# Amphastar Pharmaceuticals Reports Financial Results for the Three Months Ended March 31, 2020

May 7, 2020

RANCHO CUCAMONGA, Calif., May 07, 2020 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc. (NASDAQ: AMPH) ("Amphastar" or the "Company") today reported results for the three months ended March 31, 2020.

## First Quarter Highlights

- Net revenues of \$84.7 million for the first quarter
- GAAP net income of \$3.9 million, or \$0.08 per share, for the first quarter
- Adjusted non-GAAP net income of \$8.4 million, or \$0.17 per share, for the first quarter

Dr. Jack Zhang, Amphastar's President and Chief Executive Officer, commented: "The first quarter of 2020 was very strong for Amphastar, as we had strong sales from Primatene<sup>®</sup> Mist and from our hospital products, including sales of Sodium Bicarbonate, which we filled in our newly approved finished product facility in South El Monte, California."

	Three Months Ended				
	Ma				
	202	20	<b>20</b> 1	19	
	(in	thousands,	except	per share data)	
Net revenues	\$	84,688	\$	79,790	
GAAP net income attributable to Amphastar	\$	3,949	\$	868	
Adjusted non-GAAP net income attributable to Amphastar*	\$	8,383	\$	4,885	
GAAP diluted EPS attributable to Amphastar shareholders	\$	0.08	\$	0.02	
Adjusted non-GAAP diluted EPS attributable to Amphastar shareholders*	\$	0.17	\$	0.10	

<sup>\*</sup> 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.

## First Quarter Results

	Three Months Ended								
	March 31	Change							
	2020	2019	<b>Dollars</b>	%					
	(in thousa	(in thousands)							
Net revenues:									
Primatene <sup>®</sup> Mist	\$12,877	\$ 2,897	\$ 9,980	344	%				

Phytonadione	11,029	10,120	909	9	%
Lidocaine	10,657	11,979	(1,322	) (11	) %
Enoxaparin	9,168	14,484	(5,316	) (37	) %
Naloxone	8,875	7,364	1,511	21	%
Epinephrine	3,990	2,679	1,311	49	%
Other finished pharmaceutical products	24,702	25,016	(314	) (1	) %
Total finished pharmaceutical products net revenues	\$81,298	\$ 74,539	\$ 6,759	9	%
API	3,390	5,251	(1,861	) (35	) %
Total net revenues	\$84,688	\$ 79,790	\$ 4,898	6	%

Changes in net revenues were primarily driven by:

- Increased sale of Primatene<sup>®</sup> Mist primarily resulting from the continued success of our nationwide television, radio, and digital campaign, as well as a short-term increase due to "pantry loading" towards the end of the quarter as a result of the COVID-19 pandemic
- Phytonadione and naloxone sales increased due to higher unit volumes
- Epinephrine sales increased due to increased unit volumes and an increase in average selling price
- Enoxaparin sales decreased due to lower unit volumes and lower average selling price, as there was a competitor shortage that resulted in higher volumes in the first quarter of 2019

	Three Months Ended							
	March 31,		Change					
	2020	2019	<b>Dollars</b>	%				
	(in thousar	ıds)						
Net revenues	\$84,688	\$79,790	\$4,898	6	%			
Cost of revenues	47,865	48,887	(1,022	) (2	) %			
Gross profit	\$36,823	\$30,903	\$5,920	19	%			
as % of net revenues	43	% 39	%					

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

- Increased sales of Primatene® Mist and phytonadione, both of which have higher margins
- ullet Primatene  ${}^{\circledR}$  Mist was magnified by the use of API and components which were expensed to pre-launch inventory in prior years

	Three Mo				
	Ended				
	March 31,	Change			
	2020	2019	<b>Dollars</b>	%	
	(in thousa	nds)			
Selling, distribution and marketing	\$3,294	\$3,141	\$153	5	%

General and administrative	10,746	16,327	(5,581 )	(34	) %
Research and development	15,303	14,607	696	5	%

- Marketing and distribution expenses increased primarily related to Primatene<sup>®</sup> Mist, including the cost of a national television and radio marketing campaign, which began in July 2019
- General and administrative expenses decreased primarily due to lower legal expenses as a result of recent litigation settlements
- Research and development expenses increased primarily due the increased clinical trial expenses for our generic product pipeline, largely for our inhalation abbreviated new drug applications, or ANDAs.

Cash flow provided by operating activities for the three months ended March 31, 2020, was \$1.5 million.

# Impact of COVID-19

Except for the increased sales of Primatene<sup>®</sup> Mist and some hospital products, the financial results for the three months ended March 31, 2020, were not significantly impacted by the COVID-19 pandemic. Other than a temporary delay in re-opening our facility in China after the Lunar New Year celebration, our production facilities in all of our locations continued to operate in substantially the same manner during the quarter as they had prior to the COVID-19 pandemic with the adoption of enhanced safety measures intended to prevent the spread of the coronavirus. It is not possible at this time to estimate the impact that COVID-19 could have on our business, as the impact will depend on future developments, which are highly uncertain and cannot be predicted.

## Pipeline Information

The Company currently has six ANDAs filed with the FDA targeting products with a market size of approximately \$1.8 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 March 31, 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<sup>®</sup>, 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, May 7, 2020, 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 9246728.

