

Amphastar Pharmaceuticals Reports Financial Results for the Three Months and Fiscal Year Ended December 31, 2017

March 12, 2018

RANCHO CUCAMONGA, Calif., March 12, 2018 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) (“Amphastar” or the “Company”) today reported results for the three months and fiscal year ended December 31, 2017.

Fourth Quarter Highlights

- Net revenues of \$60.4 million for the fourth quarter
- GAAP net income of \$1.5 million, or \$0.03 per diluted share, for the fourth quarter
- Adjusted non-GAAP net income of \$4.8 million, or \$0.10 per diluted share, for the fourth quarter

Fiscal Year Highlights

- Net revenues of \$240.2 million for the fiscal year
- GAAP net income of \$4.5 million, or \$0.09 per diluted share, for the fiscal year
- Adjusted non-GAAP net income of \$18.2 million, or \$0.38 per diluted share, for the fiscal year

Dr. Jack Zhang, Amphastar’s CEO, commented: “2017 was a tremendous year for Amphastar. The five approvals we received in 2017 put us in a position for strong growth in 2018 and are a reflection of the strength of our research and development capabilities.”

	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
	(in thousands, except per share data)			
Net revenues	\$ 60,402	\$ 63,543	\$ 240,175	\$ 255,165
GAAP net income (loss)	\$ 1,468	\$ (2,742)	\$ 4,508	\$ 10,532
Adjusted non-GAAP net income*	\$ 4,796	\$ 549	\$ 18,195	\$ 23,106
GAAP diluted EPS	\$ 0.03	\$ (0.06)	\$ 0.09	\$ 0.22
Adjusted non-GAAP diluted EPS*	\$ 0.10	\$ 0.01	\$ 0.38	\$ 0.49

* Adjusted non-GAAP net income 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, 2017, the Company reported net revenues of \$60.4 million, a decrease of 5% compared to \$63.5 million for the three months ended December 31, 2016.

For the three months ended December 31, 2017, net revenues of enoxaparin were \$11.3 million, representing an increase of 36% compared to \$8.3 million for the three months ended December 31, 2016. Of the increase, \$5.3 million was due to higher unit volumes, which was partially offset by a decrease in the average selling price. Furthermore, fourth quarter 2016 sales of enoxaparin were negatively impacted due to the transition of retail customers to the Company from Actavis. Sales of epinephrine decreased to \$3.7 million for the three months ended December 31, 2017, from \$10.7 million for the three months ended December 31, 2016, as a result of the discontinuation of the Company's epinephrine injection, USP vial product in the second quarter of 2017 in accordance with the FDA's request. The Company's epinephrine injection, USP vial product, was marketed under the "grandfather" exception to the FDA's "Prescription Drug Wrap-Up" program. Sales of naloxone decreased to \$8.4 million for the three months ended December 31, 2017, from \$9.3 million for the three months ended December 31, 2016, primarily due to a decrease in the average selling price. Sales of phytonadione increased to \$10.7 million for the three months ended December 31, 2017, from \$9.8 million for the three months ended December 31, 2016, due to an increase in the average selling price.

Sales of the Company's insulin active pharmaceutical ingredient, or API, products were \$4.4 million for the three months ended December 31, 2017, compared to \$4.7 million for the three months ended December 31, 2016.

Cost of revenues were \$39.8 million, or 66% of revenues, and \$43.6 million, or 69% of revenues, for the three months ended December 31, 2017 and 2016, respectively, representing a decrease of \$3.8 million, primarily due to a reserve recorded in the fourth quarter of 2016 to adjust certain inventory items to their net realizable value.

Selling, distribution, and marketing expenses were \$1.6 million and \$1.5 million for the three months ended December 31, 2017 and 2016, respectively. For the three months ended December 31, 2017, general and administrative expenses decreased to \$9.2 million from \$10.7 million for the three months ended December 31, 2016, primarily due to a decrease in legal expenses.

For the three months ended December 31, 2017, research and development expenses decreased by 7% to \$11.4 million from \$12.3 million for the three months ended December 31, 2016, primarily due to the timing of API purchases.

