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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 JUNE 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 August 2, 2022 was 49,015,172.

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 expansion plans for our Chinese subsidiary, Amphastar Nanjing Pharmaceuticals, Ltd., or ANP;
- the potential for adverse application of environmental, health and safety and other laws and regulations on our operations;
- our expectations for market acceptance of our new products and proprietary drug delivery technologies, as well as those of our active pharmaceutical ingredient, or API, customers;
- the effects of reforms in healthcare regulations and reductions in pharmaceutical pricing, reimbursement and coverage;
- the potential for our marketed products to be withdrawn due to patient adverse events or deaths, or if we fail to secure FDA approval for products subject to the Prescription Drug Wrap-Up program;
- our expectations in obtaining insurance coverage and adequate reimbursement for our products from third-party payers;
- the amount of price concessions or exclusion of suppliers adversely affecting our business;
- variations in intellectual property laws, our ability to establish and maintain intellectual property protection for our products and our ability to successfully defend our intellectual property in cases of alleged infringement;
- the implementation of our business strategies, product development strategies and technology utilization;
- the potential for exposure to product liability claims;
- our ability to successfully bid for suitable acquisition targets or licensing opportunities, or to consummate and integrate acquisitions, divestitures or investments, including the anticipated benefits of such acquisitions, divestitures or investments;
- our ability to expand internationally;
- economic and industry trends and trend analysis;
- our ability to remain in compliance with laws and regulations that currently apply or become applicable to our business both in the United States and internationally;
- the impact of trade tariffs, export or import restrictions, or other trade barriers;
- the impact of Patient Protection and Affordable Care Act (as amended) and other legislative and regulatory healthcare reforms in the countries in which we operate including the potential for drug price controls;
- the 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)

	June 30, 2022 (unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 166,157	$ 126,353
Restricted cash	235	235
Short-term investments	17,234	10,320
Restricted short-term investments	2,200	2,200
Accounts receivable, net	80,810	78,804
Inventories	98,733	92,807
Income tax refunds and deposits	5,878	126
Prepaid expenses and other assets	5,898	7,274
Total current assets	377,145	318,119
Property, plant, and equipment, net	237,564	244,244
Finance lease right-of-use assets	201	353
Operating lease right-of-use assets	26,962	26,894
Investment in unconsolidated affiliate	3,065	3,985
Goodwill and intangible assets, net	37,700	38,870
Other assets	18,683	16,665
Deferred tax assets	22,399	22,399
Total assets	$ 723,719	$ 671,529
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 97,665	$ 89,545
Income taxes payable	597	9,081
Current portion of long-term debt	2,057	2,202
Current portion of operating lease liabilities	3,315	2,982
Total current liabilities	103,634	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	73,871	74,776
Long-term operating lease liabilities, net of current portion	24,680	24,703
Deferred tax liabilities	364	534
Other long-term liabilities	15,332	15,653
Total liabilities	224,412	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; 57,896,337 and 48,992,289 shares issued and outstanding as of June 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	443,042	422,423
Retained earnings	221,936	180,337
Accumulated other comprehensive loss	(8,709)	(6,765)
Treasury stock	(156,968)	(150,479)
Total equity	499,307	445,522
Total liabilities and stockholders' equity	$ 723,719	$ 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net revenues	$ 123,467	$ 101,663	$ 243,835	$ 204,683
Cost of revenues	60,111	54,287	124,653	112,361
Gross profit	63,356	47,376	119,182	92,322
Operating expenses:				
Selling, distribution, and marketing	5,756	4,129	11,275	8,666
General and administrative	9,979	14,565	22,449	29,903
Research and development	22,798	18,122	39,021	32,887
Total operating expenses	38,533	36,816	72,745	71,456
Income from operations	24,823	10,560	46,437	20,866
Non-operating income (expenses):				
Interest income	229	142	410	303
Interest expense	(397)	(86)	(752)	(190)
Other income (expenses), net	(1,504)	3,601	6,089	(1,648)
Total non-operating income (expenses), net	(1,672)	3,657	5,747	(1,535)
Income before income taxes	23,151	14,217	52,184	19,331
Income tax provision	5,551	5,595	9,628	6,750
Income before equity in losses of unconsolidated affiliate	17,600	8,622	42,556	12,581
Equity in losses of unconsolidated affiliate	(254)	—	(957)	—
Net income	$ 17,346	$ 8,622	$ 41,599	$ 12,581
Net income (loss) attributable to non-controlling interests	$ —	$ 855	$ —	$ (227)
Net income attributable to Amphastar Pharmaceuticals, Inc.	$ 17,346	$ 7,767	$ 41,599	$ 12,808
Net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders:				
Basic	$ 0.35	$ 0.16	$ 0.86	$ 0.27
Diluted	$ 0.33	$ 0.16	$ 0.79	$ 0.26
Weighted-average shares used to compute net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders:				
Basic	48,864	47,731	48,501	47,626
Diluted	53,227	49,552	52,603	49,535

See Accompanying Notes to Condensed Consolidated Financial Statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net income attributable to Amphastar Pharmaceuticals, Inc.	$ 17,346	$ 7,767	$ 41,599	$ 12,808
Other comprehensive income (loss) attributable to Amphastar Pharmaceuticals, Inc., net of income taxes				
Foreign currency translation adjustment	(1,464)	711	(1,944)	(1,210)
Total other comprehensive income (loss) attributable to Amphastar Pharmaceuticals, Inc.	(1,464)	711	(1,944)	(1,210)
Total comprehensive income attributable to Amphastar Pharmaceuticals, Inc.	$ 15,882	$ 8,478	$ 39,655	$ 11,598

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

	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

See Accompanying Notes to Condensed Consolidated Financial Statements.

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

	Six Months Ended June 30,	
	2022	2021
Cash Flows From Operating Activities:		
Net income	$ 41,599	$ 12,581
Reconciliation to net cash provided by operating activities:		
(Gain) loss on disposal of assets	(58)	314
Gain on interest rate swaps	(3,901)	(275)
Depreciation of property, plant, and equipment	11,411	11,449
Amortization of product rights, trademarks, and patents	696	553
Operating lease right-of-use asset amortization	1,709	1,689
Equity in losses of unconsolidated affiliate	957	—
Share-based compensation expense	9,257	10,918
Changes in operating assets and liabilities:		
Accounts receivable, net	(2,178)	(1,985)
Inventories	(7,422)	(1,659)
Prepaid expenses and other assets	4,071	1,610
Income tax refunds, deposits, and payable, net	(14,235)	2,218
Operating lease liabilities	(1,468)	(1,849)
Accounts payable and accrued liabilities	13,142	19,420
Net cash provided by operating activities	53,580	54,984
Cash Flows From Investing Activities:		
Purchases and construction of property, plant, and equipment	(12,101)	(13,359)
Proceeds from the sale of property, plant and equipment	421	—
Purchase of investments	(12,004)	(7,240)
Maturity of investments	6,391	8,475
Payment of deposits and other assets	3	(825)
Net cash used in investing activities	(17,290)	(12,949)
Cash Flows From Financing Activities:		
Proceeds from equity plans, net of withholding tax payments	12,220	6,394
Purchase of treasury stock	(7,346)	(9,344)
Settlement of ANP equity awards	—	(839)
Debt issuance costs	(89)	—
Repayments under lines of credit	—	(774)
Principal payments on long-term debt	(1,131)	(7,267)
Net cash provided by (used in) financing activities	3,654	(11,830)
Effect of exchange rate changes on cash	(140)	(121)
Net increase in cash, cash equivalents, and restricted cash	39,804	30,084
Cash, cash equivalents, and restricted cash at beginning of period	126,588	94,507
Cash, cash equivalents, and restricted cash at end of period	$ 166,392	$ 124,591
Noncash Investing and Financing Activities:		
Capital expenditure included in accounts payable	$ 5,539	$ 7,034
Operating lease right-of-use assets in exchange for operating lease liabilities	$ 1,777	$ 8,803
Equipment acquired under finance leases	$ —	$ 107
Supplemental Disclosures of Cash Flow Information:		
Interest paid, net of capitalized interest	$ 1,167	$ 998
Income taxes paid	$ 23,964	$ 4,577

See Accompanying Notes to Condensed Consolidated Financial Statements.

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

Note 1. General

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

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

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

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

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

COVID-19 Pandemic

The Company is subject to risks and uncertainties as a result of the ongoing novel coronavirus pandemic, or COVID-19. The complete extent of the impact of the COVID-19 pandemic on the Company's business is highly uncertain and difficult to predict, as the information is constantly evolving. The Company considered the impact of COVID-19 on the assumptions and estimates used to determine the results reported and asset valuations as of June 30, 2022.

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

All of the Company's production facilities continued to operate during the quarter as they had prior to the COVID-19 pandemic with very little change, other than for enhanced safety measures intended to prevent the spread of the virus. 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 delays in shipping certain APIs and starting materials. Future shutdowns could have an adverse impact on the Company's operations. However, the extent of the impact of any future shutdown or delay is highly uncertain and difficult to predict.

The Company will continue to monitor the impact of COVID-19 on all aspects of its business.

Use of Estimates

The preparation of condensed consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results could differ from those estimates. The principal accounting estimates include: determination of allowances for credit losses, fair value of financial instruments, allowance for discounts, provision for chargebacks and rebates, provision for product returns, adjustment of inventory to its net realizable values, impairment of investments, long-lived and intangible assets and goodwill, accrual for workers' compensation liabilities, litigation reserves, stock price volatility for share-based compensation expense, valuation allowances for deferred tax assets, and liabilities for uncertain income tax positions.

Foreign Currency

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

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

The unrealized gains and losses of intercompany foreign currency transactions that are of a long-term investment nature were a $2.1 million loss and a $2.7 million loss for the three and six months ended June 30, 2022, respectively. For the three and six months ended June 30, 2021, the unrealized gains and losses of intercompany foreign currency transactions that are of a long-term investment nature were a $0.4 million gain and a $1.0 million loss, respectively.

Comprehensive Income

For the three and six months ended June 30, 2022 and 2021, the Company included its foreign currency translation gains and losses as part of its comprehensive income.

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Advertising Expense

Advertising expenses, primarily associated with Primatene Mist®, are recorded as they are incurred, except for expenses related to the development of a major commercial or media campaign, which are expensed in the period in which the commercial or campaign is first presented, and are reflected as a component of selling, distribution and marketing in the Company's condensed consolidated statement of operations. For the three and six months ended June 30, 2022, advertising expenses were $2.5 million and $4.9 million, respectively. For the three and six months ended June 30, 2021, advertising expenses were $1.9 million and $4.1 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 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 statement 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 June 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 June 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 June 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.

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Litigation, Commitments and Contingencies

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

Recent Accounting Pronouncements

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

Note 3. ANP Restructuring

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

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

Hanxin continues to be a related party after the 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.

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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 six months ended June 30, 2022, revenues from research and development services at ANP were $0.7 million and $1.3 million, respectively. For the three and six months ended June 30, 2021, revenues from research and development services at ANP were $1.0 million and $1.3 million, respectively.

Provision for Chargebacks and Rebates

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

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

	Six Months Ended June 30,	
	2022	2021
	(in thousands)	
Beginning balance	$ 20,167	$ 20,380
Provision for chargebacks and rebates	96,593	97,973
Credits and payments issued to third parties	(94,526)	(99,400)
Ending balance	$ 22,234	$ 18,953

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.

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Of the provision for chargebacks and rebates as of June 30, 2022 and December 31, 2021, $17.4 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 June 30, 2022 and December 31, 2021 of $4.8 million and $4.6 million, respectively, were included in accounts payable and accrued liabilities.

Accrual for Product Returns

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

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

	Six Months Ended June 30,	
	2022	2021
	(in thousands)	
Beginning balance	$ 21,677	$ 14,204
Provision for product returns	2,929	7,770
Credits issued to third parties	(3,341)	(4,433)
Ending balance	$ 21,265	$ 17,541

Of the provision for product returns as of June 30, 2022 and December 31, 2021, $15.6 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 June 30, 2022 and December 31, 2021 of $5.7 million, were included in other long-term liabilities. For the six months ended June 30, 2022 and 2021, the Company's aggregate product return rate was 1.6% of qualified sales.

