

Amphastar Pharmaceuticals Reports Financial Results for the Three Months Ended September 30, 2022

November 7, 2022

Reports Net Revenues of \$120.1 Million for the Three Months Ended September 30, 2022

RANCHO CUCAMONGA, CA / ACCESSWIRE / November 7, 2022 / Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) ("Amphastar" or the "Company") today reported results for the three months ended September 30, 2022.

Third Quarter Highlights

- Net revenues of \$120.1 million for the third quarter
- GAAP net income of \$15.9 million, or \$0.30 per share, for the third quarter
- Adjusted non-GAAP net income of \$20.2 million, or \$0.38 per share, for the third quarter

Dr. Jack Zhang, Amphastar's President and Chief Executive Officer, commented: "We are pleased to report that our continued investment in capacity has successfully led to another quarter of solid growth driven by strong epinephrine, Primatene Mist[®], and glucagon sales. Looking ahead to next year, we remain optimistic that our multiple pipeline product candidates will continue to progress through their respective stages of development and will ultimately position us to deliver continued growth in the future."

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net revenues	\$ 120,129	\$ 112,198	\$ 363,964	\$ 316,881
GAAP net income attributable to Amphastar	\$ 15,874	\$ 29,548	\$ 57,473	\$ 42,356
Adjusted non-GAAP net income attributable to Amphastar*	\$ 20,232	\$ 22,998	\$ 65,548	\$ 47,166
GAAP diluted EPS attributable to Amphastar stockholders	\$ 0.30	\$ 0.59	\$ 1.09	\$ 0.85
Adjusted non-GAAP diluted EPS attributable to Amphastar stockholders*	\$ 0.38	\$ 0.46	\$ 1.24	\$ 0.95

* Adjusted non-GAAP net income attributable to Amphastar and Adjusted non-GAAP diluted EPS attributable to Amphastar stockholders 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.

Third Quarter Results

Three Months Ended September 30,	Change
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	<u>2022</u>	<u>2021</u>	<u>Dollars</u>	<u>%</u>
Net revenues:	(in thousands)			
Epinephrine	\$ 19,502	\$ 13,892	\$ 5,610	40 %
Primatene Mist [®]	18,359	16,561	1,798	11 %
Glucagon	14,224	12,189	2,035	17 %
Phytonadione	13,978	11,591	2,387	21 %
Lidocaine	12,621	11,649	972	8 %
Enoxaparin	7,983	8,034	(51)	(1 %
)
Naloxone	6,818	8,028	(1,210)	(15 %
)
Other finished pharmaceutical products	<u>23,635</u>	<u>27,046</u>	<u>(3,411)</u>	<u>(13 %</u>
Total finished pharmaceutical products net revenues	<u>\$ 117,120</u>	<u>\$ 108,990</u>	<u>\$ 8,130</u>	<u>7 %</u>
)
API	<u>3,009</u>	<u>3,208</u>	<u>(199)</u>	<u>(6 %</u>
Total net revenues	<u>\$ 120,129</u>	<u>\$ 112,198</u>	<u>\$ 7,931</u>	<u>7 %</u>

Changes in net revenues were primarily driven by:

- Primatene Mist[®] sales increased primarily due to increased unit volumes
- Glucagon sales increased due to an increase in inventory levels, which allowed us to fill orders for the back-to-school season and meet the corresponding seasonal demand
- Epinephrine sales increased by \$3.3 million due to an increase in average selling price, with the remainder of the increase due to increased unit volumes as a result of competitor shortages
- Phytonadione sales increased due to a combination of an increase in unit volumes and a higher average selling price
- Lidocaine sales increased primarily due to an increase in units of the injectable version
- Naloxone sales decreased primarily due to a lower average selling price
- Other finished pharmaceutical product sales changes were primarily due to:
 - Lower unit volumes of atropine and calcium chloride, largely due to competitors returning to their normal distribution levels
 - An increase in unit volume for dextrose, which was in high demand due to competitor shortages
 - Launches of ganirelix and vasopressin, in June 2022 and August 2022, respectively
- Active Pharmaceutical ingredient ("API") sales decreased primarily due to the timing of customer purchases

	Three Months Ended		Change	
	September 30,			
	<u>2022</u>	<u>2021</u>	<u>Dollars</u>	<u>%</u>
	(in thousands)			
Net revenues	\$ 120,129	\$ 112,198	\$ 7,931	7 %
Cost of revenues	<u>61,619</u>	<u>61,015</u>	<u>604</u>	<u>1 %</u>
Gross profit	<u>\$ 58,510</u>	<u>\$ 51,183</u>	<u>\$ 7,327</u>	<u>14 %</u>
<i>as % of net revenues</i>	49 %	46 %		

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 epinephrine, Primatene Mist[®], phytonadione, and glucagon, as well as the launches of ganirelix and vasopressin in 2022
- These factors were partially offset by overall increases in labor costs, as well as increases in costs for heparin, the starting material for enoxaparin

