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Amphastar Pharmaceuticals Reports Financial Results for the Three Months Ended June 30, 2020

Reports Net Revenues of \$85.8 Million for the Three Months Ended June 30, 2020

RANCHO CUCAMONGA, Calif., Aug. 06, 2020 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc. (NASDAQ: AMPH) ("Amphastar" or the "Company") today reported results for the three months ended June 30, 2020.

Second Quarter Highlights

- Net revenues of \$85.8 million for the second quarter
- GAAP net loss of \$0.2 million, or \$0.00 per share, for the second quarter
- Adjusted non-GAAP net income of \$7.6 million, or \$0.16 per share, for the second quarter

Dr. Jack Zhang, Amphastar's President and Chief Executive Officer, commented: "We are pleased with Amphastar's second quarter and the first half of the year so far. Primatene[®] Mist has been a strong performer for the Company, while our epinephrine multi-dose vial launch continues to gain momentum. Despite the challenges presented by the COVID-19 pandemic, we remain confident, heading into our catalyst-rich second half of the year."

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(in thousands, except per share data)			
Net revenues	\$ 85,806	\$ 79,047	\$ 170,494	\$ 158,837
GAAP net (loss) income attributable to Amphastar	\$ (192)	\$ 47,787	\$ 3,757	\$ 48,655
Adjusted non-GAAP net income attributable to Amphastar*	\$ 7,610	\$ 4,117	\$ 15,993	\$ 9,002
GAAP diluted EPS attributable to Amphastar shareholders	\$ (0.00)	\$ 0.96	\$ 0.08	\$ 0.97
Adjusted non-GAAP diluted EPS attributable to Amphastar shareholders*	\$ 0.16	\$ 0.08	\$ 0.33	\$ 0.18

* Adjusted non-GAAP net income attributable to Amphastar and Adjusted non-GAAP diluted EPS attributable to Amphastar shareholders 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	
	2020	2019	Dollars	%
	(in thousands)			
Net revenues:				
Primatene [®] Mist	\$ 12,468	\$ 2,512	\$ 9,956	396 %
Phytonadione	10,689	12,441	(1,752)	(14) %
Enoxaparin	10,218	9,838	380	4 %

Lidocaine	7,608	10,082	(2,474)	(25) %
Naloxone	8,723	7,833	890	11 %
Epinephrine	6,957	3,139	3,818	122 %
Other finished pharmaceutical products	24,272	27,890	(3,618)	(13) %
Total finished pharmaceutical products net revenues	<u>\$ 80,935</u>	<u>\$ 73,735</u>	<u>\$ 7,200</u>	<u>10 %</u>
API	<u>4,871</u>	<u>5,312</u>	<u>(441)</u>	<u>(8) %</u>
Total net revenues	<u><u>\$ 85,806</u></u>	<u><u>\$ 79,047</u></u>	<u><u>\$ 6,759</u></u>	<u><u>9 %</u></u>

Changes in net revenues were primarily driven by:

- Increased sales of Primatene[®] Mist primarily resulting from the continued success of our nationwide television, radio, and digital marketing campaign
- Increased epinephrine sales due to the launch of our newly-approved epinephrine injection, USP 30mg/30mL multiple-dose vial product as well as increased sales of our epinephrine pre-filled syringes
- Increased naloxone sales due to higher unit volumes
- Decreased lidocaine sales due to lower demand, largely due to reductions in elective procedures, in which the jelly form of lidocaine is often used, during the COVID-19 pandemic
- Decreases in other finished pharmaceutical products were driven by reductions in products frequently used in elective procedures including Cortrosyn[®], which were partially offset by an increase in sodium bicarbonate as we were able to utilize our new production line approved earlier in the year to meet strong demand

	Three Months Ended		Change	
	June 30,		Dollars	%
	2020	2019		
	(in thousands)			
Net revenues	\$ 85,806	\$ 79,047	\$ 6,759	9 %
Cost of revenues	52,629	46,660	5,969	13 %
Gross profit	<u>\$ 33,177</u>	<u>\$ 32,387</u>	<u>\$ 790</u>	<u>2 %</u>
<i>as % of net revenues</i>	39%	41%		

Changes in cost of revenues and the resulting decrease to gross margin were primarily driven by:

- Increase in inventory reserves including a \$3.6 million reserve for crude heparin purchases and commitments at our Chinese subsidiary, Amphastar Nanjing Pharmaceuticals, Inc.
- Increased sales of Primatene[®] Mist and the launch of epinephrine injection multiple-dose vial, both of which have higher margins, partially offset the inventory reserves

