Source: Amphastar Pharmaceuticals, Inc.

May 06, 2021 16:05 ET

# Amphastar Pharmaceuticals Reports Financial Results for the Three Months Ended March 31, 2021

Reports Net Revenues of \$103.0 Million for the Three Months Ended March 31, 2021

RANCHO CUCAMONGA, Calif., May 06, 2021 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc. (NASDAQ: AMPH) ("Amphastar" or the "Company") today reported results for the three months ended March 31, 2021.

#### First Quarter Highlights

- Net revenues of \$103.0 million for the first quarter
- GAAP net income of \$5.0 million, or \$0.10 per share, for the first guarter
- Adjusted non-GAAP net income of \$13.6 million, or \$0.27 per share, for the first quarter

Dr. Jack Zhang, Amphastar's President and Chief Executive Officer commented: "The launch of glucagon, along with strong sales growth of Primatene Mist<sup>®</sup> and our epinephrine products, contributed to one of Amphastar's strongest quarters in terms of sales growth to date. We expect that these core growth products will continue to drive growth for the remainder of the year, while we are confident in seeing our pipeline develop to diversify our portfolio."

Three Months Ended March 31, 2021 2020 (in thousands, except per share data) Net revenues \$ 103,020 \$ 84,688 \$ GAAP net income attributable to Amphastar 5,041 3,949 Adjusted non-GAAP net income attributable to Amphastar\* \$ \$ 13,553 8.383 GAAP diluted EPS attributable to Amphastar stockholders \$ 0.10 \$ 80.0 Adjusted non-GAAP diluted EPS attributable to Amphastar stockholders\* 0.27 0.17

#### First Quarter Results

	Three Months Ended  March 31,  Chang						
	- 4	2021		2020		Dollars	%
			(in th	ousands	s)		
Net revenues:							
Primatene Mist <sup>®</sup>	\$	18,383	\$	12,877	\$	5,506	43 %
Epinephrine		15,578		3,990		11,588	290 %
Enoxaparin		10,658		9,168		1,490	16 %
Phytonadione		9,565		11,029		(1,464)	(13)%
Lidocaine		9,071		10,657		(1,586)	(15)%
Glucagon		7,984		_		7,984	N/A
Naloxone		6,341		8,875		(2,534)	(29) %
Other finished pharmaceutical products		20,302		24,702		(4,400)	(18) %

<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.

Total finished pharmaceutical products net	\$ 97,882	\$	81,298 \$	16,584	20 %
revenues					
API	 5,138	_	3,390 -	1,748	52 <sup>-</sup> %
Total net revenues	\$ 103,020	\$	84,688 \$	18,332	22 %

Changes in net revenues were primarily driven by:

- $\bullet \ \ \, \text{Primatene Mist}^{\textcircled{\$}} \, \text{increased volumes resulting from} :$ 
  - The continued success of our nationwide television, radio, and digital marketing campaign
  - An increase in our distribution channels throughout 2020 and during the first quarter of 2021, including Target, which began selling Primatene Mist<sup>®</sup> in March 2021
- Glucagon for injection emergency kit launched in February 2021
- Epinephrine sales increased due to the launch of our approved epinephrine injection multi-dose vials during the second quarter of 2020 and a market shortage of the pre-filled syringes
- Naloxone sales decreased due to lower average selling price because of increased competition
- Other finished pharmaceutical product sales decreased due to lower demand, largely due to competitors returning to their normal distribution levels

	Three Months Ended										
		Marc	ch 3	1,		Chan	ge				
		2021		2020	I	Dollars	%				
			(in t	nousands	)						
Net revenues	\$	103,020	\$	84,688	\$	18,332	22%				
Cost of revenues		58,074		47,865		10,209	21%				
Gross profit	\$	44,946	\$	36,823	\$	8,123	22%				
as % of net revenues	-	44%		43%		<del></del>					