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

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

For the three and six months ended June 30, 2022, options to purchase 12,296 and 706,411 shares of stock, respectively, with a weighted-average exercise price of $37.41 per share and $34.79 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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For the three and six months ended June 30, 2021, options to purchase 2,056,803 shares of stock, with a weighted-average exercise price of $20.75 per share and the reallocation of net income attributable to non-controlling interest were excluded in the computation of diluted net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders because the effect would be anti-dilutive.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(in thousands, except per share data)			
Basic and dilutive numerator:				
Net income attributable to Amphastar Pharmaceuticals, Inc.	$ 17,346	$ 7,767	$ 41,599	$ 12,808
Denominator:				
Weighted-average shares outstanding — basic	48,864	47,731	48,501	47,626
Net effect of dilutive securities:				
Incremental shares from equity awards	4,363	1,821	4,102	1,909
Weighted-average shares outstanding — diluted	53,227	49,552	52,603	49,535
Net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders — basic	$ 0.35	$ 0.16	$ 0.86	$ 0.27
Net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders — diluted	$ 0.33	$ 0.16	$ 0.79	$ 0.26

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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(in thousands)			
Net revenues:				
Finished pharmaceutical products	$ 120,123	$ 94,722	$ 236,669	$ 192,604
API	3,344	6,941	7,166	12,079
Total net revenues	123,467	101,663	243,835	204,683
Gross profit (loss):				
Finished pharmaceutical products	67,084	49,614	124,023	94,900
API	(3,728)	(2,238)	(4,841)	(2,578)
Total gross profit	63,356	47,376	119,182	92,322
Operating expenses	38,533	36,816	72,745	71,456
Income from operations	24,823	10,560	46,437	20,866
Non-operating income (expenses)	(1,672)	3,657	5,747	(1,535)
Income before income taxes	$ 23,151	$ 14,217	$ 52,184	$ 19,331

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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(in thousands)			
Finished pharmaceutical products net revenues:				
Primatene Mist®	$ 18,974	$ 16,680	$ 43,671	$ 35,063
Epinephrine	18,119	9,192	33,275	24,770
Lidocaine	16,042	11,594	26,632	20,665
Phytonadione	13,381	10,421	23,856	19,986
Glucagon	11,795	12,131	22,779	20,115
Enoxaparin	9,031	9,328	19,155	19,986
Naloxone	7,193	6,625	14,606	12,966
Other finished pharmaceutical products	25,588	18,751	52,695	39,053
Total finished pharmaceutical products net revenues	$ 120,123	$ 94,722	$ 236,669	$ 192,604

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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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(in thousands)			
Depreciation and amortization expense				
Finished pharmaceutical products	$ 2,059	$ 1,460	$ 3,853	$ 2,895
API	937	1,179	1,885	2,227
Total depreciation and amortization expense	$ 2,996	$ 2,639	$ 5,738	$ 5,122

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

	Net Revenue				Long-Lived Assets	
	Three Months Ended June 30,		Six Months Ended June 30,		June 30,	December 31,
	2022	2021	2022	2021	2022	2021
	(in thousands)					
United States	$ 120,786	$ 95,193	$ 237,900	$ 194,363	$ 135,585	$ 134,731
China	766	1,126	1,699	2,247	89,627	91,876
France	1,915	5,344	4,236	8,073	39,515	44,884
Total	$ 123,467	$ 101,663	$ 243,835	$ 204,683	$ 264,727	$ 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 six months ended June 30, 2022 and 2021, and accounts receivable as of June 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 June 30,		Six Months Ended June 30,	
	June 30, 2022	December 31, 2021	2022	2021	2022	2021
AmerisourceBergen	17 %	13 %	24 %	23 %	23 %	24 %
McKesson	23 %	30 %	22 %	18 %	20 %	19 %
Cardinal Health	19 %	20 %	17 %	15 %	16 %	15 %

Supplier Concentrations

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

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Company is unable to secure, on a timely basis, sufficient quantities of the materials it depends on to manufacture and market its products, it could have a materially adverse effect on the Company's business, financial condition, and results of operations.

Note 8. Fair Value Measurements

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

- *Level 1* – Inputs to measure fair value are based on quoted prices (unadjusted) in active markets on identical assets or liabilities;

- *Level 2* – Inputs to measure fair value are based on the following: a) quoted prices in active markets on similar assets or liabilities, b) quoted prices for identical or similar instruments in inactive markets, or c) observable (other than quoted prices) or collaborated observable market data used in a pricing model from which the fair value is derived; and

- *Level 3* – Inputs to measure fair value are unobservable and the assets or liabilities have little, if any, market activity; these inputs reflect the Company's own assumptions about the assumptions that market participants would use in pricing the assets or liabilities based on best information available in the circumstances.

As of June 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 municipal bonds with original maturity dates between three and fifteen months. The certificates of deposit are carried at amortized cost in the Company's condensed consolidated balance sheet, which approximates their fair value determined based on Level 2 inputs. The corporate and municipal bonds are classified as held-to-maturity and are carried at amortized cost net of allowance for credit losses, which approximates their fair value determined based on Level 2 inputs. The restrictions on restricted cash and investments have a negligible effect on the fair value of these financial assets.

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

	Total	(Level 1)	(Level 2)	(Level 3)
		(in thousands)		
Cash equivalents	$ 122,382	$ 122,382	$ —	$ —
Restricted cash	235	235	—	—
Short-term investments	4,600	—	4,600	—
Restricted short-term investments	2,200	—	2,200	—
Corporate and municipal bonds	12,985	—	12,985	—
Interest rate swap related to variable rate loans	4,497	—	4,497	—
Fair value measurement as of June 30, 2022	$ 146,899	$ 122,617	$ 24,282	$ —
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	$ —

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 June 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)	$ 7,731	$ —	$ (38)	$ 7,693
Municipal bonds (due within 1 year)	5,302	—	(10)	5,292
Total investments as of June 30, 2022	$ 13,033	$ —	$ (48)	$ 12,985
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

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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 six months ended June 30, 2022 was $0.3 million and $1.0 million, respectively, which was recorded in the "Equity in losses of unconsolidated affiliate" line on the condensed consolidated statement 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 loans outstanding with those shareholders to equity. The conversion rate has not been set and none of the loans have been converted to equity as of June 30, 2022. Conversion of such loans would result in dilution of the Company's direct ownership interest in Hanxin.

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	$ 8,492	$ 5,025	$ 3,467
Patents	12	486	356	130
Land-use rights	39	2,540	716	1,824
Subtotal	12	11,518	6,097	5,421
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill - Finished pharmaceutical products	*	3,054	—	3,054
Subtotal	*	32,279	—	32,279
As of June 30, 2022	*	$ 43,797	$ 6,097	$ 37,700

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	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:

	June 30, 2022	December 31, 2021
	(in thousands)	
Beginning balance	$ 3,313	$ 3,940
ANP restructuring	—	(374)
Currency translation	(259)	(253)
Ending balance	$ 3,054	$ 3,313

Primatene® Trademark

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

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Note 11. Inventories

Inventories consist of the following:

	June 30, 2022	December 31, 2021
	(in thousands)	
Raw materials and supplies	$ 43,900	$ 41,853
Work in process	40,087	33,298
Finished goods	14,746	17,656
Total inventories	$ 98,733	$ 92,807

Charges of $0.6 million and $8.6 million were included in the cost of revenues in the Company's condensed consolidated statements of operations for the three and six months ended June 30, 2022, respectively, to adjust the Company's inventory and related firm purchase commitments to their net realizable value. For the three and six months ended June 30, 2021, charges of $1.4 million and $10.9 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.

The Company did not have any material losses on firm purchase commitments related to raw materials on order for the three months ended June 30, 2022. For the six months ended June 30, 2022, the losses on firm purchase commitments related to raw materials on order was $6.4 million. Losses on firm purchase commitments related to raw materials on order were $1.1 million and $9.3 million for the three and six months ended June 30, 2021, respectively.

Note 12. Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

	June 30, 2022	December 31, 2021
	(in thousands)	
Buildings	$ 130,381	$ 130,582
Leasehold improvements	31,548	29,221
Land	7,423	7,615
Machinery and equipment	205,274	207,883
Furniture, fixtures, and automobiles	28,012	27,376
Construction in progress	42,959	41,186
Total property, plant, and equipment	445,597	443,863
Less accumulated depreciation	(208,033)	(199,619)
Total property, plant, and equipment, net	$ 237,564	$ 244,244

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Note 13. Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consisted of the following:

	June 30, 2022	December 31, 2021
	(in thousands)	
Accrued customer fees and rebates	$ 12,473	$ 12,121
Accrued payroll and related benefits	24,640	23,256
Accrued product returns, current portion	15,578	16,028
Accrued loss on firm purchase commitments	6,311	7,133
Other accrued liabilities	7,592	8,793
Total accrued liabilities	66,594	67,331
Accounts payable	31,071	22,214
Total accounts payable and accrued liabilities	$ 97,665	$ 89,545

Note 14. Debt

Debt consists of the following:

	June 30, 2022	December 31, 2021
	(in thousands)	
Term Loan		
Term loan with Capital One N.A. due August 2026	$ 68,688	$ 69,563
Mortgage Loans		
Mortgage payable with East West Bank due June 2027	8,273	8,353
Other Loans and Payment Obligations		
French government loans due December 2026	254	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	215	398
Total debt	77,430	78,583
Less current portion of long-term debt	2,057	2,202
Less: Loan issuance costs	1,502	1,605
Long-term debt, net of current portion and unamortized debt issuance costs	$ 73,871	$ 74,776

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As of June 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 $0.9 million and $3.9 million for the three and six months ended June 30, 2022, respectively.

Covenants

At June 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(in thousands)			
Income before taxes	$ 23,151	$ 14,217	$ 52,184	$ 19,331
Income tax provision	5,551	5,595	9,628	6,750
Income before equity in losses of unconsolidated affiliate	$ 17,600	$ 8,622	$ 42,556	$ 12,581
Income tax provision as a percentage of income before income taxes	24.0 %	39.4 %	18.5 %	34.9 %

The change in the Company's effective tax rate for the three and six months ended June 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 income in prior carryback periods, future reversal of existing deferred taxable temporary differences, tax-planning strategies, and projected future taxable income.

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

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

Note 16. Stockholders' Equity

Share Buyback Program

Pursuant to the Company's existing share buyback program, the Company purchased 189,840 and 241,008 shares of its common stock during the three and six months ended June 30, 2022, for total consideration of $6.1 million and $7.3 million, respectively. The Company purchased 298,727 and 503,425 shares of its common stock during the three and six months ended June 30, 2021, for total consideration of $5.5 million and $9.3 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, which is expected to continue for an indefinite period of time. Since the inception of the program, the Company's Board of Directors have authorized an aggregate of $185.0 million to the Company's share buyback program. The primary goal of the program is to offset dilution created by the Company's equity compensation programs.

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

Amended and Restated 2015 Equity Incentive Plan

As of June 30, 2022, the Company reserved an aggregate of 6,491,959 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 June 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 six months ended June 30, 2022, the Company recorded ESPP expense of $0.2 million and $0.4 million, respectively. For the three and six months ended June 30, 2021, the Company recorded ESPP expense of $0.2 million and $0.3 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 six months ended June 30, 2022 and 2021, are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Average volatility	40.5 %	41.6 %	41.0 %	42.1 %
Average risk-free interest rate	3.0 %	1.0 %	2.3 %	1.2 %
Weighted-average expected life in years	4.8	5.1	6.1	6.1
Dividend yield rate	— %	— %	— %	— %

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A summary of option activity for the six months ended June 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	790,874	34.36		
Options exercised	(1,087,158)	14.62		
Options cancelled	(86,133)	19.30		
Options expired	(5,614)	13.79		
Outstanding as of June 30, 2022	8,067,690	$ 17.61	5.40	$ 138,665
Exercisable as of June 30, 2022	5,664,200	$ 15.64	4.09	$ 108,470
Vested and expected to vest as of June 30, 2022	7,826,182	$ 17.42	5.29	$ 135,970

(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 June 30, 2022.

