

Amphastar Pharmaceuticals Reports Financial Results for the Three Months Ended September 30, 2021

November 8, 2021

Reports Net Revenues of \$112.2 Million for the Three Months Ended September 30, 2021

RANCHO CUCAMONGA, CA / ACCESSWIRE / November 8, 2021 / Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) ("Amphastar" or the "Company") today reported results for the three months ended September 30, 2021.

Third Quarter Highlights

- Net revenues of \$112.2 million for the third quarter
- GAAP net income of \$29.5 million, or \$0.59 per share, for the third quarter
- Adjusted non-GAAP net income of \$23.0 million, or \$0.46 per share, for the third quarter

Dr. Jack Zhang, Amphastar's President and Chief Executive Officer, commented: "We delivered record sales due to the continued momentum driven by the strength of our glucagon, Primatene Mist[®] and our epinephrine products. These products should continue to be the primary drivers of growth until we receive further approvals for products in our pipeline, which we project will happen in 2022."

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2021	2020	2021	2020
	(in thousands, except per share data)			
Net revenues	\$ 112,198	\$ 83,431	\$ 316,881	\$ 253,925
GAAP net income attributable to Amphastar	\$ 29,548	\$ 3,919	\$ 42,356	\$ 7,676
Adjusted non-GAAP net income attributable to Amphastar*	\$ 22,998	\$ 7,629	\$ 47,166	\$ 23,622
GAAP diluted EPS attributable to Amphastar stockholders	\$ 0.59	\$ 0.08	\$ 0.85	\$ 0.16
Adjusted non-GAAP diluted EPS attributable to Amphastar stockholders*	\$ 0.46	\$ 0.15	\$ 0.95	\$ 0.48

* 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**

	<u>September 30,</u>		<u>Change</u>	
	<u>2021</u>	<u>2020</u>	<u>Dollars</u>	<u>%</u>
	(in thousands)			
Net revenues:				
Primatene Mist [®]	\$ 16,561	\$ 12,988	\$ 3,573	28 %
Epinephrine	13,892	5,370	8,522	159 %
Glucagon	12,189	-	12,189	N/A
Lidocaine	11,649	10,657	992	9 %
Phytonadione	11,591	10,470	1,121	11 %
))
Enoxaparin	8,034	11,647	(3,613)	(31 %)
))
Naloxone	8,028	8,739	(711)	(8 %)
Other finished pharmaceutical products	<u>27,046</u>	<u>21,464</u>	<u>5,582</u>	<u>26 %</u>
Total finished pharmaceutical products net revenues	<u>\$ 108,990</u>	<u>\$ 81,335</u>	<u>\$ 27,655</u>	<u>34 %</u>
API	<u>3,208</u>	<u>2,096</u>	<u>1,112</u>	<u>53 %</u>
Total net revenues	<u>\$ 112,198</u>	<u>\$ 83,431</u>	<u>\$ 28,767</u>	<u>34 %</u>

Changes in net revenues were primarily driven by:

- Primatene Mist[®] increased volumes resulting from the continued success of our advertising campaign
- Glucagon for injection emergency kit, which was launched in the first quarter of 2021
- Epinephrine sales increased due to higher demand as a result of competitor shortages
- Other finished pharmaceutical product sales increased due to higher demand, largely due to competitors shortages

	<u>Three Months Ended</u>		<u>Change</u>	
	<u>September 30,</u>	<u>September 30,</u>	<u>Dollars</u>	<u>%</u>
	(in thousands)			
Net revenues	\$ 112,198	\$ 83,431	\$ 28,767	34 %
Cost of revenues	<u>61,015</u>	<u>46,923</u>	<u>14,092</u>	<u>30 %</u>
Gross profit	<u>\$ 51,183</u>	<u>\$ 36,508</u>	<u>\$ 14,675</u>	<u>40 %</u>
<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[®], epinephrine injection multi-dose vials, and glucagon
- Partially offset by increased cost for heparin, the starting material for enoxaparin, and lower pricing for enoxaparin

	<u>Three Months Ended</u>	<u>Change</u>
	<u>September 30,</u>	

	<u>2021</u>	<u>2020</u>	<u>Dollars</u>	<u>%</u>
	(in thousands)			
Selling, distribution, and marketing	\$ 4,745	\$ 3,673	\$ 1,072	29 %
General and administrative	10,910	11,674	(764)	(7 %)
Research and development	10,759	17,644	(6,885)	(39 %)
Non-operating income, net	12,877	3,561	9,316	262 %

- Selling, distribution, and marketing expenses increased primarily due to the marketing and distribution expenses for Primatene Mist[®]
- General and administrative expenses decreased primarily due to a decrease in legal expenses
- Research and development expenses decreased due to:
 - A decrease in clinical trial expense as a result of the completion of one of our clinical trial studies at the end of 2020
 - A decrease in expenses in China due to the restructuring of ANP and the deconsolidation of Hanxin and its subsidiaries
- Non-operating income, net, increased as a result of the \$13.6 million gain on the deconsolidation of Hanxin relating to the ANP restructuring

Cash flow provided by operating activities for the nine months ended September 30, 2021, was \$57.6 million.