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

- Increased sales of higher margin products such as Primatene Mist<sup>®</sup>, epinephrine injection multi-dose vials, and glucagon
- Partially offset by increased sales of low margin enoxaparin and higher input cost

	Three Mo	nths	Ended			
	Mar	ch 31	l <b>,</b>		Chang	je
_	2021		2020		Dollars	%
_		(in th	nousand	s)		
Selling, distribution, and marketing \$	4,537	\$	3,294	\$	1,243	38 %
General and administrative	15,338		10,746		4,592	43 %
Research and development	14,765		15,303		(538)	(4) %
Non-operating expense, net	5,192		1,675		3,517	NM

- Selling, distribution, and marketing expenses increased due to the cost of our ongoing national television, radio, and digital marketing campaign for Primatene Mist<sup>®</sup>
- General and administrative expenses increased primarily due to increased legal expenses, including a reserve of \$1.3 million related to the settlement of employment litigation
- Research and development expenses decreased due to lower clinical trial expenses, which was partially offset by an increase in salaries and personnel-related expenses as well as an increase in depreciation expense
- We recorded an additional \$4.4 million of expense relating to the litigation with Aventis

Cash flow provided by operating activities for the three months ended March 31, 2021, was \$22.8 million.

#### **Pipeline Information**

The Company currently has five ANDAs on file with the FDA targeting products with a market size of approximately \$2.4 billion, three biosimilar products in development targeting products with a market size of approximately \$13 billion, and seven generic products in development targeting products with a market size of approximately \$10 billion. This market information is based on IQVIA data for the 12 months ended March 31, 2021. The Company is currently developing multiple proprietary products with injectable and intranasal dosage forms.

Amphastar's Chinese subsidiary, ANP, currently has 17 Drug Master Files, or DMFs, on file with the FDA and is developing several additional DMFs.

#### **Company Information**

Amphastar is a bio-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 <a href="https://www.amphastar.com">www.amphastar.com</a>.

Amphastar's logo and other trademarks or service marks of Amphastar, including, but not limited to Amphastar<sup>®</sup>, Primatene Mist<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 stockholders, 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, May 6, 2021, at 2:00 p.m. Pacific Time.

To access the conference call, dial toll-free (877) 876-9177 or (785) 424-1672 for international callers, five minutes before the conference.

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 forwardlooking statements, including, among other things, statements relating to our expectations regarding future financial performance, backlog, sales and marketing of our products, market size and growth, product development, the timing of FDA filings or approvals, including the DMFs of ANP, the timing of product launches, acquisitions and other matters related to our pipeline of product candidates, our 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 facts but rather are based on Amphastar's historical performance and our current expectations, estimates, and projections regarding our 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 our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 15, 2021. 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 our 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 our 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 Months Ended March 31,					
		2021		2020		
Net revenues Cost of revenues	\$	103,020 58,074	\$	84,688 47,865		
Gross profit		44,946		36,823		
Operating expenses: Selling, distribution, and marketing		4,537		3,294		
General and administrative		15,338		10,746		
Research and development		14,765		15,303		
Total operating expenses		34,640		29,343		
Income from operations		10,306		7,480		
Non-operating expense, net		(5,192)		(1,675)		
Income before income taxes Income tax provision		5,114 1,155		5,805 2,280		
Net income	\$	3,959	\$	3,525		
Net loss attributable to non-controlling interests	\$	(1,082)	\$	(424)		
Net income attributable to Amphastar	\$	5,041	\$	3,949		
Net income per share attributable to Amphastar stockholders:						
Basic	\$	0.11	\$	0.09		
Diluted	\$	0.10	\$	0.08		
Weighted-average shares used to compute net income per share attributable to Amphastar stockholders:						
Basic		47,520		46,408		
Diluted		49,518		48,248		

