. (the "Company"), hereby certifies, to the best of such officer's knowledge, that:

(i) the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2022 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and

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

Date: November 8, 2022

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

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. §1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 32.2

CERTIFICATIONS OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

The undersigned officer of Amphastar Pharmaceuticals, Inc. (the "Company"), hereby certifies, to the best of such officer's knowledge, that:

(i) the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2022 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and

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

Date: November 8, 2022

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

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. §1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.