Pipeline Information

The Company currently has five ANDAs on file with the FDA targeting products with a market size of approximately \$2.5 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 \$12 billion. This market information is based on IQVIA data for the 12 months ended September 30, 2021. The Company is currently 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, executive severance expense, and legal settlements, 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 8, 2021, 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, 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, 2020, filed with the SEC on March 15, 2021 and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, filed with the SEC on August 9, 2021. 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:

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

	Three Months		Nine Months Ended	
	Ended		September 30,	
	September 30,	September 30,	September 30,	September 30,
	2021	2020	2021	2020
Net revenues	\$ 112,198	\$ 83,431	\$ 316,881	\$ 253,925
Cost of revenues	<u>61,015</u>	<u>46,923</u>	<u>173,376</u>	<u>147,417</u>
Gross profit	51,183	36,508	143,505	106,508
Operating expenses:				
Selling, distribution, and marketing	4,745	3,673	13,411	10,993
General and administrative	10,910	11,674	40,813	38,344
Research and development	<u>10,759</u>	<u>17,644</u>	<u>43,646</u>	<u>49,096</u>
Total operating expenses	<u>26,414</u>	<u>32,991</u>	<u>97,870</u>	<u>98,433</u>
Income from operations	24,769	3,517	45,635	8,075
Non-operating income, net	<u>12,877</u>	<u>3,561</u>	<u>11,342</u>	<u>3,304</u>
Income before income taxes	37,646	7,078	56,977	11,379
Income tax provision	<u>6,686</u>	<u>2,285</u>	<u>13,436</u>	<u>4,490</u>
Net income	<u>\$ 30,960</u>	<u>\$ 4,793</u>	<u>\$ 43,541</u>	<u>\$ 6,889</u>
Net income (loss) attributable to non-controlling interests	<u>\$ 1,412</u>	<u>\$ 874</u>	<u>\$ 1,185</u>	<u>\$ (787)</u>
Net income attributable to Amphastar	<u>\$ 29,548</u>	<u>\$ 3,919</u>	<u>\$ 42,356</u>	<u>\$ 7,676</u>
Net income per share attributable to Amphastar stockholders:				
Basic	\$ 0.62	\$ 0.08	\$ 0.89	\$ 0.16
Diluted	\$ 0.59	\$ 0.08	\$ 0.85	\$ 0.16

Weighted-average shares used to compute net income per share attributable to Amphastar stockholders:

Basic	48,022	47,496	47,758	46,886
Diluted	50,009	49,848	49,693	48,922

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

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 106,610	\$ 92,642
Restricted cash	235	1,865
Short-term investments	8,021	12,977
Restricted short-term investments	2,200	2,200
Accounts receivable, net	78,090	66,005
Inventories	100,240	96,831
Income tax refunds and deposits	520	385
Prepaid expenses and other assets	7,755	6,777
Total current assets	<u>303,671</u>	<u>279,682</u>
Property, plant, and equipment, net	242,924	260,055
Finance lease right-of-use assets	428	612
Operating lease right-of-use assets	27,663	20,042
Equity method investment	4,193	-
Goodwill and intangible assets, net	39,192	40,615
Other assets	11,610	5,250
Deferred tax assets	21,996	24,980
Total assets	<u>\$ 651,677</u>	<u>\$ 631,236</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 88,911	\$ 95,504
Income taxes payable	3,960	1,077
Current portion of long-term debt	2,256	12,263
Current portion of operating lease liabilities	2,862	3,357
Total current liabilities	<u>97,989</u>	<u>112,201</u>
Long-term reserve for income tax liabilities	4,709	4,709
Long-term debt, net of current portion and unamortized debt issuance costs	75,552	34,186
Long-term operating lease liabilities, net of current portion	25,466	17,464

Deferred tax liabilities	2,901	741
Other long-term liabilities	<u>14,884</u>	<u>13,212</u>
Total liabilities	221,501	182,513
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; 56,051,662 and 47,982,690 shares issued and outstanding as of September 30, 2021 and 54,760,922 and 47,495,439 shares issued and outstanding as of December 31, 2020, respectively	6	5
Additional paid-in capital	412,917	410,061
Retained earnings	160,577	117,773
Accumulated other comprehensive loss	(6,277)	(3,721)
Treasury stock	<u>(137,047)</u>	<u>(121,812)</u>
Total Amphastar Pharmaceuticals, Inc. stockholders' equity	430,176	402,306
Non-controlling interests	<u>-</u>	<u>46,417</u>
Total equity	<u>430,176</u>	<u>448,723</u>
Total liabilities and stockholders' equity	<u>\$ 651,677</u>	<u>\$ 631,236</u>