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

	2021		2020
ASSETS			
Current assets:			
Cash and cash equivalents	\$ 101,601	\$	92,642
Restricted cash	235		1,865
Short-term investments	13,531		12,977
Restricted short-term investments	2,200		2,200
Accounts receivable, net	77,938		66,005
Inventories	97,110		96,831
Income tax refunds and deposits	800		385
Prepaid expenses and other assets	6,749	_	6,777
Total current assets	300,164		279,682
Property, plant, and equipment, net	253,265		260,055
Finance lease right-of-use assets	594		612
Operating lease right-of-use assets	19,280		20,042
Goodwill and intangible assets, net	40,243		40,615
Other assets	7,212		5,250
Deferred tax assets	24,980		24,980
Total assets	\$ 645,738	\$	631,236
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts payable and accrued liabilities	\$ 108,545	\$	95,504
Income taxes payable	2,676	Ψ	1,077
Current portion of long-term debt	12,173		12,263
Current portion of operating lease liabilities	3,702		3,357
Total current liabilities	127,096		112,201
Total culterit habilities	127,090		112,201
Long-term reserve for income tax liabilities	4,709		4,709
Long-term debt, net of current portion	32,334		34,186
Long-term operating lease liabilities, net of current portion	16,464		17,464
Deferred tax liabilities	755		741
Other long-term liabilities	13,420		13,212
Total liabilities	194,778		182,513
Commitments and contingencies			
Stockholders' equity:			
Preferred stock: par value \$0.0001; 20,000,000 shares authorized; no			
shares issued and outstanding	_		<del></del>
Common stock: par value \$0.0001; 300,000,000 shares authorized;			
55,184,000 and 47,718,003 shares issued and outstanding as of			
March 31, 2021 and 54,760,922 and 47,495,439 shares issued and	6		_
outstanding as of December 31, 2020, respectively	412.026		5 440.064
Additional paid-in capital	413,926		410,061
Retained earnings	122,814		117,773
Accumulated other comprehensive loss	(5,642)		(3,721)
Treasury stock	(125,546)		(121,812)
Total Amphastar Pharmaceuticals, Inc. stockholders' equity	405,558		402,306
Non-controlling interests	45,402		46,417
Total equity	450,960		448,723
Total liabilities and stockholders' equity	\$ 645,738	\$	631,236

Table III
Amphastar Pharmaceuticals, Inc.

# Reconciliation of Non-GAAP Measures (Unaudited; in thousands, except per share data)

		Three Mor		
		2021		2020
GAAP net income Adjusted for:	\$	3,959	\$	3,525
Intangible amortization Share-based compensation		276 4,834		258 5,282
Impairment of long-lived assets Reserves for litigation and settlements Income tax (benefit) provision on pre-tax adjustments		6 5,695 (2,229)		14 — (1,004)
Non-GAAP net income	\$	12,541	\$	8,075
Non-GAAP net loss attributable to non-controlling interests	\$	(1,012)	\$	(308)
Non-GAAP net income attributable to Amphastar	\$	13,553	\$	8,383
Non-GAAP net income per share attributable to Amphastar stockholders: Basic Diluted	\$ \$	0.29 0.27	\$ \$	0.18 0.17
Weighted-average shares used to compute non-GAAP net income per share attributable to Amphastar stockholders:  Basic  Diluted		47,520 49,518		46,408 48,248

### Three Months Ended March 31, 2021

		Selling,		General	R	Research	Non-		come tax	Non- controlling	
	Cost of	distributior and	1	and		and	operating expense,	•		interest	
	revenue	marketing	ad	ministrative	dev	velopment	net	(be	enefit)	adjustment	
GAAP	\$58,074	\$ 4,537	\$	15,338	\$	14,765	\$ 5,192	\$	1,155	\$ (1,082)	
Intangible											
amortization	(242)	_		(34)		_	_		_	11	
Share-based											
compensation	(1,146)	(127)		(2,968)		(593)	_		_	71	
Impairment of											
long-lived assets				(6)						2	
Reserves for	_	_		(6)		_	_		_	2	
litigation and											
settlements	_	_		(1,295)		_	(4,400)			_	
Income tax				( , ,			(				
provision											
(benefit) on											
pre-tax										,	
adjustments									2,229	(14)	