	Three Months Ended		Change	
	June 30,		Dollars	%
	2020	2019		
	(in thousands)			
Selling, distribution and marketing	\$ 4,026	\$ 2,992	\$ 1,034	35 %
General and administrative	15,924	12,426	3,498	28 %
Research and development	16,149	15,996	153	1 %

- Marketing and distribution expenses increased primarily related to Primatene[®] Mist, including the cost of a national digital, television, radio and digital marketing campaign, which began in July 2019
- General and administrative expenses increased primarily due to the separation agreement entered into with a former executive, in which we incurred an expense of \$4.9 million relating to cash compensation and share-based compensation expense
- Research and development expenses increased primarily at our ANP subsidiary

Three Months Ended	Change
June 30,	

	2020	2019	Dollars	%
	(in thousands)			
Non-operating income (expense), net	\$ 1,418	\$ 60,120	\$ (58,702)	NM

- In June 2019, we recognized a gain of \$59.9 million relating to the settlement of our patent and antitrust litigation with Momenta Pharmaceuticals, Inc. and Sandoz Inc.

Cash flow provided by operating activities for the six months ended June 30, 2020, was \$31.6 million.

Impact of COVID-19

The increase in sales of Primatene[®] Mist and certain hospital products as a result of the COVID-19 pandemic experienced towards the end of the first quarter continued into the early part of the second quarter of 2020. We also noticed a decline in demand for certain products such as Cortrosyn[®] and lidocaine, which are frequently used in elective procedures. The Company has not experienced any significant negative impacts on its cash flows or operations as a result of the COVID-19 pandemic. All of the Company's production facilities continued to operate during the quarter as they had prior to the COVID-19 pandemic with very little change, other than for enhanced safety measures intended to prevent the spread of the virus. It is not possible at this time to estimate the complete impact that the COVID-19 pandemic could have on our business, as the impact will depend on future developments of the pandemic, which are highly uncertain and cannot be predicted.

Share Buyback Program

On August 4, 2020, 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 five ANDAs filed with the FDA targeting products with a market size of approximately \$1.7 billion, three biosimilar products in development targeting products with a market size of approximately \$13 billion, and nine generic products in development targeting products with a market size of approximately \$12 billion. This market information is based on IQVIA data for the 12 months ended June 30, 2020. The Company is currently developing four proprietary products, including a new drug application for intranasal naloxone.

Amphastar's Chinese subsidiary, ANP, currently has 14 Drug Master Files, or DMFs, on file with the FDA and is developing several 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 Amphastar[®], 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, impairment charges, executive severance expense, and legal settlements, 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 6, 2020, at 2:00 p.m. Pacific Time.

To access the conference call, dial toll-free (800) 708-4540 five minutes before the conference. The passcode for the conference call is 49844225.

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 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, such as the impact of the COVID-19 pandemic and related responses of business and governments to the pandemic on our operations and personnel, and on commercial activity and demand across our business operations and results of operations. 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, including in the Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 16, 2020. In particular, the extent of COVID-19's impact on our business will depend on several factors, including the severity, duration and extent of the pandemic, as well as actions taken by governments, businesses, and consumers in response to the pandemic, all of which continue to evolve and remain uncertain at this time. 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. The forward-looking statements in this release speak only as of the date of the release. Amphastar undertakes no obligation to revise or update information or any forward-looking statements 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,
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	2020	2019	2020	2019
Net revenues	\$ 85,806	\$ 79,047	\$ 170,494	\$ 158,837
Cost of revenues	52,629	46,660	100,494	95,547
Gross profit	<u>33,177</u>	<u>32,387</u>	<u>70,000</u>	<u>63,290</u>
Operating expenses:				
Selling, distribution, and marketing	4,026	2,992	7,320	6,133
General and administrative	15,924	12,426	26,670	28,753
Research and development	16,149	15,996	31,452	30,603
Total operating expenses	<u>36,099</u>	<u>31,414</u>	<u>65,442</u>	<u>65,489</u>
(Loss) income from operations	(2,922)	973	4,558	(2,199)
Non-operating income (expenses), net	<u>1,418</u>	<u>60,120</u>	<u>(257)</u>	<u>59,659</u>
(Loss) income before income taxes	(1,504)	61,093	4,301	57,460
Income tax (benefit) provision	(75)	14,173	2,205	12,694
Net (loss) income	<u>\$ (1,429)</u>	<u>\$ 46,920</u>	<u>\$ 2,096</u>	<u>\$ 44,766</u>
Net loss attributable to non-controlling interests	\$ (1,237)	\$ (867)	\$ (1,661)	\$ (3,889)
Net (loss) income attributable to Amphastar	<u>\$ (192)</u>	<u>\$ 47,787</u>	<u>\$ 3,757</u>	<u>\$ 48,655</u>
Net (loss) income per share attributable to Amphastar shareholders:				
Basic	\$ (0.00)	\$ 1.01	\$ 0.08	\$ 1.04
Diluted	\$ (0.00)	\$ 0.96	\$ 0.08	\$ 0.97
Weighted-average shares used to compute net (loss) income per share attributable to Amphastar shareholders:				
Basic	46,753	47,107	46,581	46,925
Diluted	46,753	49,894	48,458	50,155