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2021	2020	2021	2020
GAAP net income	\$ 30,960	\$ 4,793	\$ 43,541	\$ 6,889
Adjusted for:				
Intangible amortization	377	262	930	771
Share-based compensation	3,919	4,370	14,837	13,846
Impairment of long-lived assets	25	130	339	160
Gain on ANP Restructuring	(13,587)	-	(13,587)	-
Expense related to executive separation agreement	-	-	-	4,869
Reserves for litigation and settlements	-	-	2,991	-
Income tax (benefit) provision on pre-tax adjustments	921	(943)	(1,614)	(3,392)
Non-GAAP net income	<u>\$ 22,615</u>	<u>\$ 8,612</u>	<u>\$ 47,437</u>	<u>\$ 23,143</u>
Non-GAAP net income (loss) attributable to non-controlling interests	<u>\$ (383)</u>	<u>\$ 983</u>	<u>\$ 271</u>	<u>\$ (479)</u>
Non-GAAP net income attributable to Amphastar	<u>\$ 22,998</u>	<u>\$ 7,629</u>	<u>\$ 47,166</u>	<u>\$ 23,622</u>

Non-GAAP net income per share attributable to Amphastar stockholders:

Basic	\$ 0.48	\$ 0.16	\$ 0.99	\$ 0.50
Diluted	\$ 0.46	\$ 0.15	\$ 0.95	\$ 0.48

Weighted-average shares used to compute non-GAAP net income per share attributable to Amphastar stockholders:

Basic	48,022	47,496	47,758	46,886
Diluted	50,009	49,848	49,693	48,922

Three 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 (benefit)</u>	<u>Non-controlling interest adjustment</u>
GAAP	\$ 61,015	\$ 4,745	\$ 10,910	\$ 10,759	\$ 12,877	\$ 6,686	\$ 1,412
Intangible amortization	(242)	-	(135)	-	-	-	4
Share-based compensation	(889)	(164)	(2,533)	(333)	-	-	8
Impairment of long-lived assets	-	-	(25)	-	-	-	4
Gain on ANP Restructuring	-	-	-	-	(13,587)	-	(2,062)
Income tax provision (benefit) on pre-tax adjustments	-	-	-	-	-	(921)	251
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>\$ (383)</u>

Three Months Ended September 30, 2020

	<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 (benefit)</u>	<u>Non-controlling interest adjustment</u>
GAAP	\$ 46,923	\$ 3,673	\$ 11,674	\$ 17,644	\$ 3,561	\$ 2,285	\$ 874
Intangible amortization	(229)	-	(33)	-	-	-	12
Share-based compensation	(947)	(120)	(2,899)	(404)	-	-	117
Impairment of long-lived assets	(19)	-	(111)	-	-	-	8
Income tax provision (benefit) on	-	-	-	-	-	943	(28)

pre-tax
adjustments

Non-GAAP \$ 45,728 \$ 3,553 \$ 8,631 \$ 17,240 \$ 3,561 \$ 3,228 \$ 983

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 (benefit)</u>	<u>Non- controlling interest adjustment</u>
GAAP	\$ 173,376	\$ 13,411	\$ 40,813	\$ 43,646	\$ 11,342	\$ 13,436	\$ 1,188
Intangible amortization	(728)	-	(202)	-	-	-	2
Share-based compensation	(2,967)	(438)	(10,069)	(1,363)	-	-	87
Impairment of long-lived assets	(84)	-	(33)	(222)	-	-	-
Gain on ANP Restructuring	-	-	-	-	(13,587)	-	(2,066)
Reserves for litigation and settlements	-	-	(1,295)	-	1,696	-	-
Income tax provision (benefit) on pre- tax adjustments	-	-	-	-	-	1,614	24
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>\$ 27</u>

Nine Months Ended September 30, 2020

	<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 (benefit)</u>	<u>Non- controlling interest adjustment</u>
GAAP	\$ 147,417	\$ 10,993	\$ 38,344	\$ 49,096	\$ 3,304	\$ 4,490	\$ (787)
Intangible amortization	(670)	-	(101)	-	-	-	34
Share-based compensation	(3,276)	(350)	(8,851)	(1,369)	-	-	330
Impairment of long-lived assets	(32)	-	(128)	-	-	-	15
Expense related to executive separation agreement	-	-	(4,869)	-	-	-	-
Income tax provision (benefit) on	-	-	-	-	-	3,392	(71)

pre-tax adjustments							
Non-GAAP	<u>\$ 143,439</u>	<u>\$ 10,643</u>	<u>\$ 24,395</u>	<u>\$ 47,727</u>	<u>\$ 3,304</u>	<u>\$ 7,882</u>	<u>\$ (479)</u>

SOURCE: Amphastar Pharmaceuticals, Inc.

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