

Amphastar Pharmaceuticals Reports Net Revenues of \$63.9 Million for the Third Quarter Ended September 30, 2015

November 12, 2015

RANCHO CUCAMONGA, Calif., Nov. 12, 2015 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) ("Amphastar" or the "Company") today reported results for the third quarter ended September 30, 2015.

- Net revenues of \$63.9 million for the third quarter
- GAAP net loss of \$3.0 million, or \$0.07 per diluted share for the third quarter
- Adjusted non-GAAP net loss of \$0.3 million, or \$0.01 per diluted share for the third quarter

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(in thousands, except per share data)			
Net revenues	\$ 63,868	\$ 59,711	\$ 174,607	\$ 154,584
GAAP net loss	\$ (3,008)	\$ (5,379)	\$ (10,320)	\$ (8,178)
Adjusted non-GAAP net loss*	\$ (256)	\$ (3,255)	\$ (4,889)	\$ (2,555)
GAAP diluted EPS	\$ (0.07)	\$ (0.12)	\$ (0.23)	\$ (0.20)
Adjusted non-GAAP diluted EPS*	\$ (0.01)	\$ (0.07)	\$ (0.11)	\$ (0.06)

*see Table II for reconciliation of non-GAAP measures to the most directly comparable GAAP measures

Third Quarter Results

For the three months ended September 30, 2015, the Company reported net revenues of \$63.9 million, an increase of 7% from \$59.7 million for the third quarter of 2014.

During the quarter, net revenues of enoxaparin were \$21.3 million, a decrease of 34% compared to \$32.0 million for the third quarter of 2014, due to lower average selling prices.

Other finished pharmaceutical product revenues were \$36.6 million for the quarter, an increase of 69% compared to \$21.7 million for the third quarter of 2014, which was primarily due to an increase in sales of naloxone to \$10.5 million from \$3.7 million, as a result of increased unit volumes at higher average prices.

Sales of the Company's insulin API products were \$6.0 million for the quarter compared to \$6.0 million for the third quarter of 2014.

Cost of revenues were \$46.3 million, or 72% of revenues, and \$47.9 million, or 80% of revenues, for the three months ended September 30, 2015 and 2014, respectively, representing a decrease of \$1.6 million, or 3%. Pricing declines in enoxaparin were offset by pricing increases in other finished pharmaceutical products. These pricing trends along with lower average heparin material costs, led to the improvement in gross margins.

Selling, distribution, and marketing expenses were \$1.2 million and \$1.5 million for the three months ended September 30, 2015 and 2014, respectively. General and administrative expenses were \$9.0 million and \$9.6 million for the three months ended September 30, 2015 and 2014, respectively. The decrease was primarily due to a decrease in legal expenses during the third quarter of 2015.

For the three months ended September 30, 2015, research and development expenses increased by 29% to \$11.1 million from \$8.6 million, compared to the third quarter of 2014. This increase was primarily due to an increase in clinical trial expense for intranasal naloxone and generic pipeline products. An increase of \$1.1 million in pre-launch inventory and purchases of materials relating to the approval and October 2015 re-launch of Amphadase[®] also contributed to the increase.

The Company recorded an income tax benefit of \$1.3 million and \$2.6 million for the three months ended September 30, 2015 and 2014, respectively. The decrease was primarily related to a smaller pre-tax loss that occurred during the three months ended September 30, 2015.

The Company reported a quarterly net loss of \$3.0 million, or \$0.07 per fully diluted share, for the three months ended September 30, 2015, compared to a net loss of \$5.4 million, or \$0.12 per fully diluted share, for the same period in the prior year. The Company reported an adjusted non-GAAP quarterly net loss of \$0.3 million, or \$0.01 per fully diluted share, for the three months ended September 30, 2015, compared to adjusted non-GAAP net loss of \$3.3 million, or \$0.07 per fully diluted share, for the same period in the prior year.

The Company's cash and cash equivalents, and short-term investments at September 30, 2015 were \$72.0 million. Cash flow provided by operating activities for the nine months ended September 30, 2015 was \$7.4 million.

