

Amphastar Pharmaceuticals Reports Financial Results for the Three Months and Full Year Ended December 31, 2019

March 12, 2020

Reports Net Revenues of \$83.4 Million for the Three Months Ended December 31, 2019

RANCHO CUCAMONGA, Calif., March 12, 2020 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc. (NASDAQ: AMPH) (“Amphastar” or the “Company”) today reported results for the three months and full year ended December 31, 2019.

Fourth Quarter Highlights

- Net revenues of \$83.4 million for the fourth quarter
- GAAP net loss of \$1.0 million, or \$(0.02) per share, for the fourth quarter
- Adjusted non-GAAP net income of \$3.6 million, or \$0.07 per share, for the fourth quarter

Full Year Highlights

- Net revenues of \$322.4 million for the fiscal year
- GAAP net income of \$48.9 million, or \$0.98 per share, for the fiscal year
- Adjusted non-GAAP net income of \$17.8 million, or \$0.36 per share, for the fiscal year

Dr. Jack Zhang, Amphastar’s Chief Executive Officer, commented: “We finished 2019 with very strong sales of Primatene[®] Mist, with fourth quarter sales essentially equaling sales in the previous three quarters combined. Additionally, we have made great progress with our pipeline of product candidates, as we continue to move forward with clinical trials for both our insulin and inhalation products. In addition, the FDA accepted two more of our ANDAs.”

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
	(in thousands, except per share data)			
Net revenues	\$ 83,383	\$ 89,690	\$ 322,357	\$ 294,666
GAAP net income (loss) attributable to Amphastar	\$ (1,026)	\$ 1,867	\$ 48,939	\$ (5,738)
Adjusted non-GAAP net income attributable to Amphastar*	\$ 3,639	\$ 6,231	\$ 17,810	\$ 10,399
GAAP diluted EPS attributable to Amphastar shareholders	\$ (0.02)	\$ 0.04	\$ 0.98	\$ (0.12)
Adjusted non-GAAP diluted EPS attributable to Amphastar shareholders*	\$ 0.07	\$ 0.13	\$ 0.36	\$ 0.21

* 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.

Fourth Quarter Results

	Three Months Ended		Change Dollars	%	
	December 31, 2019	2018			
(in thousands)					
Net revenues:					
Lidocaine	\$ 12,282	\$ 13,661	\$ (1,379)	(10)) %
Phytonadione	12,309	12,942	(633)	(5)) %
Primatene [®] Mist	9,002	3,574	5,428	152	%
Naloxone	8,951	7,703	1,248	16	%
Enoxaparin	8,800	19,085	(10,285)	(54)) %
Medroxyprogesterone	6,062	7,448	(1,386)	(19)) %
Epinephrine	4,311	1,264	3,047	241	%
Other finished pharmaceutical products	16,280	17,257	(977)	(6)) %
Total finished pharmaceutical products net revenues	\$ 77,997	\$ 82,934	\$ (4,937)	(6)) %
API	5,386	6,756	(1,370)	(20)) %
Total net revenues	\$ 83,383	\$ 89,690	\$ (6,307)	(7)) %

Changes in net revenues were primarily driven by:

- Increased sale of Primatene[®] Mist, which launched in December 2018
- Epinephrine and naloxone sales increased due to higher unit volumes
- Enoxaparin sales decreased due to lower unit volumes
- Medroxyprogesterone sales decreased due to lower unit volumes, which was partially offset by a higher average selling price
- Lidocaine sales decreased due to lower unit volumes

	Three Months Ended		Change Dollars	%
	December 31, 2019	2018		
(in thousands)				

Net revenues	\$ 83,383	\$ 89,690	\$ (6,307)	(7))	%
Cost of revenues	50,002	55,001	(4,999)	(9))	%
Gross profit	\$ 33,381	\$ 34,689	\$ (1,308)	(4))	%
<i>as % of net revenues</i>	40	%	39	%		

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

- Increased sales of Primatene[®] Mist, which has higher margins and were magnified by the use of API and components which were expensed to pre-launch inventory in prior years

