

Source: Amphastar Pharmaceuticals, Inc.

March 12, 2019 16:05 ET

Amphastar Pharmaceuticals Reports Financial Results for the Three Months and Full Year Ended December 31, 2018

Reports Net Revenues of \$89.7 Million for the Three Months Ended December 31, 2018

RANCHO CUCAMONGA, Calif., March 12, 2019 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc. (NASDAQ: AMPH) ("Amphastar" or the "Company") today reported results for the three months and full year ended December 31, 2018.

Fourth Quarter Highlights

- Net revenues of \$89.7 million for the fourth quarter, up 48% from the quarter ended December 31, 2017
- GAAP net income attributable to Amphastar of \$1.9 million, or \$0.04 per diluted share, for the fourth quarter
- Adjusted non-GAAP net income attributable to Amphastar of \$6.2 million, or \$0.13 per diluted share, for the fourth quarter

Full Year Highlights

- Net revenues of \$294.7 million for the fiscal year, up 23% from the previous year
- GAAP net loss attributable to Amphastar of \$5.7 million, or \$(0.12) per diluted share, for the fiscal year
- Adjusted non-GAAP net income attributable to Amphastar of \$10.4 million, or \$0.21 per diluted share, for the fiscal year

Dr. Jack Zhang, Amphastar's CEO, commented: "The fourth quarter ended a great year for our Company. During the quarter we received approval for Primatene[®] Mist, which followed multiple ANDA approvals and launches throughout the year. Sales grew 48% in the quarter with Primatene[®] Mist's launch, and capped off sales growth of 23% for the year."

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2018	2017	2018	2017
	(in thousands, except per share data)			
Net revenues	\$ 89,690	\$ 60,402	\$ 294,666	\$ 240,175
GAAP net income (loss) attributable to Amphastar	\$ 1,867	\$ 787	\$ (5,738)	\$ 3,647
Adjusted non-GAAP net income attributable to Amphastar*	\$ 6,231	\$ 4,115	\$ 10,399	\$ 17,334
GAAP diluted EPS attributable to Amphastar shareholders	\$ 0.04	\$ 0.02	\$ (0.12)	\$ 0.08
Adjusted non-GAAP diluted EPS attributable to Amphastar shareholders*	\$ 0.13	\$ 0.08	\$ 0.21	\$ 0.36

* 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

	December 31,		Change	
	2018	2017	Dollars	%
	(in thousands)			
Net revenues:				
Enoxaparin	\$ 19,085	\$ 11,347	\$ 7,738	68 %
Lidocaine	13,661	10,384	3,277	32 %
Phytonadione	12,942	10,703	2,239	21 %
Naloxone	7,703	8,434	(731)	(9)%
Medroxyprogesterone	7,448	—	7,448	N/A
Epinephrine	1,264	3,665	(2,401)	(66)%
Primatene [®] Mist	3,574	—	3,574	N/A
Other finished pharmaceutical products	17,257	11,452	5,805	51 %
Total finished pharmaceutical products net revenues	\$ 82,934	\$ 55,985	\$ 26,949	48 %
API	6,756	4,417	2,339	53 %
Total net revenues	\$ 89,690	\$ 60,402	\$ 29,288	48 %

Changes in net revenues were primarily driven by:

- Enoxaparin increases due to higher average selling prices, as well as increased unit volumes
- Medroxyprogesterone, which was launched in the first quarter of 2018
- Primatene[®] Mist, which was launched in the fourth quarter of 2018
- Epinephrine declines due to lower unit volumes

	Three Months Ended		Change	
	December 31,		Dollars	%
	2018	2017		
	(in thousands)			
Net revenues	\$ 89,690	\$ 60,402	\$ 29,288	48 %
Cost of revenues	55,001	39,912	15,089	38 %
Gross profit	\$ 34,689	\$ 20,490	\$ 14,199	69 %
<i>as % of net revenues</i>	39%	34%		

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

- The launch of medroxyprogesterone acetate, isoproterenol hydrochloride and Primatene[®] Mist, which have higher margins
- Enoxaparin sales, which had lower margins due to an increase in reserves for purchase commitments related to price increases for both crude heparin and semi-purified heparin, which are used for the production of enoxaparin