For the three and six months ended June 30, 2022, the Company recorded an expense of $2.0 million and $4.5 million, respectively, related to stock options granted under all plans. For the three and six months ended June 30, 2021, the Company recorded an expense of $1.9 million and $4.3 million, respectively, related to stock options granted under all plans.

Information relating to option grants and exercises is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(in thousands, except per share data)			
Weighted-average grant date fair value per option share	$ 12.13	$ 7.30	$ 14.75	$ 7.60
Intrinsic value of options exercised	6,510	2,087	18,710	3,116
Cash received from options exercised	4,469	6,000	16,919	8,169
Total fair value of the options vested during the period	1,004	1,278	7,990	8,050

A summary of the status of the Company's non-vested options as of June 30, 2022, and changes during the six months ended June 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	790,874	14.75
Options vested	(1,150,185)	6.95
Options forfeited	(86,133)	8.30
Non-vested as of June 30, 2022	2,403,490	9.47

As of June 30, 2022, there was $17.8 million of total unrecognized compensation cost, net of forfeitures, related to non-vested stock option based compensation arrangements granted under all plans. The cost is expected to be recognized over a weighted-average period of 2.9 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 six months ended June 30, 2022, the Company recorded total expenses of $2.0 million and $4.4 million, respectively, related to RSU awards granted under all plans. During the three and six months ended June 30, 2021, the Company recorded expenses of $2.1 million and $4.3 million, respectively, related to RSU awards granted under all plans.

As of June 30, 2022, there was $18.8 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 2.9 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	338,680	$ 11,653
RSUs forfeited	(36,927)	
RSUs vested[2]	(469,033)	
RSUs outstanding at June 30, 2022	1,017,562	

(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, 178,578 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.

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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 for the three and six months ended June 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(in thousands)			
Cost of revenues	$ 938	$ 932	$ 2,323	$ 2,078
Operating expenses:				
Selling, distribution, and marketing	194	147	362	274
General and administrative	2,718	4,568	5,579	7,536
Research and development	385	437	993	1,030
Total share-based compensation	$ 4,235	$ 6,084	$ 9,257	$ 10,918

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 six months ended June 30, 2022 were approximately $0.5 million and $1.1 million, respectively, compared to the prior year expense of $0.6 million and $1.1 million for the three and six months ended June 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 1.0% as of June 30, 2022 and December 31, 2021. The liability is included in other long-term liabilities in the accompanying condensed consolidated balance sheets. The plan is currently unfunded, and the benefit obligation under the plan was $2.6 million at June 30, 2022 and December 31, 2021. The Company recorded an immaterial amount of expense under the plan for the three and six months ended June 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

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in a lump-sum distribution or in installments, as elected by the participant in accordance with the plan. Participants can allocate their deferred compensation amongst various investment options with earnings accruing to the participant. The Company has established a Rabbi Trust to fund the plan obligations and to hold the plan assets. Eligible participants began contributing to the plan in January 2020. The plan assets were valued at approximately $3.4 million as of June 30, 2022 and December 31, 2021, respectively. The plan liabilities were valued at approximately $3.5 million as of June 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 June 30, 2022, the Company has entered into commitments to purchase equipment and raw materials for an aggregate amount of approximately $65.9 million. The Company anticipates that most of these commitments with a remaining term in excess of one year will be fulfilled by 2023.

Note 19. 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.

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

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matters is not expected to have a material adverse effect on its financial position, results of operations, or cash flows; however, the results of litigation and claims are inherently unpredictable and the Company's view of these matters may change in the future. Regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources, and other factors.

Note 21. Subsequent Event

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.

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 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. In July 2022, the FDA granted approval of our vasopressin injection, USP 20 Units/mL, 1 mL single dose vial, which we plan to launch in August 2022.

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

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

COVID-19 Pandemic

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

Some of our ongoing clinical trials experienced short-term interruptions in the recruitment of patients due to the COVID-19 pandemic, as hospitals 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 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 has 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, 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 more than 9.1% as of June 2022. The existence of inflation in the U.S. 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 June 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 June 30, 2022 Compared to Three Months Ended June 30, 2021

Net revenues

	Three Months Ended June 30,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Net revenues				
Finished pharmaceutical products	$ 120,123	$ 94,722	$ 25,401	27 %
API	3,344	6,941	(3,597)	(52)%
Total net revenues	$ 123,467	$ 101,663	$ 21,804	21 %
Cost of revenues				
Finished pharmaceutical products	$ 53,039	$ 45,108	$ 7,931	18 %
API	7,072	9,179	(2,107)	(23)%
Total cost of revenues	$ 60,111	$ 54,287	$ 5,824	11 %
Gross profit	$ 63,356	$ 47,376	$ 15,980	34 %
as % of net revenues	*51 %*	*47 %*		

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

	Three Months Ended June 30,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Finished pharmaceutical products net revenues				
Primatene Mist®	$ 18,974	$ 16,680	$ 2,294	14 %
Epinephrine	18,119	9,192	8,927	97 %
Lidocaine	16,042	11,594	4,448	38 %
Phytonadione	13,381	10,421	2,960	28 %
Glucagon	11,795	12,131	(336)	(3)%
Enoxaparin	9,031	9,328	(297)	(3)%
Naloxone	7,193	6,625	568	9 %
Other finished pharmaceutical products	25,588	18,751	6,837	36 %
Total finished pharmaceutical products net revenues	$ 120,123	$ 94,722	$ 25,401	27 %

Primatene Mist® sales continued to grow in the second quarter of 2022, as a result of increased unit volumes, which was primarily a result of the continued success of our advertising campaign. The increase in sales of epinephrine and lidocaine was primarily due to an increase in unit volumes, resulting from high demand as a result of competitor shortages. Lidocaine also increased in volumes due to our ability to fill orders that had been backordered at the end of the first quarter due to supplier constraints. The increase in sales of phytonadione was a combination of both a higher average selling price and an increase in unit volumes. The increase in other finished pharmaceutical products was primarily due to higher unit volumes of dextrose and sodium bicarbonate, which were in high demand resulting from competitor shortages, as well as the launch of our ganirelix prefilled syringe in late June 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 in 2022. We anticipate that sales of API will continue to fluctuate and may decrease due to the inherent uncertainties related to sales to MannKind pursuant to our supply agreement with them. In addition, most of our API sales are denominated in euros, and the fluctuation in the value of euros versus the U.S. dollar has had, and will continue to have, an impact on API sales revenues in the near term.

A significant portion of our customer shipments in any period relate to orders received and shipped in the same period, generally resulting in low product backlog relative to total shipments at any time. However, during the second quarter of 2022, we experienced a backlog of approximately $5.6 million for various products, partially as a result of competitor 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 Primatene Mist®, as well as the launch of our ganirelix product during the second quarter of 2022, both of which are higher-margin products, helped increase our gross margins for the three months ended June 30, 2022. Also contributing to the increased margin was a decrease of heparin and enoxaparin component purchase commitments, since these components are reserved to the lower cost or net realizable value at the time of commitment.

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

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

Selling, distribution and marketing, and general and administrative

	Three Months Ended June 30,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	$ 5,756	$ 4,129	$ 1,627	39 %
General and administrative	$ 9,979	$ 14,565	$ (4,586)	(31)%

The increase in selling, distribution and marketing expenses was primarily due to increased advertising and 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

	Three Months Ended June 30,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Salaries and personnel-related expenses	$ 6,066	$ 7,625	$ (1,559)	(20)%
Clinical trials	1,074	1,603	(529)	(33)%
FDA fees	28	40	(12)	(30)%
Materials and supplies	11,129	3,458	7,671	222 %
Depreciation	2,548	2,955	(407)	(14)%
Other expenses	1,953	2,441	(488)	(20)%
Total research and development expenses	$ 22,798	$ 18,122	$ 4,676	26 %

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. This was partially offset by a decrease in clinical trial expense as a result of a shift in timing on some of our clinical trial studies, as well as 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 June 30,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Other income (expense), net	$ (1,504)	$ 3,601	$ (5,105)	NM

Other income (expenses), net is primarily a result of foreign currency fluctuation during the three months ended June 30, 2022. In June 2021, we reached a final settlement with Aventis, which resulted in the reduction of the accrued expense by $2.7 million.

Income tax provision

	Three Months Ended June 30,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Income tax provision	$ 5,551	$ 5,595	$ (44)	(1)%
Effective tax rate	*24 %*	*39 %*		

Our effective tax rate for the three months ended June 30, 2022 decreased in comparison to the three months ended June

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.

Six Months Ended June 30, 2022 Compared to Six Months Ended June 30, 2021

Net revenues

	Six Months Ended June 30,		Change	
	2022	2021	Dollars	%
		(in thousands)		
Net revenues				
Finished pharmaceutical products	$ 236,669	$ 192,604	$ 44,065	23 %
API	7,166	12,079	(4,913)	(41)%
Total net revenues	$ 243,835	$ 204,683	$ 39,152	19 %
Cost of revenues				
Finished pharmaceutical products	$ 112,646	$ 97,704	$ 14,942	15 %
API	12,007	14,657	(2,650)	(18)%
Total cost of revenues	$ 124,653	$ 112,361	$ 12,292	11 %
Gross profit	$ 119,182	$ 92,322	$ 26,860	29 %
as % of net revenues	*49 %*	*45 %*		

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

	Six Months Ended June 30,		Change	
	2022	2021	Dollars	%
		(in thousands)		
Finished pharmaceutical products net revenues				
Primatene Mist®	$ 43,671	$ 35,063	$ 8,608	25 %
Epinephrine	33,275	24,770	8,505	34 %
Lidocaine	26,632	20,665	5,967	29 %
Phytonadione	23,856	19,986	3,870	19 %
Glucagon	22,779	20,115	2,664	13 %
Enoxaparin	19,155	19,986	(831)	(4)%
Naloxone	14,606	12,966	1,640	13 %
Other finished pharmaceutical products	52,695	39,053	13,642	35 %
Total finished pharmaceutical products net revenues	$ 236,669	$ 192,604	$ 44,065	23 %

Primatene Mist® sales continued to grow in the first half of 2022, as a result of increased unit volumes, which was primarily a result of the continued success of our advertising campaign. The increase in sales of epinephrine and lidocaine was primarily due to an increase in unit volumes, as a result of high demand as a result of competitor shortages. The increase in sales of phytonadione was primarily due to a higher average selling price. 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. 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 resulting from competitor shortages, as well as the launch of our ganirelix prefilled syringe in late June 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, 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 in 2022. We anticipate that sales of API will continue to fluctuate and may decrease due to the inherent uncertainties related to sales to MannKind pursuant to our supply agreement with them. In addition, most of our API sales are denominated in euros, and the fluctuation in the value of euros versus the U.S. dollar has had, and will continue to have, an impact on API sales revenues in the near term.

A significant portion of our customer shipments in any period relate to orders received and shipped in the same period, generally resulting in low product backlog relative to total shipments at any time. However, during the second quarter of 2022, we experienced a backlog of approximately $5.6 million for various products, partially brought on by competitor 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® and glucagon, which are higher-margin products, helped increase our gross margins for the six months ended June 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, and a lower average selling price for enoxaparin.

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

Selling, distribution and marketing, and general and administrative

	Six Months Ended June 30,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	$ 11,275	$ 8,666	$ 2,609	30 %
General and administrative	$ 22,449	$ 29,903	$ (7,454)	(25)%

The increase in selling, distribution and marketing expenses was primarily due to increased advertising and 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

	Six Months Ended June 30,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Salaries and personnel-related expenses	$ 12,550	$ 14,604	$ (2,054)	(14)%
Clinical trials	1,179	2,341	(1,162)	(50)%
FDA fees	57	80	(23)	(29)%
Materials and supplies	16,530	5,611	10,919	195 %
Depreciation	5,174	5,893	(719)	(12)%
Other expenses	3,531	4,358	(827)	(19)%
Total research and development expenses	$ 39,021	$ 32,887	$ 6,134	19 %

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. This was partially offset by a decrease in clinical trial expense as a result of a shift in timing on some of our clinical trial studies, as well as 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

	Six Months Ended June 30,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Other income (expense), net	$ 6,089	$ (1,648)	$ 7,737	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.