	Three Months Ended		Change	
	September 30,		Dollars	%
	2022	2021		
	(in thousands)			
Selling, distribution, and marketing	\$ 4,784	\$ 4,745	\$ 39	1 %
General and administrative	11,984	10,910	1,074	10 %
Research and development	18,514	10,759	7,755	72 %
Non-operating income (expense), net	(632)	12,877	(13,509)	(105 %)

- General and administrative expenses increased primarily due to an increases in legal and compensation expenses
- Research and development expenses increased due to:
 - Increases in expenditures for materials and components, primarily for our AMP-018 and insulin products candidates
 - An increase in clinical trial expense primarily due to external studies related to our insulin and inhalation product pipeline
 - The increase was partially offset by a decrease in expenses in China due to the completion of the restructuring of Amphastar's Chinese subsidiary, Amphastar Nanjing Pharmaceuticals Co., Ltd. ("ANP"), in 2021
- The change in non-operating income (expense), net is primarily a result of a \$13.6 million gain on the deconsolidation of Hanxin Pharmaceutical Technology Co., Ltd related to the ANP restructuring in 2021

Cash flow provided by operating activities for the nine months ended September 30, 2022 was \$74.0 million.

Share Buyback Program

On November 3, 2022, the Company's Board of Directors authorized a \$50 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 three ANDAs on file with the FDA targeting products with a market size of over \$3 billion, three biosimilar products in development targeting products with a market size of over \$12 billion, and eight generic products in development targeting products with a market size of over \$9 billion. This market information is based on IQVIA data for the 12 months ended September 30, 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, November 7, 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 at 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, and other future events, such as the impact of the COVID-19 pandemic including its variants, the Russia-Ukraine conflict and resulting macroeconomic conditions, such as inflation and rising interest rates, and related responses of business and governments to the pandemic and international conflict 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 our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, filed with the SEC on May 10, 2022, and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed with the SEC on August 9, 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net revenues	\$ 120,129	\$ 112,198	\$ 363,964	\$ 316,881
Cost of revenues	<u>61,619</u>	<u>61,015</u>	<u>186,272</u>	<u>173,376</u>
Gross profit	58,510	51,183	177,692	143,505
Operating expenses:				
Selling, distribution, and marketing	4,784	4,745	16,059	13,411
General and administrative	11,984	10,910	34,433	40,813
Research and development	<u>18,514</u>	<u>10,759</u>	<u>57,535</u>	<u>43,646</u>
Total operating expenses	<u>35,282</u>	<u>26,414</u>	<u>108,027</u>	<u>97,870</u>
Income from operations	23,228	24,769	69,665	45,635
Non-operating income (expenses), net	<u>(632)</u>	<u>12,877</u>	<u>5,115</u>	<u>11,342</u>
Income before income taxes	22,596	37,646	74,780	56,977
Income tax provision	<u>6,559</u>	<u>6,686</u>	<u>16,187</u>	<u>13,436</u>
Net income before equity in losses of unconsolidated affiliate	16,037	30,960	58,593	43,541
Equity in losses of unconsolidated affiliate	<u>(163)</u>	<u>-</u>	<u>(1,120)</u>	<u>-</u>
Net income	<u>\$ 15,874</u>	<u>\$ 30,960</u>	<u>\$ 57,473</u>	<u>\$ 43,541</u>
Net income attributable to non-controlling interests	<u>\$ -</u>	<u>\$ 1,412</u>	<u>\$ -</u>	<u>\$ 1,185</u>
Net income attributable to Amphastar	<u>\$ 15,874</u>	<u>\$ 29,548</u>	<u>\$ 57,473</u>	<u>\$ 42,356</u>
Net income per share attributable to Amphastar stockholders:				
Basic	\$ 0.32	\$ 0.62	\$ 1.18	\$ 0.89
Diluted	\$ 0.30	\$ 0.59	\$ 1.09	\$ 0.85
Weighted-average shares used to compute net income per share attributable to Amphastar stockholders:				
Basic	48,904	48,022	48,635	47,758
Diluted	52,788	50,009	52,665	49,693

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

	September 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 157,244	\$ 126,353

Restricted cash	235	235
Short-term investments	26,843	10,320
Restricted short-term investments	2,200	2,200
Accounts receivable, net	77,099	78,804
Inventories	103,250	92,807
Income tax refunds and deposits	11,365	126
Prepaid expenses and other assets	5,986	7,274
Total current assets	384,222	318,119
Property, plant, and equipment, net	232,741	244,244
Finance lease right-of-use assets	601	353
Operating lease right-of-use assets	26,456	26,894
Investment in unconsolidated affiliate	2,690	3,985
Goodwill and intangible assets, net	37,037	38,870
Other assets	20,549	16,665
Deferred tax assets	22,399	22,399
Total assets	\$ 726,695	\$ 671,529

