

# Amphastar Pharmaceuticals Reports Financial Results for the Three Months Ended June 30, 2019

August 7, 2019

RANCHO CUCAMONGA, Calif., Aug. 07, 2019 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc. (NASDAQ: AMPH) (“Amphastar” or the “Company”) today reported results for the three months ended June 30, 2019.

## Second Quarter Highlights

- Net revenues of \$79.0 million for the second quarter
- GAAP net income of \$47.8 million, or \$0.96 per share, for the second quarter
- Adjusted non-GAAP net income of \$4.1 million, or \$0.08 per share, for the second quarter

Dr. Jack Zhang, Amphastar’s Chief Executive Officer, commented: “We are pleased that we have settled our long-running patent dispute with Momenta and Sandoz, and have received \$59.9 million from them. Putting this case behind us will allow us to focus on research and development of our pipeline, which will be the primary use of the money that we received. We will also use some of the funds to increase our capacity for sterile injectable and inhalation products to meet the needs of production capacity when more of our pipeline products are approved. We will have the additional benefit of lower legal expenses going forward.”

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2019</b>	<b>2018</b>	<b>2019</b>	<b>2018</b>
	<b>(in thousands, except per share data)</b>			
Net revenues	\$79,047	\$71,040	\$158,837	\$129,433
GAAP net income (loss) attributable to Amphastar	\$47,787	\$(2,853)	\$48,655	\$(9,994)
Adjusted non-GAAP net income (loss) attributable to Amphastar*	\$4,117	\$1,157	\$9,002	\$(1,356)
GAAP diluted EPS attributable to Amphastar shareholders	\$0.96	\$(0.06)	\$0.97	\$(0.21)
Adjusted non-GAAP diluted EPS attributable to Amphastar shareholders*	\$0.08	\$0.02	\$0.18	\$(0.03)

\* 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

	<b>Three Months Ended</b>		<b>Change</b>		
	<b>June 30, 2019</b>	<b>2018</b>	<b>Dollars</b>	<b>%</b>	
<b>(in thousands)</b>					
<b>Net revenues:</b>					
Phytonadione	\$12,441	\$10,806	\$1,635	15	%
Lidocaine	10,082	10,010	72	1	%
Enoxaparin	9,838	8,715	1,123	13	%
Naloxone	7,833	11,133	(3,300 )	(30)	) %
Medroxyprogesterone	6,696	6,365	331	5	%
Epinephrine	3,139	3,687	(548 )	(15)	) %
Primatene <sup>®</sup> Mist	2,512	—	2,512	N/A	
Other finished pharmaceutical products	21,194	12,525	8,669	69	%
Total finished pharmaceutical products net revenues	\$73,735	\$63,241	\$10,494	17	%
API	5,312	7,799	(2,487 )	(32)	) %
Total net revenues	\$79,047	\$71,040	\$8,007	11	%

Changes in net revenues were primarily driven by:

- Enoxaparin increases due to higher average selling prices
- Phytonadione increases due to a higher average selling price
- Sales of Primatene<sup>®</sup> Mist, launched in December 2018
- Increase in sales of other finished pharmaceutical products, such as Cortrosyn<sup>®</sup>, atropine, sodium bicarbonate, and dextrose which were in high demand due to market shortages, as well as sales of Isoproterenol which we launched in the third quarter of 2018

	<b>Three Months Ended</b>		<b>Change</b>		
	<b>June 30, 2019</b>	<b>2018</b>	<b>Dollars</b>	<b>%</b>	
<b>(in thousands)</b>					
Net revenues	\$79,047	\$71,040	\$8,007	11	%
Cost of revenues	46,660	44,976	1,684	4	%
Gross profit	\$32,387	\$26,064	\$6,323	24	%
<i>as % of net revenues</i>	41	%	37	%	

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

- Sales of Primatene<sup>®</sup> Mist, which has higher margins
- Higher average selling prices for enoxaparin
- Increased sales of Cortrosyn<sup>®</sup> and medroxyprogesterone, which have high margins

	<b>Three Months Ended</b>		<b>Change</b>		
	<b>June 30,</b>		<b>Dollars</b>	<b>%</b>	
	<b>2019</b>	<b>2018</b>			
	<b>(in thousands)</b>				
Selling, distribution and marketing	\$2,992	\$1,876	\$1,116	59	%
General and administrative	12,426	11,669	757	6	%
Research and development	15,996	15,460	536	3	%

- Selling, distribution and marketing expenses increased primarily due to increased marketing expenses related to Primatene<sup>®</sup> Mist
- General and administrative expenses increased primarily due to higher legal fees
- Research and development expenses increased primarily due to personnel-related expenses, as well as depreciation expense at Amphastar Nanjing Pharmaceuticals, or ANP, due to the expansion of the research and development efforts at that facility, and increased clinical trial expenses for our generic product pipeline

	<b>Three Months Ended</b>		<b>Change</b>		
	<b>June 30,</b>		<b>Dollars</b>	<b>%</b>	
	<b>2019</b>	<b>2018</b>			
	<b>(in thousands)</b>				
Non-operating income (expense), net	\$60,120	\$(1,259 )	\$61,379	NM	

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

Cash flow provided by operating activities for the six months ended June 30, 2019, was \$48.1 million.

