

Amphastar Pharmaceuticals Reports Financial Results for the Three Months Ended March 31, 2017

May 8, 2017

RANCHO CUCAMONGA, Calif., May 08, 2017 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) (“Amphastar” or the “Company”) today reported results for the three months ended March 31, 2017.

First Quarter Highlights

- Net revenues of \$56.7 million for the first quarter
- GAAP net income of \$0.9 million, or \$0.02 per diluted share, for the first quarter
- Adjusted non-GAAP net income of \$4.5 million, or \$0.09 per diluted share, for the first quarter

Dr. Jack Zhang, Amphastar’s CEO, commented: “We continue to execute on our pipeline, having filed four ANDAs in the past two quarters. We will use our extensive research and development capabilities to further expand our pipeline.”

Three Months Ended March 31, 2017 **2016**

(in thousands, except per share data)

Net revenues	\$ 56,670	\$ 59,366
GAAP net income	\$ 893	\$ 2,489
Adjusted non-GAAP net income*	\$ 4,475	\$ 5,455
GAAP diluted EPS	\$ 0.02	\$ 0.05
Adjusted non-GAAP diluted EPS*	\$ 0.09	\$ 0.12

* 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 II of this press release.

First Quarter Results

For the three months ended March 31, 2017, the Company reported net revenues of \$56.7 million, a decrease of 5% compared to \$59.4 million for the three months ended March 31, 2016.

For the three months ended March 31, 2017, net revenues of enoxaparin were \$10.4 million, a decrease of 43% compared to \$18.4 million for the three months ended March 31, 2016. \$5.6

million of the decrease was due to lower unit volumes, while the remainder was due to lower pricing.

Other finished pharmaceutical product revenues were \$45.5 million for the three months ended March 31, 2017, representing an increase of 13% compared to \$40.2 million for the three months ended March 31, 2016. This was primarily due to an increase in sales of epinephrine to \$9.6 million from \$4.4 million resulting from increases in both average selling price and unit volumes. The FDA recently requested that the Company discontinue the manufacturing and distribution of its epinephrine injection, USP vial product, which has been marketed under the “grandfather” exception to the FDA’s “Prescription Drug Wrap-Up” program. Unless the FDA grants our request for an extension of the time to sell epinephrine vials, we will discontinue selling this product in the second quarter of 2017. Net revenues from this product were \$8.0 million for the three months ended March 31, 2017.

Additionally, sales of naloxone increased to \$10.9 million from \$10.3 million, primarily as a result of an increase in unit volumes that was partially offset by a decrease in average selling price, which resulted from an increase in rebates. Sale of lidocaine decreased to \$8.3 million from \$9.9 million, primarily as a result of a decrease in unit volumes.

Sales of the Company’s insulin active pharmaceutical ingredient, or API, products were \$0.7 million for the three months ended March 31, 2017, compared to \$0.8 million for the three months ended March 31, 2016.

A decrease in production at our IMS facility resulting from a partial plant shutdown and an increase in demand, which was primarily due to a market shortage for three of our pre-filled syringe products, resulted in a sales order backlog of approximately \$8.0 million as of March 31, 2017. Specifically, the sterile filling area of the IMS facility was shut down for the month of December 2016 and for part of the month of January 2017 for construction and installation of equipment in a new sterile suite. The backlog created by this shutdown is expected to be fulfilled in the second quarter of 2017. There were no significant backlogs as of March 31, 2016 and December 31, 2016.

Cost of revenues were \$33.8 million, or 60% of revenues, and \$34.5 million, or 58% of revenues, for the three months ended March 31, 2017 and 2016, respectively, representing a decrease of \$0.7 million. Cost of revenues of enoxaparin decreased by \$5.6 million, primarily due to a reduction in the number of units shipped. Additional factors affecting gross profit in the first quarter of 2017 included an increase in the unabsorbed manufacturing expense related to decreased production at our IMS facility due to the partial shutdown noted above.

Selling, distribution, and marketing expenses were \$1.5 million and \$1.4 million for the three months ended March 31, 2017 and 2016, respectively. For the three months ended March 31, 2017, general and administrative expenses increased to \$11.3 million from \$10.9 million for the three months ended March 31, 2016, primarily due to an increase in legal fees.

