

Amphastar Pharmaceuticals Reports Financial Results for the First Quarter Ended March 31, 2016

May 9, 2016

RANCHO CUCAMONGA, Calif., May 09, 2016 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) (“Amphastar” or the “Company”) today reported results for the first quarter ended March 31, 2016.

First Quarter Highlights

- Net revenues of \$59.4 million for the first quarter
- GAAP net income of \$2.5 million, or \$0.05 per diluted share, for the first quarter
- Adjusted non-GAAP net income of \$5.5 million, or \$0.12 per diluted share, for the first quarter

Dr. Jack Zhang, Amphastar’s CEO, commented: “We are pleased to announce that we filed our intranasal naloxone NDA in April. We believe that this will be the first of several important filings this year.”

	Three Months Ended	
	March 31,	
	2016	2015
	(in thousands, except per share data)	
Net revenues	\$ 59,366	\$ 56,886
GAAP net income (loss)	\$ 2,489	\$ (665)
Adjusted non-GAAP net income (loss)*	\$ 5,455	\$ (374)
GAAP diluted EPS	\$ 0.05	\$ (0.01)
Adjusted non-GAAP diluted EPS*	\$ 0.12	\$ (0.01)

* 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 reconciliations in Table II of this press release.

First Quarter Results

For the three months ended March 31, 2016, the Company reported net revenues of \$59.4 million, an increase of 4% compared to \$56.9 million for the first quarter of 2015.

During the first quarter of 2016, net revenues of enoxaparin were \$18.4 million, a decrease of 23% compared to \$23.8 million for the first quarter of 2015, primarily due to lower average selling prices.

Other finished pharmaceutical product revenues were \$40.2 million for the first quarter of 2016, an increase of 49% compared to \$27.0 million for the first quarter of 2015, largely due to an increase in sales of naloxone to \$10.3 million from \$6.7 million, primarily as a result of increased unit volumes. Pricing of naloxone was down in the first quarter of 2016 compared to the fourth quarter of 2015, as the company increased discounting and rebates. Additionally, sales of phytonadione increased to \$6.1 million from \$2.6 million and sales of lidocaine increased to \$9.9 million from \$7.2 million.

Sales of the Company's insulin active pharmaceutical ingredient ("API") products were \$0.8 million for the first quarter of 2016 compared to \$6.0 million for the first quarter of 2015 as a result of no sales to MannKind in the first quarter of 2016.

Cost of revenues were \$34.5 million, or 58% of revenues, and \$43.6 million, or 77% of revenues, for the three months ended March 31, 2016 and 2015, respectively, representing a decrease of \$9.1 million, or 21%. Gross margins improved primarily due to pricing increases in several finished pharmaceutical products, which were partially offset by pricing declines in enoxaparin. Lower average heparin material costs also contributed to the improvement in gross margins. Additional factors affecting gross profit in the first quarter of 2016 included an increase in manufacturing volume for both marketed and research and development products at the Amphastar site, which increased overhead absorption. This benefit was partially offset by increased personnel costs at both the Amphastar and IMS sites.

Selling, distribution, and marketing expenses were \$1.4 million and \$1.5 million for the three months ended March 31, 2016 and 2015, respectively. General and administrative expenses were \$10.9 million and \$12.5 million for the three months ended March 31, 2016 and 2015, respectively. This \$1.6 million decrease in general and administrative expenses was primarily due to the effect on the first quarter of 2015 of a \$3.3 million settlement in 2015, relating to the Company's California employment litigation. This decrease was partially offset by an increase in personnel costs and legal expenses.

For the three months ended March 31, 2016, research and development expenses increased by 28% to \$8.4 million, compared to \$6.6 million in the first quarter of 2015. This increase was primarily due to an increase in clinical trial expense for the Company's pipeline products, as well as an increase in personnel costs

The Company recorded an income tax expense of \$1.3 million for the three months ended March 31, 2016, compared to an income tax benefit of \$5.5 million for the three months ended March 31, 2015.

The Company reported a quarterly net income of \$2.5 million, or \$0.05 per fully diluted share, for the three months ended March 31, 2016, compared to a net loss of \$0.7 million, or \$0.01 per fully diluted share, for the same period in the prior year. The Company reported an adjusted non-GAAP quarterly net income of \$5.5 million, or \$0.12 per fully diluted share, for the three months ended March 31, 2016, compared to adjusted non-GAAP net loss of \$0.4 million, or \$0.01 per fully diluted share, for the same period in the prior year.

