

Amphastar Pharmaceuticals Reports Financial Results for the Three Months Ended September 30, 2016

November 8, 2016

Reports Net Revenues of \$64.2 Million for the Three Months Ended September 30, 2016

RANCHO CUCAMONGA, Calif., Nov. 08, 2016 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) (“Amphastar” or the “Company”) today reported results for the three months ended September 30, 2016.

Third Quarter Highlights

- Net revenues of \$64.2 million for the third quarter
- GAAP net income of \$3.9 million, or \$0.08 per diluted share for the third quarter
- Adjusted non-GAAP net income of \$6.6 million, or \$0.14 per diluted share for the third quarter

Dr. Jack Zhang, Amphastar’s CEO, commented: “We are pleased with the Company’s profitability for the quarter and look forward to potential product approvals in the coming months.”

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
	(in thousands, except per share data)			
Net revenues	\$ 64,223	\$ 63,868	\$ 191,622	\$ 174,607
GAAP net income (loss)	\$ 3,890	\$ (3,008)	\$ 13,274	\$ (10,320)
Adjusted non-GAAP net income (loss)*	\$ 6,648	\$ (256)	\$ 22,557	\$ (4,889)
GAAP diluted EPS	\$ 0.08	\$ (0.07)	\$ 0.29	\$ (0.23)
Adjusted non-GAAP diluted EPS*	\$ 0.14	\$ (0.01)	\$ 0.49	\$ (0.11)

* 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.

Third Quarter Results

For the three months ended September 30, 2016, the Company reported net revenues of \$64.2 million, an increase of 1% compared to \$63.9 million for the three months ended September 30, 2015.

During the three months ended September 30, 2016, net revenues of enoxaparin were \$15.4 million, a decrease of 28% compared to \$21.3 million for the three months ended September 30, 2015, primarily due to lower unit volumes in the retail market.

Other finished pharmaceutical product revenues were \$43.7 million for the three months ended September 30, 2016, an increase of 19% compared to \$36.6 million for the three months ended September 30, 2015, largely due to an increase in sales of phytonadione to \$8.7 million from \$5.9 million. Sales of naloxone increased to \$12.4 million from \$10.5 million, as a result of an increase in unit volumes, which were partially offset by \$0.9 million of increased rebates. Additionally, sales of lidocaine increased to \$8.3 million from \$6.2 million.

Sales of the Company's insulin active pharmaceutical ingredient ("API") products were \$5.2 million for the three months ended September 30, 2016, compared to \$6.0 million for the three months ended September 30, 2015, as MannKind purchased its remaining unfulfilled 2015 commitments during the third quarter of 2016, but has not purchased any of its 2016 commitments under its Supply Agreement.

Cost of revenues were \$36.6 million, or 57% of revenues, and \$46.3 million, or 72% of revenues, for the three months ended September 30, 2016 and 2015, respectively, representing a decrease of \$9.7 million, or 21%. Cost of revenues of enoxaparin decreased by \$6.7 million, primarily due to a decrease in average cost per unit of \$1.8 million as a result of lower heparin input costs and a decrease in unit volumes of \$4.9 million. In addition, there was an increase in manufacturing volumes in the third quarter of 2016, which increased overhead absorption. This benefit was partially offset by increased personnel costs at both the Amphastar and IMS facilities.

Selling, distribution, and marketing expenses were \$1.3 million and \$1.2 million for the three months ended September 30, 2016 and 2015, respectively. General and administrative expenses were \$10.8 million and \$9.0 million for the three months ended September 30, 2016 and 2015, respectively. This \$1.8 million increase in general and administrative expenses was primarily due to an increase in legal fees.

For the three months ended September 30, 2016, research and development expenses decreased by 13% to \$9.7 million, compared to \$11.1 million in the third quarter of 2015. This decrease was primarily due to a decrease in clinical trials expense.

The Company recorded an income tax expense of \$2.1 million for the three months ended September 30, 2016, compared to an income tax benefit of \$1.3 million for the three months ended September 30, 2015.

The Company reported a quarterly net income of \$3.9 million, or \$0.08 per fully diluted share, for the three months ended September 30, 2016, compared to a net loss of \$3.0 million, or \$0.07 per fully diluted share, for the three months ended September 30, 2015. The Company reported an adjusted non-GAAP quarterly net income of \$6.6 million, or \$0.14 per fully diluted share, for the three months ended September 30, 2016, compared to adjusted non-GAAP net loss of \$0.3 million, or \$0.01 per fully diluted share, for the three months ended September 30, 2015. 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 as of September 30, 2016, were \$66.6 million. Cash flow provided by operating activities for the nine months ended September 30, 2016, was \$24.6 million.

Share buyback program

On November 7, 2016, 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 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 11 generic products in development targeting products with a market size of over \$11.0 billion. This market information is based on IMS Health data for the 12 months ended September 30, 2016. The Company's proprietary pipeline includes new drug applications 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 ("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, November 8, 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 98643531.