Share buyback program

On November 10, 2015, the Company's Board of Directors authorized an increase of \$10.0 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, and another 11 generic products in development targeting products with a market size of over \$17.0 billion. This market information is based on IMS Health data for the 12 months ended September 30, 2015. The proprietary pipeline

includes a new drug application, or NDA, for Primatene[®]. The Company is currently developing six other proprietary drugs including injectables, inhalation products, and other dosage forms.

Dr. Jack Zhang, CEO, commented: "We are pleased with our sales increase and pipeline progress this quarter and look forward to filing our NDA for intranasal naloxone soon."

Company Information

Amphastar is a specialty pharmaceutical company that focuses primarily on developing, manufacturing, marketing, and selling technically-challenging generic and proprietary injectable and inhalation products. Additionally, in 2014, the Company commenced sales of 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.

Non-GAAP Financial Measures

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 generally accepted accounting principles in the U.S. or "GAAP." In addition to disclosing its financial results determined in accordance with GAAP, the Company is disclosing certain non-GAAP results 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, November 12, 2015, 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 73231171. The call will be webcast live and 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 that are not historical are forward-looking statements, including, among other things, statements relating to the Company's expectations regarding sales and marketing of its products, the timing of FDA filings and other matters related to its pipeline of product candidates and other future events. These statements are not historical facts but rather are based on Amphastar's 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. Amphastar undertakes no obligation to revise or update information in this press release to reflect events or circumstances in the future, even if new information becomes available.

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,	
	2015	2014	2015	2014
Net revenues	\$ 63,868	\$ 59,711	\$ 174,607	\$ 154,584
Cost of revenues	46,290	47,920	130,431	115,288
Gross profit	17,578	11,791	44,176	39,296
Operating expenses:				
Selling, distribution, and marketing	1,171	1,454	4,163	4,066
General and administrative	9,034	9,556	32,793	25,040
Research and development	11,117	8,585	28,411	20,788
Impairment of long-lived assets	4	13	78	361
Total operating expenses	21,326	19,608	65,445	50,255
Loss from operations	(3,748)	(7,817)	(21,269)	(10,959)
Non-operating income (expense), net	(528)	(167)	567	(1,372)
Loss before income taxes	(4,276)	(7,984)	(20,702)	(12,331)
Income tax benefit	(1,268)	(2,605)	(10,382)	(4,153)
Net loss	\$ (3,008)	\$ (5,379)	\$ (10,320)	\$ (8,178)

Net loss per share:				
Basic	\$ (0.07)	\$ (0.12)	\$ (0.23)	\$ (0.20)
Diluted	\$ (0.07)	\$ (0.12)	\$ (0.23)	\$ (0.20)

Weighted-average shares used to compute net loss per share:

Basic	45,310	44,644	44,920	41,060
Diluted	45,310	44,644	44,920	41,060

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

	Three Months Ended September 30,					
	2015		2014			
	GAAP	Non-GAAP Adjustments*	Non-GAAP As Adjusted	GAAP	Non-GAAP Adjustments*	Non-GAAP As Adjusted
Net revenues	\$ 63,868	\$ —	\$ 63,868	\$ 59,711	\$ —	\$ 59,711
Cost of revenues	46,290	(1,084)	45,206	47,920	(896)	47,024
Gross profit	17,578	1,084	18,662	11,791	896	12,687
Operating expenses:						
Selling, distribution, and marketing	1,171	(49)	1,122	1,454	(46)	1,408
General and administrative	9,034	(2,571)	6,463	9,556	(1,984)	7,572
Research and development	11,117	(204)	10,913	8,585	(214)	8,371
Impairment of long-lived assets	4	(4)	—	13	(13)	—
Total operating expenses	21,326	(2,828)	18,498	19,608	(2,257)	17,351
Loss from operations	(3,748)	3,912	164	(7,817)	3,153	(4,664)