	Three Months Ended		Change			
	December 31,	December 31,				
	2019	2018				
	(in thousands)					
Selling, distribution and marketing	\$ 3,476	\$ 2,596	\$ 880	34)	%
General and administrative	10,505	13,814	(3,309)	(24)	%
Research and development	19,644	16,734	2,910	17)	%

- Marketing expenses related to Primatene[®] Mist increased due to the cost of a national television and radio marketing campaign, which began in July 2019
- General and administrative expenses decreased primarily due to lower legal expenses
- Research and development expenses increased primarily due the increased clinical trial expenses for our generic product pipeline, largely for our inhalation abbreviated new drug applications, or ANDAs, as well as an increase in expenses at our Amphastar Nanjing Pharmaceuticals, or ANP, subsidiary.

Year-End Results

	Year Ended		Change			
	December 31,	December 31,				
	2019	2018				
	(in thousands)					
Net revenues:						
Lidocaine	\$ 46,013	\$ 43,328	\$ 2,685	6)	%
Phytonadione	45,786	41,897	3,889	9)	%
Enoxaparin	42,695	53,371	(10,676)	(20)	%
Naloxone	34,761	37,195	(2,434)	(7)	%
Medroxyprogesterone	27,850	24,071	3,779	16)	%
Primatene [®] Mist	18,065	3,574	14,491	405)	%
Epinephrine	13,885	10,055	3,830	38)	%

Other finished pharmaceutical products	72,945	57,568	15,377	27	%
Total finished pharmaceutical products net revenues	\$ 302,000	\$ 271,059	\$ 30,941	11	%
API	20,357	23,607	(3,250)	(14) %
Total net revenues	\$ 322,357	\$ 294,666	\$ 27,691	9	%

Changes in net revenues were primarily driven by:

- A full year of Primatene[®] Mist sales, which launched in December 2018
- Lidocaine sales increased due to a higher average selling price, as well as higher unit volumes
- Phytonadione sales increased primarily due to a higher average selling price
- Epinephrine sales increased due to higher unit volumes
- A full year of Medroxyprogesterone sales, which launched in 2018
- Other finished pharmaceutical products sales increased, including atropine, calcium chloride, and dextrose, which were in high demand due to market shortages
- Enoxaparin sales decreased due to lower unit volumes, partially offset by an increase in average selling price due to a change in customer mix
- Naloxone sales decreased due to a lower average selling price

	Year Ended December 31,		Change		
	2019	2018	Dollars	%	
	(in thousands)				
Net revenues	\$ 322,357	\$ 294,666	\$ 27,691	9	%
Cost of revenues	190,434	187,681	2,753	1	%
Gross profit	\$ 131,923	\$ 106,985	\$ 24,938	23	%
<i>as % of net revenues</i>	41	%	36	%	

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

- Increased sales of Primatene[®] Mist and phytonadione, which have higher margins than many of our other products
- Gross margins for Primatene[®] Mist were magnified by the use of API and components which were expensed to pre-launch inventory in prior years

	Year Ended December 31,		Change		
	2019	2018	Dollars	%	
	(in thousands)				
Selling, distribution and marketing	\$ 12,830	\$ 8,156	\$ 4,674	57	%
General and administrative	50,279	49,888	391	1	%
Research and development	68,853	57,564	11,289	20	%

- Marketing expenses related to Primatene[®] Mist increased due to the cost of a national television and radio marketing campaign, which began in July 2019

- General and administrative expenses increased primarily due to personnel costs and consulting and accounting audit fees, partially offset by lower legal expenses
- Research and development expenses increased primarily due to personnel-related expenses and depreciation due to API and key component development at ANP
- Clinical trial expense increased due to external studies related to our generic product pipeline, primarily for our inhalation ANDAs and our insulin biosimilar programs

	Year Ended December 31,		Change	
	2019	2018	Dollars	%
	(in thousands)			
Non-operating income (expense), net	\$ 60,267	\$ (1,303)	\$ 61,570	NM

- In June 2019, we recognized a gain of \$59.9 million relating to the settlement of our patent and antitrust litigation with Momenta Pharmaceuticals, Inc. and Sandoz Inc.