Income tax provision

	Six Months Ended June 30,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Income tax provision	$ 9,628	$ 6,750	$ 2,878	43 %
Effective tax rate	*18 %*	*35 %*		

Our effective tax rate for the six months ended June 30, 2022 decreased in comparison to the six months ended June 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 in 2022. We plan to fund this facility expansion with cash flows from operations. Our cash obligations include the principal and interest payments due on our existing loans and lease payments, as described below and throughout this Quarterly Report.

As of June 30, 2022, our foreign subsidiaries collectively held $13.2 million in cash and cash equivalents. Cash or cash equivalents held at foreign subsidiaries are not available to fund the parent company's operations in the United States. We believe that our cash reserves, operating cash flows, and borrowing availability under our credit facilities will be sufficient to fund our operations for at least the next 12 months from the date of filing of this Quarterly Report on Form 10-Q. We expect additional cash flows to be generated in the longer term from future product introductions, although there can be no assurance as to the receipt of regulatory approval for any product candidates that we are developing or the timing of any product introductions, which could be lengthy or ultimately unsuccessful.

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

Working capital increased by $59.2 million to $273.5 million at June 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 six months ended June 30, 2022 and 2021:

	Six Months Ended June 30,	
	2022	2021
	(in thousands)	
Statement of Cash Flow Data:		
Net cash provided by (used in)		
Operating activities	$ 53,580	$ 54,984
Investing activities	(17,290)	(12,949)
Financing activities	3,654	(11,830)
Effect of exchange rate changes on cash	(140)	(121)
Net increase in cash, cash equivalents, and restricted cash	$ 39,804	$ 30,084

Sources and Use of Cash

Operating Activities

Net cash provided by operating activities was $53.6 million for the six months ended June 30, 2022, which included net income of $41.6 million. Non-cash items comprised primarily of $13.8 million of depreciation and amortization and $9.3 million of share-based compensation expense.

Additionally, for the six months ended June 30, 2022, there was a net cash outflow from changes in operating assets and liabilities of $8.1 million, which resulted from an increase in accounts receivables 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.

Net cash provided by operating activities was $55.0 million for the six months ended June 30, 2021, which included net income of $12.6 million. Non-cash items comprised primarily of $13.7 million of depreciation and amortization, and $10.9 million of share-based compensation expense. Additionally, for the six months ended June 30, 2021, there was a net cash inflow from changes in operating assets and liabilities of $17.8 million, which resulted from an increase in accounts payable and accrued liabilities, which was partially offset by an increase in accounts receivable. Accounts payable and accrued liabilities increased primarily due to the timing of payments. The increase in accounts receivable was due to both increases in sales and the timing of sales.

Investing Activities

Net cash used in investing activities was $17.3 million for the six months ended June 30, 2022, primarily as a result of $12.1 million in purchases of property, plant, and equipment, which included $8.4 million incurred in the United States, $0.6 million in France, and $3.1 million in China. Additionally, cash outflow from short-term investing activities during the period was $5.6 million.

Net cash used in investing activities was $12.9 million for the six months ended June 30, 2021, primarily as a result of $13.4 million in purchases of property, plant, and equipment, which included $6.9 million incurred in the United States, $0.3 million in France, and $6.2 million in China.

Financing Activities

Net cash provided by financing activities was $3.7 million for the six months ended June 30, 2022, primarily as a result of $12.2 million in net proceeds from the settlement of share-based compensation awards under our equity plan, which was partially offset by the use of $7.3 million to purchase treasury stock. Additionally, we also made $1.1 million in principal payments on our long-term debt.

Net cash used in financing activities was $11.8 million for the six months ended June 30, 2021, primarily as a result of $9.3 million used to purchase treasury stock and $0.8 million relating to the cash settlement of certain awards under the 2018 ANP equity plan in connection with the ANP restructuring. This was partially offset by $6.4 million in net proceeds from the settlement of share-based compensation awards under our equity plans. Additionally, we also made $8.0 million in principal payments on our long-term debt and line of credit.

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.

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 June 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 or other epidemics.

The ongoing COVID-19 pandemic, including the emergence of recent 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 impose additional burdens on our business to comply with regulations imposed by the State of California and other governmental bodies to reduce the spread of the virus. The COVID-19 pandemic may also disrupt the operations of our customers, suppliers and partners for an indefinite period of time, including as a result of travel restrictions and/or business shutdowns, all of which could negatively impact our business and results of operations, including cash flows. Disruptions to our manufacturing partners and suppliers could result in disruption to the production of our products and failure to satisfy demand. More generally, the ongoing COVID-19 pandemic could continue to adversely affect economies and financial markets globally and nationally, potentially leading to an economic downturn, which could decrease spending and adversely affect demand for our products and harm our business and results of operations. Even after the COVID-19 pandemic has subsided, we may continue to experience an adverse impact to our business as a result of its global economic impact, including any recession that has occurred or may occur in the future. Specifically, difficult macroeconomic conditions, increased and prolonged unemployment or a decline in business confidence as a result of the COVID-19 pandemic, could have a continuing adverse effect on the demand for some of our products. The degree of impact of the COVID-19 pandemic on our business will depend on several factors, such as the duration and the extent of the pandemic, as well as actions taken by governments, businesses, and consumers in response to the pandemic, all of which continue to evolve and remain uncertain at this time.

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

Some of our ongoing clinical trials have experienced short term interruptions in the recruitment of patients due to the COVID-19 pandemic, as hospitals 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 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 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.

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

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

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

- disruptions in the construction of the manufacturing facility;
- interruptions to our operations in China or the inability of our manufacturing facility to produce adequate quantities of raw materials or APIs to meet our needs as a result of natural catastrophic events or other causes beyond our control such as power disruptions or widespread disease outbreaks, including the recent outbreaks that impact animal-derived products, such as the importation of pig-derived crude heparin from countries impacted by the African swine flu, and the ongoing COVID-19 pandemic, which has resulted in and may in the future result in, business closures, transportation restrictions, import and export complications, and otherwise cause shortages in the supply of raw materials or cause disruptions in our manufacturing capability;
- product supply disruptions and increased costs as a result of heightened exposure to changes in the policies of the Chinese government, political unrest or unstable economic conditions in China;
- the imposition of tariffs or other trade barriers as a result of changes in social, political, and economic conditions or in laws, regulations, and policies governing foreign trade, including U.S. and foreign export controls, 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 such as coronavirus, or outbreaks in livestock or animals that impact or restrict importation, use, or distribution of animal-derived products.

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

We are actively monitoring and assessing the ongoing impact of the COVID-19 pandemic. This includes evaluating the impact on our employees, suppliers, and logistics providers as well as evaluating governmental actions being taken to curtail the spread of the virus. 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 technological goods as a whole, including potentially tighter controls on exports and reexports of dual-use items, 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 API 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 epinephrine prefilled syringe is marketed without FDA approval and may be subject to enforcement actions by the FDA.

Our epinephrine prefilled syringe prescription product is marketed without FDA approval. This product, like many other prescription drugs on the market that have not been formally evaluated as being effective by the FDA, contains active ingredients that were first marketed prior to the enactment of the Federal Food, Drug, and Cosmetic Act, or FFDCA. The FDA has assessed this product in a program known as the “Prescription Drug Wrap-Up” and has stated that this drug cannot be lawfully marketed unless they comply with certain “grandfather” exceptions to the definition of “new drug” in the FFDCA. These exceptions have been strictly construed by FDA and by the courts, and the FDA has stated that it is unlikely that any of the unapproved prescription drugs on the market, including of our drug, qualify for the exceptions. At any time, the FDA may require that our unapproved prescription drug be submitted for approval and may direct us to recall this product and/or cease marketing the product until they are approved. The FDA may also take enforcement actions based on our marketing of this unapproved product, including but not limited to the issuance of an untitled letter or a warning letter, judicial action seeking an injunction, product seizure and/or civil or criminal penalties. The enforcement posture could change at any time and our ability to market such drugs could terminate with little or no notice. Moreover, if our competitors seek and obtain approval and market FDA-approved prescription products that compete against our unapproved prescription product, we would be subject to a higher likelihood that the FDA may seek to take action against our unapproved product. Such competitors have brought and may bring claims against us alleging unfair competition or related claims.

As a result of our meetings with the FDA in 2009, we decided to discontinue all of our products that were subject to the Prescription Drug Wrap-Up program, with the exception of epinephrine in vial form. These products were all produced at our subsidiary, IMS. During the third quarter of 2010, the FDA requested that we reintroduce several of the withdrawn products to help address a national drug shortage, while we prepared and filed applications for approval of the products. Between August and October 2010, we reintroduced our epinephrine prefilled syringes.

In February 2017, the FDA requested that we discontinue the manufacturing and distribution of our epinephrine injection, USP vial product, which had been marketed under the "grandfather" exception to the "FDA's Prescription Drug Wrap-Up program". We discontinued selling this product in the second quarter of 2017. In April 2020, the FDA granted approval of our epinephrine injection, USP 30mg/mL multiple dose vial, and we launched the product in May 2020.

The FDA granted approval of our products that were previously marketed under the "grandfather" exception, such as atropine sulfate injection 0.1mg/mL in the 10mL Luer-Jet® prefilled syringe in October 2020, dextrose injection 50% in the 50mL Luer-Jet® prefilled syringe in March 2021 and our morphine sulfate injection USP, 1mg/mL 30mL in April 2021.

Our only unapproved product currently on the market is the epinephrine prefilled syringe. For the years ended December 31, 2021, 2020, and 2019, we recorded net revenues of $27.8 million, $13.2 million, and $13.9 million, respectively, for epinephrine prefilled syringes and for the six months ended June 30, 2022 and 2021, we recorded net revenues of $14.7 million and $12.3 million, respectively, for this product. We submitted an NDA for our epinephrine prefilled syringe in order to mitigate all risk associated with the marketing of unapproved drug products. Prior to the approval of our NDA submission, we continue to operate in compliance with the FDA Compliance Policy Guide, CPG Sec. 440.100 Marketed New Drugs Without Approved NDAs and ANDAs. In 2020, the HHS announced that termination of the FDA Unapproved Drugs Initiative (UDI), citing that the Compliance Policy Guide (CPG) issued with the UDI was "linked to prescription drug price increases and shortages" and announced its withdrawal. However, under the Biden administration, in May 2021, HHS and FDA, each under new leadership, jointly issued a withdrawal-of-the-termination notice, withdrawing the prior HHS notice of termination issued under the Trump administration, citing multiple legal and factual inaccuracies. New guidance from the agency is anticipated in the future. The long-term impact of this policy and other measures promulgated by the Biden administration on our business remains unclear.

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

We, our collaborators, third-party providers, distributors, customers and other contractors utilize information technology systems and networks to transmit, store and otherwise process electronic data in connection with our business activities, including our supply chain processes, operations and communications. This includes our clinical data and business proprietary information, Electronic Data Interchange, or EDI, on purchase orders, invoices, chargebacks, etc. We, and others on our behalf, also collect, transmit, store and otherwise process certain data relating to individuals, including about our personnel, business partners, and others, which may be subject to applicable data protection, security and privacy laws and regulations that require adoption of minimum information security standards. The cost of compliance with applicable data protection, security and privacy laws and regulations have increased and may increase in the future.

Despite our implementation of security measures to protect the confidentiality, integrity, and availability of the systems, networks and data within our control from various threats (e.g., cyber-attacks, system breaches, malware, viruses, hacking, fraudulent use, social engineering attacks, phishing attacks, ransomware attacks, credential-stuffing attacks, denial-of-service attacks, unauthorized access, insider threats, accidental disclosures, intellectual property theft and economic espionage, exploitable vulnerabilities, defects or bugs in our or our third-party providers' systems, natural disasters, war, terrorism, telecommunications and electrical outages, breakdowns, damage, interruptions), 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.

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

of damages for actual or asserted contract breaches. Any such security incident could have a material adverse effect on our business and prospects.

