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Amphastar Pharmaceuticals Reports Financial Results for the Three Months Ended September 30, 2018

Reports Net Revenues of \$75.5 Million for the Three Months Ended September 30, 2018

RANCHO CUCAMONGA, Calif., Nov. 08, 2018 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc. (NASDAQ: AMPH) ("Amphastar" or the "Company") today reported results for the three months ended September 30, 2018.

Third Quarter Highlights

- Net revenues of \$75.5 million for the third quarter
- GAAP net income attributable to Amphastar of \$2.4 million, or \$0.05 per diluted share, for the third quarter
- Adjusted non-GAAP net income attributable to Amphastar of \$5.7 million, or \$0.12 per diluted share, for the third quarter

Dr. Jack Zhang, Amphastar's CEO, commented: "This is a very exciting time for Amphastar with our recent approval of Primatene[®] Mist, our strong sales growth in the quarter and our return to profitability."

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
	(in thousands, except per share data)			
Net revenues	\$ 75,543	\$ 57,916	\$ 204,976	\$ 179,773
GAAP net income (loss) attributable to Amphastar	\$ 2,389	\$ 99	\$ (7,605)	\$ 2,860
Adjusted non-GAAP net income attributable to Amphastar*	\$ 5,721	\$ 3,419	\$ 4,168	\$ 13,219
GAAP diluted EPS attributable to Amphastar shareholders	\$ 0.05	\$ 0.00	\$ (0.16)	\$ 0.06
Adjusted non-GAAP diluted EPS attributable to Amphastar shareholders*	\$ 0.12	\$ 0.07	\$ 0.09	\$ 0.28

* Adjusted non-GAAP net income attributable to Amphastar and Adjusted non-GAAP diluted EPS attributable to Amphastar shareholders 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	%
	2018	2017		
	(in thousands)			
Net revenues:				
Enoxaparin	\$ 18,564	\$ 6,549	\$ 12,015	183 %
Lidocaine	9,875	9,596	279	3 %
Naloxone	9,432	12,709	(3,277)	(26) %

Phytonadione	8,968	9,352	(384)	(4) %
Medroxyprogesterone	7,552	—	7,552	N/A
Epinephrine	1,881	2,027	(146)	(7) %
Other finished pharmaceutical products	15,495	14,222	1,273	9 %
Total finished pharmaceutical products net revenues	<u>\$ 71,767</u>	<u>\$ 54,455</u>	<u>\$ 17,312</u>	<u>32 %</u>
API	<u>3,776</u>	<u>3,461</u>	<u>315</u>	<u>9 %</u>
Total net revenues	<u>\$ 75,543</u>	<u>\$ 57,916</u>	<u>\$ 17,627</u>	<u>30 %</u>

Changes in net revenues were primarily driven by:

- Increased sales of enoxaparin, primarily driven by higher average selling prices, as well as an increase in unit volumes
- Sales of medroxyprogesterone acetate which launched in the first quarter of 2018 so was not included in third quarter of 2017 results
- Decreased sales of naloxone primarily due to lower unit volumes

	Three Months Ended September 30,		Change	
	2018	2017 (in thousands)	Dollars	%
Net Revenues	\$ 75,543	\$ 57,916	\$ 17,627	30 %
Cost of Revenues	46,283	37,363	8,920	24 %
Gross Profit	<u>\$ 29,260</u>	<u>\$ 20,553</u>	<u>\$ 8,707</u>	42 %
<i>as % of net revenues</i>	39%	35%		

Changes in cost of revenues and the resulting increase to gross margin were primarily due to:

- The launch of medroxyprogesterone acetate and isoproterenol hydrochloride, which both have higher margins
- Higher average selling prices of enoxaparin

	Three Months Ended September 30,		Change	
	2018	2017 (in thousands)	Dollars	%
Selling, distribution and marketing	\$ 1,963	\$ 1,756	\$ 207	12 %
General and administrative	13,407	11,665	1,742	15 %
Research and development	11,340	10,075	1,265	13 %

- Selling, distribution and marketing expenses increased primarily due to increased freight costs
- General and administrative expenses increased primarily due to higher legal fees
- Research and development expenses increased primarily due to expenditures related to the expansion of our ANP facility as well as an increase in FDA, or Food and Drug Administration filing fees

Cash flow provided by operating activities for the nine months ended September 30, 2018 was \$28.7 million.

Certain GAAP and non-GAAP measures for comparative periods in 2017 were revised for immaterial errors.