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

	June 30, 2020	December 31, 2019
	<u>(unaudited)</u>	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 87,388	\$ 73,685
Restricted cash	1,865	1,865
Short-term investments	11,101	11,675
Restricted short-term investments	2,200	2,290
Accounts receivable, net	49,862	45,376
Inventories	104,726	110,501

Income tax refunds and deposits	682	311
Prepaid expenses and other assets	8,997	9,538
Total current assets	<u>266,821</u>	<u>255,241</u>
Property, plant, and equipment, net	238,236	233,856
Finance lease right-of-use assets	774	887
Operating lease right-of-use assets	17,086	18,805
Goodwill and intangible assets, net	40,271	41,153
Other assets	12,635	11,156
Deferred tax assets	24,235	25,873
Total assets	<u>\$ 600,058</u>	<u>\$ 586,971</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable and accrued liabilities	\$ 75,385	\$ 77,051
Income taxes payable	2,345	2,042
Current portion of long-term debt	12,075	7,741
Current portion of operating lease liabilities	3,481	3,175
Total current liabilities	<u>93,286</u>	<u>90,009</u>
Long-term reserve for income tax liabilities	3,425	3,425
Long-term debt, net of current portion	34,622	39,394
Long-term operating lease liabilities, net of current portion	14,530	16,315
Deferred tax liabilities	760	867
Other long-term liabilities	10,998	9,433
Total liabilities	<u>157,621</u>	<u>159,443</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; 54,372,275 and 47,494,909 shares issued and outstanding as of June 30, 2020 and 52,495,483 and 46,576,968 shares issued and outstanding as of December 31, 2019, respectively	5	5
Additional paid-in capital	396,841	367,305
Retained earnings	120,127	116,370
Accumulated other comprehensive loss	(5,173)	(4,687)
Treasury stock	(114,119)	(97,627)
Total Amphastar Pharmaceuticals, Inc. stockholders' equity	<u>397,681</u>	<u>381,366</u>
Non-controlling interests	44,756	46,162
Total equity	<u>442,437</u>	<u>427,528</u>
Total liabilities and stockholders' equity	<u>\$ 600,058</u>	<u>\$ 586,971</u>

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

Three Months Ended		Six Months Ended	
June 30,		June 30,	
2020	2019	2020	2019

GAAP net (loss) income	\$	(1,429)	\$	46,920	\$	2,096	\$	44,766
Adjusted for:								
Intangible amortization		251		256		509		526
Share-based compensation		4,194		4,032		9,476		8,706
Impairment of long-lived assets		16		46		30		183
Expense related to executive separation agreement		4,869		—		4,869		—
Gain on litigation settlement		—		(59,900)		—		(59,900)
Income tax (benefit) provision on pre-tax adjustments		(1,445)		11,955		(2,449)		11,020
Non-GAAP net income	\$	<u>6,456</u>	\$	<u>3,309</u>	\$	<u>14,531</u>	\$	<u>5,301</u>
Non-GAAP net loss attributable to non-controlling interests	\$	(1,154)	\$	(808)	\$	(1,462)	\$	(3,701)
Non-GAAP net income attributable to Amphastar	\$	<u>7,610</u>	\$	<u>4,117</u>	\$	<u>15,993</u>	\$	<u>9,002</u>
Non-GAAP net income per share attributable to Amphastar shareholders:								
Basic	\$	0.16	\$	0.09	\$	0.34	\$	0.19
Diluted	\$	0.16	\$	0.08	\$	0.33	\$	0.18
Weighted-average shares used to compute non-GAAP net income per share attributable to Amphastar shareholders:								
Basic		46,753		47,107		46,581		46,925
Diluted		48,668		49,894		48,458		50,155