The Company's cash and cash equivalents, and short-term investments as of March 31, 2016 were \$63.3 million. Cash flow provided by operating activities for the three months ended March 31, 2016 was \$13.9 million.

Pipeline Information

The Company currently has four abbreviated new drug applications filed with the FDA, targeting products with a market size of over \$0.5 billion, three biosimilar products in development with a market size of \$15.0 billion, and another 10 generic products in development targeting products with a market size of over \$10.0 billion. This market information is based on IMS Health data for the 12 months ended March 31, 2016. The Company's proprietary pipeline includes new drug applications for Primatene[®] 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 ("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 the 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 9, 2016, 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 3106465.

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, sales and marketing of its products, market size and growth, the timing of FDA filings, acquisitions and other matters related to its pipeline of product candidates, material weakness in our internal controls 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," "will," "could," "would," "should," "anticipate," "predict," "potential," "continue," "expects," "intends," "plans," "projects," "believes," "estimates," 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 our 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,	
	2016	2015
Net revenues	\$ 59,366	\$ 56,886
Cost of revenues	34,464	43,606
Gross profit	24,902	13,280
Operating expenses:		
Selling, distribution, and marketing	1,352	1,522
General and administrative	10,870	12,451
Research and development	8,388	6,568
Impairment of long-lived assets	217	—
Total operating expenses	20,827	20,541
Income (loss) from operations	4,075	(7,261)
Non-operating income (expense), net	(259)	1,064

Income (loss) before income taxes	3,816	(6,197)
Income tax expense (benefit)	1,327	(5,532)
Net income (loss)	\$ 2,489	\$ (665)
Net income (loss) per share:		
Basic	\$ 0.06	\$ (0.01)
Diluted	\$ 0.05	\$ (0.01)
Weighted-average shares used to compute net income (loss) per share:		
Basic	45,041	44,601
Diluted	46,810	44,601

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

	Three Months Ended March 31, 2016			2015		
	GAAP	Non-GAAP Adjustments*	Non-GAAP As Adjusted	GAAP	Non-GAAP Adjustments*	Non-GAAP As Adjusted
Net revenues	\$ 59,366	\$ —	\$ 59,366	\$ 56,886	\$ —	\$ 56,886
Cost of revenues	34,464	(1,245)	33,219	43,606	(933)	42,673
Gross profit	24,902	1,245	26,147	13,280	933	14,213
Operating expenses:						
Selling, distribution, and marketing	1,352	(66)	1,286	1,522	(39)	1,483
General and administrative	10,870	(2,680)	8,190	12,451	(1,525)	10,926
Research and development	8,388	(340)	8,048	6,568	(212)	6,356
Impairment of long-lived assets	217	(217)	—	—	—	—

Total operating expenses	20,827	(3,303)	17,524	20,541	(1,776)	18,765
Income (loss) from operations	4,075	4,548	8,623	(7,261)	2,709	(4,552)
Non-operating income (expense), net	(259)	—	(259)	1,064	—	1,064
Income (loss) before income taxes	3,816	4,548	8,364	(6,197)	2,709	(3,488)
Income tax expense (benefit)	1,327	1,582	2,909	(5,532)	2,418	(3,114)
Net income (loss)	\$ 2,489	\$ 2,966	\$ 5,455	\$ (665)	\$ 291	\$ (374)
Net income (loss) per share:						
Basic	\$ 0.06		\$ 0.12	\$ (0.01)		\$ (0.01)
Diluted	\$ 0.05		\$ 0.12	\$ (0.01)		\$ (0.01)
Weighted-average shares used to compute net income (loss) per share:						
Basic	45,041		45,041	44,601		44,601
Diluted	46,810		46,810	44,601		44,601

* Non-GAAP adjustments include reversal of intangible amortization expense and share-based compensation as well as impairment of long-lived assets:

**Three Months Ended March 31,
2016**

2015

Impairment

	Intangible Amortization Expense	Share-Based Compensation Expense	of Long- Lived Assets	Total Non- GAAP Adjustment	Intangible Amortization Expense	Share-Based Compensatio Expense
Cost of revenues	(446)	(799)	—	(1,245)	(445)	(488)
Selling, distribution, and marketing	—	(66)	—	(66)	—	(39)
General and administrative	(34)	(2,646)	—	(2,680)	(35)	(1,490)
Research and development	—	(340)	—	(340)	—	(212)
Impairment of long-lived assets	—	—	(217)	(217)	—	—

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