The Company recorded an income tax benefit of \$2.5 million for the three months ended December 31, 2017, compared to \$1.9 million for the three months ended December 31, 2016, primarily due to excess share-based compensation benefits.

The Company recognized net income of \$1.5 million, or \$0.03 per fully diluted share, for the three months ended December 31, 2017, compared to a net loss of \$2.7 million, or \$0.06 per fully diluted share, for the three months ended December 31, 2016. The Company's adjusted non-GAAP quarterly net income was \$4.8 million, or \$0.10 per fully diluted share, for the three months ended December 31, 2017, compared to an adjusted non-GAAP net income of \$0.5 million, or \$0.01 per fully diluted share, for the three months ended December 31, 2016. 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, 2017, the Company reported net revenues of \$240.2 million, a decrease of 6% compared to \$255.2 million for the year ended December 31, 2016.

For fiscal 2017, net revenues of enoxaparin were \$36.6 million, representing a decrease of 38% compared to \$59.3 million for fiscal 2016. Of the decrease, \$13.1 million was due to lower unit volumes, while the remainder was due to lower pricing. Sales of phytonadione increased to \$37.9 million for fiscal 2017 from \$33.3 million for fiscal 2016, due to increases in both the unit sales volume and the average selling price. Sales of lidocaine increased to \$37.6 million for fiscal 2017 from \$36.6 million for fiscal 2016, primarily due to increases in the average selling price. Sales of naloxone decreased to \$42.3 million in fiscal 2017 from \$47.5 million in fiscal 2016, due to a decrease in unit sales as well as a lower average selling price. An increase in the average selling price of epinephrine resulted in an increase of approximately \$10.4 million in net revenues, which was partially offset by the decrease in unit volumes, primarily a result of the aforementioned discontinuation of the Company's epinephrine injection, USP vial product.

Sales of the Company's insulin API products were \$10.0 million for fiscal 2017, compared to \$14.9 million for fiscal 2016, due to lower shipments to MannKind.

Cost of revenues were \$149.4 million, or 62% of revenues, and \$151.0 million, or 59% of revenues, for the years ended December 31, 2017 and 2016, respectively, representing a decrease of \$1.6 million. Gross margins declined due to lower selling prices for enoxaparin and naloxone.

Selling, distribution, and marketing expenses were \$6.5 million and \$5.5 million for the years ended December 31, 2017 and 2016, respectively. For the year ended December 31, 2017, general and administrative expenses increased to \$44.5 million from \$41.8 million for the year ended December 31, 2016, primarily due to an increase in legal expenses relating to the Company's July 2017 enoxaparin patent trial.

For the year ended December 31, 2017, research and development expenses increased by 5% to \$43.4 million from \$41.2 million for the year ended December 31, 2016, primarily due to pre-launch API inventory purchased for medroxyprogesterone acetate and sodium nitroprusside prior to approval, and increased clinical trial expenses for the Company's inhalation products.

The Company recorded an income tax benefit of \$2.9 million for the year ended December 31, 2017, compared to an income tax expense of \$4.4 million for the year ended December 31, 2016. The change was primarily due to changes in pre-tax income positions and excess share-based compensation benefits directly recorded as an income tax benefit in 2017.

The Company recognized net income of \$4.5 million, or \$0.09 per fully diluted share, for the year ended December 31, 2017, compared to a net income of \$10.5 million, or \$0.22 per fully diluted share, for the year ended December 31, 2016. The Company's adjusted non-GAAP quarterly net income was \$18.2 million, or \$0.38 per fully diluted share, for the year ended December 31, 2017, compared to an adjusted non-GAAP net income of \$23.1 million, or \$0.49 per fully diluted share, for the year ended December 31, 2016. 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, short-term investments, and restricted cash equivalents and short-term investments were \$72.4 million as of December 31, 2017. Cash flow provided by operating activities for the year ended December 31, 2017, was \$39.2 million.

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, three biosimilar products in development targeting products with a market size of over \$15.0 billion, and 12 generic products in development targeting products with a market size of over \$12.0 billion. This market information is based on IQVIA data for the 12 months ended December 31, 2017. 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 API 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.

