

Amphastar Pharmaceuticals Reports Financial Results for the Three Months Ended March 31, 2022

May 9, 2022

Reports Net Revenues of \$120.4 Million for the Three Months Ended March 31, 2022

RANCHO CUCAMONGA, CA / ACCESSWIRE / May 9, 2022 / Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) ("Amphastar" or the "Company") today reported results for the three months ended March 31, 2022.

First Quarter Highlights

- Net revenues of \$120.4 million for the first quarter
- GAAP net income of \$24.3 million, or \$0.47 per share, for the first quarter
- Adjusted non-GAAP net income of \$24.6 million, or \$0.47 per share, for the first quarter

Dr. Jack Zhang, Amphastar's President and Chief Executive Officer, commented: "The first quarter continued where 2021 ended, with strong sales of our recently launched products, which confirms our strategy focused on complex products with commercial strength. We are optimistic that our growth trend will continue in 2022."

	Three Months Ended March 31,	
	2022	2021
	(in thousands, except per share data)	
Net revenues	\$ 120,368	\$ 103,020
GAAP net income attributable to Amphastar	\$ 24,253	\$ 5,041
Adjusted non-GAAP net income attributable to Amphastar*	\$ 24,586	\$ 13,553
GAAP diluted EPS attributable to Amphastar stockholders	\$ 0.47	\$ 0.10
Adjusted non-GAAP diluted EPS attributable to Amphastar stockholders*	\$ 0.47	\$ 0.27

* Adjusted non-GAAP net income and Adjusted non-GAAP diluted EPS are non-GAAP financial measures. Please see the discussion in the section entitled "Non-GAAP Financial Measures" and the reconciliation of GAAP to non-GAAP financial measures in Table III of this press release.

	Three Months Ended March 31,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Net revenues:				
Primatene Mist [®]	\$ 24,697	\$ 18,383	\$ 6,314	34 %

Epinephrine	15,156	15,578	(422)	(3 %)
Glucagon	10,984	7,984	3,000	38 %
Lidocaine	10,590	9,071	1,519	17 %
Phytonadione	10,475	9,565	910	10 %
)
Enoxaparin	10,124	10,658	(534)	(5 %)
Naloxone	7,413	6,341	1,072	17 %
Other finished pharmaceutical products	<u>27,107</u>	<u>20,302</u>	<u>6,805</u>	<u>34 %</u>
Total finished pharmaceutical products net revenues	<u>\$ 116,546</u>	<u>\$ 97,882</u>	<u>\$ 18,664</u>	<u>19 %</u>
)
API	<u>3,822</u>	<u>5,138</u>	<u>(1,316)</u>	<u>(26 %)</u>
Total net revenues	<u><u>\$ 120,368</u></u>	<u><u>\$ 103,020</u></u>	<u><u>\$ 17,348</u></u>	<u><u>17 %</u></u>

Changes in net revenues were primarily driven by:

- Primatene Mist[®] sales increased due to an increase in unit volumes as a result of the continued success of our advertising campaign
- Glucagon sales increased due to an increase in unit volumes resulting from a full quarter of sales in 2022, compared to the same period in 2021, as the product was launched in February 2021
- Lidocaine sales increased due to an increase in unit volumes
- Phytonadione sales increased due to an increase in higher average selling price
- Naloxone sales increased due to an increase in unit volumes
- Other finished pharmaceutical product sales increased due to higher demand for certain products such as calcium chloride and sodium bicarbonate, largely due to market shortages
- API sales decreased due to the timing of orders from MannKind and other customers

	Three Months Ended		Change	
	March 31,		Dollars	%
	2022	2021		
	(in thousands)			
Net revenues	\$ 120,368	\$ 103,020	\$ 17,348	17 %
Cost of revenues	<u>64,542</u>	<u>58,074</u>	<u>6,468</u>	11 %
Gross profit	<u>\$ 55,826</u>	<u>\$ 44,946</u>	<u>\$ 10,880</u>	24 %
<i>as % of net revenues</i>	46 %	44 %		

Changes in the cost of revenues and the resulting increase in gross margin were primarily driven by:

- Increased sales of higher-margin products such as Primatene Mist[®] and glucagon
- Partially offset by an overall increase in labor cost, as well as increased costs for heparin, the starting material for enoxaparin, and a lower average selling price for enoxaparin