	Three Months Ended		Change	
	December 31,		Dollars	%
	2018	2017		
	(in thousands)			
Selling, distribution and marketing	\$ 2,596	\$ 1,629	\$ 967	59 %
General and administrative	13,814	9,221	4,593	50 %
Research and development	16,734	11,386	5,348	47 %

- Selling, distribution and marketing expenses increased due to higher freight costs and marketing expenses related to the launch of Primatene[®] Mist
- General and administrative expenses increased primarily due to higher legal fees and expenses at the Company's subsidiary Amphastar Nanjing Pharmaceuticals, or ANP
- Research and development expenses increased primarily due to material expenditures at ANP for pipeline product candidates, increased clinical trial expenses, and Food and Drug Administration, or FDA, filing fees

Year-End Results

	Year Ended December 31,		Change	
	2018	2017	Dollars	%
	(in thousands)			
Net revenues:				
Enoxaparin	\$ 53,371	\$ 36,593	\$ 16,778	46 %
Lidocaine	43,328	37,602	5,726	15 %
Phytonadione	41,897	37,946	3,951	10 %
Naloxone	37,195	42,342	(5,147)	(12)%
Medroxyprogesterone	24,071	—	24,071	N/A
Epinephrine	10,055	25,914	(15,859)	(61)%
Primatene [®] Mist	3,574	—	3,574	N/A
Other finished pharmaceutical products	57,568	49,742	7,826	16 %
Total finished pharmaceutical products net revenues	<u>\$ 271,059</u>	<u>\$ 230,139</u>	<u>\$ 40,920</u>	<u>18 %</u>
API	23,607	10,036	13,571	135 %
Total net revenues	<u>\$ 294,666</u>	<u>\$ 240,175</u>	<u>\$ 54,491</u>	<u>23 %</u>

Changes in net revenues were primarily driven by:

- Enoxaparin increases due to higher average selling prices, as well as increased unit volumes
- Medroxyprogesterone, which was launched in the first quarter of 2018
- Primatene[®] Mist, which was launched in the fourth quarter of 2018
- Lidocaine increases primarily due to increased unit volumes
- Epinephrine declines due to the discontinuation of the unapproved vial product in 2017
- Naloxone declines due to lower unit volumes

	Year Ended December 31,		Change	
	2018	2017	Dollars	%
	(in thousands)			
Net revenues	\$ 294,666	\$ 240,175	\$ 54,491	23 %
Cost of revenues	187,681	149,666	38,015	25 %
Gross profit	<u>\$ 106,985</u>	<u>\$ 90,509</u>	<u>\$ 16,476</u>	<u>18 %</u>
<i>as % of net revenues</i>	<i>36%</i>	<i>38%</i>		

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

- The launch of medroxyprogesterone acetate, isoproterenol hydrochloride and Primatene[®] Mist, which have higher margins
- Enoxaparin sales, which had lower margins due to an increase in reserves for purchase commitments related to price increases for both crude heparin and semi-purified heparin, which are used for the production of enoxaparin

	Year Ended December 31,		Change	
	2018	2017	Dollars	%
	(in thousands)			
Selling, distribution and marketing	\$ 8,156	\$ 6,460	\$ 1,696	26 %
General and administrative	49,888	44,458	5,430	12 %
Research and development	57,564	43,503	14,061	32 %
Gain on sale of intangible assets	—	(2,643)	2,643	(100)%

- Selling, distribution and marketing expenses increased primarily due to increased freight costs and marketing expenses related to the launch of Primatene[®] Mist

- General and administrative expenses increased primarily due to higher legal fees and expenses at ANP
- Research and development expenses increased primarily due to expenditures related to the expansion of our ANP facility, as well as an increase in FDA filing fees and an increase in clinical trial expenses

Cash flow provided by operating activities for the year ended December 31, 2018 was \$38.2 million.

