

Amphastar Pharmaceuticals Reports Financial Results for the Three Months Ended March 31, 2018

May 9, 2018

Reports Net Revenues of \$58.4 Million for the Three Months Ended March 31, 2018

RANCHO CUCAMONGA, Calif., May 09, 2018 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) (“Amphastar” or the “Company”) today reported results for the three months ended March 31, 2018.

First Quarter Highlights

- Net revenues of \$58.4 million for the first quarter
- GAAP net loss of \$7.2 million, or \$0.16 per share, for the first quarter
- Adjusted non-GAAP net loss of \$2.5 million, or \$0.05 per share, for the first quarter

Dr. Jack Zhang, Amphastar’s CEO, commented: “We are pleased to announce that we have resubmitted our NDA for Primatene[®] Mist after receiving good results from our recent human factors study. While we don’t have a PDUFA date yet, we plan to begin producing inventory in preparation for a launch.”

	Three Months Ended March 31,	
	2018	2017
	(in thousands, except per share data)	
Net revenues	\$ 58,393	\$ 56,670
GAAP net income (loss)	\$ (7,246)	\$ 893
Adjusted non-GAAP net income (loss)*	\$ (2,452)	\$ 4,475
GAAP diluted EPS	\$ (0.16)	\$ 0.02
Adjusted non-GAAP diluted EPS*	\$ (0.05)	\$ 0.09

* Adjusted non-GAAP net income (loss) and Adjusted non-GAAP diluted EPS 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.

First Quarter Results

Three Months Ended March 31,	Change
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	2018 (in thousands)	2017	Dollars	%	
Net revenues:					
Lidocaine	\$ 9,782	\$ 8,289	\$ 1,493	18	%
Phytonadione	9,181	7,886	1,295	16	%
Naloxone	8,927	10,939	(2,012)	(18)	%
Enoxaparin	7,007	10,410	(3,403)	(33)	%
Epinephrine	3,223	9,574	(6,351)	(66)	%
Medroxyprogesterone	2,706	—	2,706	N/A	
Other finished pharmaceutical products	12,291	8,836	3,455	39	%
Total finished pharmaceutical products net revenues	\$ 53,117	\$ 55,934	\$ (2,817)	(5)	%
API	5,276	736	4,540	617	%
Total net revenues	\$ 58,393	\$ 56,670	\$ 1,723	3	%

Changes in net revenues were primarily driven by:

- Launch of medroxyprogesterone acetate in a vial form in January 2018 and a pre-filled syringe form in February 2018
- Discontinuation of epinephrine injection vial product in the second quarter of 2017
- Decline of enoxaparin sales due to lower unit sales at lower net average selling prices
- Increase in sales of insulin active pharmaceutical ingredient, or API, products due to the timing of customer purchases

	Three Months Ended March 31,		Change	
	2018 (in thousands)	2017	Dollars	%
Cost of Revenues	\$ 41,332	\$ 33,842	\$ 7,490	22 %
<i>% of net revenues</i>	<i>71</i>	<i>% 60</i>	<i>%</i>	

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

- Increased labor costs due to implementing new quality standards and increased hourly rates
- Lower productivity at the Company's U.S. facilities as the Company is in the process of increasing production of newly launched products
- Increased inventory write-down, partially due to increased cost of heparin
- Discontinuation of epinephrine injection vial product in the second quarter of 2017
- Launch of medroxyprogesterone acetate, which partially offset the changes noted above

	Three Months Ended March 31,		Change	
	2018 (in thousands)	2017	Dollars	%
Selling, distribution and marketing	\$ 1,721	\$ 1,479	\$ 242	16 %
General and administrative	10,998	11,338	(340)	(3)

Research and development	14,260	11,250	3,010	27	%
Gain on sale of intangible assets	—	(2,643)	2,643	(100)	%

- Selling, distribution and marketing expenses increased primarily due to increased expenses at the Company's Amphastar Nanjing Pharmaceuticals subsidiary as well as increased freight costs
- General and administrative expenses decreased primarily due to lower legal fees
- Research and development expenses increased primarily due to an NDA filing fee for a product that the Company currently markets under the grandfather exception as well as increased expenditures on materials for the Company's pipeline products

Cash flow provided by operating activities for the three months ended March 31, 2018, was \$8.4 million.

Share buyback program

On May 7, 2018, the Company's Board of Directors authorized an increase of \$20.0 million to the Company's share buyback program, which is expected to continue for an indefinite period of time. The primary goal of the program is to offset dilution created by the Company's equity compensation programs.

Purchases may be made through the open market and private block transactions pursuant to Rule 10b5-1 plans, privately negotiated transactions, or other means, as determined by the Company's management and in accordance with the requirements of the Securities and Exchange Commission.

The timing and actual number of shares repurchased will depend on a variety of factors including price, corporate and regulatory requirements, and other conditions.