	Three Months Ended	Change
	March 31,	

	<u>2022</u>	<u>2021</u>	<u>Dollars</u>	<u>%</u>
	(in thousands)			
Selling, distribution, and marketing	\$ 5,519	\$ 4,537	\$ 982	22 %
General and administrative	12,470	15,338	(2,868)	(19) %
Research and development	16,223	14,765	1,458	10 %
Non-operating income (expense), net	7,419	(5,192)	12,611	(243) %

- Selling, distribution, and marketing expenses increased primarily due to increased freight expenses
- General and administrative expenses decreased primarily due to a decrease in legal expenses and a decrease in expenses in China due to the previously-announced ANP restructuring
- Research and development expenses increased due to:
 - An increase in expenses in testing, operating, and lab supplies as a result of an increase in expenditures on materials for our pipeline products
 - Partially offset by a decrease in clinical trial expense as a result of a shift in timing on some of our clinical trial studies
- The change in non-operating income (expense), net is primarily a result of:
 - A \$5.4 million gain related to a settlement in connection with the Regadenoson patent litigation in January 2022
 - A \$4.4 million expense recorded in the first quarter of 2021 in connection with the Aventis litigation

Cash flow provided by operating activities for the three months ended March 31, 2022, was \$50.8 million.

Share Buyback Program

On May 5, 2022, the Company's Board of Directors authorized a \$25 million increase to the Company's share buyback program, which is expected to continue for an indefinite period of time. The primary goal of the program is to offset dilution created by the Company's equity compensation programs.

Purchases may be made through the 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 Securities and Exchange Commission and applicable laws.

The timing and actual number of shares repurchased will depend on a variety of factors including price, corporate and regulatory requirements, and other conditions.

Pipeline Information

The Company currently has four ANDAs on file with the FDA targeting products with a market size of approximately \$4 billion, three biosimilar products in development targeting products with a market size of approximately \$13 billion, and eight generic products in development targeting products with a market size of approximately \$9 billion. This market information is based on IQVIA data for the 12 months ended March 31, 2022. The Company is developing multiple proprietary products with injectable and intranasal dosage forms.

Amphastar's Chinese subsidiary, ANP, currently has 17 Drug Master Files, or DMFs, on file with the FDA and is developing several additional DMFs.

Company Information

Amphastar is a bio-pharmaceutical company that focuses primarily on developing, manufacturing, marketing, and selling technically-challenging generic and proprietary injectable, inhalation, and intranasal products. Additionally, the Company sells insulin API products. Most of the Company's finished products are used in hospital or urgent care clinical settings and are primarily contracted and distributed through group purchasing organizations and drug wholesalers. More information and resources are available at www.amphastar.com.

Amphastar's logo and other trademarks or service marks of Amphastar, including, but not limited to Amphastar[®], Primatene Mist[®], Amphadase[®], and Cortrosyn[®], are the property of Amphastar.

Non-GAAP Financial Measures

To supplement its consolidated financial statements, which are prepared and presented in accordance with U.S. generally accepted accounting principles ("GAAP"), the Company is disclosing non-GAAP financial measures when providing financial results. The Company believes that an evaluation of its ongoing operations (and comparisons of its current operations with historical and future operations) would be difficult if the disclosure of its financial results were limited to financial measures prepared only in accordance with GAAP. As a result, the Company is disclosing certain non-GAAP results, including (i) Adjusted non-GAAP net income (loss) attributed to Amphastar and (ii) Adjusted non-GAAP diluted EPS attributed to Amphastar's stockholders, which exclude amortization expense, share-based compensation, impairment charges, legal settlements, and other one-time events in order to supplement investors' and other readers' understanding and assessment of the Company's financial performance because the Company's management uses these measures internally for forecasting, budgeting, and measuring its operating performance. Whenever the Company uses such non-GAAP measures, it will provide a reconciliation of non-GAAP financial measures to their most directly comparable GAAP financial measures. Investors and other readers are encouraged to review the related GAAP financial measures and the reconciliation of non-GAAP measures to their most directly comparable GAAP measures set forth below and should consider non-GAAP measures only as a supplement to, not as a substitute for or as a superior measure to, measures of financial performance prepared in accordance with GAAP.

Conference Call Information

The Company will hold a conference call to discuss its financial results today, May 9, 2022, at 2:00 p.m. Pacific Time.

To access the conference call, dial toll-free (877) 407-0989 or (201) 389-0921 for international callers, five minutes before the conference.

The call can also be accessed on the Investors page on the Company's website www.amphastar.com.

