

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

August 8, 2016

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

## Second Quarter Highlights

- Net revenues of \$68.0 million for the second quarter
- GAAP net income of \$6.9 million, or \$0.15 per diluted share for the second quarter
- Adjusted non-GAAP net income of \$10.3 million, or \$0.23 per diluted share for the second quarter

Dr. Jack Zhang, Amphastar’s CEO, commented: “Resubmitting our Primatene<sup>®</sup> NDA this quarter is a big milestone for the company and its inhalation platform. We look forward to the possibility of bringing this product back to the market in early 2017.”

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
	<b>(in thousands, except per share data)</b>			
Net revenues	\$ 68,033	\$ 53,853	\$ 127,399	\$ 110,739
GAAP net income (loss)	\$ 6,895	\$ (6,647 )	\$ 9,384	\$ (7,312 )
Adjusted non-GAAP net income (loss)*	\$ 10,347	\$ (3,870 )	\$ 15,906	\$ (4,204 )
GAAP diluted EPS	\$ 0.15	\$ (0.15 )	\$ 0.21	\$ (0.16 )
Adjusted non-GAAP diluted EPS*	\$ 0.23	\$ (0.09 )	\$ 0.35	\$ (0.09 )

\* 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.

## Second Quarter Results

For the three months ended June 30, 2016, the Company reported net revenues of \$68.0 million, an increase of 26% compared to \$53.9 million for the three months ended June 30, 2015.

During the three months ended June 30, 2016, net revenues of enoxaparin were \$17.3 million, a decrease of 11% compared to \$19.5 million for the three months ended June 30, 2015, primarily due to lower average selling prices.

Other finished pharmaceutical product revenues were \$46.4 million for the three months ended June 30, 2016, an increase of 52% compared to \$30.6 million for the three months ended June 30, 2015, largely due to an increase in sales of naloxone to \$15.6 million from \$10.7 million, as a result of an increase in unit volumes. Pricing of naloxone declined in the three months ended June 30, 2016 compared to the three months ended June 30, 2015, as the Company increased discounting and rebates. Additionally, sales of phytonadione increased to \$8.8 million from \$1.8 million, sales of epinephrine increased to \$5.2 million from \$2.2 million and sales of lidocaine increased to \$8.2 million from \$7.3 million.

Sales of the Company's insulin active pharmaceutical ingredient ("API") products were \$4.3 million for the three months ended June 30, 2016 compared to \$3.8 million for the three months ended June 30, 2015, as MannKind purchased part of their unfulfilled 2015 commitments during the second quarter of 2016.

Cost of revenues were \$36.3 million, or 53% of revenues, and \$40.5 million, or 75% of revenues, for the three months ended June 30, 2016 and 2015, respectively, representing a decrease of \$4.2 million, or 10%. Gross margins improved primarily due to pricing increases in several finished pharmaceutical products, which were partially offset by pricing declines in enoxaparin and naloxone. Lower average heparin material costs also contributed to the improvement in gross margins. Additional factors affecting gross profit in the second quarter of 2016 included an increase in manufacturing volume, 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 \$1.5 million for the three months ended June 30, 2016 and 2015, respectively. General and administrative expenses were \$9.5 million and \$11.3 million for the three months ended June 30, 2016 and 2015, respectively. This \$1.8 million decrease in general and administrative expenses was primarily due to a decrease in personnel costs.

For the three months ended June 30, 2016, research and development expenses decreased by 2% to \$10.5 million, compared to \$10.7 million in the second quarter of 2015. This decrease was primarily due to a decrease in clinical trial expense and research and development supplies. This decrease was partially offset by an increase in FDA fees pertaining to the NDA filing of the Company's intranasal naloxone product candidate.

The Company recorded an income tax expense of \$2.9 million for the three months ended June 30, 2016, compared to an income tax benefit of \$3.6 million for the three months ended June 30, 2015.

The Company reported a quarterly net income of \$6.9 million, or \$0.15 per fully diluted share, for the three months ended June 30, 2016, compared to a net loss of \$6.6 million, or \$0.15 per fully diluted share, for the three months ended June 30, 2015. The Company reported an adjusted non-GAAP quarterly net income of \$10.3 million, or \$0.23 per fully diluted share, for the three months ended June 30, 2016, compared to adjusted non-GAAP net loss of \$3.9 million, or \$0.09 per fully diluted share, for the three months ended June 30, 2015. Please see the discussion in the section entitled "Non-GAAP Financial Measures" and the reconciliations in Table II of this press release.

The Company's cash and cash equivalents, as of June 30, 2016 were \$66.7 million. Cash flow provided by operating activities for the six months ended June 30, 2016 was \$23.3 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 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 June 30, 2016. The Company's proprietary pipeline includes new drug applications for Primatene<sup>®</sup> 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](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, August 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 52341658.