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

Pipeline Information

The Company currently has five abbreviated new drug applications, or ANDAs, filed with the FDA targeting products with a market size of over \$750 million, 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 December 31, 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, ANP, 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, 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, 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 and (ii) Adjusted non-GAAP diluted EPS attributed to Amphastar's 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, March 12, 2019, 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 4878419.

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,	
	2018	2017	2018	2017
Net revenues	\$ 89,690	\$ 60,402	\$ 294,666	\$ 240,175
Cost of revenues	55,001	39,912	187,681	149,666
Gross profit	<u>34,689</u>	<u>20,490</u>	<u>106,985</u>	<u>90,509</u>
Operating (income) expenses:				
Selling, distribution, and marketing	2,596	1,629	8,156	6,460
General and administrative	13,814	9,221	49,888	44,458
Research and development	16,734	11,386	57,564	43,503
Gain on sale of intangible assets	—	—	—	(2,643)
Total operating expenses	<u>33,144</u>	<u>22,236</u>	<u>115,608</u>	<u>91,778</u>
Income (loss) from operations	1,545	(1,746)	(8,623)	(1,269)
Non-operating income (expense), net	<u>(956)</u>	<u>601</u>	<u>(1,303)</u>	<u>2,518</u>
Income (loss) before income taxes	589	(1,145)	(9,926)	1,249
Income tax expense (benefit)	(1,129)	(1,932)	(3,266)	(2,398)
Net income (loss)	<u>\$ 1,718</u>	<u>\$ 787</u>	<u>\$ (6,660)</u>	<u>\$ 3,647</u>
Net loss attributable to non-controlling interests	\$ (149)	\$ —	\$ (922)	\$ —
Net income (loss) attributable to Amphastar	<u><u>\$ 1,867</u></u>	<u><u>\$ 787</u></u>	<u><u>\$ (5,738)</u></u>	<u><u>\$ 3,647</u></u>
Net income (loss) per share attributable to Amphastar				

shareholders:

Basic	\$ 0.04	\$ 0.02	\$ (0.12)	\$ 0.08
Diluted	\$ 0.04	\$ 0.02	\$ (0.12)	\$ 0.08

Weighted-average shares used to compute net income (loss) per share attributable to Amphastar shareholders:

Basic	46,268	46,233	46,395	46,107
Diluted	49,181	49,330	46,395	48,367

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)

	<u>December 31,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 86,337	\$ 65,594
Short-term investments	2,831	2,635
Restricted cash and short-term investments	4,155	4,155
Accounts receivable, net	52,163	35,996
Inventories	69,322	63,609
Income tax refunds and deposits	49	6,036
Prepaid expenses and other assets	5,485	9,753
Total current assets	<u>220,342</u>	<u>187,778</u>
Property, plant, and equipment, net	210,418	180,545
Goodwill and intangible assets, net	42,267	45,140
Other assets	9,918	8,663
Deferred tax assets	30,618	28,946
	<u>\$ 513,563</u>	<u>\$ 451,072</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 87,418	\$ 57,555
Income taxes payable	1,187	3,325
Current portion of long-term debt and capital leases	18,229	6,312
Total current liabilities	<u>106,834</u>	<u>67,192</u>
Long-term reserve for income tax liabilities	415	879
Long-term debt and capital leases, net of current portion	31,984	40,844
Deferred tax liabilities	1,031	1,361
Other long-term liabilities	8,940	7,060
Total liabilities	<u>149,204</u>	<u>117,336</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; 51,438,675 and 46,631,118 shares issued and outstanding as of December 31, 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	344,434	313,891
Retained earnings	67,485	72,642
Accumulated other comprehensive loss	(4,013)	(2,100)
Treasury stock	(75,476)	(50,702)
Total Amphastar stockholders' equity	<u>332,435</u>	<u>333,736</u>
Non-controlling interests	31,924	—
Total equity	<u>364,359</u>	<u>333,736</u>
Total liabilities and stockholders' equity	<u>\$ 513,563</u>	<u>\$ 451,072</u>

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)