Pipeline Information

The Company currently has four abbreviated new drug applications, or ANDAs, filed with the FDA targeting products with a market size of approximately \$0.7 billion, three biosimilar products in development targeting products with a market size of over \$14 billion, and 11 generic products in development targeting products with a market size of over \$12 billion. This market information is based on IQVIA data for the 12 months ended September 30, 2018. The Company's proprietary pipeline includes a new drug application for intranasal naloxone. The Company is currently developing four other proprietary products, which include injectable, inhalation and intranasal dosage forms.

Amphastar's Chinese subsidiary, Amphastar Nanjing Pharmaceuticals, currently has nine Drug Master Files, or DMFs, on file with the FDA and is developing nine 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 is available at the Company's website at www.amphastar.com.

Amphastar's logo and other trademarks or service marks of Amphastar Pharmaceuticals, Inc., including, but not limited to Primatene[®], Amphadase[®] and Cortrosyn[®], are the property of Amphastar Pharmaceuticals, Inc.

Non-GAAP Financial Measures

To supplement its consolidated financial statements, which are prepared and presented in accordance with U.S. generally accepted accounting principles, or 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 Pharmaceuticals, Inc. and (ii) Adjusted non-GAAP diluted EPS attributed to Amphastar Pharmaceuticals, Inc. shareholders, which exclude amortization expense, share-based compensation, and impairment charges 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, 2018, at 2:00 p.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 5587773.

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, 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. 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. 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. Amphastar undertakes no obligation to revise or update information 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:

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,	
	2018	2017	2018	2017
Net revenues	\$ 75,543	\$ 57,916	\$ 204,976	\$ 179,773
Cost of revenues	46,283	37,363	132,680	109,754
Gross profit	29,260	20,553	72,296	70,019
Operating (income) expenses:				
Selling, distribution, and marketing	1,963	1,756	5,560	4,831
General and administrative	13,407	11,665	36,074	35,237
Research and development	11,340	10,075	40,830	32,117
Gain on sale of intangible assets	—	—	—	(2,643)
Total operating expenses	26,710	23,496	82,464	69,542
Income (loss) from operations	2,550	(2,943)	(10,168)	477
Non-operating income (expense), net	24	829	(347)	1,917
Income (loss) before income taxes	2,574	(2,114)	(10,515)	2,394
Income tax expense (benefit)	958	(2,213)	(2,137)	(466)
Net income (loss)	\$ 1,616	\$ 99	\$ (8,378)	\$ 2,860
Net loss attributable to non-controlling interests	\$ (773)	\$ —	\$ (773)	\$ —
Net income (loss) attributable to Amphastar	\$ 2,389	\$ 99	\$ (7,605)	\$ 2,860
Net income (loss) per share attributable to Amphastar shareholders:				
Basic	\$ 0.05	\$ 0.00	\$ (0.16)	\$ 0.06
Diluted	\$ 0.05	\$ 0.00	\$ (0.16)	\$ 0.06
Weighted-average shares used to compute net income (loss) per share attributable to Amphastar shareholders:				
Basic	46,241	46,101	46,437	46,065
Diluted	48,281	48,215	46,437	48,046

The comparative periods in 2017 were revised for immaterial errors.

Table II
Amphastar Pharmaceuticals, Inc.

Condensed Consolidated Balance Sheet
(Unaudited; in thousands, except per share data)

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 68,734	\$ 65,594
Short-term investments	2,829	2,635
Restricted cash and short-term investments	4,155	4,155
Accounts receivable, net	43,816	35,996
Inventories	65,414	63,609
Income tax refunds and deposits	3,186	6,036
Prepaid expenses and other assets	6,670	9,753
Total current assets	194,804	187,778
Property, plant, and equipment, net	202,526	180,545
Goodwill and intangible assets, net	42,727	45,140
Other assets	11,127	8,663
Deferred tax assets	29,458	28,946
Total assets	\$ 480,642	\$ 451,072
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 76,362	\$ 57,555
Income taxes payable	1,667	3,325
Current portion of long-term debt and capital leases	18,592	6,312
Total current liabilities	96,621	67,192
Long-term reserve for income tax liabilities	879	879
Long-term debt and capital leases, net of current portion	32,606	40,844
Deferred tax liabilities	1,303	1,361
Other long-term liabilities	7,963	7,060
Total liabilities	139,372	117,336
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; 50,883,467 and 46,159,652 shares issued and outstanding as of September 30, 2018 and 50,039,212 and 46,623,581 shares issued and outstanding as of December 31, 2017, respectively	5	5
Additional paid-in capital	330,265	313,891
Retained earnings	65,618	72,642
Accumulated other comprehensive loss	(3,576)	(2,100)
Treasury stock	(72,896)	(50,702)
Total Amphastar stockholders' equity	319,416	333,736
Non-controlling interests	21,854	—
Total equity	341,270	333,736
Total liabilities and stockholders' equity	\$ 480,642	\$ 451,072

The December 31, 2017 figures were revised for immaterial errors.

