Amphastar Pharmaceuticals Reports Financial Results for the Three Months and Full-Year Ended December 31, 2021

March 10, 2022

Reports Net Revenues of \$120.9 Million for the Three Months Ended December 31, 2021

RANCHO CUCAMONGA, CA / ACCESSWIRE / March 10, 2022 / Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) ("Amphastar" or the "Company") today reported results for the three months and full-year ended December 31, 2021.

Fourth Quarter Highlights

- Net revenues of \$120.9 million for the fourth quarter
- GAAP net income of \$19.8 million, or \$0.39 per share, for the fourth quarter
- Adjusted non-GAAP net income of \$20.8 million, or \$0.42 per share, for the fourth quarter

Full-Year Highlights

- Net revenues of \$437.8 million for the fiscal year
- GAAP net income of \$62.1 million, or \$1.25 per share, for the fiscal year
- Adjusted non-GAAP net income of \$68.0 million, or \$1.37 per share, for the fiscal year

Dr. Jack Zhang, Amphastar's President and Chief Executive Officer commented: "Last year was a turning point for Amphastar - with financial strength driven by the continued growth of our higher-margin products. We expect a number of pipeline milestones to be reached in 2022 as we continue to execute the Company's strategy."

	Three Months Ended			Year Ended					
		Decem	ber	31,		December 31,			
	2021			2020		2021		2020	
		(in the	usa	nds, exce	pt	per shar	e da	ita)	
Net revenues	\$	120,887	\$	95,921	\$	437,768	\$	349,846	
GAAP net income (loss) attributable to Amphastar	\$	19,760	\$	(6,273)	\$	62,116	\$	1,403	
Adjusted non-GAAP net income attributable to Amphastar*	\$	20,833	\$	7,994	\$	67,999	\$	31,616	
GAAP diluted EPS attributable to Amphastar stockholders	\$	0.39	\$	(0.13)	\$	1.25	\$	0.03	
Adjusted non-GAAP diluted EPS attributable to Amphastar stockholders*	\$	0.42	\$	0.16	\$	1.37	\$	0.64	

^{*} Adjusted non-GAAP net income attributable to Amphastar and Adjusted non-GAAP diluted EPS attributable to Amphastar stockholders 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.

Fourth Quarter Results

		Three En						
	December 31, Chan				ge			
		2021 2020		Dollars		%		
	(in thousands)							
Net revenues:								
Primatene Mist [®]	\$	21,489	\$	13,392	\$	8,097	60 %	
Epinephrine		18,868		7,482		11,386	152 %	
Glucagon		15,335		-		15,335	N/A	
Phytonadione		13,921		10,458		3,463	33 %	
Lidocaine		12,099		12,191		(92)) (1 %	
Enoxaparin		7,942		17,648		(9,706)	(55 %	
Naloxone		6,546		7,079		(533)) (8 %	
Other finished pharmaceutical products		21,776		19,550		2,226	11 %	
Total finished pharmaceutical products net revenues	\$	117,976	\$	87,800	\$	30,176	34 %	
API		2,911		8,121		(5,210)	(64 %	
Total net revenues	\$	120,887	\$	95,921	\$	24,966	26 %	

Changes in net revenues were primarily driven by:

- $\bullet\,$ Primatene $\mathsf{Mist}^{\circledR}$ increased volumes resulting due to the continued success of our advertising campaign
- Epinephrine sales increased due to our launch of the multi-dose vial in 2020 and higher demand for the pre-filled syringe as a result of competitor shortages
- Glucagon for injection emergency kit, which was launched in the first quarter of 2021
- Phytonadione sales increased due to an increase in unit volumes and higher average selling price
- Enoxaparin sales decreased due to lower unit volumes and lower average selling price as competitors re-entered the market in 2021
- Other finished pharmaceutical product sales increased due to higher demand, largely due to competitors' shortages
- API decrease due to timing of orders from MannKind and other customers

