

# Amphastar Pharmaceuticals Reports Financial Results for the Three Months Ended September 30, 2020

November 6, 2020

RANCHO CUCAMONGA, Calif., Nov. 06, 2020 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc. (NASDAQ: AMPH) (“Amphastar” or the “Company”) today reported results for the three months ended September 30, 2020.

## Third Quarter Highlights

- Net revenues of \$83.4 million for the third quarter
- GAAP net income of \$3.9 million, or \$0.08 per share, for the third quarter
- Adjusted non-GAAP net income of \$7.6 million, or \$0.15 per share, for the third quarter

Dr. Jack Zhang, Amphastar’s President and Chief Executive Officer, commented: “We once again demonstrated growth due to the continued strength of Primatene Mist<sup>®</sup> and the re-launch of our epinephrine vial product. Additionally, we are very excited about the significant progress on our intranasal epinephrine product as this product once again illustrates our scientific and technical strengths.”

	Three Months Ended		Nine Months Ended	
	September 30, 2020	2019	September 30, 2020	2019
	<b>(in thousands, except per share data)</b>			
Net revenues	\$ 83,431	\$ 80,137	\$ 253,925	\$ 238,974
GAAP net income attributable to Amphastar	\$ 3,919	\$ 1,310	\$ 7,676	\$ 49,965
Adjusted non-GAAP net income attributable to Amphastar*	\$ 7,629	\$ 5,169	\$ 23,622	\$ 14,171
GAAP diluted EPS attributable to Amphastar stockholders	\$ 0.08	\$ 0.03	\$ 0.16	\$ 1.00
Adjusted non-GAAP diluted EPS attributable to Amphastar stockholders*	\$ 0.15	\$ 0.10	\$ 0.48	\$ 0.28

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\* 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

	<b>Three Months Ended</b>		<b>Change</b>	
	<b>September 30,</b>	<b>September 30,</b>	<b>Dollars</b>	<b>%</b>
	<b>2020</b>	<b>2019</b>		
	<b>(in thousands)</b>			
<b>Net revenues:</b>				
Primatene Mist <sup>®</sup>	\$ 12,988	\$ 3,654	\$ 9,334	255 %
Enoxaparin	11,647	9,573	2,074	22 %
Lidocaine	10,657	11,670	(1,013 )	(9)%
Phytonadione	10,470	10,916	(446 )	(4)%
Naloxone	8,739	10,613	(1,874 )	(18)%
Epinephrine	5,370	3,756	1,614	43 %
Other finished pharmaceutical products	21,464	25,547	(4,083 )	(16)%
Total finished pharmaceutical products net revenues	\$ 81,335	\$ 75,729	\$ 5,606	7 %
API	2,096	4,408	(2,312 )	(52)%
Total net revenues	\$ 83,431	\$ 80,137	\$ 3,294	4 %

Changes in net revenues were primarily driven by:

- Increased sales of Primatene Mist<sup>®</sup> primarily resulting from
  - The continued success of our nationwide television, radio, and digital marketing campaign
  - Growth in online sales through Amazon
  - Launching Primatene Mist<sup>®</sup> at Kroger, the largest grocery store chain in the United States
- Increased sales of enoxaparin primarily due to higher unit volumes
- Increased epinephrine sales due to the launch of our recently approved epinephrine injection, USP 30mg/30mL multi-dose vial product during the second quarter of 2020
- Decreased naloxone sales due to lower average selling price because of increased competition
- Decreased lidocaine and other finished pharmaceutical product sales due to lower demand, largely due to competitors returning to their normal distribution levels

	<b>Three Months Ended</b>		<b>Change</b>	
	<b>September 30,</b>	<b>September 30,</b>	<b>Dollars</b>	<b>%</b>
	<b>2020</b>	<b>2019</b>		
	<b>(in thousands)</b>			
Net revenues	\$ 83,431	\$ 80,137	\$ 3,294	4%
Cost of revenues	46,923	44,885	2,038	5%
Gross profit	\$ 36,508	\$ 35,252	\$ 1,256	4%
<i>as % of net revenues</i>	<i>44%</i>	<i>44%</i>		

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

- Increased sales of Primatene Mist<sup>®</sup> and the launch of epinephrine injection multi-dose vial, both of which have higher margins

- Decreased sales of naloxone and other finished pharmaceutical products with higher margins

	<b>Three Months Ended</b>		<b>Change</b>	
	<b>September 30,</b>	<b>September 30,</b>	<b>Dollars</b>	<b>%</b>
	<b>2020</b>	<b>2019</b>		
	<b>(in thousands)</b>			
Selling, distribution, and marketing	\$ 3,673	\$ 3,221	\$ 452	14 %
General and administrative	11,674	11,021	653	6 %
Research and development	17,644	18,606	(962 )	(5)%

- Marketing and distribution expenses increased primarily related to Primatene Mist<sup>®</sup>, including the cost of a national television, radio and digital marketing campaign, which began in July 2019
- General and administrative expenses increased primarily due to increased legal expenses
- Research and development expenses decreased due to lower expenses in China, partially offset by increased domestic expenses related to our generic inhalation product pipeline, our insulin biosimilar programs and our intranasal epinephrine program

Cash flow provided by operating activities for the nine months ended September 30, 2020, was \$40.4 million.

