Amphastar Pharmaceuticals Reports Financial Results for the Three Months and Fiscal Year Ended December 31, 2016

March 13, 2017

RANCHO CUCAMONGA, Calif., March 13, 2017 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) ("Amphastar" or the "Company") today reported results for the three months and fiscal year ended December 31, 2016.

Fourth Quarter Highlights

- Net revenues of $63.5 million for the fourth quarter
- GAAP net loss of $2.7 million, or $0.06 per share, for the fourth quarter
- Adjusted non-GAAP net income of $0.5 million, or $0.01 per diluted share, for the fourth quarter

Fiscal Year Highlights

- Net revenues of $255.2 million for the fiscal year
- GAAP net income of $10.5 million, or $0.22 per diluted share, for the fiscal year
- Adjusted non-GAAP net income of $23.1 million, or $0.49 per diluted share, for the fiscal year

	Three Months Ended December 31,		Year Ended December 31,	
	2016	2015	2016	2015
	(in thousands, except per share data)			
Net revenues	$ 63,543	$ 76,912	$ 255,165	$ 251,519
GAAP net income (loss)	$ (2,742)	$ 7,533	$ 10,532	$ (2,787)
Adjusted non-GAAP net income*	$ 549	$ 9,074	$ 23,106	$ 2,895
GAAP diluted EPS	$ (0.06)	$ 0.16	$ 0.22	$ (0.06)
Adjusted non-GAAP diluted EPS*	$ 0.01	$ 0.19	$ 0.49	$ 0.06

* 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.

Fourth Quarter Results

For the three months ended December 31, 2016, the Company reported net revenues of $63.5 million, a decrease of 17% compared to $76.9 million for the three months ended December 31, 2015.

For the three months ended December 31, 2016, net revenues of enoxaparin were $8.3 million, a decrease of 58% compared to $19.9 million for the three months ended December 31, 2015, primarily due to lower unit volumes in the retail market as a result of the termination of the distribution agreement with Actavis Inc. (“Actavis”). Under the terms of the Company’s distribution agreement with Actavis, the Company was unable to ship enoxaparin for retail clients from August 2016 until the agreement was terminated in late December 2016.

Other finished pharmaceutical product revenues were $50.6 million for the three months ended December 31, 2016, representing an increase of 10% compared to $46.2 million for the three months ended December 31, 2015. This was primarily due to an increase in sales of epinephrine to $10.7 million from $5.0 million due to increases in both average selling price and unit volumes. This increase was partially offset by a decrease in sales of naloxone to $9.3 million from $10.7 million, primarily as a result of a decrease in average selling price, which resulted from an increase in rebates. The FDA recently requested that the Company discontinue the manufacturing and distribution of its epinephrine injection, USP vial product, which has been marketed under the “grandfather” exception to the FDA’s “Prescription Drug Wrap-Up” program. The Company is currently in discussions with the FDA regarding the timing of the discontinuation of this product. For the three months ended December 31, 2016, the Company recognized $8.7 million in net revenues for the sale of this product.

Sales of the Company’s insulin active pharmaceutical ingredient, or API, products were $4.7 million for the three months ended December 31, 2016, compared to $10.8 million for the three months ended December 31, 2015, as MannKind did not purchase any of its 2016 commitments under the supply agreement entered into in 2014.

Cost of revenues were $43.6 million, or 69% of revenues, and $43.7 million, or 57% of revenues, for the three months ended December 31, 2016 and 2015, respectively, representing a decrease of $0.1 million. Cost of revenues of enoxaparin and insulin API decreased by $10.9 million and $3.5 million, respectively, primarily due to a decrease in unit volumes. The Company also recorded an inventory reserve of $7.3 million in December 2016, to adjust certain inventory items to their net realizable value. This reserve included $3.1 million for enoxaparin inventory items due to a decrease in the forecasted average selling price and $3.3 million for the epinephrine injection vial inventory items and related firm inventory purchase commitments due to the anticipated discontinuation of this product.

Selling, distribution, and marketing expenses were $1.5 million and $1.3 million for the three months ended December 31, 2016 and 2015, respectively. For the three months ended December 31, 2016, general and administrative expenses increased to $10.7 million from $8.7 million for the three months ended December 31, 2015, primarily due to an increase in legal fees.

For the three months ended December 31, 2016, research and development expenses increased by 40% to $12.3 million from $8.8 million for the three months ended December 31, 2015, primarily due to an increase in pre-launch inventory as well as other research and development supplies, which was partially offset by a decrease in clinical trials expense.

The Company recorded an income tax benefit of $1.9 million for the three months ended December 31, 2016, compared to an income tax expense of $2.8 million for the three months ended December 31, 2015.