	Three Mon	ıths	Ended						
	Decem	December 31,			Change				
	2021		2020	Ι	Oollars	%			
	(i	(in thousands)							
Net revenues	\$ 120,887	\$	95,921	\$	24,966	26%			

Cost of revenues	64,653	59,089	5,564	9%
Gross profit	\$ 56,234	\$ 36,832	\$ 19,402	53%
as % of net revenues	47%	38%		

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[®], epinephrine injection multi-dose vials, and glucagon
- Partially offset by increased cost for heparin, the starting material for enoxaparin, and lower pricing for enoxaparin

		Three En	Mo ded							
		December 31,				ge				
		2021		2020	Dollars		%			
	(in thousands)									
Selling, distribution, and marketing	\$	4,075	\$	3,787	\$	288	8 %			
General and administrative		10,621		12,033		(1,412)	(12 %			
Research and development		17,286		18,133		(847)	(5 %			
Non-operating income, net		2,910		(9,621)		12,531) (130 %			

- Selling, distribution, and marketing expenses increased primarily due to the ongoing marketing and distribution expenses for Primatene Mist[®]
- General and administrative expenses decreased primarily due to a decrease in legal expenses, as we settled several lawsuits
- Research and development expenses decreased due to a decrease in expenses in China resulting from the restructuring of our Chinese subsidiary, Amphastar Nanjing Pharmaceuticals (ANP), and the deconsolidation of Hanxin and its subsidiaries
- Non-operating income, net, increased as a result of:
 - $\circ~$ A \$2.7 million gain related to a settlement of a legal dispute, net of contingent legal fees
 - $\circ~$ A \$12.8 million expense in the fourth quarter of 2020 relating to litigation with Aventis

Year-End Results

		Ended iber 31,	Change								
	2021	2020	Dollars	%							
	((in thousands)									
Net revenues:											
Primatene Mist [®]	\$ 73,113	\$ 51,725	\$ 21,388	41 %							
Epinephrine	57,530	23,799	33,731	142 %							
Glucagon	47,639	-	47,639	N/A							
Phytonadione	45,498	42,646	2,852	7 %							

Lidocaine	44,413	41,113	3,300	8 %
Enoxaparin	35,962	48,681	(12,719)) (26 %
Naloxone	27,540	33,416	(5,876)	(18 %
Other finished pharmaceutical products	87,875	89,988	(2,113)	(2 %
Total finished pharmaceutical products net revenues	\$ 419,570	\$ 331,368	\$ 88,202	27 %
API	18,198	18,478	(280)	(2 %
Total net revenues	\$ <u>437,768</u>	\$ 349,846	\$ 87,922	<u>25</u> %

Changes in net revenues were primarily driven by:

- \bullet Primatene $\mathsf{Mist}^{\circledR}$ increased volumes resulting from the continued success of our advertising campaign
- Glucagon for injection emergency kit, which was launched in the first quarter of 2021
- Epinephrine and lidocaine sales increased due to our launch of the epinephrine multi-dose vials in 2020 and higher demand for the pre-filled syringe as a result of competitor shortages
- Phytonadione sales increased due to higher average selling price
- Enoxaparin and naloxone sales decreased due to lower unit volumes and lower average selling prices as competitors entered the market in 2021
- Other finished pharmaceutical product sales decreased due to lower unit volumes as a result of competitors returning to their normal distribution levels during the year

	Year l				
	Decem	ber 31,	Change		
	2021	2020	Dollars	<u>%</u>	
	(
Net revenues	\$ 437,768	\$ 349,846	\$ 87,922	25%	
Cost of revenues	_ 238,029	206,506	31,523	15%	
Gross profit	<u>\$ 199,739</u>	\$ <u>143,340</u>	\$ 56,399	39%	
as % of net revenues	46%	41%			

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 ${\sf Mist}^{{\Bbb R}}$, epinephrine injection multi-dose vials, and glucagon
- Partially offset by increased cost for heparin, the starting material for enoxaparin, and lower pricing for enoxaparin