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

	<u>Three Months Ended</u> <u>September 30,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
GAAP net income (loss)	\$ 1,616	\$ 99	\$ (8,378)	\$ 2,860
Adjusted for:				
Intangible amortization	271	713	1,722	2,139
Share-based compensation	3,908	4,157	12,770	12,905
Impairment of long-lived assets	10	—	390	—
Income tax expense on pre-tax adjustments	(788)	(1,550)	(3,040)	(4,685)
Non-GAAP net income	<u>\$ 5,017</u>	<u>\$ 3,419</u>	<u>\$ 3,464</u>	<u>\$ 13,219</u>
Non-GAAP net loss attributable to non-controlling interests	\$ (704)	\$ —	\$ (704)	\$ —
Non-GAAP net income attributable to Amphastar	<u>\$ 5,721</u>	<u>\$ 3,419</u>	<u>\$ 4,168</u>	<u>\$ 13,219</u>
Non-GAAP net income per share attributable to Amphastar shareholders:				
Basic	\$ 0.12	\$ 0.07	\$ 0.09	\$ 0.29
Diluted	\$ 0.12	\$ 0.07	\$ 0.09	\$ 0.28
Weighted-average shares used to compute non-GAAP net income per share attributable to Amphastar shareholders:				
Basic	46,241	46,101	46,437	46,065
Diluted	48,281	48,215	48,713	48,046

	<u>Three Months Ended September 30, 2018</u>				
	<u>Cost of revenue</u>	<u>Selling, distribution and marketing</u>	<u>General and administrative</u>	<u>Research and development</u>	<u>Income tax expense (benefit)</u>
GAAP	\$ 46,283	\$ 1,963	\$ 13,407	\$ 11,340	\$ 958
Intangible amortization	(230)	—	(41)	—	—
Share-based compensation	(884)	(86)	(2,615)	(323)	—
Impairment of long-lived assets	—	—	—	(10)	—
Income tax expense on pre-tax adjustments	—	—	—	—	788
Non-GAAP	<u>\$ 45,169</u>	<u>\$ 1,877</u>	<u>\$ 10,751</u>	<u>\$ 11,007</u>	<u>\$ 1,746</u>

Three Months Ended September 30, 2017

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Income tax expense (benefit)
GAAP	\$ 37,363	\$ 1,756	\$ 11,665	\$ 10,075	\$ (2,213)
Intangible amortization	(677)	—	(36)	—	—
Share-based compensation	(815)	(88)	(2,948)	(306)	—
Income tax expense on pre-tax adjustments	—	—	—	—	1,550
Non-GAAP	<u>\$ 35,871</u>	<u>\$ 1,668</u>	<u>\$ 8,681</u>	<u>\$ 9,769</u>	<u>\$ (663)</u>

The comparative periods in 2017 were revised for immaterial errors.

Reconciliation of Non-GAAP Measures (continued)

Nine Months Ended September 30, 2018

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Income tax expense (benefit)
GAAP	\$ 132,680	\$ 5,560	\$ 36,074	\$ 40,830	\$ (2,137)
Intangible amortization	(1,602)	—	(120)	—	—
Share-based compensation	(3,025)	(297)	(8,251)	(1,197)	—
Impairment of long-lived assets	(77)	—	(4)	(309)	—
Income tax expense on pre-tax adjustments	—	—	—	—	3,040
Non-GAAP	<u>\$ 127,976</u>	<u>\$ 5,263</u>	<u>\$ 27,699</u>	<u>\$ 39,324</u>	<u>\$ 903</u>

Nine Months Ended September 30, 2017

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Income tax expense (benefit)
GAAP	\$ 109,754	\$ 4,831	\$ 35,237	\$ 32,117	\$ (466)
Intangible amortization	(2,031)	—	(108)	—	—
Share-based compensation	(2,843)	(237)	(8,715)	(1,110)	—
Income tax expense on pre-tax adjustments	—	—	—	—	4,685
Non-GAAP	<u>\$ 104,880</u>	<u>\$ 4,594</u>	<u>\$ 26,414</u>	<u>\$ 31,007</u>	<u>\$ 4,219</u>

The comparative periods in 2017 were revised for immaterial errors.