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

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

(c) Issuer Purchases of Equity Securities

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

Period	Total Number of Shares Purchased [1]	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
April 1 – April 30, 2022	—	$ —	—	—
May 1 – May 31, 2022	44,270	34.27	44,270	—
June 1 – June 30, 2022	145,570	31.58	145,570	—

[1] On May 9, 2022, we announced that our Board of Directors authorized an increase of $25.0 million to our share buyback program. The share buyback program does not have an expiration date. As of June 30, 2022, $26.2 million remained available for repurchase under such program.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

Exhibit No.	Description
10.1*	Contract Manufacturing Agreement by and between Amphastar Nanjing Pharmaceuticals, Inc. and Nanjing Hanxin Pharmaceutical Technology Co., Ltd, dated April 19, 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: August 9, 2022

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

Date: August 9, 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 MANUFACTURING AGREEMENT

委托生产协议

This Contract Manufacturing Agreement (this "**Agreement**") is entered into by and between the following parties on April 19, 2022 (the "**Effective Date**"):
本委托生产协议（"本协议"）由以下双方于 2022 年 4 月19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: ********** (the "**Customer**"); and

(1) 南京汉欣医药科技有限公司, 一家根据中国法律注册并存续的有限责任公司，社会统一信用代码为：**********（"委托方"）；及

(2) **Amphastar Nanjing Pharmaceuticals, Inc.**, a limited liability company duly incorporated and validly existing under the laws of PRC, with the unified social credit code: ********** (**"ANP"**).

(2) 美药星（南京）制药有限公司，一家根据中国法律注册并存续的有限责任公司，社会统一信用代码为：**********（"**ANP**"）。

ANP and the Customer are sometimes referred to herein collectively as the "**Parties**" and individually as a "**Party**".
本协议项下ANP和委托方合称为"双方"，单独称为"一方"。

Whereas, the Customer intends to engage ANP to manufacture certain active pharmaceutical ingredients and/or finished pharmaceutical product based on specifications and formula provided by the Customer, and ANP intends to accept such engagement.
鉴于，委托方有意委托ANP依照其质量标准及规程进行相关活性药物成分和/或成品药的生产，ANP有意接受该等委托。

Therefore, based on the principle of good faith, the Parties hereby agree as follows:
因此，双方基于诚实信用原则达成如下约定：

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, including but not limited to, a Quality Agreement, may be executed between the Parties. In the event of conflicting terms, the terms of this Agreement shall prevail.

1.2 双方可以签署为实现本协议所必需的附属协议，包括但不限于质量协议。如有冲突，则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 本协议中使用的术语含义解释如下：

(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、受一方控制或与一方受共同控制的任何个人或实体。在本协议中，"**控制**"指(i)在公司实体中，直接或间接持有该实体不少于百分之五十(50%)的有权选举董事的投票权的股权或股份；或(ii)在非公司实体中，拥有直接或间接参与该实体的管理、决定或指导该实体管理政策的方向的权力。

(b) "**Applicable Law**" means all ordinances, rules, regulations, laws, and requirements of any authority applicable to the Manufacture, supply and/or use of the Product, as amended from time-to-time, including cGMP.

(b) 适用的法律：指不断修订的适用于产品的制造、供应和/或使用的任何监管机构的所有法令、规则、法规、法律和要求，包括 cGMP。

(c) "**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:

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

(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,

(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

(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.

(c) 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、底层知识产权、技术、科学知识、专有技术流程、现有的和/或预期的产品和服务、软件、生物材料、示意图、研究和开发、生产、成本及利润信息、财务和财务预测、顾客、客户、被许可方、市场销售以及当前或未来的商业计划和模式有关的技术和商业信息，无论该等信息在披露时是否被指定为"保密信息"。"保密信息"不包括以下信息：

(i) 在接收方披露前，已是公开或公众普遍可用的，

(ii) 在披露方提供或代表披露方提供信息之前，接收方已拥有的信息，前提是接收方的信息来源对披露方没有保密义务，

(iii) 接收方在非保密的基础上已从披露方以外的信息提供方获得的信息，前提是信息提供方对披露方没有保密义务，或

(iv) 接收方的员工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，已独立开发获得的信息，且有接收方的书面记录证明。

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

(d) **合同年**：指协议期限内每一连续的十二（12）个月，第一个合同年从上市日期开始至一周年后结束。

(e) (e) "**Finished Product**" means for each Product, packaged with primary packaging and/or secondary packaging, in a commercially presented outer carton labelled for the purpose of sale or use in the Territory.

(e) "**成品**"：指就每项产品而言，用商业展示的贴有标签外纸箱进行初级包装和/或次级包装，以用于在区域内销售或使用。

(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损毁、火灾、洪水、破坏、海难、禁运、罢工、爆炸、罢工、流行病和相关限制、事故、暴乱，政府当局的行为（包括但不限于与原材料或产品分配有关的行为，以及政府药事文件）、天灾、战争行为以及材料、供应品、设备或运输的延误或损坏。

(g) "**NMPA**" means the National Medical Products Administration and any successor agency having substantially the same functions.

(g) **NMPA**：指国家药品监督管理局，或具备相同职能的任一下属机构。

(h) "**Launch Date**" means, with respect to each Product under this Agreement, the date of the first commercial sale of such Product by the Customer or its Affiliates or their respective designees in the Territory.

(h) **上市日期**：指就本协议项下的某一产品，委托方或其关联方或各自的指定人员在区域内首次商业化销售本协议中该产品的日期。

(i) "**Manufacture**" and "**Manufacturing**" means any steps, processes and activities necessary to produce the Product, including without limitation, the manufacturing, processing, bulk packaging and labeling, quality control testing, release and storage of the Product.

(i) **生产**：指产品生产所需的任何步骤、流程及操作，包括但不限于产品的制造、加工、批量包装和贴签、质量控制测试、放行和储存。

(j) "**Marketing Authorization**" means, with respect to each Product, the regulatory filing made by or on behalf of the Customer with, and approved by, the NMPA, that allows the Customer to market products comprised of or containing such Product in the Territory, including without limitation, any supplements or amendments thereto.

(j) **上市许可**：就某一产品而言，指由委托方或委托方代表向NMPA提交并经NMPA批准的监管文件，该文件允许委托方在区域内销售由该产品组成或含有该产品的药品，包括但不限于针对该等文件内容的任何补充和修改。

(k) "**PRC**" means the People's Republic of China, but solely for the purposes of this Agreement, excluding the Hong Kong Special Administrative Region, the Macau Special Administrative Region and the islands of Taiwan.

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

(l) "**Product**" means the active pharmaceutical ingredients or finished pharmaceutical product listed in Appendix A hereof.

(l) **产品**：指本协议附录A中列明的活性药物成分和成品药。

(m) "**Regulatory Dossiers**" means all registration, permits, licenses, authorizations, approvals, presentations, notifications or filings (together with all applications therefore), which are filed with or granted by the governing health authority of any country, and which are required to develop, make, use, or sell the Product.

(m) **监管档案**：指产品的研发、生产、销售及使用所需的，向任一国家的卫生政府部门提交的或由任一国家的卫生政府部门授权的所有注册、许可、执照、授权、批准、介绍、通知或备案文件（及其全部申请材料）。

(n) "**Specifications**" means the specifications set fort in Appendix B hereof, as such specifications may be adjusted from time to time by mutual written consent of the Parties.

(n) **质量标准**：指本协议附录B列明的质量标准，可经由双方共同书面同意不时调整。

(o) "**Term**" means the period during which this Agreement is in effect as set forth in Section 13.

(o) **协议期限**：指本协议第13条所约定的本协议的生效期限。

(p) "**Territory**" means the PRC. No other territory rights are granted or applicable to this Agreement. The Customer is specifically prohibited from making any use of the Product outside of the PRC.

(p) **区域**：指中国。其他地区规定的权利不适用于本协议。委托方禁止在中国境外使用产品。

(q) "**Contract Price**" means, with respect to each Product, the Selling Price for each Product as provided in Appendix A, as such selling price may be adjusted based on the terms and conditions of this Agreement.

(q) **合同价格**：指附录A列明的每项产品的销售价格，可根据本协议的条款和条件进行调整。

2. The Customer's Rights and Obligations

2. 委托方权利义务

2.1 At least thirty (30) days prior to the Launch Date, and the first day of each calendar quarter after such Launch Date, the Customer shall provide ANP with a good faith estimate of the Customer's projected quantity requirements of such Product for delivery during each of the following four (4) calendar quarters (each such estimate being a "**Forecast**"). The Forecast corresponding to the first two (2) calendar quarters shall be legally binding on the Customer and shall not be amended without prior written consent of ANP. ANP will prepare and deliver a manufacture plan ("**Manufacture Plan**") to the Customer within thirty (30) business days after receipt of the Forecast provided by the Customer. The Customer shall confirm or raise objections (if any) within ten (10) business days after receipt of the Manufacture Plan. If the Customer fails to confirm or raise an objection within the aforementioned period, it shall be deemed that the Customer agrees to the Manufacture Plan formulated by ANP, and the Manufacture Plan of the first two (2) calendar quarters of the Manufacture Plan confirmed or deemed to be agreed by the Customer shall bind the Customer to purchase at least the amount of Product specified in the Manufacture Plan from ANP.

2.1 于产品上市日期前至少三十（30）日，以及于上市日期后的每个日历季度的首日，委托方应向ANP提供关于委托方在随后四（4）个日历季度中每一（1）季度该等产品数量需求的

善意预估（该等预估称为“**预测**”）。前两（2）个日历季度对应预测对委托方具备法律约束力，未经ANP事先书面同意，不得变更。ANP在收悉委托方提供的预测后的 30 个工作日内制订生产计划（“**生产计划**”）并提供给委托方。委托方应当在收悉ANP生产计划后10日内进行确认，如存在异议的，应当于前述期限内提出。如委托方未能于前述期限内确认或提出异议的，视为委托方同意ANP制定的生产计划，委托方确认或视为同意的生产计划中前两（2）个日历季度的生产计划对委托方具备法律约束力，委托方有义务向ANP购买不低于前述生产计划约定数量的产品。

2.2 The Customer shall issue purchase orders to ANP in accordance with the Manufacture Plan set forth in section 2.1. The purchase order shall specify the quantity, standard, expected delivery date and other matters mutually agreed by the Parties. The Parties hereby agree that the Customer shall provide ANP with a delivery period of no less than ninety (90) days. ANP shall confirm within ten (10) business days after receipt of the purchase order, and in the event that the purchase order does not conforms to this Agreement, or quantity of the Product is less than or exceeds the committed quantity agreed in the Manufacture Plan, ANP shall be entitled to reject such order. In the event that the Customer does not issue purchase orders for all of the committed quantity in any quarter, ANP may bill the Customer at the end of the quarter for the balance of the binding quantity for such calendar quarter and the Customer shall remit payment to ANP upon receipt of the invoice.

2.2 委托方应根据本协议第2.1条约定的生产计划向ANP发出采购订单，采购订单中应明确委托生产药品的数量、规格、拟要求交付时间以及其他双方共同同意的事项。双方确认，委托方应为ANP提供至少九十（90）日的交货周期。ANP应当于收悉委托方采购订单10个工作日内进行确认，如委托方采购订单不符合本协议约定、低于或超出生产计划约定的数量，ANP有权拒绝。如果委托方于任一季度未能下达满足本协议约定的所有承诺需求的采购订单，ANP可在该季度末向委托方开具该季度承诺需求对应的费用发票，委托方应在收悉发票后支付相应款项。

2.3 The Customer shall purchase from ANP the minimum quantities of the Product (the “**Committed Purchase Quantities**”) at the Contract Price in each calendar year as provided in the table set forth below. In the event that the Customer fails to meet the Committed Purchase Quantities in any given calendar year, the Customer shall pay ANP for the difference between the amount of the Committed Purchase Quantities and the actual amount purchased for the corresponding calendar year (such difference, the “**Committed Purchase Difference**”). ANP shall issue an invoice and the Customer shall pay the Committed Purchase Difference no later than thirty (30) days after the end of the

corresponding calendar year.

