

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

August 8, 2022

Reports Net Revenues of \$123.5 Million for the Three Months Ended June 30, 2022

RANCHO CUCAMONGA, CA / ACCESSWIRE / August 8, 2022 / Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) ("Amphastar" or the "Company") today reported results for the three months ended June 30, 2022.

Second Quarter Highlights

- Net revenues of \$123.5 million for the second quarter
- GAAP net income of \$17.3 million, or \$0.33 per share, for the second quarter
- Adjusted non-GAAP net income of \$20.7 million, or \$0.39 per share, for the second quarter

Dr. Jack Zhang, Amphastar's President and Chief Executive Officer, commented: "We've maintained momentum through the first half of 2022. Sales remained strong through the second quarter, allowing us to increase our investment in research and development. We are optimistic that sales will continue their upward trajectory into the third quarter, particularly with ganirelix's full quarter of sales and the upcoming launch of vasopressin this month, each of which presents new opportunities for further diversification of our revenue streams."

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2022	2021	2022	2021
	(in thousands, except per share data)			
Net revenues	\$ 123,467	\$ 101,663	\$ 243,835	\$ 204,683
GAAP net income attributable to Amphastar	\$ 17,346	\$ 7,767	\$ 41,599	\$ 12,808
Adjusted non-GAAP net income attributable to Amphastar*	\$ 20,730	\$ 10,615	\$ 45,316	\$ 24,168
GAAP diluted EPS attributable to Amphastar stockholders	\$ 0.33	\$ 0.16	\$ 0.79	\$ 0.26
Adjusted non-GAAP diluted EPS attributable to Amphastar stockholders*	\$ 0.39	\$ 0.21	\$ 0.86	\$ 0.49

* 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.

Second Quarter Results

Three Months Ended

	<u>June 30,</u>		<u>Change</u>	
	<u>2022</u>	<u>2021</u>	<u>Dollars</u>	<u>%</u>
	(in thousands)			
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	<u>25,588</u>	<u>18,751</u>	<u>6,837</u>	<u>36 %</u>
Total finished pharmaceutical products net revenues	<u>\$ 120,123</u>	<u>\$ 94,722</u>	<u>\$ 25,401</u>	<u>27 %</u>
)	
API	<u>3,344</u>	<u>6,941</u>	<u>(3,597)</u>	<u>(52 %</u>
Total net revenues	<u><u>\$ 123,467</u></u>	<u><u>\$ 101,663</u></u>	<u><u>\$ 21,804</u></u>	<u><u>21 %</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
- Epinephrine sales increased due to an increase in unit volumes as a result of competitor shortages
- Lidocaine sales increased as a result of an increase in unit volumes
- Phytonadione sales increased due to an increase in unit volumes and higher average selling price
- Other finished pharmaceutical product sales increased due to higher demand for certain products such as dextrose and sodium bicarbonate, largely resulting from competitor shortages, as well as the launch of ganirelix prefilled syringe in late June 2022
- API sales decreased due to the timing of orders from MannKind Corporation

	<u>Three Months Ended</u>		<u>Change</u>	
	<u>June 30,</u>		<u>Dollars</u>	<u>%</u>
	<u>2022</u>	<u>2021</u>	(in thousands)	
Net revenues	\$ 123,467	101,663	\$ 21,804	21 %
Cost of revenues	<u>60,111</u>	<u>54,287</u>	<u>5,824</u>	11 %
Gross profit	<u><u>\$ 63,356</u></u>	<u><u>47,376</u></u>	<u><u>\$ 15,980</u></u>	34 %
<i>as % of net revenues</i>	51 %	47 %		

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[®]

- Decreased in heparin and enoxaparin component purchase commitments since these components are reserved to the lower of cost or net realizable value at the time of commitment
- These factors were partially offset by an overall increases in labor costs, as well as increased costs for heparin, the starting material for enoxaparin, and a lower average selling price for enoxaparin