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 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 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		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Net revenues	\$ 64,223	\$ 63,868	\$ 191,622	\$ 174,607

Cost of revenues	36,611	46,290	107,394	130,431
Gross profit	27,612	17,578	84,228	44,176
Operating expenses:				
Selling, distribution, and marketing	1,291	1,171	3,975	4,163
General and administrative	10,801	9,034	31,129	32,793
Research and development	9,723	11,117	28,591	28,411
Impairment of long-lived assets	—	4	331	78
Total operating expenses	21,815	21,326	64,026	65,445
Income (loss) from operations	5,797	(3,748)	20,202	(21,269)
Non-operating income (expense), net	204	(528)	(633)	567
Income (loss) before income taxes	6,001	(4,276)	19,569	(20,702)
Income tax expense (benefit)	2,111	(1,268)	6,295	(10,382)
Net income (loss)	\$ 3,890	\$ (3,008)	\$ 13,274	\$ (10,320)
Net income (loss) per share:				
Basic	\$ 0.09	\$ (0.07)	\$ 0.29	\$ (0.23)
Diluted	\$ 0.08	\$ (0.07)	\$ 0.29	\$ (0.23)
Weighted-average shares used to compute net income (loss) per share:				
Basic	45,398	45,310	45,132	44,920
Diluted	47,953	45,310	46,365	44,920

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
GAAP net income (loss)	\$ 3,890	\$ (3,008)	\$ 13,274	\$ (10,320)
Adjusted for:				

Intangible amortization	701	481	1,751	1,459
Share-based compensation	3,555	3,427	11,604	9,357
Impairment of long-lived assets	—	4	331	78
Income tax expense (benefit) on pre-tax adjustments	(1,498)	(1,160)	(4,403)	(5,463)
Non-GAAP net income (loss)	\$ 6,648	\$ (256)	\$ 22,557	\$ (4,889)

Non-GAAP net income (loss) per share:

Basic	\$ 0.15	\$ (0.01)	\$ 0.50	\$ (0.11)
Diluted	\$ 0.14	\$ (0.01)	\$ 0.49	\$ (0.11)

Weighted-average shares used to compute non-GAAP net income (loss) per share:

Basic	45,398	45,310	45,132	44,920
Diluted	47,953	45,310	46,365	44,920

**Three Months Ended September 30,
2016**

	Cost of Revenue	Selling, distribution and marketing	General and administrative	Research and development	Impairment of long-lived assets	Income tax expense
GAAP	\$ 36,611	\$ 1,291	\$ 10,801	\$ 9,723	\$ —	\$ —
Intangible amortization	(511)	—	(190)	—	—	—
Share-based compensation	(675)	(45)	(2,593)	(242)	—	—
Impairment of long-lived assets	—	—	—	—	—	—
Income tax expense (benefit) on pre-tax adjustments	—	—	—	—	—	—
Non-GAAP	\$ 35,425	\$ 1,246	\$ 8,018	\$ 9,481	\$ —	\$ —

**Three Months Ended September 30,
2015**

	Cost of Revenue	Selling, distribution and marketing	General and administrative	Research and development	Impairment of long-lived assets	Income tax expense (benefit)
GAAP	\$ 46,290	\$ 1,171	\$ 9,034	\$ 11,117	\$ 4	\$ (1,268)
Intangible amortization	(446)	—	(35)	—	—	—
Share-based compensation	(638)	(49)	(2,536)	(204)	—	—
Impairment of long-lived assets	—	—	—	—	(4)	—
Income tax expense (benefit) on pre-tax adjustments	—	—	—	—	—	1,160
Non-GAAP	\$ 45,206	\$ 1,122	\$ 6,463	\$ 10,913	\$ —	\$ (108)

Reconciliation of Non-GAAP Measures (continued)

Nine Months Ended September 30, 2016

	Cost of Revenue	Selling, distribution and marketing	General and administrative	Research and development	Impairment of long-lived assets	Income tax expense (benefit)
GAAP	\$ 107,394	\$ 3,975	\$ 31,129	\$ 28,591	\$ 331	\$ 6,295
Intangible amortization	(1,492)	—	(259)	—	—	—
Share-based compensation	(2,245)	(176)	(8,339)	(844)	—	—
Impairment of long-lived assets	—	—	—	—	(331)	—
Income tax expense (benefit) on pre-tax adjustments	—	—	—	—	—	4,403
Non-GAAP	\$ 103,657	\$ 3,799	\$ 22,531	\$ 27,747	\$ —	\$ 10,698

Nine Months Ended September 30,

	2015					
	Cost of Revenue	Selling, distribution and marketing	General and administrative	Research and development	Impairment of long-lived assets	Income tax expense (benefit)
GAAP	\$ 130,431	\$ 4,163	\$ 32,793	\$ 28,411	\$ 78	\$ (10,382)
Intangible amortization	(1,337)	—	(122)	—	—	—
Share-based compensation	(1,856)	(148)	(6,676)	(677)	—	—
Impairment of long-lived assets	—	—	—	—	(78)	—
Income tax expense (benefit) on pre-tax adjustments	—	—	—	—	—	5,463
Non-GAAP	\$ 127,238	\$ 4,015	\$ 25,995	\$ 27,734	\$ —	\$ (4,919)

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Source: Amphastar Pharmaceuticals Inc.