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Amphastar Pharmaceuticals Reports Financial Results for the Three Months Ended June 30, 2018

Reports Net Revenues of \$71.0 Million for the Three Months Ended June 30, 2018

RANCHO CUCAMONGA, Calif., Aug. 08, 2018 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc. (NASDAQ: AMPH) ("Amphastar" or the "Company") today reported results for the three months ended June 30, 2018.

Second Quarter Highlights

- Net revenues of \$71.0 million for the second quarter
- GAAP net loss of \$2.8 million, or \$0.06 per diluted share, for the second quarter
- Adjusted non-GAAP net income of \$1.2 million, or \$0.03 per diluted share, for the second quarter

Dr. Jack Zhang, Amphastar's CEO, commented: "We had an exciting three months with FDA approvals of calcium chloride, isoproterenol, and semi-purified heparin and heparin USP, the starting materials for enoxaparin. We also announced the expansion of our Amphastar Nanjing Pharmaceuticals business. ANP has been making good progress and filed three Drug Master Files in the second quarter, including one for insulin API. We consider this an important milestone for our diabetes franchise."

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(in thousands, except per share data)			
Net revenues	\$ 71,040	\$ 65,187	\$ 129,433	\$ 121,857
GAAP net income (loss)	\$ (2,790)	\$ 1,972	\$ (10,036)	\$ 2,865
Adjusted non-GAAP net income (loss)*	\$ 1,220	\$ 5,430	\$ (1,232)	\$ 9,905
GAAP diluted EPS	\$ (0.06)	\$ 0.04	\$ (0.22)	\$ 0.06
Adjusted non-GAAP diluted EPS*	\$ 0.03	\$ 0.11	\$ (0.03)	\$ 0.21

* 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 III of this press release.

Second Quarter Results

	Three Months Ended June 30,		Change	
	2018	2017	Dollars	%
	(in thousands)			
Net revenues:				
Naloxone	\$ 11,133	\$ 10,261	\$ 872	8%
Phytonadione	10,806	10,003	803	8%
Lidocaine	10,010	9,334	676	7%
Enoxaparin	8,715	8,288	427	5%
Medroxyprogesterone	6,365	—	6,365	N/A
Epinephrine	3,687	10,648	(6,961)	(65)%
Other finished pharmaceutical products	12,525	15,231	(2,706)	(18)%

Total finished pharmaceutical products net revenues	\$ 63,241	\$ 63,765	\$ (524)	(1)%
API	7,799	1,422	6,377	448%
Total net revenues	\$ 71,040	\$ 65,187	\$ 5,853	9%

Changes in net revenues were primarily driven by:

- Launch of medroxyprogesterone acetate in the first quarter of 2018
- Discontinuation of epinephrine injection vial product in the second quarter of 2017
- Increased sales of insulin active pharmaceutical ingredient, or API, products due to the timing of customer purchases, as MannKind began purchasing RHI API under the Company's purchase agreement

	Three Months Ended		Change	
	June 30,		Dollars	%
	2018	2017		
	(in thousands)			
Cost of Revenues	\$ 44,884	\$ 38,440	\$ 6,444	17%
<i>% of net revenues</i>	63%	59%		

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

- Increased labor costs due to implementing new quality standards and increased hourly rates
- Discontinuation of epinephrine injection vial product in the second quarter of 2017
- These trends were partially offset by the launch of medroxyprogesterone, which has higher margins

	Three Months Ended		Change	
	June 30,		Dollars	%
	2018	2017		
	(in thousands)			
Selling, distribution and marketing	\$ 1,876	\$ 1,596	\$ 280	18%
General and administrative	11,669	12,234	(565)	(5)%
Research and development	15,468	10,732	4,736	44%

- Selling, distribution and marketing expenses increased primarily due to increased expenses at the Company's Chinese subsidiary, Amphastar Nanjing Pharmaceuticals, as well as increased freight costs
- General and administrative expenses decreased primarily due to lower legal fees
- Research and development expenses increased primarily due to increased expenditures for the Company's pipeline products as well as an increase in pre-launch inventory relating to the production of Primatene[®] Mist ahead of its planned launch later this year, if we receive FDA approval

Cash flow provided by operating activities for the six months ended June 30, 2018 was \$12.9 million.

Pipeline Information

The Company currently has two abbreviated new drug applications, or ANDAs, filed with the FDA targeting products with a market size of over \$0.35 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 June 30, 2018. 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.

Amphastar Nanjing Pharmaceuticals currently has four APIs and starting materials approved by the FDA, ten Drug Master Files, or DMFs on file with the FDA and is developing eight 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 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, 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, August 8, 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 8783989.

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, including of DMFs of ANP, 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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net revenues	\$ 71,040	\$ 65,187	\$ 129,433	\$ 121,857
Cost of revenues	44,884	38,440	86,216	72,282
Gross profit	<u>26,156</u>	<u>26,747</u>	<u>43,217</u>	<u>49,575</u>
Operating (income) expenses:				
Selling, distribution, and marketing	1,876	1,596	3,597	3,075
General and administrative	11,669	12,234	22,667	23,572
Research and development	15,468	10,732	29,728	21,982
Gain on sale of intangible assets	—	—	—	(2,643)
Total operating expenses	<u>29,013</u>	<u>24,562</u>	<u>55,992</u>	<u>45,986</u>
Income (loss) from operations	(2,857)	2,185	(12,775)	3,589
Non-operating income (expense), net	<u>(1,259)</u>	<u>988</u>	<u>(371)</u>	<u>1,088</u>
Income (loss) before income taxes	(4,116)	3,173	(13,146)	4,677
Income tax expense (benefit)	(1,326)	1,201	(3,110)	1,812
Net income (loss)	<u>\$ (2,790)</u>	<u>\$ 1,972</u>	<u>\$ (10,036)</u>	<u>\$ 2,865</u>
Net income (loss) per share:				
Basic	\$ (0.06)	\$ 0.04	\$ (0.22)	\$ 0.06
Diluted	\$ (0.06)	\$ 0.04	\$ (0.22)	\$ 0.06
Weighted-average shares used to compute net income (loss) per share:				
Basic	46,557	46,025	46,535	46,047
Diluted	46,557	47,866	46,535	47,962

