

Source: Amphastar Pharmaceuticals, Inc.

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

Reports Net Revenues of \$83.4 Million for the Three Months Ended September 30, 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[®] 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, | | September 30, | |
| | 2020 | 2019 | 2020 | 2019 |
| | (in thousands, except per share data) | | | |
| 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 |

* 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 | | Change | |
|-----------------------------|--------------------|----------|----------|-------|
| | September 30, | | Dollars | % |
| | 2020 | 2019 | | |
| | (in thousands) | | | |
| Net revenues: | | | | |
| Primatene Mist [®] | \$ 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 | <u>\$81,335</u> | <u>\$75,729</u> | <u>\$ 5,606</u> | <u>7 %</u> |
| API | <u>2,096</u> | <u>4,408</u> | <u>(2,312)</u> | <u>(52)%</u> |
| Total net revenues | <u><u>\$83,431</u></u> | <u><u>\$80,137</u></u> | <u><u>\$ 3,294</u></u> | <u><u>4 %</u></u> |

Changes in net revenues were primarily driven by:

- Increased sales of Primatene Mist[®] primarily resulting from
 - The continued success of our nationwide television, radio, and digital marketing campaign
 - Growth in online sales through Amazon
 - Launching Primatene Mist[®] 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

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

| | Three Months Ended | | Change | |
|--------------------------------------|--------------------|----------|---------|------|
| | September 30, | | Dollars | % |
| | 2020 | 2019 | | |
| | (in thousands) | | | |
| 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[®], 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[®] and certain hospital products increased, while sales of certain products frequently used in elective procedures, such as Cortrosyn[®] 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.

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 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.

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. 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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 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 | | Nine Months Ended | |
|--------------------------------------|---------------------------|-------------|--------------------------|-------------|
| | September 30, | | September 30, | |
| | 2020 | 2019 | 2020 | 2019 |
| 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 | <u>\$ 4,793</u> | <u>\$ 984</u> | <u>\$ 6,889</u> | <u>\$ 45,750</u> |
| Net income (loss) attributable to non-controlling interests | \$ 874 | \$ (326) | \$ (787) | \$ (4,215) |
| Net income attributable to Amphastar | <u>\$ 3,919</u> | <u>\$ 1,310</u> | <u>\$ 7,676</u> | <u>\$ 49,965</u> |
| 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)

| | <u>September 30,</u> <u>2020</u> <u>(unaudited)</u> | <u>December 31,</u> <u>2019</u> |
|---|---|------------------------------------|
| ASSETS | | |
| 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 | <u>276,541</u> | <u>255,241</u> |
| 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 | <u>\$ 613,718</u> | <u>\$ 586,971</u> |
| 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 | <u>96,717</u> | <u>90,009</u> |
| 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 | <u>162,756</u> | <u>159,443</u> |
| 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 | <u>405,232</u> | <u>381,366</u> |
| Non-controlling interests | 45,730 | 46,162 |
| Total equity | <u>450,962</u> | <u>427,528</u> |
| Total liabilities and stockholders' equity | <u>\$ 613,718</u> | <u>\$ 586,971</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, | |
| | 2020 | 2019 | 2020 | 2019 |
| 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 | <u>\$ 8,612</u> | <u>\$ 4,942</u> | <u>\$ 23,143</u> | <u>\$ 10,243</u> |
| Non-GAAP net income (loss) attributable to non-controlling interests | \$ 983 | \$ (227) | \$ (479) | \$ (3,928) |

| | | | | |
|---|-----------------|-----------------|------------------|------------------|
| Non-GAAP net income attributable to Amphastar | <u>\$ 7,629</u> | <u>\$ 5,169</u> | <u>\$ 23,622</u> | <u>\$ 14,171</u> |
|---|-----------------|-----------------|------------------|------------------|

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

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

Reconciliation of Non-GAAP Measures (continued)

Three Months Ended September 30, 2019

| | Selling, Cost of revenue | 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 | <u>\$43,964</u> | <u>\$ 3,125</u> | <u>\$ 7,837</u> | <u>\$ 18,251</u> | <u>\$ (822)</u> | <u>\$ 1,196</u> | <u>\$ (227)</u> |

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 | <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> |

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 | (2,939) | (285) | (8,577) | (1,199) | — | — | 257 |

| | | | | | | | |
|---|-------------------|-----------------|------------------|------------------|-------------------|-----------------|-------------------|
| compensation | | | | | | | |
| 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 | <u>\$ 136,755</u> | <u>\$ 9,069</u> | <u>\$ 31,066</u> | <u>\$ 47,908</u> | <u>\$ (1,063)</u> | <u>\$ 2,870</u> | <u>\$ (3,928)</u> |