Cash flow provided by operating activities for the year ended December 31, 2019, was \$41.8 million.

Pipeline Information

The Company currently has seven ANDAs filed with the FDA targeting products with a market size of approximately \$1.9 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 December 31, 2019. 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 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 four 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 Primatene[®], 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 shareholders, which exclude amortization expense, share-based compensation, impairment charges, 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, March 12, 2020, 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 4863509.

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:

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

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2019	2018	2019	2018
Net revenues	\$ 83,383	\$ 89,690	\$ 322,357	\$ 294,666
Cost of revenues	50,002	55,001	190,434	187,681
Gross profit	33,381	34,689	131,923	106,985
Operating expenses:				
Selling, distribution, and marketing	3,476	2,596	12,830	8,156
General and administrative	10,505	13,814	50,279	49,888
Research and development	19,644	16,734	68,853	57,564
Total operating expenses	33,625	33,144	131,962	115,608
Income (loss) from operations	(244)	1,545	(39)	(8,623)
Non-operating income (expenses), net	1,430	(956)	60,267	(1,303)
Income (loss) before income taxes	1,186	589	60,228	(9,926)
Income tax provision (benefit)	431	(1,129)	13,723	(3,266)
Net income (loss)	\$ 755	\$ 1,718	\$ 46,505	\$ (6,660)
Net income (loss) attributable to non-controlling interests	\$ 1,781	\$ (149)	\$ (2,434)	\$ (922)
Net income (loss) attributable to Amphastar	\$ (1,026)	\$ 1,867	\$ 48,939	\$ (5,738)
Net income (loss) per share attributable to Amphastar shareholders:				
Basic	\$ (0.02)	\$ 0.04	\$ 1.04	\$ (0.12)
Diluted	\$ (0.02)	\$ 0.04	\$ 0.98	\$ (0.12)
Weighted-average shares used to compute net income (loss) per share attributable to Amphastar shareholders:				
Basic	46,840	46,268	46,982	46,395

Diluted	46,840	49,181	49,907	46,395
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Table II
Amphastar Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheet
(Unaudited; in thousands, except share data)

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 73,685	\$ 86,337
Restricted cash	1,865	1,865
Short-term investments	11,675	2,831
Restricted short-term investments	2,290	2,290
Accounts receivable, net	45,376	52,163
Inventories	110,501	69,322
Income tax refunds and deposits	311	49
Prepaid expenses and other assets	9,538	5,485
Total current assets	255,241	220,342
Property, plant, and equipment, net	233,856	210,418
Finance lease right-of-use assets	887	—
Operating lease right-of-use assets	18,805	—
Goodwill and intangible assets, net	41,153	42,267
Other assets	11,156	9,918
Deferred tax assets	25,873	30,618
Total assets	\$ 586,971	\$ 513,563
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 77,051	\$ 87,418
Income taxes payable	2,042	1,187
Current portion of long-term debt	7,741	18,229
Current portion of operating lease liabilities	3,175	—
Total current liabilities	90,009	106,834
Long-term reserve for income tax liabilities	3,425	415
Long-term debt, net of current portion	39,394	31,984
Long-term operating lease liabilities, net of current portion	16,315	—
Deferred tax liabilities	867	1,031
Other long-term liabilities	9,433	8,940
Total liabilities	159,443	149,204
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; 52,495,483 and 46,576,968 shares issued and outstanding as of December 31, 2019 and 51,438,675 and 46,631,118 shares issued and outstanding as of December 31, 2018, respectively	5	5
Additional paid-in capital	367,305	344,434
Retained earnings	116,370	67,485
Accumulated other comprehensive loss	(4,687)	(4,013)
Treasury stock	(97,627)	(75,476)
Total Amphastar Pharmaceuticals, Inc. stockholders' equity	381,366	332,435
Non-controlling interests	46,162	31,924
Total equity	427,528	364,359
Total liabilities and stockholders' equity	\$ 586,971	\$ 513,563