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable and accrued liabilities	\$ 95,796	\$ 89,545
Income taxes payable	1,531	9,081
Current portion of long-term debt	1,680	2,202
Current portion of operating lease liabilities	3,183	2,982
Total current liabilities	102,190	103,810
Long-term reserve for income tax liabilities	6,531	6,531
Long-term debt, net of current portion and unamortized debt issuance costs	74,011	74,776
Long-term operating lease liabilities, net of current portion	24,366	24,703
Deferred tax liabilities	242	534
Other long-term liabilities	14,190	15,653
Total liabilities	221,530	226,007

Commitments and contingencies

Stockholders' equity:

Preferred stock: par value \$0.0001; 20,000,000 shares authorized; no shares issued and outstanding

- -

Common stock: par value \$0.0001; 300,000,000 shares authorized; 57,994,848 and 48,612,545 shares issued and outstanding as of September 30, 2022 and 56,440,202 and 47,714,912 shares issued and outstanding as of December 31, 2021, respectively

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Additional paid-in capital

448,741 422,423

Retained earnings

237,810 180,337

Accumulated other comprehensive loss

(9,931) (6,765)

Treasury stock

(171,461) (150,479)

Total equity	505,165	445,522
Total liabilities and stockholders' equity	<u>\$ 726,695</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 September 30, 2022

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Non- operating income (expense), net	Income tax provision	Non- controlli interes adjustm
GAAP	\$ 61,619	\$ 4,784	\$ 11,984	\$ 18,514	\$ (632)	\$ 6,559	\$
Intangible amortization	(206)	-	(186)	-	-	-	-
Share-based compensation	(915)	(178)	(2,810)	(396)	-	-	-
Reserves for litigation and settlements	-	-	(800)	-	-	-	-
Income tax provision on pre-tax adjustments	-	-	-	-	-	1,133	-
Non-GAAP	<u>\$ 60,498</u>	<u>\$ 4,606</u>	<u>\$ 8,188</u>	<u>\$ 18,118</u>	<u>\$ (632)</u>	<u>\$ 7,692</u>	<u>\$</u>

Three Months Ended September 30, 2021

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Non- operating income (expense), net	Income tax provision	Non- controlli intere adjustm
GAAP	\$ 61,015	\$ 4,745	\$ 10,910	\$ 10,759	\$ 12,877	\$ 6,686	\$ 1
Intangible amortization	(242)	-	(135)	-	-	-	-
Share-based compensation	(889)	(164)	(2,533)	(333)	-	-	-
Impairment of long-lived assets	-	-	(25)	-	-	-	-
Gain on ANP Restructuring	-	-	-	-	(13,587)	-	(2
Income tax provision on pre-tax adjustments	-	-	-	-	-	(921)	-
Non-GAAP	<u>\$ 59,884</u>	<u>\$ 4,581</u>	<u>\$ 8,217</u>	<u>\$ 10,426</u>	<u>\$ (710)</u>	<u>\$ 5,765</u>	<u>\$</u>

Nine Months Ended September 30, 2022

	<u>Cost of revenue</u>	<u>Selling, distribution and marketing</u>	<u>General and administrative</u>	<u>Research and development</u>	<u>Non- operating income (expense), net</u>	<u>Income tax provision</u>	<u>Non- control interest adjustment</u>
GAAP	\$ 186,272	\$ 16,059	\$ 34,433	\$ 57,535	\$ 5,115	\$ 16,187	\$ -
Intangible amortization	(660)	-	(428)	-	-	-	-
Share-based compensation	(3,238)	(540)	(8,389)	(1,389)	-	-	-
Reserves for litigation and settlements	-	-	(800)	-	(5,729)	-	-
Income tax provision on pre-tax adjustments	-	-	-	-	-	1,640	-
Non-GAAP	<u>\$ 182,374</u>	<u>\$ 15,519</u>	<u>\$ 24,816</u>	<u>\$ 56,146</u>	<u>\$ (614)</u>	<u>\$ 17,827</u>	<u>\$ -</u>

Nine Months Ended September 30, 2021

	<u>Cost of revenue</u>	<u>Selling, distribution and marketing</u>	<u>General and administrative</u>	<u>Research and development</u>	<u>Non- operating income (expense), net</u>	<u>Income tax provision</u>	<u>Non- control interest adjustment</u>
GAAP	\$ 173,376	\$ 13,411	\$ 40,813	\$ 43,646	\$ 11,342	\$ 13,436	\$ 1,614
Intangible amortization	(728)	-	(202)	-	-	-	-
Share-based compensation	(2,967)	(438)	(10,069)	(1,363)	-	-	-
Impairment of long-lived assets	(84)	-	(33)	(222)	-	-	-
Gain on ANP Restructuring	-	-	-	-	(13,587)	-	(2,000)
Reserves for litigation and settlements	-	-	(1,295)	-	1,696	-	-
Income tax provision on pre-tax adjustments	-	-	-	-	-	1,614	-
Non-GAAP	<u>\$ 169,597</u>	<u>\$ 12,973</u>	<u>\$ 29,214</u>	<u>\$ 42,061</u>	<u>\$ (549)</u>	<u>\$ 15,050</u>	<u>\$ -</u>

SOURCE: Amphastar Pharmaceuticals, Inc.

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