Non-GAAP \$56	6,686 \$	4,410	\$	11,035	\$	14,172	\$	792	\$	3,384	\$	(1,012)
---------------	----------	-------	----	--------	----	--------	----	-----	----	-------	----	---------

## Three Months Ended March 31, 2020

	5	Selling,	(	General	R	Research			lr	ncome		Non- ntrolling				
Cost of	distribution and				and		and			and	Non- and operating expense,		pr	tax ovision	ir	nterest
revenue	m	arketing	adn	ninistrative	de	velopment		net	(b	enefit)	adj	ustment				
\$47,865	\$	3,294	\$	10,746	\$	15,303	\$	1,675	\$	2,280	\$	(424)				
(224)		_		(34)		_		_		_		11				
(1,359)		(107)		(3,219)		(597)		_		_		127				
(10)		_		(4)		_		_		_		1				
<u> </u>	\$	3,187	\$		\$	<u> </u>	\$	<u> </u>	\$	1,004 3,284	\$	(23)				
	revenue \$47,865 (224) (1,359) (10)	Cost of dis revenue m \$47,865 \$ (224) (1,359) (10)	revenue       and marketing         \$47,865       \$ 3,294         (224)       —         (1,359)       (107)         (10)       —	Cost of distribution and marketing \$47,865 \$3,294 \$\$ (224) \$ (107) \$ (10) \$ (10) \$ \$ (10) \$ (	Cost of revenue         distribution and marketing         administrative           \$47,865         \$ 3,294         \$ 10,746           (224)         — (34)           (1,359)         (107)         (3,219)           (10)         — (4)	Cost of and revenue \$47,865         distribution and marketing \$3,294         administrative \$10,746         devenue \$10,746           (224)         —         (34)           (1,359)         (107)         (3,219)           (10)         —         (4)	Cost of revenue         distribution and marketing         administrative         development           \$47,865         \$ 3,294         \$ 10,746         \$ 15,303           (224)         —         (34)         —           (1,359)         (107)         (3,219)         (597)           (10)         —         (4)         —	Cost of revenue         distribution and marketing         administrative         development         certain development           \$47,865         \$3,294         \$10,746         \$15,303         \$15,3	Cost of revenue \$\frac{1}{347,865}\$         distribution and and marketing \$\frac{1}{3}\$         administrative administrative \$\frac{1}{3}\$         development \$\frac{1}{3}\$         Non-operating expense, net \$\frac{1}{3}\$           (224)         —         (34)         —         —           (1,359)         (107)         (3,219)         (597)         —           (10)         —         (4)         —         —	Cost of revenue \$\frac{\text{distribution and and }}{\text{\$47,865}}\$         administrative \\ \frac{\text{\$3,294}}{\text{\$10,746}}\$         development \\ \frac{\text{\$15,303}}{\text{\$\$1,675}}\$         (224)         —         (34)         —         —         —         (1,359)         (107)         (3,219)         (597)         — <t< td=""><td>Cost of revenue         distribution and and marketing         administrative administrative         development station         Non-operating expense, net stax provision         (benefit)           \$47,865         \$3,294         \$10,746         \$15,303         \$1,675         \$2,280           (224)         —         (34)         —         —         —           (1,359)         (107)         (3,219)         (597)         —         —           (10)         —         (4)         —         —         —           —         —         —         —         —         1,004</td><td>Cost of revenue         General distribution and and revenue         Administrative administrative         General and and and and and and and and and and</td></t<>	Cost of revenue         distribution and and marketing         administrative administrative         development station         Non-operating expense, net stax provision         (benefit)           \$47,865         \$3,294         \$10,746         \$15,303         \$1,675         \$2,280           (224)         —         (34)         —         —         —           (1,359)         (107)         (3,219)         (597)         —         —           (10)         —         (4)         —         —         —           —         —         —         —         —         1,004	Cost of revenue         General distribution and and revenue         Administrative administrative         General and				