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

	June 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 48,070	\$ 65,594
Short-term investments	2,818	2,635
Restricted cash and short-term investments	4,155	4,155
Accounts receivable, net	41,279	35,996
Inventories	61,678	63,609

Income tax refunds and deposits	7,542	6,036
Prepaid expenses and other assets	4,404	9,753
Total current assets	<u>169,946</u>	<u>187,778</u>
Property, plant, and equipment, net	198,241	185,339
Goodwill and intangible assets, net	43,450	45,140
Other assets	11,752	8,663
Deferred tax assets	28,257	27,745
Total assets	<u>\$ 451,646</u>	<u>\$ 454,665</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 67,092	\$ 57,555
Income taxes payable	1,607	3,325
Current portion of long-term debt and capital leases	18,891	6,312
Total current liabilities	<u>87,590</u>	<u>67,192</u>
Long-term reserve for income tax liabilities	879	879
Long-term debt and capital leases, net of current portion	33,695	40,844
Deferred tax liabilities	1,325	1,361
Other long-term liabilities	7,631	7,060
Total liabilities	<u>131,120</u>	<u>117,336</u>
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; 50,661,676 and 46,416,789 shares issued and outstanding as of June 30, 2018 and 50,039,212 and 46,623,581 shares issued and outstanding as of December 31, 2017, respectively	5	5
Additional paid-in capital	322,357	313,891
Retained earnings	66,780	76,235
Accumulated other comprehensive loss	(3,166)	(2,100)
Treasury stock	(65,450)	(50,702)
Total stockholders' equity	<u>320,526</u>	<u>337,329</u>
Total liabilities and stockholders' equity	<u>\$ 451,646</u>	<u>\$ 454,665</u>

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

	Three Months		Six Months Ended	
	Ended		June 30,	
	June 30,		June 30,	
	2018	2017	2018	2017
GAAP net income (loss)	\$ (2,790)	\$ 1,972	\$ (10,036)	\$ 2,865

Adjusted for:				
Intangible amortization	722	705	1,451	1,426
Share-based compensation	4,196	4,298	8,862	8,749
Impairment of long-lived assets	145	—	743	—
Income tax expense on pre-tax adjustments	(1,053)	(1,545)	(2,252)	(3,135)
Non-GAAP net income (loss)	<u>\$ 1,220</u>	<u>\$ 5,430</u>	<u>\$ (1,232)</u>	<u>\$ 9,905</u>

Non-GAAP net income (loss) per share:

Basic	\$ 0.03	\$ 0.12	\$ (0.03)	\$ 0.22
Diluted	\$ 0.03	\$ 0.11	\$ (0.03)	\$ 0.21

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

Basic	46,557	46,025	46,535	46,047
Diluted	48,495	47,866	46,535	47,962

Three Months Ended June 30, 2018

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Income tax expense (benefit)
GAAP	\$44,884	\$ 1,876	\$ 11,669	\$ 15,468	\$ (1,326)
Intangible amortization	(683)	—	(39)	—	—
Share-based compensation	(981)	(104)	(2,743)	(368)	—
Impairment of long-lived assets	(3)	—	(1)	(141)	—
Income tax expense on pre-tax adjustments	—	—	—	—	1,053
Non-GAAP	<u>\$43,217</u>	<u>\$ 1,772</u>	<u>\$ 8,886</u>	<u>\$ 14,959</u>	<u>\$ (273)</u>

Three Months Ended June 30, 2017

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Income tax expense (benefit)
GAAP	\$ 38,440	\$ 1,596	\$ 12,234	\$ 10,732	\$ 1,201
Intangible amortization	(669)	—	(36)	—	—
Share-based compensation	(897)	(65)	(2,985)	(351)	—
Income tax expense on pre-tax adjustments	—	—	—	—	1,545
Non-GAAP	<u>\$ 36,874</u>	<u>\$ 1,531</u>	<u>\$ 9,213</u>	<u>\$ 10,381</u>	<u>\$ 2,746</u>

Reconciliation of Non-GAAP Measures (continued)

Six Months Ended June 30, 2018

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Income tax expense (benefit)
GAAP	\$ 86,216	\$ 3,597	\$ 22,667	\$ 29,728	\$ (3,110)
Intangible amortization	(1,372)	—	(79)	—	—
Share-based compensation	(2,141)	(211)	(5,636)	(874)	—
Impairment of long-lived assets	(77)	—	(4)	(662)	—
Income tax expense on pre-tax adjustments	—	—	—	—	2,252
Non-GAAP	<u>\$ 82,626</u>	<u>\$ 3,386</u>	<u>\$ 16,948</u>	<u>\$ 28,192</u>	<u>\$ (858)</u>

Six Months Ended June 30, 2017

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Income tax expense (benefit)
GAAP	\$ 72,282	\$ 3,075	\$ 23,572	\$ 21,982	\$ 1,812
Intangible amortization	(1,354)	—	(72)	—	—
Share-based compensation	(2,028)	(149)	(5,768)	(804)	—
Income tax expense on pre-tax adjustments	—	—	—	—	3,135
Non-GAAP	<u>\$ 68,900</u>	<u>\$ 2,926</u>	<u>\$ 17,732</u>	<u>\$ 21,178</u>	<u>\$ 4,947</u>