Three Months Ended June 30, 2020

	Cost of	Selling,	General	Research	Non-	Income	Non-
	revenue	distribution	and	and	operating	tax	controlling
	<u> </u>	<u>and</u>	<u>administrative</u>	<u>development</u>	<u>income</u>	<u>provision</u>	<u>interest</u>
	<u>\$</u>	<u>marketing</u>	<u>\$</u>	<u>\$</u>	<u>net</u>	<u>(benefit)</u>	<u>adjustment</u>
	<u>\$</u>	<u>\$</u>	<u>\$</u>	<u>\$</u>	<u>\$</u>	<u>\$</u>	<u>\$</u>
GAAP	\$ 52,629	\$ 4,026	\$ 15,924	\$ 16,149	\$ 1,418	\$ (75)	\$ (1,237)
Intangible amortization	(217)	—	(34)	—	—	—	11
Share-based compensation	(970)	(123)	(2,733)	(368)	—	—	86
Impairment of long-lived assets	(3)	—	(13)	—	—	—	6
Expense related to executive separation agreement	—	—	(4,869)	—	—	—	—
Income tax provision (benefit) on pre-tax adjustments	—	—	—	—	—	1,445	(20)
Non-GAAP	<u>\$ 51,439</u>	<u>\$ 3,903</u>	<u>\$ 8,275</u>	<u>\$ 15,781</u>	<u>\$ 1,418</u>	<u>\$ 1,370</u>	<u>\$ (1,154)</u>

Reconciliation of Non-GAAP Measures (continued)

Three Months Ended June 30, 2019

	Selling, Cost of revenue	distribution and marketing	General and administrative	Research and development	Non- operating income (expense), net	Income tax provision (benefit)	Non- controlling interest adjustment
GAAP	\$ 46,660	\$ 2,992	\$ 12,426	\$ 15,996	\$ 60,120	\$ 14,173	\$ (867)
Intangible amortization	(223)	—	(33)	—	—	—	11
Share-based compensation	(959)	(95)	(2,648)	(330)	—	—	56
Impairment of long-lived assets	(43)	—	(3)	—	—	—	1
Gain on litigation settlement	—	—	—	—	(59,900)	—	—
Income tax (benefit) provision on pre-tax adjustments	—	—	—	—	—	(11,955)	(9)
Non-GAAP	<u>\$ 45,435</u>	<u>\$ 2,897</u>	<u>\$ 9,742</u>	<u>\$ 15,666</u>	<u>\$ 220</u>	<u>\$ 2,218</u>	<u>\$ (808)</u>

Six Months Ended June 30, 2020

	Selling, Cost of revenue	distribution and marketing	General and administrative	Research and development	Non- operating income (expense), net	Income tax provision (benefit)	Non- controlling interest adjustment
GAAP	\$ 100,494	\$ 7,320	\$ 26,670	\$ 31,452	\$ (257)	\$ 2,205	\$ (1,661)
Intangible amortization	(441)	—	(68)	—	—	—	22
Share-based compensation	(2,329)	(230)	(5,952)	(965)	—	—	213
Impairment of long-lived assets	(13)	—	(17)	—	—	—	7
Expense related to executive separation agreement	—	—	(4,869)	—	—	—	—
Income tax provision	—	—	—	—	—	2,449	(43)

(benefit) on pre-tax adjustments

Non-GAAP	<u>\$ 97,711</u>	<u>\$ 7,090</u>	<u>\$ 15,764</u>	<u>\$ 30,487</u>	<u>\$ (257)</u>	<u>\$ 4,654</u>	<u>\$ (1,462)</u>
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Six Months Ended June 30, 2019

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Non-operating income (expense), net	Income tax provision (benefit)	Non-controlling interest adjustment
GAAP	<u>\$ 95,547</u>	<u>\$ 6,133</u>	<u>\$ 28,753</u>	<u>\$ 30,603</u>	<u>\$ 59,659</u>	<u>\$ 12,694</u>	<u>\$ (3,889)</u>
Intangible amortization	(453)	—	(73)	—	—	—	22
Share-based compensation	(2,238)	(189)	(5,439)	(840)	—	—	150
Impairment of long-lived assets	(65)	—	(12)	(106)	—	—	49
Gain on litigation settlement	—	—	—	—	(59,900)	—	—
Income tax (benefit) provision on pre-tax adjustments	—	—	—	—	—	(11,020)	(33)
Non-GAAP	<u>\$ 92,791</u>	<u>\$ 5,944</u>	<u>\$ 23,229</u>	<u>\$ 29,657</u>	<u>\$ (241)</u>	<u>\$ 1,674</u>	<u>\$ (3,701)</u>