2.3 委托方应按合同价格在每个日历年度向ANP购买不低于如下表所示的最低数量的产品（“**承诺采购数量**”）。如果委托方在任何特定日历年度未能满足承诺采购数量，委托方应向ANP支付承诺采购数量金额与实际采购数量金额之间的差额（该等差额称为“**承诺采购差额**”）。ANP应不迟于相应日历年度结束后三十（30）日内就该等差额向委托方开具发票，且委托方应不迟于前述日期向ANP支付承诺采购差额。

Calendar Year 日历年度	Committed Purchase Quantities (Units) 承诺采购数量(单位)	Contract Price (per Unit) 合同价格(每单位)
2024 -2028	To be agreed by both parties after the Launch Date	Selling Price as provided in Appendix A

3. ANP's Rights and Obligations

3. ANP权利义务

3.1 ANP shall deliver the Product to the Customer according to the requirements of the purchase orders confirmed by ANP, and FCA rules under International Rules for the Interpretation of Trade Terms 2020 (Incoterms 2020) shall apply to such delivery. The Parties hereby agree that ANP's additional costs arising from such delivery (including but not limited to, costs for transportation, customs and late receipt of the Customer's designated carrier) shall be borne by the Customer.

3.1 ANP应根据ANP确认的订单要求向委托方交付产品，产品交付方式依照《国际贸易术语解释通则（2020年版）》FCA术语规则。双方确认，ANP因产品交付产生的额外费用成本（包括但不限于运输费用、出口清关费用、委托方指定承运人逾期收货费用）应由委托方承担。

3.2 ANP shall Manufacture and deliver the Product in conformance with the Applicable Law and regulations and Specifications.

3.2 ANP应依据适用法律、法规及质量标准的相关规定生产和交付产品。

3.3 ANP shall make commercially reasonable efforts to ensure that it can supply the Customer with sufficient quantities of the Product pursuant to the Forecast.

3.3 ANP应尽合理商业努力以确保交付满足委托方预测数量的产品。

4. Contract Price, Invoice and Payment

4. 合同价格、开票及结算

4.1 ANP shall issue invoices within five (5) business days after shipment, unless the Parties determine that the Product does not conform to the Specifications, payment shall be due thirty (30) days after the date of an invoice from ANP.

4.1 ANP应在发货后五（5）个工作日内向委托方开具发票，除非经由双方确认产品不符合质量标准，委托方应在ANP开具发票后三十（30）日内完成付款。

4.2 During the Term of this Agreement and not more than once during any twelve (12) month period, the Contract Price may be subject to an adjustment, provided that ANP provides the Customer with two (2) months prior written notice of such proposed Contract Price adjustment.

4.2 于协议期限内，ANP可经提前两（2）个月向委托方发出书面通知调整合同价格，该等合同价格调整在每十二（12）个月内不得超过一（1）次。

4.3 If ANP's manufacturing costs rise due to increased costs (e.g., due to increased power or labor costs, increased standards on environmental protection), the Parties shall separately agree on the Contract Price change after the Customer's verification of the increased costs using information supplied by ANP. During the negotiation of Contract Price change, ANP shall provide the relevant staff salary information, power cost invoices, environmental protection expenditure information, or other supporting materials. If the Customer adjusts the Specifications or relevant requirements unilaterally, or direct ANP to purchase designated raw materials and packaging materials, the Contract Price shall be adjusted accordingly. For the avoidance of doubt, the adjustment of the Contract Price under this section 4.3 shall not be subject to the advance notice and time limit set forth in section 4.2 hereof.

4.3 如果ANP的生产成本因相关成本增加（例如因能耗、人工成本增加、环境保护标准提高等原因增加），双方应在委托方核实ANP提供的成本增加的相关信息后另行商定合同价格的变更。在双方合同价格变更沟通期间，ANP应提供相关人员工资信息、电费发票、环保支出信息等配套材料。如果委托方要求单方变更质量标准或产品要求，或向ANP指定原材料、包材的采购，合同价格需相应调整。为免疑义，本第4.3条合同价格调整不受限于本协议第4.2条约定的提前通知期限及次数限制。

5. Quality Agreement

5. 质量协议

5.1 The Parties will separately enter into a Quality Agreement setting forth in detail the certain rights and responsibilities divided among themselves that relate to the quality of the Product.

5.1 双方将另行签订质量协议以详细约定彼此之间与产品质量相关的权利义务的划分。

6. Supply of the Product

6. 产品供应

6.1 ANP shall promptly notify the Customer of any circumstances that result or are likely to result in any failure or delay in the supply or delivery of any Product in writing. If the Parties have a good faith belief, after mutual communication, that such circumstances may result in the failure or delay in the supply or delivery of such Product for more than ninety (90) days from the date of ANP's written notice, the Customer shall have the right to terminate such delivery after the full payment of costs and expenses of such Product to ANP.

6.1 ANP应将任何导致或可能导致任何产品交付失败或延误的问题及时书面告知委托方，双方经沟通后认为该等情形将导致ANP无法于ANP发出书面通知之日起九十（90）日内完成产品交付的，委托方有权在支付ANP该等产品成本及费用的情况下终止该等产品的该等交付。

7. Inspection of the Product

7. 产品检验

7.1 All Product received by the Customer will be subject to inspection and testing by the Customer, in accordance with the Customer's quality assurance program, within a period of thirty (30) days from the date of receipt of such Product ("**Inspection Period**"). The Customer will notify ANP if the results of any inspection or testing indicate that the Product does not conform to the applicable Specifications or the other requirements under this Agreement. ANP will have ten (10) business days to respond to the Customer's notice of non-conformance. Disputes between the Parties not resolved within ten (10) business days will be resolved by an independent laboratory selected by mutual consent of the Parties. A laboratory will be appointed not later than fifteen (15) business days after the expiry of the ten (10) business day period. If the laboratory finds the Product to be nonconforming, then at ANP's sole discretion, ANP will (a) promptly deliver, at ANP's sole expense, the replacement Product that conforms to the requirements under this Agreement, or (b)

refund or credit to the Customer all payments made by the Customer with respect of such nonconforming shipment. The Customer will, at the ANP's sole discretion, return or destroy the nonconforming Product at ANP's sole expense, including without limitation transportation and handling costs.

7.1 收悉产品的三十（30）天内（"**检验期**"），委托方将根据其质量保证程序对产品质量进行检验与测试。若检验或测试结果显示产品不符合质量标准或本协议的其他要求，委托方将通知ANP。ANP应在十（10）个工作日内进行回复。若在十（10）个工作日内双方未达成一致，争议将通过经双方一致认可的独立实验室解决。双方将在上述十（10）个工作日期限届满后的十五（15）个工作日内就独立实验室的选择达成一致。若实验室检验结果仍不合格，ANP应做出下列选择：(a)立即进行产品更换且费用自理，更换的产品应满足本协议要求；(b)将委托方就此类不合格产品支付的所有款项退还给委托方或调整为对委托方的应付款。经由ANP决定，委托方将退回或销毁不合格产品，相关费用由ANP承担，包括但不限于运输和处理费用。

8. Regulatory Matters

8. 监管条款

8.1 The Customer is responsible for filing and obtaining any Marketing Authorization that is required for the marketing and sale of the Product supplied by ANP; however, ANP shall reasonably cooperate with the Customer in such activities. Each Party shall notify the other Party promptly upon becoming aware of any (a) defective, adulterated or misbranded Product or of any information which may suggest that any Product is or may be defective, adulterated or misbranded, or (b) the Product which fails to meet the Specifications, the requirements of the applicable Marketing Authorization and Applicable Law. ANP will make reasonable commercial efforts to assist the Customer in investigating adverse experiences and customer complaints relating to the Product. ANP agrees to notify the Customer promptly of any inspections by the NMPA or any other authority which pertain to or have any quality implications for the Product. ANP will provide the Customer with any necessary authorization to allow the NMPA or any other authority to inspect, audit and review the facilities at which the Product is Manufactured. ANP will retain originals of all batch documentation, any and all other records or documentation generated by ANP in connection with the manufacturing and testing of the Product under the terms of this Agreement, and all records which may be reasonably necessary to assist the Customer in the event of the Product Recall or adverse drug event, for the longer of (a) two (2) years after the expiration date of the batch

of the Product to which they pertain or (b) the period required by Applicable Law. The costs and expenses incurred by ANP in cooperating with the Customer in investigations, inspections and obtaining relevant Marketing Authorization set forth in this section 8.1 shall be borne by the Customer.

8.1 委托方负责申请和获得ANP所生产产品的上市许可，ANP应与委托方充分合作以获得该等许可。一方发现任何问题，应立即通知另一方，包括：(1) 产品有缺陷、掺货、贴错标签或任何可能表明产品存在或可能存在缺陷、假货或贴错标签的情形；(2) 产品不符合质量标准、相关上市许可及适用法律要求的情形。ANP将尽合理商业努力协助委托方调查与产品相关的不良体验和投诉问题。ANP应将NMPA或任何其他机构进行的与产品有关或能反应产品质量的所有检查通知给委托方。ANP将向委托方提供必要范围的授权，以允许NMPA和其他机构对ANP产品设施进行必要检查、审计和审查。ANP将保留所有与产品相关的必要的审批记录的原件，所有与本协议项下产品生产或测试有关的记录或文件，以及所有为协助委托方完成产品召回或产品不良反应调查而合理需要的记录文件，该等文件的保留时间应按(a) 每批产品到期日后两（2）年或(b) 适用法律规定的时限（以较长者为准）。本8.1条项下ANP因配合委托方相关调查、检查、获得相关上市许可所产生的费用应由委托方承担。

9. Facility Qualification

9. 设施资质

9.1 ANP shall, take all commercially reasonable actions to qualify (and thereafter to maintain qualification of) the facility at which ANP Manufactures the Product, as required under Applicable Law, to enable the Customer to obtain and maintain all applicable Regulatory Dossiers for the Customer's Finished Product. ANP will permit the Customer and its agents, at the Customer's expense, during normal business hours and upon reasonable prior notice to ANP, and no more than once per year, to inspect the Facility where the Product is Manufactured, handled, stored, or tested, as well as all batch records (without making any copies) and processes relating to the Manufacture, storage, handling, or testing of the Product and all Manufacturing, handling, storage, and test records regarding the Product. ANP will respond to any non-conformances noted by the Customer, within thirty (30) business days of the written notification of such non-conformances, by submitting to the Customer a written report stating causes and corrective actions planned, and providing a timetable for the correction. Notwithstanding the foregoing, all data relating to the process which is contained in the closed part of the DMF will remain confidential and Customer

has no right to review or receive such information during any inspection, audit, or review described in this Section 9.1.

9.1 ANP应根据相关法律要求，采取一切商业上合理的措施使其生产产品的设施获得（并维持）相应资质，以确保委托方能够获得并维持所有与药品成品有关的监管档案。ANP应允许委托方及其代理商在事先通知的情况下，在正常工作时间内对与产品生产、处理、贮存或测试相关的设施、或与产品生产、贮存、处理或测试相关的批次记录（不可复制副本）和工艺流程、以及产品的所有生产、处理、贮存或测试记录进行每年不超过一（1）次的检查，相关费用由委托方承担。ANP应在收到委托方的不合格书面通知后三十（30）个工作日内向委托方进行回复，通过纸质报告说明不合格原因与相应改正措施，并提供改正的具体时间安排。尽管有上述约定，就药品主文件中已经封闭的部分中与工艺相关的全部数据应保密，且委托方无权在第9.1条约定的任何检查、审计或审查过程中要求审阅或获取该等信息。

10. Manufacturing Practices

10. 生产操作

10.1 ANP shall Manufacture the Product in conformance with the Specifications and the Marketing Authorization. ANP shall provide the Customer with such information, including analytical and manufacturing documentation, requested by Customer regarding quality control of Product supplied hereunder. ANP will solely be responsible for keeping proper records and documentation of the manufacturing and testing of the Product, intermediates, and starting materials, including batch records, testing records, laboratory notebooks, equipment usage, starting material batch numbers, and certifications. ANP will be responsible for investigating any test results or in-process testing of the Product that does not conform with the Specification. ANP will conduct such laboratory investigation, which must be approved by ANP's quality unit, and ANP will promptly notify the Customer of any adverse reactions or other safety or toxicity problems known to or reasonably suspected by ANP regarding the Product or its use. ANP will promptly notify Customer of the results of any regulatory inspection, comments, responses or notices received from the NMPA or other applicable regulatory authorities, which relate to or may impact the Manufacture and supply of the Product to the Customer.