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 or approvals, acquisitions and other matters related to its pipeline of product candidates, its 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 the Company's 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 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)**

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
Net revenues	\$ 68,033	\$ 53,853	\$ 127,399	\$ 110,739
Cost of revenues	36,319	40,535	70,783	84,141
Gross profit	31,714	13,318	56,616	26,598
Operating expenses:				
Selling, distribution, and marketing	1,332	1,470	2,684	2,992
General and administrative	9,458	11,308	20,328	23,759
Research and development	10,480	10,726	18,868	17,294
Impairment of long-lived assets	114	74	331	74
Total operating expenses	21,384	23,578	42,211	44,119
Income (loss) from operations	10,330	(10,260 )	14,405	(17,521 )
Non-operating income (expense), net	(578 )	31	(837 )	1,095
Income (loss) before income taxes	9,752	(10,229 )	13,568	(16,426 )

Income tax expense (benefit)	2,857	(3,582 )	4,184	(9,114 )
Net income (loss)	\$ 6,895	\$ (6,647 )	\$ 9,384	\$ (7,312 )
Net income (loss) per share:				
Basic	\$ 0.15	\$ (0.15 )	\$ 0.21	\$ (0.16 )
Diluted	\$ 0.15	\$ (0.15 )	\$ 0.21	\$ (0.16 )
Weighted-average shares used to compute net income (loss) per share:				
Basic	44,957	44,849	44,999	44,725
Diluted	45,968	44,849	45,712	44,725

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

	Three Months Ended June 30, 2016			2015		
	GAAP	Non-GAAP Adjustments*	Non-GAAP As Adjusted	GAAP	Non-GAAP Adjustments*	Non-GAAP As Adjusted
Net revenues	\$ 68,033	\$ —	\$ 68,033	\$ 53,853	\$ —	\$ 53,853
Cost of revenues	36,319	(1,306 )	35,013	40,535	(1,177 )	39,358
Gross profit	31,714	1,306	33,020	13,318	1,177	14,495
Operating expenses:						
Selling, distribution, and marketing	1,332	(65 )	1,267	1,470	(60 )	1,410
General and administrative	9,458	(3,135 )	6,323	11,308	(2,702 )	8,606
Research and development	10,480	(262 )	10,218	10,726	(261 )	10,465
Impairment of long-lived assets	114	(114 )	—	74	(74 )	—
Total operating expenses	21,384	(3,576 )	17,808	23,578	(3,097 )	20,481

Income (loss) from operations	10,330	4,882	15,212	(10,260 )	4,274	(5,986 )
Non-operating income (expense), net	(578 )	—	(578 )	31	—	31
Income (loss) before income taxes	9,752	4,882	14,634	(10,229 )	4,274	(5,955 )
Income tax expense (benefit)	2,857	1,430	4,287	(3,582 )	1,497	(2,085 )
Net income (loss)	\$ 6,895	\$ 3,452	\$ 10,347	\$ (6,647 )	\$ 2,777	\$ (3,870 )
Net income (loss) per share:						
Basic	\$ 0.15		\$ 0.23	\$ (0.15 )		\$ (0.09 )
Diluted	\$ 0.15		\$ 0.23	\$ (0.15 )		\$ (0.09 )
Weighted-average shares used to compute net income (loss) per share:						
Basic	44,957		44,957	44,849		44,849
Diluted	45,968		45,968	44,849		44,849

\* 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 June 30, 2016			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	(535 )	(771 )	—	(1,306 )	(448 )	(729 )

Selling, distribution, and marketing	—	(65 )	—	(65 )	—	(60 )
General and administrative	(35 )	(3,100 )	—	(3,135 )	(51 )	(2,651 )
Research and development	—	(262 )	—	(262 )	—	(261 )
Impairment of long-lived assets	—	—	(114 )	(114 )	—	—

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

	Six Months Ended June 30, 2016			2015		
	GAAP	Non-GAAP Adjustments*	Non-GAAP As Adjusted	GAAP	Non-GAAP Adjustments*	Non-GAAP As Adjusted
Net revenues	\$ 127,399	\$ —	\$ 127,399	\$ 110,739	\$ —	\$ 110,739
Cost of revenues	70,783	(2,551 )	68,232	84,141	(2,110 )	82,031
Gross profit	56,616	2,551	59,167	26,598	2,110	28,708
Operating expenses:						
Selling, distribution, and marketing	2,684	(131 )	2,553	2,992	(99 )	2,893
General and administrative	20,328	(5,815 )	14,513	23,759	(4,227 )	19,532
Research and development	18,868	(602 )	18,266	17,294	(473 )	16,821
Impairment of long-lived assets	331	(331 )	—	74	(74 )	—
Total operating expenses	42,211	(6,879 )	35,332	44,119	(4,873 )	39,246
Income (loss) from operations	14,405	9,430	23,835	(17,521 )	6,983	(10,538 )

Non-operating income (expense), net	(837 )	—	(837 )	1,095	—	1,095
Income (loss) before income taxes	13,568	9,430	22,998	(16,426 )	6,983	(9,443 )
Income tax expense (benefit)	4,184	2,908	7,092	(9,114 )	3,875	(5,239 )
Net income (loss)	\$ 9,384	\$ 6,522	\$ 15,906	\$ (7,312 )	\$ 3,108	\$ (4,204 )
Net income (loss) per share:						
Basic	\$ 0.21		\$ 0.35	\$ (0.16 )		\$ (0.09 )
Diluted	\$ 0.21		\$ 0.35	\$ (0.16 )		\$ (0.09 )
Weighted-average shares used to compute net Income (loss) per share:						
Basic	44,999		44,999	44,725		44,725
Diluted	45,712		45,712	44,725		44,725

\* 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:

	Six Months Ended June 30,				2015	
	2016				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	(981 )	(1,570 )	—	(2,551 )	(893 )	(1,217 )
Selling, distribution, and marketing	—	(131 )	—	(131 )	—	(99 )



General and administrative	(69 )	(5,746 )	—	(5,815 )	(86 )	(4,141
Research and development	—	(602 )	—	(602 )	—	(473
Impairment of long-lived assets	—	—	(331 )	(331 )	—	—

Contact Information:

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

Source: Amphastar Pharmaceuticals Inc.