Forward Looking Statements

All statements in this press release and in the conference call referenced above that are not historical are forward-looking statements, including, among other things, statements relating to our expectations regarding future financial performance and business trends, backlog, sales and marketing of our products, market size and growth, product development, the timing of FDA filings or approvals, including the DMFs of ANP, the timing of product launches, acquisitions and other matters related to our pipeline of product candidates, the timing and results of clinical trials, our share buyback program, the impact of the restructuring of ANP, and other future events, such as the

impact of the COVID-19 pandemic including its variants and related responses of business and governments to the pandemic on our operations and personnel, and on commercial activity and demand across our business operations and results of operations. These statements are not facts but rather are based on Amphastar's historical performance and our current expectations, estimates, and projections regarding our business, operations, and other similar or related factors. Words such as "may," "might," "will," "could," "would," "should," "anticipate," "predict," "potential," "continue," "expect," "intend," "plan," "project," "believe," "estimate," and other similar or related expressions are used to identify these forward-looking statements, although not all forward-looking statements contain these words. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and assumptions that are difficult or impossible to predict and, in some cases, beyond Amphastar's control. Actual results may differ materially from those in the forward-looking statements as a result of a number of factors, including those described in Amphastar's filings with the Securities and Exchange Commission, including in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 11, 2022. In particular, the extent of COVID-19's impact on our business will depend on several factors, including the severity, duration and extent of the pandemic including its variants, 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. You can locate these reports through our website at <http://ir.amphastar.com> and on the SEC's website at www.sec.gov. The forward-looking statements in this release speak only as of the date of the release. Amphastar undertakes no obligation to revise or update information or any forward-looking statements in this press release or the conference call referenced above to reflect events or circumstances in the future, even if new information becomes available or if subsequent events cause our expectations to change.

Contact Information:

Amphastar Pharmaceuticals, Inc.
 Bill Peters
 Chief Financial Officer
 (909) 980-9484

Table I
Amphastar Pharmaceuticals, Inc.
Condensed Consolidated Statement of Operations
(Unaudited; in thousands, except per share data)

	Three Months Ended	
	March 31,	
	2022	2021
Net revenues	\$ 120,368	\$ 103,020
Cost of revenues	<u>64,542</u>	<u>58,074</u>
Gross profit	55,826	44,946
Operating expenses:		
Selling, distribution, and marketing	5,519	4,537
General and administrative	12,470	15,338
Research and development	<u>16,223</u>	<u>14,765</u>
Total operating expenses	<u>34,212</u>	<u>34,640</u>
Income from operations	21,614	10,306

Non-operating income (expenses), net	7,419	(5,192)
Income before income taxes	29,033	5,114
Income tax provision	4,077	1,155
Net income before equity in losses of unconsolidated affiliate	24,956	3,959
Equity in losses of unconsolidated affiliate	(703)	-
Net income	<u>\$ 24,253</u>	<u>\$ 3,959</u>
Net loss attributable to non-controlling interests	<u>\$ -</u>	<u>\$ (1,082)</u>
Net income attributable to Amphastar	<u><u>\$ 24,253</u></u>	<u><u>\$ 5,041</u></u>
Net income per share attributable to Amphastar stockholders:		
Basic	\$ 0.50	\$ 0.11
Diluted	\$ 0.47	\$ 0.10
Weighted-average shares used to compute net income per share attributable to Amphastar stockholders:		
Basic	48,138	47,520
Diluted	51,979	49,518

Table II
Amphastar Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheet
(Unaudited; in thousands, except per share data)

	March 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 172,627	\$ 126,353
Restricted cash	235	235
Short-term investments	14,383	10,320
Restricted short-term investments	2,200	2,200
Accounts receivable, net	73,166	78,804
Inventories	95,147	92,807
Income tax refunds and deposits	223	126
Prepaid expenses and other assets	6,434	7,274
Total current assets	<u>364,415</u>	<u>318,119</u>
Property, plant, and equipment, net	243,248	244,244
Finance lease right-of-use assets	278	353
Operating lease right-of-use assets	27,843	26,894
Investment in unconsolidated affiliate	3,318	3,985
Goodwill and intangible assets, net	38,436	38,870
Other assets	16,301	16,665
Deferred tax assets	<u>22,399</u>	<u>22,399</u>