	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 %)
Research and development	22,798	18,122	4,676	26 %
Non-operating income (expense), net	(1,672)	3,657	(5,329)	(146 %)

- Selling, distribution, and marketing expenses increased primarily due to increased advertising and 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 restructuring of our subsidiary, Amphastar Nanjing Pharmaceuticals, Co., Ltd. ("ANP"), in 2021
- Research and development expenses increased due to:
 - An increase in expenditure for materials and components, primarily for our AMP-018 and insulin products
 - This increase was partially offset by a decrease in clinical trial expense as a result of a shift in timing for some of our clinical trial studies, as well as a decrease in expenses in China due to the restructuring of ANP in 2021
- The change in non-operating income (expense) net is primarily a result of:
 - Foreign currency fluctuations in 2022
 - A final settlement with Aventis in June 2021 which resulted in the reduction of accrued expense by \$2.7 million

Cash flow provided by operating activities for the six months ended June 30, 2022 was \$53.6 million.

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 June 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, August 8, 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 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 and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, filed with the SEC on May 10, 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		Six Months Ended	
	June 30,		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	<u>38,533</u>	<u>36,816</u>	<u>72,745</u>	<u>71,456</u>
Income from operations	24,823	10,560	46,437	20,866
Non-operating income (expenses), net	<u>(1,672)</u>	<u>3,657</u>	<u>5,747</u>	<u>(1,535)</u>
Income before income taxes	23,151	14,217	52,184	19,331
Income tax provision	<u>5,551</u>	<u>5,595</u>	<u>9,628</u>	<u>6,750</u>
Net income before equity in losses of unconsolidated affiliate	17,600	8,622	42,556	12,581
Equity in losses of unconsolidated affiliate	<u>(254)</u>	<u>-</u>	<u>(957)</u>	<u>-</u>
Net income	<u>\$ 17,346</u>	<u>\$ 8,622</u>	<u>\$ 41,599</u>	<u>\$ 12,581</u>
Net income (loss) attributable to non-controlling interests	<u>\$ -</u>	<u>\$ 855</u>	<u>\$ -</u>	<u>\$ (227)</u>
Net income attributable to Amphastar	<u><u>\$ 17,346</u></u>	<u><u>\$ 7,767</u></u>	<u><u>\$ 41,599</u></u>	<u><u>\$ 12,808</u></u>
Net income per share attributable to Amphastar 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 stockholders:				
Basic	48,864	47,731	48,501	47,626
Diluted	53,227	49,552	52,603	49,535

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

	<u>June 30,</u>	<u>December</u>
	<u>2022</u>	<u>31,</u>
		<u>2021</u>
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	<u>5,898</u>	<u>7,274</u>
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	<u>\$ 723,719</u>	<u>\$ 671,529</u>
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	<u>\$ 723,719</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		Six Months Ended	
June 30,		June 30,	
2022	2021	2022	2021

GAAP net income	\$ 17,346	\$ 8,622	\$ 41,599	\$ 12,581
Adjusted for:				
Intangible amortization	344	277	696	553
Share-based compensation	4,235	6,084	9,257	10,918
Impairment of long-lived assets	-	308	-	314
Reserves for litigation and settlements	(383)	(2,704)	(5,729)	2,991
Income tax provision on pre-tax adjustments	(812)	(306)	(507)	(2,535)
Non-GAAP net income	<u>\$ 20,730</u>	<u>\$ 12,281</u>	<u>\$ 45,316</u>	<u>\$ 24,822</u>
Non-GAAP net loss attributable to non-controlling interests	<u>\$ -</u>	<u>\$ 1,666</u>	<u>\$ -</u>	<u>\$ 654</u>
Non-GAAP net income attributable to Amphastar	<u><u>\$ 20,730</u></u>	<u><u>\$ 10,615</u></u>	<u><u>\$ 45,316</u></u>	<u><u>\$ 24,168</u></u>
Non-GAAP net income per share attributable to Amphastar stockholders:				
Basic	\$ 0.42	\$ 0.22	\$ 0.93	\$ 0.51
Diluted	\$ 0.39	\$ 0.21	\$ 0.86	\$ 0.49
Weighted-average shares used to compute non-GAAP net income per share attributable to Amphastar stockholders:				
Basic	48,864	47,731	48,501	47,626
Diluted	53,227	49,552	52,603	49,535