10.1 ANP应按照质量标准和上市许可进行生产，应委托方书面要求，ANP应向委托方提供本协议项下供应产品质量控制的相关信息，包括分析和生产文件。ANP将负责适当保存与产品、中间体和起始物料的生产与测试有关的记录和文件，包括：审批记录、测试记录、实

验记录、设备使用记录、起始物料批号以及检验报告。ANP将负责调查产品发生任何不符合质量标准的测试结果或过程测试，该等调查采取实验室调查，须经ANP质量部门批准方可进行。ANP将及时通知委托方针对产品已知的或合理怀疑的不良反应或其他安全或毒性问题以及自NMPA或其他机构收悉的可能影响产品生产及交付的检查、意见、答复或通知。

11. Recall

11. 召回

11.1 During the Term, if either Party believes that it may be necessary to conduct a recall, field correction, market withdrawal, stock recovery, or other similar actions with respect to any Customer's Finished Product containing the Product (a "**Recall**"), ANP and the Customer shall consult with each other as to how best to proceed. The Parties hereby agree that the final decision as to any Recall of any such Customer's Finished Product shall be made by the Customer; provided, however, that ANP will not be prohibited hereunder from taking any action that is required by Applicable Law. The Customer shall be in charge of the Recall and establish a product recall system and recall management procedures, and ANP shall cooperate with the Customer as required by Applicable Law. In the event of a Recall, the Parties shall jointly find out and confirm reasons for the Recall, and except for reasonable costs borne by ANP if a Recall incurred solely attribute to it, the Customer shall bear all costs incurred thereby.

11.1 于协议期限内，如果任一方认为有必要对任何产品的成品进行召回、现场更正、市场撤回、库存回收或其他类似行动（"召回"），双方应协商达成最佳解决方案。双方同意，该等方案的最终决定权归委托方所有，但前提是ANP也可根据相关法律要求采取相应行动。委托方应当建立产品召回体系及召回管理程序，并负责召回工作，ANP在适用法律要求的范围内配合委托方。产品发生召回的，由双方共同确认产品召回原因，除因ANP单方原因导致的产品召回由ANP承担合理费用外，任何与召回有关的费用由委托方承担。

12. Certificate of Analysis

12. 检验报告

12.1 ANP shall supply the same information on the certificate of analysis as is listed in the Specifications incorporated as Appendix B. No changes in Specifications will be made unless the Customer and ANP have agreed to such changes in writing prior to adoption of the modified Specifications.

12.1 ANP应在检验报告中提供与附录B中所列质量标准相同的信息。除非经双方事先书面同

意，否则质量标准不得更改。

13. Term, Amendment and Termination

13. 协议期限、变更、解除或终止

13.1 This Agreement will remain in full force and effect for a period of five (5) Contract Years.

13.1 本协议五合同年内保持完全效力。

13.2 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.

13.2 于协议期限内，因法律法规、质量标准、生产规程或其他实质性条件发生变化，经双方一致同意可对本协议进行变更，对本协议及其附件的修改，须经双方签署书面协议方能生效。

13.3 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:

(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;

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

(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;

(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.

13.3 除本协议另有约定外，任一方（"解除方"）可在出现下述情形之一时书面通知另一方（"被解除方"）立即解除本协议：

(a) 被解除方违反本协议约定且(i) 在收悉解除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) 实际上已不存在纠正违约行为的可能或(iii) 存在违约行为导致不能实现协议目的；

(b) 被解除方遭遇不可抗力且不可抗力致使不能实现协议目的；

(c) 被解除方明确表示或以行为表明不履行本协议义务，或者迟延履行本协议义务且经催告后仍未全面履行的；

(d) 被解除方丧失协议履行能力，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。

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

13.4 本协议可经由双方共同书面同意而终止。

13.5 Upon expiration or termination of this Agreement, ANP will promptly complete and invoice for all deliverables of open and accepted purchase orders received from the Customer prior to the termination or expiration of this Agreement, and the Customer shall pay to ANP within thirty (30) days from the date of invoice. If there is any inventory of raw and packaging materials purchased by ANP according to the Manufacturing Plan confirmed by the Customer, the Customer shall purchase such inventory from ANP in accordance with the actual purchase amount. If there is any inventory of Product, the Customer shall pay ANP corresponding fees in accordance with the amount agreed herein.

13.5 本协议到期或终止时，ANP应根据本协议到期或终止前已接受但未完成的委托方采购订单交付产品并开具发票，委托方应在ANP前述开票之日起三十 日内支付ANP款项。若存在ANP按照委托方确认的生产计划所采购产品的原辅料、包材等库存的，委托方应按照ANP实际采购金额向ANP购买，若存在产品的成品库存的，委托方应按照本协议约定金额向ANP支付相应费用。

13.6 ANP may terminate this Agreement prior to the expiration of this Agreement in the event that the Customer fails to receive Marketing Authorization for the Customer's Finished Product within five (5) years from the Effective Date

13.6 如果委托方在生效日起五（5）年内未取得产品的上市许可，ANP有权通知委托方单方终止本协议。

13.7 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.

13.7 本协议的解除、终止或到期不免除任一方在该等解除、终止或到期前产生的任何义务，包括但不限于对该等义务的任何违约，或本协议项下的任何存续义务。

13.8 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.

13.8 任何一方应在本协议解除、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。

13.9 Unless otherwise provided for herein, after termination or expiration of this Agreement, section 1 (*General*), this section 13 (*Term, Amendment and Termination*), section 14 (*Intellectual Property Rights*), section 15 (*Warranties*), section 16 (*Indemnities*), section 18 (*Force Majeure*), section 19 (*Notices*), section 20 (*Binding Effect*), section 21 (*Governing Law and Dispute Resolution*), section 22 (*Assignment*), section 23 (*Severability*), section 24 (*Entire Agreement*), section 25 (*Waiver*), section 26 (*Publicity*), section 27 (*Appendices*), section 28 (*Limitation of liability*), section 29 (*Counterparts and Language*) shall survive.

13.9 除本协议另有约定外，本协议解除、终止、到期后，本协议第1条（*总则*）、本13条（*协议期限、变更、解除或终止*）、第14条（*知识产权*）、第15条（*保证*）、第16条（*赔偿*）、第17条（*保密信息*）、第18条（*不可抗力*）、第19条（*通知*）、第20条（*合同约束力*）、第21条（*适用法律及争议解决*）、第22条（*转让*）、第23条（*可分割性*）、第24条（*完整协议*）、第25条（*弃权*）、第26条（*宣传*）、第27条（*附件*）、第28条（*责任限制*）及第29条（*副本和语言*）仍持续有效。

14. Intellectual Property Rights

14. 知识产权

14.1 ANP will retain ownership of all ANP Confidential Information that may be shared with the Customer during the Term of this Agreement, including retention of any manufacturing and production process for the Product (and all know-how of such process).

14.1 ANP将保留在执行本协议的过程中可能与委托方共享的所有ANP保密信息的所有权，包括保留任何产品的生产和制作流程（以及相应的专有技术）。

14.2 The Customer will retain ownership of all Confidential Information the Customer shares with ANP during the Term of this Agreement.

14.2 委托方将保留在执行本协议过程中与ANP共享的所有委托方保密信息的所有权。

14.3 In the course of Manufacturing, ANP shall have the right to improve the Manufacturing technology based on the technical information provided by the Customer. The Parties hereby agree that the derivative intellectual property rights arising from such improvement shall be owned by ANP. If any derivative intellectual property is created by relying upon Customer confidential information, ANP may provide to Customer a non-exclusive license to the derivative intellectual property. Customer shall not disclose the improved technology to any third party without the prior written consent of ANP. If the improved technology applies for the protection of intellectual property rights, ANP may make applications and act as the right holder of such derivative intellectual property rights at ANP's expense.

14.3 在委托生产过程中，ANP有权基于委托方提供的技术资料，对生产产品的技术进行改进。双方一致同意，如ANP对产品技术进行改进的，因技术改进产生的知识产权，归ANP所有。若有技术改进的知识产权是基于委托方的保密信息产生的，ANP可以向委托方提供该技术改进知识产权的非排他性许可。未经ANP事先书面同意，委托方不得将改进后的技术对外披露。如改进后的技术需申请知识产权保护的，ANP可以申请并作为该知识产权的权利人，费用由ANP承担。

15. Warranties

15. 保证

15.1 ANP warrants that the Product 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. ANP represents and warrants that it will comply with all present and future statutes, laws, ordinances and regulations relating to the Manufacture, assembly and supply of the Product being provided hereunder, including without limitation, those enforced by the NMPA. ANP makes no other warranties, expressed or implied, with respect to the Product. All other warranties, expressed or implied, including without limitation, the implied warranties of merchantability and fitness for

a particular purpose are hereby disclaimed by ANP. It is the sole responsibility of the Customer to determine the suitability of the Product delivered by ANP for any intended use.

15.1 ANP保证其根据本协议所交付的产品不会因违背任何法律而被视为假药或贴错标签。ANP声明并保证其将遵守与本协议中产品的生产、制备和供应相关的所有现行和未来法令、法律、法规和条例，包括但不限于NMPA的法规。除此之外，ANP对产品不做任何明示或暗示的保证，包括但不限于适销性和和为特定用途下的适用性。委托方自行负责确定ANP交付的产品是否符合其预期用途。

15.2 The Customer warrants that it has obtained all licenses, filings or approvals required by all Applicable Law regarding the entrusted manufacturing of the Product hereunder, all Product shall be transported, warehoused, stored, processed, handled and marketed by the Customer and its distributors in accordance with the Specifications and Applicable Law. The Customer warrants that it will not put on the market any Product with known or assumed defects. The Customer warrants that all advertising and promotional materials as well as user manuals and other information, instructions and directions of use relating to safety and risk issues, use, transport, handling, and storage of the Product shall comply with this Agreement, including, without limitation, the Specifications, and all Applicable Law, and will be adequate, accurate and not misleading in all material respects. The Customer warrants that before Manufacture, packaging, promotion, labeling, marketing, supply, import, offer to sell, sale, distribution or use of the Product, the Customer will perform any risk analyses required by Applicable Law related to the Product and will continue to perform such analyses as long as required by Applicable Law. The Customer further warrants that its provision of technical materials, design packaging, labels, manuals and other documents and information to ANP will not infringe any rights of any third party, and the Customer shall indemnify and hold harmless ANP for any losses incurred resulting from claims threatened or initiated against ANP for the Manufacture, sale, or distribution of the Product.

15.2 委托方声明并保证，就本协议项下产品的委托生产已取得所有适用法律、法规相关的许可、备案或审批，所有产品均由委托方及其经销商依照质量标准和所有适用法律进行运输、仓储、储存、加工、处理和销售；委托方将不会将任何已知或可能存在缺陷的产品投放市场，所有产品相关的广告、宣传材料、用户手册、说明及其他信息均应符合本协议、质量标准及所有适用法律的规定，同时在所有重要方面充分、准确、不具误导性；在产品的制造、包装、促销、贴标、营销、供应、进口、要约销售、销售、分销或使用之前，委托方将根据适用法律的要求进行与产品相关的任何风险分析，并将在适用法律要求的情况下持续进行该等分析以监测产品风险。委托方进一步保证，其提供予ANP的技术资料、设计包

装、标签及说明书等文件及信息不会侵犯任何第三方合法权利，对于因生产、销售或分销产品引发的针对ANP的索赔造成的任何损失，应当由委托方负责赔偿并使ANP免受损失。

16. Indemnities

16. 赔偿

16.1 Unless arising from the willful misconduct of ANP, the Customer will defend, indemnify and hold ANP 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) any third party claims made or proceedings brought against ANP, including claims of intellectual property infringement, relating to a Product set forth herein; (ii) the Customer's material breach of this Agreement and (iii) the Customer's breach of any warranty made under this Agreement.

