

Amphastar Pharmaceuticals Reports Financial Results for the Three Months Ended March 31, 2019

May 9, 2019

RANCHO CUCAMONGA, Calif., May 09, 2019 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc. (NASDAQ: AMPH) (“Amphastar” or the “Company”) today reported results for the three months ended March 31, 2019.

First Quarter Highlights

- Net revenues of \$79.8 million for the first quarter
- GAAP net income of \$0.9 million, or \$0.02 per share, for the first quarter
- Adjusted non-GAAP net income of \$4.9 million, or \$0.10 per share, for the first quarter

Dr. Jack Zhang, Amphastar’s Chief Executive Officer, commented: “We are very pleased with the strong sales growth in the quarter and believe that increased promotion of Primatene[®] Mist and potential additional generic approvals this year will help us achieve strong sales growth for 2019.”

	Three Months Ended	
	March 31,	
	2019	2018
	(in thousands, except per share data)	
Net revenues	\$ 79,790	\$ 58,393
GAAP net income (loss) attributable to Amphastar	\$ 868	\$ (7,141)
Adjusted non-GAAP net income (loss) attributable to Amphastar*	\$ 4,885	\$ (2,513)
GAAP diluted EPS attributable to Amphastar shareholders	\$ 0.02	\$ (0.15)
Adjusted non-GAAP diluted EPS attributable to Amphastar shareholders*	\$ 0.10	\$ (0.05)

* 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 III of this press release.

First Quarter Results

	Three Months Ended		Change	
	March 31,		Dollars	
	2019	2018	Dollars	%
	(in thousands)			
Net revenues:				
Enoxaparin	\$ 14,484	\$ 7,007	\$ 7,477	107 %

Lidocaine	11,979	9,782	2,197	22	%
Phytonadione	10,120	9,181	939	10	%
Naloxone	7,364	8,927	(1,563)	(18))%
Medroxyprogesterone	7,213	2,706	4,507	167	%
Primatene [®] Mist	2,897	—	2,897	N/A	
Epinephrine	2,679	3,223	(544)	(17))%
Other finished pharmaceutical products	17,803	12,291	5,512	45	%
Total finished pharmaceutical products net revenues	\$ 74,539	\$ 53,117	\$ 21,422	40	%
API	5,251	5,276	(25)	(0))%
Total net revenues	\$ 79,790	\$ 58,393	\$ 21,397	37	%

Changes in net revenues were primarily driven by:

- Enoxaparin increases due to higher average selling prices, as well as increased unit volumes
- A full quarter of sales of medroxyprogesterone and Primatene[®] Mist
- Lidocaine increases due to increased unit volumes and a higher average selling price

	Three Months Ended		Change		
	March 31,				
	2019	2018			
	(in thousands)				
Net revenues	\$ 79,790	\$ 58,393	\$ 21,397	37	%
Cost of revenues	48,887	41,421	7,466	18	%
Gross profit	\$ 30,903	\$ 16,972	\$ 13,931	82	%
<i>as % of net revenues</i>	39	% 29	%		

Changes in cost of revenues and the resulting gross margin were primarily due to:

- A full quarter of sales of medroxyprogesterone and Primatene[®] Mist, which have higher margins
- A higher average selling price of enoxaparin
- Increased sales of Cortrosyn[®], which has high margins

	Three Months Ended		Change		
	March 31,				
	2019	2018			
	(in thousands)				
Selling, distribution and marketing	\$ 3,141	\$ 1,721	\$ 1,420	83	%
General and administrative	16,327	10,998	5,329	48	%
Research and development	14,607	14,030	577	4	%

- Selling, distribution and marketing expenses increased primarily due to marketing expenses related to Primatene[®] Mist and higher freight costs
- General and administrative expenses increased primarily due to higher legal fees

- Research and development expenses increased primarily due to salaries and personnel-related expenses at Amphastar Nanjing Pharmaceuticals, or ANP, due to the expansion of the facility, and increased clinical trial expenses for both ANDA and NDA pipeline products

Cash flow used in operating activities for the three months ended March 31, 2019, was \$3.6 million.

Share Buyback Program

On May 6, 2019, the Company's Board of Directors authorized an increase of \$20 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 and applicable laws.

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 four abbreviated new drug applications, or ANDAs, filed with the FDA targeting products with a market size of approximately \$800 million, three biosimilar products in development targeting products with a market size of approximately \$14 billion, and 11 generic products in development targeting products with a market size of approximately \$14 billion. This market information is based on IQVIA data for the 12 months ended March 31, 2019. The Company's proprietary pipeline includes a new drug application for intranasal naloxone. The Company is currently developing four other proprietary products, which include injectable, inhalation and intranasal dosage forms.

Amphastar's Chinese subsidiary, ANP, currently has nine Drug Master Files, or DMFs, on file with the FDA and is developing nine additional DMFs.

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 and resources are available at www.amphastar.com.

Amphastar's logo and other trademarks or service marks of Amphastar, including, but not limited to Primatene[®], Amphadase[®] and Cortrosyn[®], are the property of Amphastar.

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) attributed to Amphastar and (ii) Adjusted non-GAAP diluted EPS attributed to Amphastar's shareholders, which 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, May 9, 2019, 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 8047099.