Amphastar's 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, 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 measures. 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 measures 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 12, 2018, 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 7299298.

The call 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 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, backlog, 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 Amphastar's expectations to change.

Contact Information:

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Table I
Amphastar Pharmaceuticals, Inc.
Condensed Consolidated Statement of Operations
(Unaudited; in thousands, except per share data)

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2017	2016	2017	2016
Net revenues	\$ 60,402	\$ 63,543	\$ 240,175	\$ 255,165
Cost of revenues	39,823	43,582	149,380	150,976
Gross profit	20,579	19,961	90,795	104,189
Operating (income) expenses:				
Selling, distribution, and marketing	1,629	1,491	6,460	5,466
General and administrative	9,221	10,703	44,458	41,832
Research and development	11,393	12,277	43,415	41,199

Gain on sale of intangible assets	—	—	(2,643)	—
Total operating expenses	22,243	24,471	91,690	88,497
Income (loss) from operations	(1,664)	(4,510)	(895)	15,692
Non-operating income (expense), net	601	(113)	2,518	(746)
Income (loss) before income taxes	(1,063)	(4,623)	1,623	14,946
Income tax expense (benefit)	(2,531)	(1,881)	(2,885)	4,414
Net income (loss)	\$ 1,468	\$ (2,742)	\$ 4,508	\$ 10,532
Net income (loss) per share:				
Basic	\$ 0.03	\$ (0.06)	\$ 0.10	\$ 0.23
Diluted	\$ 0.03	\$ (0.06)	\$ 0.09	\$ 0.22
Weighted-average shares used to compute net income (loss) per share:				
Basic	46,233	46,104	46,107	45,375
Diluted	49,330	46,104	48,367	47,504

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

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2017	2016	2017	2016
GAAP net income (loss)	\$ 1,468	\$ (2,742)	\$ 4,508	\$ 10,532
Adjusted for:				
Intangible amortization	717	766	2,856	2,517
Share-based compensation	4,182	3,520	17,087	15,124
Impairment of long-lived assets	—	235	—	566
Income tax expense on pre-tax adjustments	(1,571)	(1,230)	(6,256)	(5,633)
Non-GAAP net income	\$ 4,796	\$ 549	\$ 18,195	\$ 23,106
Non-GAAP net income per share:				
Basic	\$ 0.10	\$ 0.01	\$ 0.39	\$ 0.51
Diluted	\$ 0.10	\$ 0.01	\$ 0.38	\$ 0.49

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

Basic	46,233	46,104	46,107	45,375
Diluted	49,330	49,285	48,367	47,504

Three Months Ended December 31, 2017

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Income tax expense (benefit)
GAAP	\$ 39,823	\$ 1,629	\$ 9,221	\$ 11,393	\$ (2,531)
Intangible amortization	(675)	—	(42)	—	—
Share-based compensation	(913)	(65)	(2,928)	(276)	—
Income tax expense on pre-tax adjustments	—	—	—	—	1,571
Non-GAAP	\$ 38,235	\$ 1,564	\$ 6,251	\$ 11,117	\$ (960)

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 on pre-tax adjustments	—	—	—	—	1,230
Non-GAAP	\$ 41,612	\$ 1,447	\$ 8,294	\$ 12,179	\$ (651)

Reconciliation of Non-GAAP Measures (continued)

Year Ended December 31, 2017

	Selling,	General	Research	Income
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	Cost of revenue	distribution and marketing	and administrative	and development	tax expense (benefit)
GAAP	\$ 149,380	\$ 6,460	\$ 44,458	\$ 43,415	\$ (2,885)
Intangible amortization	(2,706)	—	(150)	—	—
Share-based compensation	(3,756)	(302)	(11,643)	(1,386)	—
Income tax expense on pre-tax adjustments	—	—	—	—	6,256
Non-GAAP	\$ 142,918	\$ 6,158	\$ 32,665	\$ 42,029	\$ 3,371

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 on pre-tax adjustments	—	—	—	—	5,633
Non-GAAP	\$ 145,269	\$ 5,246	\$ 30,825	\$ 39,926	\$ 10,047

Source: Amphastar Pharmaceuticals, Inc.