Certain GAAP and non-GAAP measures for comparative periods in 2018 were revised for immaterial errors identified in a previous quarter.

#### 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 June 30, 2019. The Company's proprietary pipeline includes a new drug application for intranasal naloxone. The Company is currently developing three other proprietary products, which include injectable and intranasal dosage forms.

Amphastar's Chinese subsidiary, ANP, currently has 12 Drug Master Files, or DMFs, on file with the FDA and is developing six 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](http://www.amphastar.com).

Amphastar's logo and other trademarks or service marks of Amphastar, including, but not limited to Primatene<sup>®</sup>, Amphadase<sup>®</sup> and Cortrosyn<sup>®</sup>, 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, 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 7, 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 7375585.

The call can also be accessed on the Investors page on the Company's website at [www.amphastar.com](http://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](http://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:

Amphastar Pharmaceuticals, Inc.  
 Bill Peters  
 Chief Financial Officer  
 (909) 980-9484

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

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2019</b>	<b>2018</b>	<b>2019</b>	<b>2018</b>
Net revenues	\$ 79,047	\$ 71,040	\$ 158,837	\$ 129,433
Cost of revenues	46,660	44,976	95,547	86,397
Gross profit	32,387	26,064	63,290	43,036
Operating expenses:				
Selling, distribution, and marketing	2,992	1,876	6,133	3,597
General and administrative	12,426	11,669	28,753	22,667
Research and development	15,996	15,460	30,603	29,490
Total operating expenses	31,414	29,005	65,489	55,754
Income (loss) from operations	973	(2,941 )	(2,199 )	(12,718 )
Non-operating income (expense), net	60,120	(1,259 )	59,659	(371 )
Income (loss) before income taxes	61,093	(4,200 )	57,460	(13,089 )
Income tax provision (benefit)	14,173	(1,347 )	12,694	(3,095 )
Net income (loss)	\$ 46,920	\$ (2,853 )	\$ 44,766	\$ (9,994 )

Net loss attributable to non-controlling interests	\$ (867	) \$—	\$ (3,889	) \$—
Net income (loss) attributable to Amphastar	\$ 47,787	\$ (2,853	) \$ 48,655	\$ (9,994
Net income (loss) per share attributable to Amphastar shareholders:				
Basic	\$ 1.01	\$ (0.06	) \$ 1.04	\$ (0.21
Diluted	\$ 0.96	\$ (0.06	) \$ 0.97	\$ (0.21
Weighted-average shares used to compute net income (loss) per share attributable to Amphastar shareholders:				
Basic	47,107	46,557	46,925	46,535
Diluted	49,894	46,557	50,155	46,535

The comparative period in 2018 was revised for immaterial errors.

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

	<b>June 30, 2019</b>	<b>December 31, 2018</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 120,373	\$ 86,337
Restricted cash	1,865	1,865
Short-term investments	2,836	2,831
Restricted short-term investments	2,290	2,290
Accounts receivable, net	48,823	52,163
Inventories	99,232	69,322
Income tax refunds and deposits	226	49
Prepaid expenses and other assets	8,489	5,485
Total current assets	284,134	220,342
Property, plant, and equipment, net	220,060	210,418
Finance lease right-of-use assets	985	—
Operating lease right-of-use assets	20,143	—
Goodwill and intangible assets, net	41,718	42,267
Other assets	13,515	9,918
Deferred tax assets	20,746	30,618
Total assets	\$ 601,301	\$ 513,563

**LIABILITIES AND STOCKHOLDERS' EQUITY**

Current liabilities:

Accounts payable and accrued liabilities	\$ 88,171	\$ 87,418
Income taxes payable	3,150	1,187
Current portion of long-term debt	6,941	18,229
Current portion of operating lease liabilities	2,737	—
Total current liabilities	100,999	106,834
Long-term reserve for income tax liabilities	415	415
Long-term debt, net of current portion	39,793	31,984
Long-term operating lease liabilities, net of current portion	17,754	—
Deferred tax liabilities	1,025	1,031
Other long-term liabilities	9,027	8,940
Total liabilities	169,013	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; 52,212,760 and 47,217,675 shares issued and outstanding as of June 30, 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	355,436	344,434
Retained earnings	116,086	67,485
Accumulated other comprehensive loss	(4,223 )	(4,013 )
Treasury stock	(79,459 )	(75,476 )
Total Amphastar Pharmaceuticals, Inc. stockholders' equity	387,845	332,435
Non-controlling interests	44,443	31,924
Total equity	432,288	364,359
Total liabilities and stockholders' equity	\$ 601,301	\$ 513,563

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

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2019</b>	<b>2018</b>	<b>2019</b>	<b>2018</b>
GAAP net income (loss)	\$46,920	\$(2,853 )	\$44,766	\$(9,994 )
Adjusted for:				
Intangible amortization	256	722	526	1,451
Share-based compensation	4,032	4,196	8,706	8,862
Impairment of long-lived assets	46	145	183	521
Gain on litigation settlement	(59,900 )	—	(59,900 )	—

Income tax provision (benefit) on pre-tax adjustments	11,955	(1,053 )	11,020	(2,196 )
Non-GAAP net income (loss)	\$ 3,309	\$ 1,157	\$ 5,301	\$ (1,356 )
Non-GAAP net loss attributable to non-controlling interests	\$ (808 )	\$ —	\$ (3,701 )	\$ —
Non-GAAP net income (loss) attributable to Amphastar	\$ 4,117	\$ 1,157	\$ 9,002	\$ (1,356 )
Non-GAAP net income (loss) per share attributable to Amphastar shareholders:				
Basic	\$ 0.09	\$ 0.02	\$ 0.19	\$ (0.03 )
Diluted	\$ 0.08	\$ 0.02	\$ 0.18	\$ (0.03 )
Weighted-average shares used to compute non-GAAP net income (loss) per share attributable to Amphastar shareholders:				
Basic	47,107	46,557	46,925	46,535
Diluted	49,894	48,495	50,155	46,535

### Three 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	\$ 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 provision (benefit) on pre-tax adjustments	—	—	—	—	—	(11,955)	(9 )
Non-GAAP	\$ 45,435	\$ 2,897	\$ 9,742	\$ 15,666	\$ 220	\$ 2,218	\$ (808 )

### Reconciliation of Non-GAAP Measures (continued)



### Three Months Ended June 30, 2018

	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	\$44,976	\$ 1,876	\$ 11,669	\$ 15,460	\$ (1,259 )	\$ (1,347 )	\$ —
Intangible amortization	(683 )	—	(39 )	—	—	—	—
Share-based compensation	(981 )	(104 )	(2,743 )	(368 )	—	—	—
Impairment of long-lived assets	(3 )	—	(1 )	(141 )	—	—	—
Income tax provision (benefit) on pre-tax adjustments	—	—	—	—	—	1,053	—
Non-GAAP	\$43,309	\$ 1,772	\$ 8,886	\$ 14,951	\$ (1,259 )	\$ (294 )	\$ —

The comparative period in 2018 was revised for immaterial errors.

### 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	\$95,547	\$ 6,133	\$ 28,753	\$ 30,603	\$59,659	\$12,694	\$ (3,889 )
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 provision (benefit) on pre-tax adjustments	—	—	—	—	—	(11,020)	(33 )
Non-GAAP	\$92,791	\$ 5,944	\$ 23,229	\$ 29,657	\$ (241 )	\$ 1,674	\$ (3,701 )

**Six Months Ended June 30, 2018**

	<b>Cost of revenue</b>	<b>Selling, distribution and marketing</b>	<b>General and administrative</b>	<b>Research and development</b>	<b>Non-operating income (expense) net</b>	<b>Income tax provision (benefit)</b>	<b>Non-controlling interest adjustment</b>
GAAP	\$86,397	\$ 3,597	\$ 22,667	\$ 29,490	\$ (371 )	\$ (3,095 )	\$ —
Intangible amortization	(1,372 )	—	(79 )	—	—	—	—
Share-based compensation	(2,141 )	(211 )	(5,636 )	(874 )	—	—	—
Impairment of long-lived assets	(77 )	—	(4 )	(440 )	—	—	—
Income tax provision (benefit) on pre-tax adjustments	—	—	—	—	—	2,196	—
Non-GAAP	\$82,807	\$ 3,386	\$ 16,948	\$ 28,176	\$ (371 )	\$ (899 )	\$ —

The comparative period in 2018 was revised for immaterial errors.

Source: Amphastar Pharmaceuticals, Inc.