Three Months Ended June 30, 2022

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Non-operating income (expense), net	Income tax provision	Non-controlling interest adjustments
GAAP	\$ 60,111	\$ 5,756	\$ 9,979	\$ 22,798	\$ (1,672)	\$ 5,551	\$
Intangible amortization	(219)	-	(125)	-	-	-	-
Share-based compensation	(938)	(194)	(2,718)	(385)	-	-	-
Reserves for litigation and settlements	-	-	-	-	(383)	-	-
Income tax provision on pre-tax adjustments	-	-	-	-	-	812	-
Non-GAAP	<u>\$ 58,954</u>	<u>\$ 5,562</u>	<u>\$ 7,136</u>	<u>\$ 22,413</u>	<u>\$ (2,055)</u>	<u>\$ 6,363</u>	<u>\$</u>

Three Months Ended June 30, 2021

	Cost of	Selling, distribution	General and	Research and	Non-operating income	Income	Non-controlling interest
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	<u>revenue</u>	<u>and marketing</u>	<u>administrative</u>	<u>development</u>	<u>(expense), net</u>	<u>tax provision</u>	<u>adjustm</u>
GAAP	\$ 54,287	\$ 4,129	\$ 14,565	\$ 18,122	\$ 3,657	\$ 5,595	\$
Intangible amortization	(244)	-	(33)	-	-	-	-
Share-based compensation	(932)	(147)	(4,568)	(437)	-	-	-
Impairment of long-lived assets	(84)	-	(2)	(222)	-	-	-
Reserves for litigation and settlements	-	-	-	-	(2,704)	-	-
Income tax provision on pre-tax adjustments	-	-	-	-	-	306	-
Non-GAAP	<u>\$ 53,027</u>	<u>\$ 3,982</u>	<u>\$ 9,962</u>	<u>\$ 17,463</u>	<u>\$ 953</u>	<u>\$ 5,901</u>	<u>\$ 1,</u>

Six Months Ended June 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 interc adjustr</u>
GAAP	\$ 124,653	\$ 11,275	\$ 22,449	\$ 39,021	\$ 5,747	\$ 9,628	\$
Intangible amortization	(454)	-	(242)	-	-	-	-
Share-based compensation	(2,323)	(362)	(5,579)	(993)	-	-	-
Reserves for litigation and settlements	-	-	-	-	(5,729)	-	-
Income tax provision on pre-tax adjustments	-	-	-	-	-	507	-
Non-GAAP	<u>\$ 121,876</u>	<u>\$ 10,913</u>	<u>\$ 16,628</u>	<u>\$ 38,028</u>	<u>\$ 18</u>	<u>\$ 10,135</u>	<u>\$</u>

Six Months Ended June 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 interc adjustr</u>
GAAP	\$ 112,361	\$ 8,666	\$ 29,903	\$ 32,887	\$ (1,535)	\$ 6,750	\$
Intangible amortization	(486)	-	(67)	-	-	-	-

Share-based compensation	(2,078)	(274)	(7,536)	(1,030)	-	-
Impairment of long-lived assets	(84)	-	(8)	(222)	-	-
Reserves for litigation and settlements	-	-	(1,295)	-	1,696	-
Income tax provision on pre-tax adjustments	-	-	-	-	-	2,535
Non-GAAP	<u>\$ 109,713</u>	<u>\$ 8,392</u>	<u>\$ 20,997</u>	<u>\$ 31,635</u>	<u>\$ 161</u>	<u>\$ 9,285</u>

SOURCE: Amphastar Pharmaceuticals, Inc.

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