#### Impact of COVID-19

As a result of the COVID-19 pandemic, during the first quarter and second quarter, sales of Primatene Mist<sup>®</sup> and certain hospital products increased, while sales of certain products frequently used in elective procedures, such as Cortrosyn<sup>®</sup> and lidocaine jelly, decreased. During the third quarter of 2020, sales of these products returned to levels closer to those experienced prior to the COVID-19 pandemic. The Company has not experienced any significant negative impacts on its cash flows or operations as a result of the COVID-19 pandemic. 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. It is not possible at this time to estimate the complete impact that the COVID-19 pandemic could have on our business, including our customers and suppliers, as the impact will depend on future developments of the pandemic, which are highly uncertain and cannot be predicted.

#### Pipeline Information

The Company currently has five ANDAs on file with the FDA targeting products with a market size of approximately \$1.5 billion, three biosimilar products in development targeting products with a market size of approximately \$13 billion, and nine 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, 2020. The Company is currently developing multiple proprietary products for injectable and intranasal dosage forms.

Amphastar's Chinese subsidiary, ANP, currently has 14 Drug Master Files, or DMFs, on file with the FDA and is developing several additional DMFs.

#### Company Information

Amphastar is a specialty 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](http://www.amphastar.com).

Amphastar's logo and other trademarks or service marks of Amphastar, including, but not limited to Amphastar<sup>®</sup>, Primatene Mist<sup>®</sup>, Amphadase<sup>®</sup> and Cortrosyn<sup>®</sup>, 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 6, 2020, at 9:00 a.m. Pacific Time.

To access the conference call, dial toll-free (877) 881-2595 or (315) 625-3083 for international callers, five minutes before the conference. The passcode for the conference call is 7086853.

The call can also be accessed on the Investors page on the Company's website at [www.amphastar.com](http://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 the Company's expectations regarding future financial performance, backlog, sales and marketing of its 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 its pipeline of product candidates, its share buyback program and other future events, such as the impact of the COVID-19 pandemic 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 historical facts but rather are based on Amphastar’s historical performance and its current expectations, estimates, and projections regarding Amphastar’s 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 the Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 16, 2020. 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, 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 the Company’s website at <http://ir.amphastar.com> and on the SEC’s website at [www.sec.gov](http://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 Amphastar’s 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)**

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30, 2020</b>	<b>2019</b>	<b>September 30, 2020</b>	<b>2019</b>
Net revenues	\$83,431	\$80,137	\$253,925	\$238,974
Cost of revenues	46,923	44,885	147,417	140,432
Gross profit	36,508	35,252	106,508	98,542
Operating expenses:				
Selling, distribution, and marketing	3,673	3,221	10,993	9,354
General and administrative	11,674	11,021	38,344	39,774
Research and development	17,644	18,606	49,096	49,209
Total operating expenses	32,991	32,848	98,433	98,337

Income from operations	3,517	2,404	8,075	205
Non-operating income (expenses), net	3,561	(822 )	3,304	58,837
Income before income taxes	7,078	1,582	11,379	59,042
Income tax provision	2,285	598	4,490	13,292
Net income	\$4,793	\$984	\$6,889	\$45,750
Net income (loss) attributable to non-controlling interests	\$874	\$(326 )	\$(787 )	\$(4,215 )
Net income attributable to Amphastar	\$3,919	\$1,310	\$7,676	\$49,965
Net income per share attributable to Amphastar stockholders:				
Basic	\$0.08	\$0.03	\$0.16	\$1.06
Diluted	\$0.08	\$0.03	\$0.16	\$1.00
Weighted-average shares used to compute net income per share attributable to Amphastar stockholders:				
Basic	47,496	47,239	46,886	47,030
Diluted	49,848	50,075	48,922	50,128

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

	September 30, 2020 (unaudited)	December 31, 2019
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 87,910	\$ 73,685
Restricted cash	1,865	1,865
Short-term investments	10,873	11,675
Restricted short-term investments	2,200	2,290
Accounts receivable, net	52,382	45,376
Inventories	108,870	110,501
Income tax refunds and deposits	1,455	311
Prepaid expenses and other assets	10,986	9,538
Total current assets	276,541	255,241

Property, plant, and equipment, net	245,881	233,856
Finance lease right-of-use assets	693	887
Operating lease right-of-use assets	20,256	18,805
Goodwill and intangible assets, net	40,377	41,153
Other assets	7,735	11,156
Deferred tax assets	22,235	25,873
Total assets	\$ 613,718	\$ 586,971

#### **LIABILITIES AND STOCKHOLDERS' EQUITY**

##### Current liabilities:

Accounts payable and accrued liabilities	\$ 79,292	\$ 77,051
Income taxes payable	1,619	2,042
Current portion of long-term debt	12,167	7,741
Current portion of operating lease liabilities	3,639	3,175
Total current liabilities	96,717	90,009