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

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2019	2018	2019	2018
GAAP net income (loss)	\$ 755	\$ 1,718	\$ 46,505	\$ (6,660)
Adjusted for:				
Intangible amortization	260	265	1,037	1,987
Share-based compensation	4,296	3,910	17,296	16,680
Impairment of long-lived assets	171	1,257	365	1,647
Gain on litigation settlement	—	—	(59,900)	—
Income tax provision (benefit) on pre-tax adjustments	72	(1,004)	10,494	(4,044)
Non-GAAP net income	\$ 5,554	\$ 6,146	\$ 15,797	\$ 9,610
Non-GAAP net income (loss) attributable to non-controlling interests	\$ 1,915	\$ (85)	\$ (2,013)	\$ (789)
Non-GAAP net income attributable to Amphastar	\$ 3,639	\$ 6,231	\$ 17,810	\$ 10,399
Non-GAAP net income per share attributable to Amphastar shareholders:				
Basic	\$ 0.08	\$ 0.13	\$ 0.38	\$ 0.22
Diluted	\$ 0.07	\$ 0.13	\$ 0.36	\$ 0.21

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

Basic	46,840	46,268	46,982	46,395
Diluted	49,242	49,181	49,907	48,830

Three Months Ended December 31, 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	\$ 50,002	\$ 3,476	\$ 10,505	\$ 19,644	\$ 1,430	\$ 431	\$ 1,781
Intangible amortization	(226)	—	(34)	—	—	—	11
Share-based compensation	(880)	(103)	(2,961)	(352)	—	—	98
Impairment of long-lived assets	(30)	—	(141)	—	—	—	58
Income tax provision (benefit) on pre-tax adjustments	—	—	—	—	—	(72)	(33)
Non-GAAP	\$ 48,866	\$ 3,373	\$ 7,369	\$ 19,292	\$ 1,430	\$ 359	\$ 1,915

Reconciliation of Non-GAAP Measures (continued)

Three Months Ended December 31, 2018

	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	\$ 55,001	\$ 2,596	\$ 13,814	\$ 16,734	\$ (956)	\$ (1,129)	\$ (149)
Intangible amortization	(224)	—	(41)	—	—	—	11
Share-based compensation	(898)	(86)	(2,602)	(324)	—	—	62

Impairment of long-lived assets	(1,010)	—	(5)	(242)	—	—	1
Income tax provision (benefit) on pre-tax adjustments	—	—	—	—	—	1,004	(10)
Non-GAAP	\$ 52,869	\$ 2,510	\$ 11,166	\$ 16,168	\$ (956)	\$ (125)	\$ (85)

Year Ended December 31, 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	\$ 190,434	\$ 12,830	\$ 50,279	\$ 68,853	\$ 60,267	\$ 13,723	\$ (2,434)
Intangible amortization	(895)	—	(142)	—	—	—	45
Share-based compensation	(3,819)	(388)	(11,538)	(1,551)	—	—	355
Impairment of long-lived assets	(99)	—	(164)	(102)	—	—	113
Gain on litigation settlement	—	—	—	—	(59,900)	—	—
Income tax provision (benefit) on pre-tax adjustments	—	—	—	—	—	(10,494)	(92)
Non-GAAP	\$ 185,621	\$ 12,442	\$ 38,435	\$ 67,200	\$ 367	\$ 3,229	\$ (2,013)

Year Ended December 31, 2018

	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
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GAAP	\$ 187,681	\$ 8,156	\$ 49,888	\$ 57,564	\$ (1,303)	\$ (3,266)	\$ (922)
Intangible amortization	(1,826)	—	(161)	—	—	—	22
Share-based compensation	(3,923)	(383)	(10,853)	(1,521)	—	—	130
Impairment of long-lived assets	(1,087)	—	(9)	(551)	—	—	2
Income tax provision (benefit) on pre-tax adjustments	—	—	—	—	—	4,044	(21)
Non-GAAP	\$ 180,845	\$ 7,773	\$ 38,865	\$ 55,492	\$ (1,303)	\$ 778	\$ (789)

Source: Amphastar Pharmaceuticals, Inc.