Total assets	<u>\$ 716,238</u>	<u>\$ 671,529</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 95,810	\$ 89,545
Income taxes payable	13,116	9,081
Current portion of long-term debt	2,159	2,202
Current portion of operating lease liabilities	<u>3,279</u>	<u>2,982</u>
Total current liabilities	114,364	103,810
Long-term reserve for income tax liabilities	6,531	6,531
Long-term debt, net of current portion and unamortized debt issuance costs	74,348	74,776
Long-term operating lease liabilities, net of current portion	25,489	24,703
Deferred tax liabilities	487	534
Other long-term liabilities	<u>15,494</u>	<u>15,653</u>
Total liabilities	236,713	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; 57,495,402 and 48,752,175 shares issued and outstanding as of March 31, 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	433,454	422,423
Retained earnings	204,590	180,337
Accumulated other comprehensive loss	(7,245)	(6,765)
Treasury stock	<u>(151,280)</u>	<u>(150,479)</u>
Total equity	<u>479,525</u>	<u>445,522</u>
Total liabilities and stockholders' equity	<u>\$ 716,238</u>	<u>\$ 671,529</u>

Table III
Amphastar Pharmaceuticals, Inc.
Reconciliation of Non-GAAP Measures
(Unaudited; in thousands, except per share data)

	Three Months Ended	
	March 31,	
	<u>2022</u>	<u>2021</u>
GAAP net income	\$ 24,253	\$ 3,959
Adjusted for:		
Intangible amortization	352	276
Share-based compensation	5,022	4,834
Impairment of long-lived assets	-	6

Reserves for litigation and settlements	(5,346)	5,695
Income tax provision (benefit) on pre-tax adjustments	<u>305</u>	<u>(2,229)</u>
Non-GAAP net income	<u>\$ 24,586</u>	<u>\$ 12,541</u>
Non-GAAP net loss attributable to non-controlling interests	<u>\$ -</u>	<u>\$ (1,012)</u>
Non-GAAP net income attributable to Amphastar	<u><u>\$ 24,586</u></u>	<u><u>\$ 13,553</u></u>
Non-GAAP net income per share attributable to Amphastar stockholders:		
Basic	\$ 0.51	\$ 0.29
Diluted	\$ 0.47	\$ 0.27
Weighted-average shares used to compute non-GAAP net income per share attributable to Amphastar stockholders:		
Basic	48,138	47,520
Diluted	51,979	49,518

Three Months Ended March 31, 2022

	Cost of	Selling,	General	Research	Non-	Income	Non-
	revenue	distribution	and	and	operating	tax	control
	and	and	administrative	development	income	provision	interests
	marketing	and	development	net	(expense),	(benefit)	adjustments
	net	marketing	and	development	(expense),	(benefit)	adjustments
GAAP	\$ 64,542	\$ 5,519	\$ 12,470	\$ 16,223	\$ 7,419	\$ 4,077	\$
Intangible amortization	(235)	-	(117)	-	-	-	-
Share-based compensation	(1,385)	(168)	(2,861)	(608)	-	-	-
Reserves for litigation and settlements	-	-	-	-	(5,346)	-	-
Income tax provision (benefit) on pre-tax adjustments	-	-	-	-	-	(305)	-
Non-GAAP	<u><u>\$ 62,922</u></u>	<u><u>\$ 5,351</u></u>	<u><u>\$ 9,492</u></u>	<u><u>\$ 15,615</u></u>	<u><u>\$ 2,073</u></u>	<u><u>\$ 3,772</u></u>	<u><u>\$</u></u>

Three Months Ended March 31, 2021

	Cost of	Selling,	General	Research	Non-	Income	Non-
	revenue	distribution	and	and	operating	tax	control
	and	and	administrative	development	income	provision	interests
	marketing	and	development	net	(expense),	(benefit)	adjustments
	net	marketing	and	development	(expense),	(benefit)	adjustments
GAAP	\$ 58,074	\$ 4,537	\$ 15,338	\$ 14,765	\$ 5,192	\$ 1,155	\$ (1,000)

Intangible amortization	(242)	-	(34)	-	-	-
Share-based compensation	(1,146)	(127)	(2,968)	(593)	-	-
Impairment of long-lived assets	-	-	(6)	-	-	-
Reserves for litigation and settlements	-	-	(1,295)	-	(4,400)	-
Income tax provision (benefit) on pre-tax adjustments	-	-	-	-	-	2,229
Non-GAAP	<u>\$ 56,686</u>	<u>\$ 4,410</u>	<u>\$ 11,035</u>	<u>\$ 14,172</u>	<u>\$ 792</u>	<u>\$ 3,384</u>
						<u>\$ (1,000)</u>

SOURCE: Amphastar Pharmaceuticals, Inc.

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