Long-term reserve for income tax liabilities	3,425	3,425
Long-term debt, net of current portion	32,903	39,394
Long-term operating lease liabilities, net of current portion	17,534	16,315
Deferred tax liabilities	823	867
Other long-term liabilities	11,354	9,433
Total liabilities	162,756	159,443

##### 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; 54,623,837 and 47,534,215 shares issued and outstanding as of September 30, 2020 and 52,495,483 and 46,576,968 shares issued and outstanding as of December 31, 2019, respectively	5	5
Additional paid-in capital	404,084	367,305
Retained earnings	124,046	116,370
Accumulated other comprehensive loss	(4,478 )	(4,687 )
Treasury stock	(118,425 )	(97,627 )
Total Amphastar Pharmaceuticals, Inc. stockholders' equity	405,232	381,366
Non-controlling interests	45,730	46,162
Total equity	450,962	427,528
Total liabilities and stockholders' equity	\$ 613,718	\$ 586,971

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

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30, 2020</b>	<b>2019</b>	<b>September 30, 2020</b>	<b>2019</b>
GAAP net income	\$4,793	\$984	\$6,889	\$45,750
Adjusted for:				
Intangible amortization	262	251	771	777
Share-based compensation	4,370	4,294	13,846	13,000
Impairment of long-lived assets	130	11	160	194
Expense related to executive separation agreement	—	—	4,869	—
Gain on litigation settlement	—	—	—	(59,900)
Income tax (benefit) provision on pre-tax adjustments	(943 )	(598 )	(3,392 )	10,422
Non-GAAP net income	\$8,612	\$4,942	\$23,143	\$10,243
Non-GAAP net income (loss) attributable to non-controlling interests	\$983	\$(227 )	\$(479 )	\$(3,928 )
Non-GAAP net income attributable to Amphastar	\$7,629	\$5,169	\$23,622	\$14,171
Non-GAAP net income per share attributable to Amphastar stockholders:				
Basic	\$0.16	\$0.11	\$0.50	\$0.30
Diluted	\$0.15	\$0.10	\$0.48	\$0.28
Weighted-average shares used to compute non-GAAP net income per share attributable to Amphastar stockholders:				
Basic	47,496	47,239	46,886	47,030
Diluted	49,848	50,075	48,922	50,128

### Three Months Ended September 30, 2020

	<b>Cost of revenue</b>	<b>Selling, distribution and marketing</b>	<b>General and administrative</b>	<b>Research and development</b>	<b>Non-operating income (expense), net</b>	<b>Income tax provision (benefit)</b>	<b>Non-controlling interest adjustment</b>
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 pre-tax adjustments	—	—	—	—	—	943	(28 )
Non-GAAP	\$45,728	\$ 3,553	\$ 8,631	\$ 17,240	\$ 3,561	\$ 3,228	\$ 983

### Reconciliation of Non-GAAP Measures (continued)

#### Three Months Ended September 30, 2019

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Non-operating income (expense), net	Income tax provision (benefit)	Non-controlling interest adjustment
GAAP	\$44,885	\$ 3,221	\$ 11,021	\$ 18,606	\$ (822 )	\$ 598	\$ (326 )
Intangible amortization	(216 )	—	(35 )	—	—	—	12
Share-based compensation	(701 )	(96 )	(3,138 )	(359 )	—	—	107
Impairment of long-lived assets	(4 )	—	(11 )	4	—	—	6
Income tax provision (benefit) on pre-tax adjustments	—	—	—	—	—	598	(26 )
Non-GAAP	\$43,964	\$ 3,125	\$ 7,837	\$ 18,251	\$ (822 )	\$ 1,196	\$ (227 )

#### Nine Months Ended September 30, 2020

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Non-operating income (expense), net	Income tax provision (benefit)	Non-controlling interest adjustment
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 pre-tax adjustments	—	—	—	—	—	3,392	(71 )
Non-GAAP	\$ 143,439	\$ 10,643	\$ 24,395	\$ 47,727	\$ 3,304	\$ 7,882	\$ (479 )

#### Nine Months Ended September 30, 2019

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Non-operating income (expense), net	Income tax provision (benefit)	Non-controlling interest adjustment
GAAP	\$ 140,432	\$ 9,354	\$ 39,774	\$ 49,209	\$ 58,837	\$ 13,292	\$ (4,215 )
Intangible amortization	(669 )	—	(108 )	—	—	—	34
Share-based compensation	(2,939 )	(285 )	(8,577 )	(1,199 )	—	—	257
Impairment of long-lived assets	(69 )	—	(23 )	(102 )	—	—	55
Gain on litigation settlement	—	—	—	—	(59,900)	—	—
Income tax benefit on pre-tax adjustments	—	—	—	—	—	(10,422)	(59 )
Non-GAAP	\$ 136,755	\$ 9,069	\$ 31,066	\$ 47,908	\$ (1,063 )	\$ 2,870	\$ (3,928 )

Source: Amphastar Pharmaceuticals, Inc.