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, 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 <a href="http://ir.amphastar.com">http://ir.amphastar.com</a> and on the SEC's website at <a href="http://www.sec.gov">www.sec.gov</a>. 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 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)

	Three M March 32	ths Ended 2019	l	
Net revenues	\$84,688		\$79,790	
Cost of revenues	47,865		48,887	
Gross profit	36,823		30,903	
Operating expenses:				
Selling, distribution, and marketing	3,294		3,141	
General and administrative	10,746		16,327	
Research and development	15,303		14,607	
Total operating expenses	29,343		34,075	
Income (loss) from operations	7,480		(3,172	)
Non-operating expenses, net	(1,675	)	(461	)
Income (loss) before income taxes	5,805		(3,633	)
Income tax provision (benefit)	2,280		(1,479	)
Net income (loss)	\$3,525		\$(2,154	)
Net loss attributable to non-controlling interests	\$(424	)	\$(3,022	)
Net income attributable to Amphastar	\$3,949		\$868	
Net income per share attributable to Amphastar shareholders: Basic	\$0.09		\$0.02	

Diluted	\$0.08	\$0.02
Weighted-average shares used to compute net income per share attributab to Amphastar shareholders:	le	
Basic	46,408	46,744
Diluted	48,248	50,416

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

	2	Iarch 31, 020 inaudited)	ecember 31, 119
ASSETS	`	,	
Current assets:			
Cash and cash equivalents	\$	54,845	\$ 73,685
Restricted cash		1,865	1,865
Short-term investments		12,203	11,675
Restricted short-term investments		2,290	2,290
Accounts receivable, net		57,784	45,376
Inventories		107,900	110,501
Income tax refunds and deposits		814	311
Prepaid expenses and other assets		9,023	9,538
Total current assets		246,724	255,241
Property, plant, and equipment, net		231,476	233,856
Finance lease right-of-use assets		798	887
Operating lease right-of-use assets		17,934	18,805
Goodwill and intangible assets, net		40,472	41,153
Other assets		11,192	11,156
Deferred tax assets		24,235	25,873
Total assets	\$	572,831	\$ 586,971
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts payable and accrued liabilities	\$	65,438	\$ 77,051
Income taxes payable		2,994	2,042
Current portion of long-term debt		11,458	7,741
Current portion of operating lease liabilities		3,481	3,175
Total current liabilities		83,371	90,009
Long-term reserve for income tax liabilities		3,425	3,425
Long-term debt, net of current portion		36,410	39,394
Long-term operating lease liabilities, net of current portion		15,230	16,315
Deferred tax liabilities		765	867

Other long-term liabilities	10,257	9,433	
Total liabilities	149,458	159,443	
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;			
52,864,991 and 46,306,103 shares issued and outstanding as of March	5	5	
31, 2020 and 52,495,483 and 46,495,483 shares issued and	5	J	
outstanding as of December 31, 2019, respectively			
Additional paid-in capital	371,144	367,305	
Retained earnings	120,319	116,370	
Accumulated other comprehensive loss	(5,461)	(4,687	)
Treasury stock	(108,493)	(97,627	)
Total Amphastar Pharmaceuticals, Inc. stockholders' equity	377,514	381,366	
Non-controlling interests	45,859	46,162	
Total equity	423,373	427,528	
Total liabilities and stockholders' equity	\$ 572,831	\$ 586,971	

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

	Three M March 3	onths Ended 1,
	2020	2019
GAAP net income (loss) Adjusted for:	\$3,525	\$(2,154)
Intangible amortization Share-based compensation Impairment of long-lived assets	258 5,282 14	270 4,674 137
Income tax provision (benefit) on pre-tax adjustments Non-GAAP net income	(1,004 \$8,075	) (935 ) \$1,992
Non-GAAP net loss attributable to non-controlling interests	\$(308	) \$(2,893 )
Non-GAAP net income attributable to Amphastar	\$8,383	\$4,885
Non-GAAP net income per share attributable to Amphastar shareholders: Basic Diluted	\$0.18 \$0.17	\$0.10 \$0.10
Weighted-average shares used to compute non-GAAP net income per share attributable to Amphastar shareholders:		46 744
Basic	46,408	46,744

Diluted 48,248 50,416

# Three Months Ended March 31, 2020

			Selling,		G	eneral		Research		Income	Non- control	ling
	Cost of		distribut	distribution		ı and		and		tax provision	interest	
	revenue		and marketin	ıg	ac	lministra	ativ	e developm	ent	(benefit)	adjustn	nent
GAAP	\$47,865		\$ 3,294	_	\$	10,746		\$ 15,303		\$2,280	\$ (424	)
Intangible amortization	(224	)	_			(34	)	_			11	
Share-based compensation	(1,359	)	(107	)		(3,219	)	(597	)		127	
Impairment of long- lived assets	(10	)				(4	)	_		_	1	
Income tax provision (benefit) on pre-tax adjustments	<u> </u>		_			_		_		1,004	(23	)
Non-GAAP	\$46,272		\$ 3,187		\$	7,489		\$ 14,706		\$3,284	\$ (308	)

# Three Months Ended March 31, 2019

			Selling,		General			Research			Income		Non- controlling	
	Cost of		distribution			and			nd	tax provision	interest n			
	revenue		and marketi	ng	ac	lministra	ativ	e d	evelopm	ent	(benefit)		adjustme	ent
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 provision (benefit) on pre-tax adjustments	_		_			_			_		935		(24	)
Non-GAAP	\$47,356		\$ 3,047		\$	13,487		\$	13,991		\$(544	)	\$ (2,893	)

Source: Amphastar Pharmaceuticals, Inc.