Pipeline Information

The Company currently has three abbreviated new drug applications, or ANDAs, filed with the FDA targeting products with a market size of over \$0.5 billion, three biosimilar products in development targeting products with a market size of over \$15.0 billion, and 12 generic products in development targeting products with a market size of over \$12.0 billion. This market information is based on IQVIA data for the 12 months ended March 31, 2018. The Company's proprietary pipeline includes NDAs for Primatene[®] Mist and intranasal naloxone. The Company is currently developing four other proprietary products, which include injectable, inhalation and intranasal dosage forms.

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) and (ii) Adjusted non-GAAP diluted EPS, that 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, May 9, 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 5298899.

The call can also be accessed on the Investors page on the Company's website 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, 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	
	March 31,	
	2018	2017
Net revenues	\$ 58,393	\$ 56,670
Cost of revenues	41,332	33,842
Gross profit	17,061	22,828
Operating (income) expenses:		
Selling, distribution, and marketing	1,721	1,479
General and administrative	10,998	11,338
Research and development	14,260	11,250
Gain on sale of intangible assets	—	(2,643)
Total operating expenses	26,979	21,424
Income (loss) from operations	(9,918)	1,404
Non-operating income (expense), net	888	100
Income (loss) before income taxes	(9,030)	1,504
Income tax expense (benefit)	(1,784)	611
Net income (loss)	\$ (7,246)	\$ 893
Net income (loss) per share:		
Basic	\$ (0.16)	\$ 0.02
Diluted	\$ (0.16)	\$ 0.02
Weighted-average shares used to compute net income (loss) per share:		
Basic	46,514	46,069
Diluted	46,514	48,057

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

	March 31,	December 31,
	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 54,547	\$ 65,594
Short-term investments	2,826	2,635
Restricted cash and short-term investments	4,155	4,155
Accounts receivable, net	31,883	35,996
Inventories	62,780	63,609
Income tax refunds and deposits	12,194	6,036
Prepaid expenses and other assets	5,661	9,753
Total current assets	174,046	187,778
Property, plant, and equipment, net	191,915	185,339
Goodwill and intangible assets, net	44,850	45,140
Other assets	10,714	8,663
Deferred tax assets	28,257	27,745
Total assets	\$ 449,782	\$ 454,665
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 58,498	\$ 57,555
Income taxes payable	7,983	3,325
Current portion of long-term debt and capital leases	6,061	6,312
Total current liabilities	72,542	67,192
Long-term reserve for income tax liabilities	879	879
Long-term debt and capital leases, net of current portion	39,706	40,844
Deferred tax liabilities	1,425	1,361
Other long-term liabilities	8,126	7,060
Total liabilities	122,678	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; 50,471,687 and 46,656,793 shares issued and outstanding as of March 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	316,665	313,891
Retained earnings	69,570	76,235
Accumulated other comprehensive loss	(910)	(2,100)
Treasury stock	(58,226)	(50,702)

Total stockholders' equity	327,104	337,329
Total liabilities and stockholders' equity	\$ 449,782	\$ 454,665

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

	Three Months Ended	
	March 31,	
	2018	2017
GAAP net income (loss)	\$ (7,246)	\$ 893
Adjusted for:		
Intangible amortization	729	721
Share-based compensation	4,666	4,451
Impairment of long-lived assets	598	—
Income tax expense on pre-tax adjustments	(1,199)	(1,590)
Non-GAAP net income (loss)	\$ (2,452)	\$ 4,475
Non-GAAP net income (loss) per share:		
Basic	\$ (0.05)	\$ 0.10
Diluted	\$ (0.05)	\$ 0.09
Weighted-average shares used to compute non-GAAP net income (loss) per share:		
Basic	46,514	46,069
Diluted	46,514	48,057

Three Months Ended March 31, 2018

	Cost of	Selling,	General	Research	Income
	revenue	distribution	and	and	tax
		and	administrative	development	expense
		marketing	development		(benefit)
GAAP	\$ 41,332	\$ 1,721	\$ 10,998	\$ 14,260	\$ (1,784)
Intangible amortization	(689)	—	(40)	—	—
Share-based compensation	(1,160)	(107)	(2,893)	(506)	—

Impairment of long-lived assets	(74)	—	(3)	(521)	—
Income tax expense on pre-tax adjustments	—	—	—	—	1,199
Non-GAAP	\$ 39,409	\$ 1,614	\$ 8,062	\$ 13,233	\$ (585)

Three Months Ended March 31, 2017

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Income tax expense (benefit)
GAAP	\$ 33,842	\$ 1,479	\$ 11,338	\$ 11,250	\$ 611
Intangible amortization	(685)	—	(36)	—	—
Share-based compensation	(1,131)	(84)	(2,783)	(453)	—
Income tax expense on pre-tax adjustments	—	—	—	—	1,590
Non-GAAP	\$ 32,026	\$ 1,395	\$ 8,519	\$ 10,797	\$ 2,201

Source: Amphastar Pharmaceuticals, Inc.