

# Amphastar Pharmaceuticals Reports Financial Results for the Fourth Quarter and Fiscal Year Ended December 31, 2015

March 14, 2016

RANCHO CUCAMONGA, Calif., March 14, 2016 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) (“Amphastar” or the “Company”) today reported results for the fourth quarter and fiscal year ended December 31, 2015.

## Fourth Quarter Highlights

- Net revenues of \$76.9 million for the fourth quarter
- GAAP net income of \$7.5 million, or \$0.16 per diluted share for the fourth quarter
- Adjusted non-GAAP net income of \$9.1 million, or \$0.19 per diluted share for the fourth quarter

## Fiscal Year Highlights

- Net revenues of \$251.5 million for the fiscal year
- GAAP net loss of \$2.8 million, or \$0.06 per diluted share, for the fiscal year
- Adjusted non-GAAP net income of \$2.9 million, or \$0.06 per diluted share, for the fiscal year

Dr. Jack Zhang, Amphastar’s CEO, commented: “We are pleased with the progress of our pipeline development and happy with recent acquisitions and product launches which diversify our portfolio and expand our vertical integration strategy.”

	<b>Three Months Ended</b>		<b>Year Ended</b>	
	<b>December 31,</b>		<b>December 31,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
	<b>(in thousands, except per share data)</b>			
Net revenues	\$ 76,912	\$ 55,877	\$ 251,519	\$ 210,461
GAAP net income (loss)	\$ 7,533	\$ (2,521 )	\$ (2,787 )	\$ (10,699 )
Adjusted non-GAAP net income (loss)*	\$ 9,074	\$ (1,496 )	\$ 2,895	\$ (5,003 )
GAAP diluted EPS	\$ 0.16	\$ (0.06 )	\$ (0.06 )	\$ (0.25 )
Adjusted non-GAAP diluted EPS*	\$ 0.19	\$ (0.03 )	\$ 0.06	\$ (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 reconciliations in Table II of this press release.

## Fourth Quarter Results

For the three months ended December 31, 2015, the Company reported net revenues of \$76.9 million, an increase of 38% from \$55.9 million for the fourth quarter of 2014.

During the quarter, net revenues of enoxaparin were \$19.9 million, a decrease of 10% compared to \$22.1 million for the fourth quarter of 2014, primarily due to lower average selling prices.

Other finished pharmaceutical product revenues were \$46.2 million for the fourth quarter, an increase of 66% compared to \$27.9 million for the fourth quarter of 2014, primarily due to an increase in sales of naloxone to \$10.7 million from \$7.6 million, as a result of increased unit volumes at higher average prices. Additionally, there were price increases in several other finished pharmaceutical products.

Sales of the Company's insulin active pharmaceutical ingredient ("API") products were \$10.8 million for the quarter compared to \$5.9 million for the fourth quarter of 2014. A majority of the API revenues were related to sales to MannKind.

Cost of revenues were \$43.7 million, or 57% of revenues, and \$43.9 million, or 79% of revenues, for the three months ended December 31, 2015 and 2014, respectively, representing a decrease of \$0.2 million. Gross margins improved primarily due to pricing increases in several finished pharmaceutical products, which were partially offset by pricing declines in enoxaparin. Additionally, lower average heparin material costs contributed to the improvement in gross margins.

Selling, distribution, and marketing expenses were \$1.3 million and \$1.5 million for the three months ended December 31, 2015 and 2014, respectively. General and administrative expenses were \$8.7 million and \$9.8 million for the three months ended December 31, 2015 and 2014, respectively. This decrease was primarily due to a decrease in corporate compensation expenses during the fourth quarter of 2015.

For the three months ended December 31, 2015, research and development expenses increased by 14% to \$8.7 million from \$7.6 million, compared to the fourth quarter of 2014. This increase was primarily due to an increase in clinical trial expense for the Company's generic pipeline products.

The Company recorded an income tax expense of \$2.8 million for the three months ended December 31, 2015, and an income tax benefit of \$3.3 million for the three months ended December 31, 2014.

The Company reported a quarterly net income of \$7.5 million, or \$0.16 per fully diluted share, for the three months ended December 31, 2015, compared to a net loss of \$2.5 million, or \$0.06 per fully diluted share, for the same period in the prior year. The Company reported an adjusted non-GAAP quarterly net income of \$9.1 million, or \$0.19 per fully diluted share, for the three months ended December 31, 2015, compared to adjusted non-GAAP net loss of \$1.5 million, or \$0.03 per fully diluted share, for the same period in the prior year.

## Year-End Results

For the year ended December 31, 2015, the Company reported net revenues of \$251.5 million, an increase of 20% from \$210.5 million for fiscal 2014.

During fiscal 2015, net revenues of enoxaparin were \$84.5 million, a decrease of 21% compared to \$107.5 million for fiscal 2014, primarily due to lower average selling prices.

Other finished pharmaceutical product revenues were \$140.4 million for the year, an increase of 54% compared to \$91.0 million for fiscal 2014, primarily due to an increase in sales of naloxone to \$38.6 million from \$19.2 million, as a result of increased unit volumes at higher average prices. Additionally, there were price increases in several other finished pharmaceutical products.