The Company reported a quarterly net loss of $2.7 million, or $0.06 per share, for the three months ended December 31, 2016, compared to a net income of $7.5 million, or $0.16 per fully diluted share, for the three months ended December 31, 2015. The Company reported an adjusted non-GAAP quarterly net income of $0.5 million, or $0.01 per fully diluted share, for the three months ended December 31, 2016, compared to an adjusted non-GAAP net income of $9.1 million, or $0.19 per fully diluted share, for the three months ended December 31, 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.

Year-End Results

For the year ended December 31, 2016, the Company reported net revenues of $255.2 million, an increase of 1% compared to $251.5 million for the year ended December 31, 2015.

For fiscal 2016, net revenues of enoxaparin were $59.3 million, a decrease of 30% compared to $84.5 million for fiscal 2015. Lower unit volumes led to a decrease of approximately $18.8 million in the retail market as a result of the termination of the Company’s distribution agreement with Actavis. The remaining decrease of $6.4 million resulted from lower average selling prices of enoxaparin.

Other finished pharmaceutical product revenues were $180.9 million for fiscal 2016, an increase of 29% compared to $140.4 million for fiscal 2015. Sales of phytonadione increased to $33.3 million from $19.8 million, and sales of epinephrine increased to $25.7 million from $14.9 million, in each case primarily due to higher average selling prices. Sales of naloxone increased to $47.5 million from $38.6 million, as a result of an increase in unit volumes, which was partially offset by a decrease in average selling price of $1.4 million primarily due to increased rebates. Additionally, sales of lidocaine increased to $36.6 million from $30.3 million, primarily as a result of increased unit volumes, as well as the average selling price. For fiscal 2016, the Company recognized $18.6 million in net revenues for the sale of epinephrine injection vials. The Company is currently in discussions with the FDA regarding the timing of the discontinuation of this product.

Sales of the Company’s insulin API products were $14.9 million for fiscal 2016, compared to $26.6 million for fiscal 2015, as MannKind purchased its remaining unfulfilled 2015 commitments during the third quarter of 2016 but did not purchase any of its 2016 commitments under the supply agreement entered into in 2014.

Cost of revenues were $151.0 million, or 59% of revenues, and $174.2 million, or 69% of revenues, for the years ended December 31, 2016 and 2015, respectively, representing a decrease of $23.2 million, or 13%. Cost of revenues of enoxaparin decreased by $22.6 million, primarily due to a decrease in unit volumes of $16.0 million and a decrease in average cost per unit of $6.7 million as a result of lower heparin input costs. In addition, cost of revenues for insulin API decreased $7.4 million, primarily due to a decrease in unit volume.

Selling, distribution, and marketing expenses were $5.5 million and $5.5 million for the years ended December 31, 2016 and 2015, respectively. For the year ended December 31, 2016, general and administrative expenses increased to $41.8 million from $41.5 million for the year ended December 31, 2015, primarily due to an increase in personnel cost and legal fees, which was partially offset by the effect of a one-time $3.3 million settlement charge in 2015 relating to a California employment lawsuit.

For the year ended December 31, 2016, research and development expenses increased by 11% to $41.2 million, from $37.3 million for the year ended December 31, 2015, primarily due to an increase in FDA fees pertaining to the filing of a new drug application, or NDA, for the Company’s

intranasal naloxone product candidate and an increase of pre-launch inventory expense of $1.1 million related to Primatene® Mist in fiscal 2016. Additionally, the Company increased its spending on API and component materials for its ANDA pipeline products. These increases were partially offset by a decrease in clinical trials expense.

The Company recorded an income tax expense of $4.4 million for the year ended December 31, 2016, compared to an income tax benefit of $7.6 million for fiscal 2015.

The Company reported annual net income of $10.5 million, or $0.22 per fully diluted share, for the year ended December 31, 2016, compared to a net loss of $2.8 million, or $0.06 per share, for the year ended December 31, 2015. The Company reported adjusted non-GAAP annual net income of $23.1 million, or $0.49 per fully diluted share, for the year ended December 31, 2016, compared to adjusted non-GAAP net income of $2.9 million, or $0.06 per fully diluted share, for the year ended December 31, 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 December 31, 2016, were $72.4 million. Cash flow provided by operating activities for the year ended December 31, 2016, was $38.6 million.

Pipeline Information

The Company currently has five abbreviated new drug applications, or ANDAs filed with the FDA, targeting products with a market size of over $1.0 billion, three biosimilar products in development targeting products with a market size of $15.0 billion, and another 11 generic products in development targeting products with a market size of over $12.0 billion. This market information is based on IMS Health data for the 12 months ended December 31, 2016. The Company’s proprietary pipeline includes NDAs 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.

Non-GAAP Financial Measures

To supplement its consolidated financial statements, which are prepared and presented in accordance with U.S. generally accepted accounting principles, or 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, March 13, 2017, 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 82660524.