	Three Months		Year Ended	
	Ended		December 31,	
	December 31,		December 31,	
	2018	2017	2018	2017
GAAP net income (loss)	\$ 1,718	\$ 787	\$ (6,660)	\$ 3,647
Adjusted for:				
Intangible amortization	265	717	1,987	2,856
Share-based compensation	3,910	4,182	16,680	17,087
Impairment of long-lived assets	1,257	—	1,647	—
Income tax expense on pre-tax adjustments	(1,004)	(1,571)	(4,044)	(6,256)
Non-GAAP net income	<u>\$ 6,146</u>	<u>\$ 4,115</u>	<u>\$ 9,610</u>	<u>\$ 17,334</u>
Non-GAAP net loss attributable to non-controlling interests	\$ (85)	\$ —	\$ (789)	\$ —
Non-GAAP net income attributable to Amphastar	<u>\$ 6,231</u>	<u>\$ 4,115</u>	<u>\$ 10,399</u>	<u>\$ 17,334</u>
Non-GAAP net income per share attributable to Amphastar shareholders:				
Basic	\$ 0.13	\$ 0.09	\$ 0.22	\$ 0.38
Diluted	\$ 0.13	\$ 0.08	\$ 0.21	\$ 0.36
Weighted-average shares used to compute non-GAAP net income per share attributable to Amphastar shareholders:				
Basic	46,268	46,233	46,395	46,107
Diluted	49,181	49,330	48,830	48,367

Three Months Ended December 31, 2018

	Cost of	Selling, distribution and marketing	General and administrative	Research and development	Income tax expense (benefit)	Non- controlling interest adjustment
GAAP	\$ 55,001	\$ 2,596	\$ 13,814	\$ 16,734	\$ (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 expense on pre-tax adjustments	—	—	—	—	1,004	(10)
Non-GAAP	<u>\$ 52,869</u>	<u>\$ 2,510</u>	<u>\$ 11,166</u>	<u>\$ 16,168</u>	<u>\$ (125)</u>	<u>\$ (85)</u>

Three Months Ended December 31, 2017

	Cost of	Selling, distribution and marketing	General and administrative	Research and development	Income tax expense (benefit)	Non- controlling interest adjustment
GAAP	\$ 39,912	\$ 1,629	\$ 9,221	\$ 11,386	\$ (1,932)	\$ —
Intangible amortization	(675)	—	(42)	—	—	—
Share-based compensation	(913)	(65)	(2,928)	(276)	—	—
Income tax expense on pre-tax adjustments	—	—	—	—	1,571	—
Non-GAAP	<u>\$ 38,324</u>	<u>\$ 1,564</u>	<u>\$ 6,251</u>	<u>\$ 11,110</u>	<u>\$ (361)</u>	<u>\$ —</u>

The comparative periods in 2017 were revised for immaterial errors.

Reconciliation of Non-GAAP Measures (continued)

Year Ended December 31, 2018

	Cost of	Selling, distribution and marketing	General and administrative	Research and development	Income tax expense (benefit)	Non- controlling interest adjustment
GAAP	\$ 187,681	\$ 8,156	\$ 49,888	\$ 57,564	\$ (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 expense on pre-tax adjustments	—	—	—	—	4,044	(21)
Non-GAAP	<u>\$ 180,845</u>	<u>\$ 7,773</u>	<u>\$ 38,865</u>	<u>\$ 55,492</u>	<u>\$ 778</u>	<u>\$ (789)</u>

Year Ended December 31, 2017

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Income tax expense (benefit)	Non-controlling interest adjustment
GAAP	\$ 149,666	\$ 6,460	\$ 44,458	\$ 43,503	\$ (2,398)	\$ —
Intangible amortization	(2,706)	—	(150)	—	—	—
Share-based compensation	(3,756)	(302)	(11,643)	(1,386)	—	—
Income tax expense on pre-tax adjustments	—	—	—	—	6,256	—
Non-GAAP	<u>\$ 143,204</u>	<u>\$ 6,158</u>	<u>\$ 32,665</u>	<u>\$ 42,117</u>	<u>\$ 3,858</u>	<u>\$ —</u>

The comparative periods in 2017 were revised for immaterial errors.