Sales of the Company's insulin API products were \$26.6 million for the year compared to \$12.0 million for fiscal 2014. A majority of the API revenues were related to sales to MannKind.

Cost of revenues were \$174.2 million, or 69% of revenues, and \$159.2 million, or 76% of revenues, for the years ended December 31, 2015 and 2014, respectively, representing an increase of \$15.0 million, or 9%. Gross margins improved primarily due to pricing increases in several finished pharmaceutical products, which were partially offset by pricing declines in enoxaparin. Additionally, lower average heparin material costs contributed to the improvement in gross margins.

Selling, distribution, and marketing expenses were \$5.5 million and \$5.6 million for the years ended December 31, 2015 and 2014, respectively. General and administrative expenses were \$41.5 million and \$34.8 million for the years ended December 31, 2015 and 2014, respectively. The \$6.7 million increase in general and administrative expenses was primarily due to a \$3.3 million expense relating to a litigation settlement as well as expenses related to costs associated with the Company's compliance with public company reporting obligations. Additionally, the inclusion of expenses generated at the Company's French subsidiary, AFP, which we acquired in April 2014 contributed to the increase.

For the year ended December 31, 2015, research and development expenses increased by 30% to \$37.1 million from \$28.4 million, compared to fiscal 2014. This increase was primarily due to an increase in clinical trial expense for intranasal naloxone and the Company's other generic pipeline products. Additionally, the Company had an increase in pre-launch inventory and purchases of materials relating to the approval and re-launch of Amphadase<sup>®</sup> in October 2015.

The Company recorded an income tax benefit of \$7.6 million and \$7.4 million for the years ended December 31, 2015 and 2014, respectively.

The Company reported a net loss of \$2.8 million, or \$0.06 per fully diluted share, for the year ended December 31, 2015, compared to a net loss of \$10.7 million, or \$0.25 per fully diluted share, for the same period in the prior year. The Company reported an adjusted non-GAAP net income of \$2.9 million, or \$0.06 per fully diluted share, for the year ended December 31, 2015, compared to adjusted non-GAAP net loss of \$5.0 million, or \$0.12 per fully diluted share, for fiscal 2014.

The Company's cash and cash equivalents, and short-term investments at December 31, 2015, were \$67.4 million. Cash flow provided by operating activities for the year ended December 31, 2015 was \$10.7 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, and another 12 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 December 31, 2015. The proprietary pipeline includes a new drug application for Primatene<sup>®</sup>. The Company is currently developing five other proprietary drugs including injectables, inhalation products, and other 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, 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](http://www.amphastar.com).

The Amphastar Pharmaceuticals logo and other trademarks or service marks of Amphastar Pharmaceuticals, Inc., including, but not limited to Primatene<sup>®</sup>, Amphadase<sup>®</sup> and Cortrosyn<sup>®</sup>, 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, March 14, 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 65494178.

The call can also be accessed on the Investors page on the Company's website [www.amphastar.com](http://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](http://www.sec.gov). Amphastar undertakes no obligation to revise or update information in this press release or the conference call referenced about 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)**

	<b>Three Months Ended</b>		<b>Year Ended</b>	
	<b>December 31,</b>		<b>December 31,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Net revenues	\$ 76,912	\$ 55,877	\$ 251,519	\$ 210,461
Cost of revenues	43,741	43,916	174,172	159,205
Gross profit	33,171	11,961	77,347	51,256
Operating expenses:				
Selling, distribution, and marketing	1,307	1,497	5,470	5,564
General and administrative	8,711	9,770	41,504	34,809
Research and development	8,654	7,639	37,065	28,427
Impairment of long-lived assets	128	79	206	439
Total operating expenses	18,800	18,985	84,245	69,239
Income (loss) from operations	14,371	(7,024 )	(6,898 )	(17,983 )
Non-operating income (expense), net	(4,033 )	1,207	(3,466 )	(165 )
Income (loss) before income taxes	10,338	(5,817 )	(10,364 )	(18,148 )
Income tax expense (benefit)	2,805	(3,296 )	(7,577 )	(7,449 )
Net income (loss)	\$ 7,533	\$ (2,521 )	\$ (2,787 )	\$ (10,699 )
Net income (loss) per share:				
Basic	\$ 0.17	\$ (0.06 )	\$ (0.06 )	\$ (0.25 )

Diluted \$ 0.16 \$ (0.06 ) \$ (0.06 ) \$ (0.25 )