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 December 31,		Year Ended December 31,	
	2016	2015	2016	2015
Net revenues	$ 63,543	$ 76,912	$ 255,165	$ 251,519
Cost of revenues	43,582	43,741	150,976	174,172
Gross profit	19,961	33,171	104,189	77,347
Operating expenses:				
Selling, distribution, and marketing	1,491	1,307	5,466	5,470
General and administrative	10,703	8,711	41,832	41,504
Research and development	12,277	8,782	41,199	37,271
Total operating expenses	24,471	18,800	88,497	84,245
Income (loss) from operations	(4,510)	14,371	15,692	(6,898)
Non-operating expense, net	(113)	(4,033)	(746)	(3,466)
Income (loss) before income taxes	(4,623)	10,338	14,946	(10,364)
Income tax expense (benefit)	(1,881)	2,805	4,414	(7,577)
Net income (loss)	$ (2,742)	$ 7,533	$ 10,532	$ (2,787)
Net income (loss) per share:				
Basic	$ (0.06)	$ 0.17	$ 0.23	$ (0.06)
Diluted	$ (0.06)	$ 0.16	$ 0.22	$ (0.06)
Weighted-average shares used to compute net income (loss) per share:				
Basic	46,104	45,085	45,375	44,961
Diluted	46,104	46,709	47,504	44,961

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

	Three Months Ended December 31,		Year Ended December 31,	
	2016	2015	2016	2015
GAAP net income (loss)	$ (2,742)	$ 7,533	$ 10,532	$ (2,787)

Adjusted for:				
Intangible amortization	766	479	2,517	1,938
Share-based compensation	3,520	3,458	15,124	12,815
Impairment of long-lived assets	235	128	566	206
Income tax expense (benefit) on pre-tax adjustments	(1,230)	(2,524)	(5,633)	(9,277)
Non-GAAP net income	$ 549	$ 9,074	$ 23,106	$ 2,895
Non-GAAP net income per share:				
Basic	$ 0.01	$ 0.20	$ 0.51	$ 0.06
Diluted	$ 0.01	$ 0.19	$ 0.49	$ 0.06
Weighted-average shares used to compute non-GAAP net income per share:				
Basic	46,104	45,085	45,375	44,961
Diluted	49,285	46,742	47,504	46,820

Three Months Ended December 31, 2016

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Income tax expense (benefit)
GAAP	$ 43,582	$ 1,491	$ 10,703	$ 12,277	$ (1,881)
Intangible amortization	(883)	—	117	—	—
Share-based compensation	(722)	(44)	(2,526)	(228)	—
Impairment of long-lived assets	(365)	—	—	130	—
Income tax expense (benefit) on pre-tax adjustments	—	—	—	—	1,230
Non-GAAP	$ 41,612	$ 1,447	$ 8,294	$ 12,179	$ (651)

Three Months Ended December 31, 2015

	Selling,	General	Research	Income

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Income tax expense (benefit)
GAAP	$ 43,741	$ 1,307	$ 8,711	$ 8,782	$ 2,805
Intangible amortization	(445)	—	(34)	—	—
Share-based compensation	(671)	(44)	(2,508)	(235)	—
Impairment of long-lived assets	—	—	—	(128)	—
Income tax expense (benefit) on pre-tax adjustments	—	—	—	—	2,524
Non-GAAP	$ 42,625	$ 1,263	$ 6,169	$ 8,419	$ 5,329

Reconciliation of Non-GAAP Measures (continued)

Year Ended December 31, 2016

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Income tax expense (benefit)
GAAP	$ 150,976	$ 5,466	$ 41,832	$ 41,199	$ 4,414
Intangible amortization	(2,375)	—	(142)	—	—
Share-based compensation	(2,967)	(220)	(10,865)	(1,072)	—
Impairment of long-lived assets	(365)	—	—	(201)	—
Income tax expense (benefit) on pre-tax adjustments	—	—	—	—	5,633
Non-GAAP	$ 145,269	$ 5,246	$ 30,825	$ 39,926	$ 10,047

Year Ended December 31, 2015

	Selling,	General	Research	Income

	Cost of revenue	distribution and marketing	and administrative	and development	tax expense (benefit)
GAAP	$ 174,172	$ 5,470	$ 41,504	$ 37,271	$ (7,577)
Intangible amortization	(1,782)	—	(156)	—	—
Share-based compensation	(2,526)	(192)	(9,185)	(912)	—
Impairment of long-lived assets	—	—	—	(206)	—
Income tax expense (benefit) on pre-tax adjustments	—	—	—	—	9,277
Non-GAAP	$ 169,864	$ 5,278	$ 32,163	$ 36,153	$ 1,700

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Source: Amphastar Pharmaceuticals Inc.