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, backlog, sales and marketing of its products, market size and growth, the timing of FDA filings or approvals, including the DMFs of ANP, the timing of product launches, 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	
	March 31,	
	2019	2018
Net revenues	\$ 79,790	\$ 58,393
Cost of revenues	48,887	41,421
Gross profit	30,903	16,972
Operating expenses:		
Selling, distribution, and marketing	3,141	1,721
General and administrative	16,327	10,998
Research and development	14,607	14,030
Total operating expenses	34,075	26,749
Loss from operations	(3,172)	(9,777)
Non-operating income (expense), net	(461)	888
Loss before income taxes	(3,633)	(8,889)
Income tax benefit	(1,479)	(1,748)
Net loss	\$ (2,154)	\$ (7,141)
Net loss attributable to non-controlling interests	\$ (3,022)	\$ —
Net income (loss) attributable to Amphastar	\$ 868	\$ (7,141)
Net income (loss) per share attributable to Amphastar shareholders:		
Basic	\$ 0.02	\$ (0.15)
Diluted	\$ 0.02	\$ (0.15)
Weighted-average shares used to compute net income (loss) per share attributable to Amphastar shareholders:		
Basic	46,744	46,514
Diluted	50,416	46,514

The comparative period in 2018 was revised for immaterial errors.

Table II
Amphastar Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheet
(Unaudited; in thousands, except per share data)

	March 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 79,096	\$ 86,337
Restricted cash	1,865	1,865
Short-term investments	2,834	2,831
Restricted short-term investments	2,290	2,290
Accounts receivable, net	54,930	52,163
Inventories	78,580	69,322
Income tax refunds and deposits	1,592	49
Prepaid expenses and other assets	8,956	5,485
Total current assets	230,143	220,342
Property, plant, and equipment, net	214,836	210,418
Finance lease right-of-use assets	1,094	—
Operating lease right-of-use assets	13,480	—
Goodwill and intangible assets, net	42,255	42,267
Other assets	12,292	9,918
Deferred tax assets	30,618	30,618
Total assets	\$ 544,718	\$ 513,563
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 90,795	\$ 87,418
Income taxes payable	1,017	1,187
Current portion of long-term debt	17,587	18,229
Current portion of lease liabilities	2,560	—
Total current liabilities	111,959	106,834
Long-term reserve for income tax liabilities	415	415
Long-term debt, net of current portion	30,973	31,984
Long-term lease liabilities, net of current portion	11,174	—
Deferred tax liabilities	1,067	1,031
Other long-term liabilities	8,864	8,940
Total liabilities	164,452	149,204
Commitments and contingencies:		
Stockholders' equity:		
Preferred stock: par value \$0.0001; 20,000,000 shares authorized; no shares issued and outstanding	—	—

Common stock: par value \$0.0001; 300,000,000 shares authorized; 52,043,326 and 47,098,624 shares issued and outstanding as of March 31, 2019 and 51,438,675 and 46,631,118 shares issued and outstanding as of December 31, 2018, respectively	5	5
Additional paid-in capital	349,201	344,434
Retained earnings	68,299	67,485
Accumulated other comprehensive loss	(4,126)	(4,013)
Treasury stock	(78,393)	(75,476)
Total Amphastar stockholders' equity	334,986	332,435
Non-controlling interests	45,280	31,924
Total equity	380,266	364,359
Total liabilities and stockholders' equity	\$ 544,718	\$ 513,563

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

	Three Months Ended	
	March 31,	
	2019	2018
GAAP net loss	\$ (2,154)	\$ (7,141)
Adjusted for:		
Intangible amortization	270	729
Share-based compensation	4,674	4,666
Impairment of long-lived assets	137	376
Income tax expense on pre-tax adjustments	(935)	(1,143)
Non-GAAP net income (loss)	\$ 1,992	\$ (2,513)
Non-GAAP net loss attributable to non-controlling interests	\$ (2,893)	\$ —
Non-GAAP net income (loss) attributable to Amphastar	\$ 4,885	\$ (2,513)
Non-GAAP net income (loss) per share attributable to Amphastar shareholders:		
Basic	\$ 0.10	\$ (0.05)
Diluted	\$ 0.10	\$ (0.05)
Weighted-average shares used to compute non-GAAP net income (loss) per share attributable to Amphastar shareholders:		
Basic	46,744	46,514
Diluted	50,416	46,514

Three Months Ended March 31, 2019

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Income tax expense (benefit)	Non-controlling interest adjustment
GAAP	\$48,887	\$3,141	\$ 16,327	\$ 14,607	\$(1,479)	\$(3,022)
Intangible amortization	(230)	—	(40)	—	—	11
Share-based compensation	(1,279)	(94)	(2,791)	(510)	—	94
Impairment of long-lived assets	(22)	—	(9)	(106)	—	48
Income tax expense on pre-tax adjustments	—	—	—	—	935	(24)
Non-GAAP	\$47,356	\$3,047	\$ 13,487	\$ 13,991	\$(544)	\$(2,893)

Three Months Ended March 31, 2018

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Income tax expense (benefit)	Non-controlling interest adjustment
GAAP	\$41,421	\$1,721	\$ 10,998	\$ 14,030	\$(1,748)	\$—
Intangible amortization	(689)	—	(40)	—	—	—
Share-based compensation	(1,160)	(107)	(2,893)	(506)	—	—
Impairment of long-lived assets	(74)	—	(3)	(299)	—	—
Income tax expense on pre-tax adjustments	—	—	—	—	1,143	—
Non-GAAP	\$39,498	\$1,614	\$ 8,062	\$ 13,225	\$(605)	\$—

The comparative period in 2018 was revised for immaterial errors.

Source: Amphastar Pharmaceuticals, Inc.