16.1 除非因ANP故意不当行为引起，当(i) 任何第三方对ANP提出的与本协议项下产品有关的，包括知识产权侵权相关的主张或诉讼；(ii) 委托方实质性违反本协议；或(iii) 委托方违反其在本协议项下的任何保证时，委托方应为ANP及ANP关联方、ANP及其关联方的雇员、服务人员、代理商提供抗辩及赔偿，以使得ANP及ANP前述主体免受任何责任、判决、要求、行为、诉讼、损失、损害或费用支出（包括合理的律师费及其他辩护费用）。

16.2 Unless arising from the willful misconduct of the Customer, ANP will defend, indemnify and hold the Customer and their Affiliates and their respective employees, servants and agents harmless against any liability resulting from any third party claims made or proceeding brought against the Customer to the extent that such liability arises from (i) ANP's gross negligence in the Manufacture, storage or delivery of Product; (ii) ANP's material breach of this Agreement; or (iii) ANP's breach of any warranty made under this Agreement.

16.2 除非因委托方故意不当行为引起，当(i) ANP在产品的生产、贮存、运输方面存在重大过失；(ii) ANP实质性违反本协议；或(iii) ANP违反其在本协议项下的任何保证，ANP应为委托方及委托方关联方、委托方及其关联方的雇员、服务人员、代理商提供抗辩及赔偿，以使得委托方及委托方前述主体免受损害。

16.3 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 16. 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.

16.3 受偿方同意立即书面通知赔偿方，其根据本协议第16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的辩护、和解或其他方式处理赔偿主要的活动。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。

16.4 Unless otherwise provided for herein, if the Customer pays the entrusted manufacturing fees under this Agreement which are overdue, ANP shall have the right to require the Customer to pay interest of the overdue payment per day as liquidated damages. If the payment is overdue for more than thirty (30) days, except for the aforementioned liquidated damages, ANP shall be entitled to terminate this Agreement without any liabilities and the Customer shall compensate ANP for any loss incurred thereof.

16.4 除本协议另有约定外，委托方逾期支付ANP本协议项下委托生产费用，每逾期一天，ANP有权要求委托方支付逾期付款部分利息 作为违约金，如逾期付款超过三十（30）日的，在有权获得前述违约金的同时，ANP有权解除本协议且不承担任何违约责任，如委托方因

此给ANP造成任何损失的，委托方应当赔偿ANP全部损失。

17. Confidential Information

17. 保密信息

17.1 The 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 to execute 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.

17.1 接收方应对披露方直接或间接以口头、书面或检查的形式提供的所有信息（保密信息）进行保密。接收方仅可在履行与本协议目的所必需的范围内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收悉的任何保密信息，并将采取任何可行的措施保护保密信息的保密性，程度不得低于其对自身保密内容或同样性质内容的保护，并避免泄露和非授权使用。在披露方要求下，接收方应立即向披露方返还或销毁所有与保密信息有关的图纸、数据、备忘录和实物形式的信息。

17.2 Each Party agrees to keep the Confidential Information confidential, which includes (but is not limited to) not disclosing the disclosing party's Confidential Information, or any part thereof (except as otherwise may be provided herein), absent the disclosing party's prior written consent, unless required to do so by Applicable Law, act or a valid order of a court or other governing, regulatory body with authority over the receiving party ("**Required Disclosure**"); provided that the receiving party 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.

17.2 每一方同意对保密信息予以保密，包括（但不限于）不得在未经披露方书面同意（除非本协议另有规定），披露披露方提供的保密信息，除非适用法律、法令或对接收方有管辖权的法院或其他管理、监管机构的有效命令要求披露（“**必要披露**”）。前提是接收方应在任何必要披露前向披露方发出书面通知，且需尽最大努力获得法令或其他可靠保证以确保所披露的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。

17.3 This 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.

17.3 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，也无意于转让任何专利、商标、版权或其他知识产权项下的保密信息的任何权利。所有保密信息（包括其所有复印件）将始终为披露方所有。此外，除非本协议另有规定，不会向接收方披露保密信息，也不会产生披露方和接收方之间的任何形式或类型的代理。

17.4 The 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.

17.4 接收方同意本协议项下的义务对于保护披露方均为必要且合理的，如违反本协议约定，不仅应赔偿披露方经济损失，除法律或衡平法上可获得的任何和所有其他救济之外，披露方有权针对任何实际或可能违反本协议的行为寻求衡平法救济，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。

18. Force Majeure

18. 不可抗力

18.1 If the performance by either Party of any obligation under this Agreement, other than the payment of money, 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.

18.1 协议双方除履行付款义务外，因不可抗力的持续造成一方无法履行协议约定的义务时，该方可免除履行义务，前提是一方应立即告知另一方不可抗力的性质、持续时间及其他具体细节，并始终依照行业惯例尽合理的商业努力以恢复协议义务的履行。

18.2 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.

18.2 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。

18.3 In the event of a Force Majeure event affecting ANP, ANP may prorate and allocate manufacturing capacity among its Affiliates, in such manner as may be deemed fair and reasonable based upon purchases of the Product over the past year.

18.3 若不可抗力对ANP造成影响，ANP可根据过去一（1）年的产品采购情况，以公平合理的方式在其关联公司之间合理分配生产力。

19. Notices

19. 通知

19.1. 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:

If to the Customer: **Nanjing HanXin Pharmaceutical Technology Co., Ltd.**
Address: Building C5, No.9 Weidi Road, Xianlin University Town, Qixia District, Nanjing, Jiangsu, China
Attn: Bob Bao
Post Code: 210033

Amphastar Nanjing Pharmaceuticals, Inc.

Address: No. 5 Xinghe Road, Nanjing Economic and Technological Development Zone, Jiangsu, China

Attn: Perky Qiu

Post Code: 210038

If to ANP:

19.1. 本协议项下的所有通知均采用书面形式，应通过亲自递送、隔夜递送、挂号信、预付邮资或传真方式发送至各方的地址，具体如下：

委托方：南京汉欣医药科技有限公司
地址：中国江苏省南京市栖霞区仙林大学城纬地路9号C5栋
联系人：鲍海涛
邮箱：2110033

ANP：美药星（南京）制药有限公司
地址：中国江苏省南京经济技术开发区兴和路5号
联系人：邱银华
邮编：210038

20. Binding Effect
20. 合同约束力

20.1. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective assigns and successors in interest.
20.1. 本协议将对双方及其各自的受让人和利益继承人具有约束力并及于其各自之利益。

21. Governing Law and Dispute Resolution
21. 管辖法律及争议解决

21.1 The Agreement shall be construed, interpreted and governed by the laws of the PRC.

21.1 本协议应受中国法律管辖并解释。

21.2 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 in Shanghai under the auspices of the Shanghai International Economic and Trade Arbitration Commission with its then effective arbitration rules. The arbitration tribunal shall be consisted by three (3) members. One (1) arbitrator shall be appointed by the Party initiating the arbitration, one (1) arbitrator shall be appointed by the other Party, and the third arbitrator shall be jointly selected by the two (2) appointed arbitrators.

21.2 本协议以及因本协议及其内容或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）（以下简称"**争议**"）应由双方通过友好协商解决。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）应提交上海国际经济贸易仲裁委员会，按照其届时有效的仲裁规则在上海进行仲裁。仲裁庭由三（3）名成员组成。其中一（1）名仲裁员由提起仲裁方指定，一（1）名仲裁员由答辩方指定，第三名仲裁员由该两名仲裁员共同选定。

21.3 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.

21.3 仲裁裁决应为终局的，对双方均具有约束力，并可根据有关条款规定强制执行。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。

22. <u>Assignment</u>

22. <u>转让</u>

22.1 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 each Party to any of its Affiliate, and either Party, may assign or sell the same in connection with the transfer or sale of substantially its entire business to which this Agreement pertains or in the event of its merger or consolidation with

another company without such consent. Any permitted assignee will assume all obligations of its assignor under this Agreement.

22.1 未经另一方事先书面同意，任何一方均不得转让本协议。尽管有前述约定，一方可将其本协议项下权利义务转让给其关联方，且一方转让或出售其与本协议有关的绝大部分业务或与另一家公司合并时转让本协议则无需征得另一方同意。任一获准受让人应承担其转让人在本协议项下的所有义务。

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

22.2 任何形式的转让都不会免除任何一方履行本协议项下任何义务的责任。

23. Severability

23. 可分割性

23.1. 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.

23.1. 若本协议的任何条款或约定被有管辖权的法院认定为无效或不可强制执行，其余条款将在适用法律允许的最大范围内有效并可强制执行。如果本协议的任何条款或约定因适用范围过宽而被法院认定为不可强制执行，则该条款将在有限范围内进行解释以使其具有可强制执行性。

24. Entire Agreement

24. 完整协议

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

24.1. 本协议构成双方之间关于就本协议主题事项的全部约定，并取代双方之前所有的约定或谅解。

25. Waiver

25. 弃权

25.1. 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.

25.1. 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无效。任何一方未能行使本协议项下的权利不应被解释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解释为持续性弃权或视为在其它情况下的弃权。

26. Publicity

26. 公开发布

26.1. 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.

26.1. 除适用法律要求外，在双方间无具体协议或约定的情况下，任何一方不得向公众媒体、股东或以其他方式发起与本协议相关的任何书面或口头的宣传、新闻发布或其他公告。

27. Appendices

27. 附录

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

27.1. 本协议中所有附录均构成本协议的一部分。

28. Limitation of Liability

28. 责任限制

28.1 In no event, however, to the extent permitted by the 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.

28.1 在法律允许的范围内，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。

28.2 To the extent permitted by Applicable Law and subject to the provisions of this Section 28.1 each Party's total liability under this Agreement shall be limited to an amount of a half million US Dollars (US$500,000.00) in the aggregate, excluding insurance coverage, provided, however that each Party is only liable to the other Party, if such Party has materially fulfilled all of its relevant obligations under this Agreement at the time of the breach of this Agreement.

28.2 在适用法律允许的范围内，且受限于本协议第28.1条之约定，任一方在本协议项下的合计责任金额应以500,000美元为限（不包括保险赔付的金额），但违约一方仅在其违约行为发生时另一方已经实质履行其在本协议项下全部相关义务的情况下，对另一方承担违约责任。

29. Counterparts and Language

29. 副本和语言

29.1.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.

29.1.本协议可签署多份副本，每一份副本均应被视为原件，且所有副本应共同构成同一文件。为避免疑义，本协议以中文和英文书就。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.

兹证明，双方已由其正式授权代表签署本协议。

Amphastar Nanjing Pharmaceuticals, Inc. 美药星（南京）制药有限公司	Nanjing Hanxin Pharmaceutical Technology Co., Ltd. 南京汉欣医药科技有限公司
By/签署: /s/Perky Qiu	By/签署: /s/Bob Bao
Name/姓名: Perky Qiu 邱银华	Name/姓名: Bob Bao 鲍海涛
Title/职位: General manager 总经理	Title/职位: Vice General Manager 副总经理
Date/日期: 2022-04-18	Date/日期: 2022-04-18

APPENDIX A: PRODUCT AND CONTRACT PRICE

附录**A**：产品及合同价格

Product:

1. ********** ********
2. ********** ********
3. ********** ********
4. ********** ********
5. ********** ********
6. ********** ********
7. ********** ********

Selling Price means, with respect to each Product, an amount equal to the sum of (i) the Direct Costs to manufacture such Product, plus (ii) **% of the amount of such Direct Costs plus any applicable taxes.

出售价格：金额等于产品直接成本加上直接成本的**%以及所适用税款的总和。

"Direct Costs" means, with respect to a Product, the actual cost of raw materials, packaging components, overhead expense applied on a consistent basis with other products manufactured by ANP, and direct labor used to produce such Product. In no event will Direct Costs include expenses related to unutilized facility capacity, or allocations for corporate overheads.

直接成本：指乙方用于产品生产及相关的实际费用，包括：原材料，包装材料，管理及人工费用。任何情况下，直接成本都不包括未参与生产的设施费用，或公司内部管理费用。

APPENDIX B: SPECIFICATIONS

附录**B**：质量标准

Part of the product development works.

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: August 9, 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: August 9, 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 June 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: August 9, 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 June 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: August 9, 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.