Non-operating income (expense), net	(528)	—	(528)	(167)	—	(167)
Loss before income taxes	(4,276)	3,912	(364)	(7,984)	3,153	(4,831)
Income tax benefit	(1,268)	1,160	(108)	(2,605)	1,029	(1,576)
Net loss	\$ (3,008)	\$ 2,752	\$ (256)	\$ (5,379)	\$ 2,124	\$ (3,255)
Net income loss per share:						
Basic	\$ (0.07)		\$ (0.01)	\$ (0.12)		\$ (0.07)
Diluted	\$ (0.07)		\$ (0.01)	\$ (0.12)		\$ (0.07)
Weighted-average shares used to compute net loss per share:						
Basic	45,310		45,310	44,644		44,644
Diluted	45,310		45,130	44,644		44,644

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

	Three Months Ended September 30,			2014			Impa of Long Asset
	2015						
	Intangible Amortization Expense	Share-Based Compensation Expense	Impairment of Long-Lived Assets	Total Non-GAAP Adjustment	Intangible Amortization Expense	Share-Based Compensation Expense	
Cost of revenues	(446)	(638)	—	(1,084)	(446)	(450)	—
Selling, distribution, and marketing	—	(49)	—	(49)	—	(46)	—
General and administrative	(35)	(2,536)	—	(2,571)	(35)	(1,949)	—
Research and development	—	(204)	—	(204)	—	(214)	—

Impairment of long-lived assets	—	—	(4)	(4)	—	—	(13)
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Reconciliation of Non-GAAP Measures (continued)

	Nine Months Ended September 30,					
	2015			2014		
	GAAP	Non-GAAP Adjustments*	Non-GAAP As Adjusted	GAAP	Non-GAAP Adjustments*	Non-GAAP As Adjusted
Net revenues	\$ 174,607	\$ —	\$ 174,607	\$ 154,584	\$ —	\$ 154,584
Cost of revenues	130,431	(3,193)	127,238	115,288	(2,438)	112,850
Gross profit	44,176	3,193	47,369	39,296	2,438	41,734
Operating expenses:						
Selling, distribution, and marketing	4,163	(148)	4,015	4,066	(96)	3,970
General and administrative	32,793	(6,798)	25,995	25,040	(5,098)	19,942
Research and development	28,411	(677)	27,734	20,788	(485)	20,303
Impairment of long-lived assets	78	(78)	—	361	(361)	—
Total operating expenses	65,445	(7,701)	57,744	50,255	(6,040)	44,215
Loss from operations	(21,269)	10,894	(10,375)	(10,959)	8,478	(2,481)
Non-operating income (expense), net	567	—	567	(1,372)	—	(1,372)
Loss before income taxes	(20,702)	10,894	(9,808)	(12,331)	8,478	(3,853)
Income tax benefit	(10,382)	5,463	(4,919)	(4,153)	2,855	(1,298)

Net loss	\$ (10,320)	\$ 5,431	\$ (4,889)	\$ (8,178)	\$ 5,623	\$ (2,555)
Net loss per share:						
Basic	\$ (0.23)		\$ (0.11)	\$ (0.20)		\$ (0.06)
Diluted	\$ (0.23)		\$ (0.11)	\$ (0.20)		\$ (0.06)
Weighted-average shares used to compute net loss per share:						
Basic	44,920		44,920	41,060		41,060
Diluted	44,920		44,920	41,060		41,060

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

	Nine Months Ended September 30,						
	2015			2014			
	Intangible Amortization Expense	Share-Based Compensation Expense	Impairment of Long-Lived Assets	Total Non-GAAP Adjustment	Intangible Amortization Expense	Share-Based Compensation Expense	Impairment of Long-Lived Assets
Cost of revenues	(1,337)	(1,856)	—	(3,193)	(1,335)	(1,103)	—
Selling, distribution, and marketing	—	(148)	—	(148)	—	(96)	—
General and administrative	(122)	(6,676)	—	(6,798)	(102)	(4,996)	—
Research and development	—	(677)	—	(677)	—	(485)	—
Impairment of long-lived assets	—	—	(78)	(78)	—	—	(361)

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Source: Amphastar Pharmaceuticals, Inc.