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

Basic	45,085	44,648	44,961	41,957
Diluted	46,709	44,648	44,961	41,957

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

	Three Months Ended December 31, 2015			2014		
	GAAP	Non-GAAP Adjustments*	Non-GAAP As Adjusted	GAAP	Non-GAAP Adjustments*	Non-GAAP As Adjusted
Net revenues	\$ 76,912	\$ —	\$ 76,912	\$ 55,877	\$ —	\$ 55,877
Cost of revenues	43,741	(1,116 )	42,625	43,916	(751 )	43,165
Gross profit	33,171	1,116	34,287	11,961	751	12,712
Operating expenses:						
Selling, distribution, and marketing	1,307	(44 )	1,263	1,497	(35 )	1,462
General and administrative	8,711	(2,542 )	6,169	9,770	(1,323 )	8,447
Research and development	8,654	(235 )	8,419	7,639	(177 )	7,462
Impairment of long-lived assets	128	(128 )	—	79	(79 )	—
Total operating expenses	18,800	(2,949 )	15,851	18,985	(1,614 )	17,371
Income (loss) from operations	14,371	4,065	18,436	(7,024 )	2,365	(4,659 )

Non-operating income (expense), net	(4,033 )	—	(4,033 )	1,207	—	1,207
Income (loss) before income taxes	10,338	4,065	14,403	(5,817 )	2,365	(3,452 )
Income tax expense (benefit)	2,805	2,524	5,329	(3,296 )	1,340	(1,956 )
Net income (loss)	\$ 7,533	\$ 1,541	\$ 9,074	\$ (2,521 )	\$ 1,025	\$ (1,496 )
Net income (loss) per share:						
Basic	\$ 0.17		\$ 0.20	\$ (0.06 )		\$ (0.03 )
Diluted	\$ 0.16		\$ 0.19	\$ (0.06 )		\$ (0.03 )
Weighted-average shares used to compute net income (loss) per share:						
Basic	45,085		45,085	44,648		44,648
Diluted	46,709		46,742	44,648		44,648

\* 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 December 31,			2014		
	2015		Impairment	Total Non-	Intangible	Share-Based
	Intangible Amortization Expense	Share-Based Compensation Expense	of Long-Lived Assets	GAAP Adjustment	Amortization Expense	Compensation Expense
Cost of revenues	(445 )	(671 )	—	(1,116 )	(445 )	(306 )
Selling, distribution,	—	(44 )	—	(44 )	—	(35 )

and marketing						
General and administrative	(34 )	(2,508 )	—	(2,542 )	(35 )	(1,288 )
Research and development	—	(235 )	—	(235 )	—	(177 )
Impairment of long-lived assets	—	—	(128 )	(128 )	—	—

### Reconciliation of Non-GAAP Measures (continued)

	Year Ended December 31, 2015			2014		
	GAAP	Non-GAAP Adjustments*	Non-GAAP As Adjusted	GAAP	Non-GAAP Adjustments*	Non-GAAP As Adjusted
Net revenues	\$ 251,519	\$ —	\$ 251,519	\$ 210,461	\$ —	\$ 210,461
Cost of revenues	174,172	(4,308 )	169,864	159,205	(3,360 )	155,845
Gross profit	77,347	4,308	81,655	51,256	3,360	54,616
Operating expenses:						
Selling, distribution, and marketing	5,470	(192 )	5,278	5,564	(120 )	5,444
General and administrative	41,504	(9,341 )	32,163	34,809	(5,082 )	29,727
Research and development	37,065	(912 )	36,153	28,427	(661 )	27,766
Impairment of long-lived assets	206	(206 )	—	439	(439 )	—
Total operating expenses	84,245	(10,651 )	73,594	69,239	(6,302 )	62,937
Income (loss) from operations	(6,898 )	14,959	8,061	(17,983 )	9,662	(8,322 )
Non-operating	(3,466 )	—	(3,466 )	(165 )	—	(165 )



income  
(expense), net

Income (loss) before income taxes	(10,364 )	14,959	4,595	(18,148 )	9,662	(8,483 )
Income tax expense (benefit)	(7,577 )	9,277	1,700	(7,449 )	3,966	(3,483 )
Net income (loss)	\$ (2,787 )	\$ 5,682	\$ 2,895	\$ (10,699 )	\$ 5,696	\$ (5,003 )
Net income (loss) per share:						
Basic	\$ (0.06 )		\$ 0.06	\$ (0.25 )		\$ (0.12 )
Diluted	\$ (0.06 )		\$ 0.06	\$ (0.25 )		\$ (0.12 )
Weighted- average shares used to compute net Income (loss) per share:						
Basic	44,961		44,961	41,957		41,957
Diluted	44,961		46,820	41,957		41,957

\* 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:

	Year Ended December 31,			Total Non- GAAP Adjustment	2014	
	2015 Intangible Amortization Expense	Share-Based Compensation Expense	Impairment of Long- Lived Assets		Intangible Amortization Expense	Share-Based Compensation Expense
Cost of revenues	(1,782 )	(2,526 )	—	(4,308 )	(1,782 )	(1,578 )
Selling, distribution, and marketing	—	(192 )	—	(192 )	—	(120 )
General and administrative	(156 )	(9,185 )	—	(9,341 )	(137 )	(4,945 )

Research and development	—	(912 )	—	(912 )	—	(661
Impairment of long-lived assets	—	—	(206 )	(206 )	—	—

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Source: Amphastar Pharmaceuticals Inc.