For the three months ended March 31, 2017, research and development expenses increased by 31% to \$11.3 million from \$8.6 million for the three months ended March 31, 2016, primarily due to expenses related to the production of APIs for our pipeline at the Company’s ANP facility.

In February 2017, the Company sold the ANDAs that it acquired in March 2016 and recognized a gain of \$2.6 million.

The Company recorded an income tax expense of \$0.6 million for the three months ended March 31, 2017, compared to an income tax expense of \$1.3 million for the three months ended March 31, 2016.

The Company recognized net income of \$0.9 million, or \$0.02 per diluted share, for the three months ended March 31, 2017, compared to a net income of \$2.5 million, or \$0.05 per fully diluted share, for the three months ended March 31, 2016. The Company's adjusted non-GAAP quarterly net income was \$4.5 million, or \$0.09 per fully diluted share, for the three months ended March 31, 2017, compared to an adjusted non-GAAP net income of \$5.5 million, or \$0.12 per fully diluted share, for the three months ended March 31, 2016. Please see the discussion in the section entitled "Non-GAAP Financial Measures" and the reconciliation of GAAP to non-GAAP measures in Table II of this press release.

The Company's cash and cash equivalents, short-term investments, and unrestricted short-term investments were \$79.0 million as of March 31, 2017. Cash flow provided by operating activities for the three months ended March 31, 2017, was \$22.4 million.

Pipeline Information

The Company currently has six abbreviated new drug applications, or ANDAs filed with the FDA, targeting products with a market size of over \$1.1 billion, three biosimilar products in development targeting products with a market size of \$15.0 billion, and 11 generic products in development targeting products with a market size of over \$12.0 billion. This market information is based on IMS Health data for the 12 months ended March 31, 2017. 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 active pharmaceutical ingredient 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.

The Amphastar Pharmaceuticals' 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 measure. 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 measure 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 8, 2017, 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 1824897.

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, the timing for completion of construction at the Company's IMS facility, 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 the Company's expectations to change.

Table I

Amphastar Pharmaceuticals, Inc.

Condensed Consolidated Statement of Operations

(Unaudited; in thousands, except per share data)

	Three Months Ended	
	March 31,	
	2017	2016
Net revenues	\$ 56,670	\$ 59,366

Cost of revenues	33,842	34,464
Gross profit	22,828	24,902
Operating (income) expenses:		
Selling, distribution, and marketing	1,479	1,352
General and administrative	11,338	10,870
Research and development	11,250	8,605
Gain on sale of intangible assets	(2,643)	—
Total operating expenses	21,424	20,827
Income from operations	1,404	4,075
Non-operating income (expense), net	100	(259)
Income before income taxes	1,504	3,816
Income tax expense	611	1,327
Net income	\$ 893	\$ 2,489
Net income per share:		
Basic	\$ 0.02	\$ 0.06
Diluted	\$ 0.02	\$ 0.05
Weighted-average shares used to compute net income per share:		
Basic	46,069	45,041
Diluted	48,057	46,810

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

	Three Months Ended March 31,	
	2017	2016
GAAP net income	\$ 893	\$ 2,489
Adjusted for:		
Intangible amortization	721	480

Share-based compensation	4,451	3,851
Impairment of long-lived assets	—	217
Income tax expense on pre-tax adjustments	(1,590)	(1,582)
Non-GAAP net income	\$ 4,475	\$ 5,455
Non-GAAP net income per share:		
Basic	\$ 0.10	\$ 0.12
Diluted	\$ 0.09	\$ 0.12
Weighted-average shares used to compute non-GAAP net income per share:		
Basic	46,069	45,041
Diluted	48,057	46,810

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

Three Months Ended March 31, 2016

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Income tax expense (benefit)
GAAP	\$ 34,464	\$ 1,352	\$ 10,870	\$ 8,605	\$ 1,327
Intangible amortization	(446)	—	(34)	—	—
Share-based compensation	(799)	(66)	(2,646)	(340)	—
Impairment of long-lived assets	—	—	—	(217)	—
Income tax expense on pre-tax adjustments	—	—	—	—	1,582

Non-GAAP	\$ 33,219	\$ 1,286	\$ 8,190	\$ 8,048	\$ 2,909
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Contact Information:

Amphastar Pharmaceuticals, Inc.
Bill Peters
Chief Financial Officer
(909) 980-9484

Source: Amphastar Pharmaceuticals Inc.