		Year Ended December 31,				Change		
		2021 2020		D	ollars	%		
	(in thousands)							
Selling, distribution, and marketing	\$	17,486	\$	14,780	\$	2,706	18 %	
General and administrative		51,434		50,377		1,057	2 %	

- Selling, distribution, and marketing expenses increased primarily due to the ongoing marketing and distribution expenses for Primatene Mist[®], including the cost of developing a new commercial for television
- General and administrative expenses increased primarily due to an increase in legal expenses, which was partially offset by a decrease in cash compensation and share-based compensation expense relating to the separation agreement that we entered into with a former executive during the second quarter of 2020
- Research and development expenses decreased due to:
 - A decrease in clinical trial expense as a result of delays in beginning certain clinical trials due to changes in COVID-19 protocols
 - A decrease in expenses in China due to the restructuring of ANP and the deconsolidation of Hanxin and its subsidiaries
- Non-operating income, net, increased as a result of:
 - A \$13.6 million gain on the deconsolidation of Hanxin relating to the ANP restructuring
 - $\circ~$ A \$2.7 million gain related to a settlement of a legal dispute, net of contingent legal fees
 - $\circ~$ A \$12.8 million expense in the fourth quarter of 2020 relating to the litigation with Aventis

Cash flow provided by operating activities for the year ended December 31, 2021 was \$98.0 million.

Pipeline Information

The Company currently has five ANDAs on file with the FDA targeting products with a market size of approximately \$4 billion, three biosimilar products in development targeting products with a market size of approximately \$13 billion, and eight 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 December 31, 2021. The Company is 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 www.amphastar.com.

Amphastar's logo and other trademarks or service marks of Amphastar, including, but not limited to Amphastar[®], Primatene Mist[®], 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 stockholders, which exclude amortization expense, share-based compensation, impairment charges, executive severance expense, legal settlements, and other one-time events 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, March 10, 2022, at 2:00 p.m. Pacific Time.

To access the conference call, dial toll-free (877) 407-0989 or (201) 389-0921 for international callers, five minutes before the conference.

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 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, the timing and results of clinical trials, our share buyback program, the impact of the restructuring of ANP, and other future events, such as the impact of the COVID-19 pandemic including its variants 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, and in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, filed with the SEC on November 9, 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 including its variants, 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 December 31,					Year Ended December 31,			
		2021		2020		2021		2020	
Net revenues	\$	120,887	\$	95,921	\$	437,768	\$	349,846	
Cost of revenues		64,653	_	59,089	_	238,029	_	206,506	
Gross profit		56,234		36,832		199,739		143,340	
Operating expenses:									
Selling, distribution, and marketing		4,075		3,787		17,486		14,780	
General and administrative		10,621		12,033		51,434		50,377	
Research and development		17,286	_	18,133	_	60,932	_	67,229	
Total operating expenses		31,982	_	33,953	_	129,852	_	132,386	
Income from operations		24,252		2,879		69,887		10,954	
Non-operating income (expenses), net	_	2,910	_	(9,621)	_	14,252	_	(6,317)	
Income (loss) before income taxes		27,162		(6,742)		84,139		4,637	
Income tax provision (benefit)		7,194		(950)	_	20,630	_	3,540	
Net income before equity in losses of unconsolidated affiliate		19,968		(5,792)		63,509		1,097	
Equity in losses of unconsolidated affiliate		(208)		_		(208)		_	
Net income (loss)	\$	19,760	\$	(5,792)	\$	63,301	\$	1,097	
Net income (loss) attributable to non- controlling interests	\$		\$	481	\$	1,185	\$	(306)	

Net income (loss) attributable to Amphastar	\$ 19,760	\$ (6,273) \$	62,116	\$_	1,403
Net income (loss) per share attributable to Amphastar stockholders:					
Basic	\$ 0.41	\$ (0.13) \$	1.30	\$	0.03
Diluted	\$ 0.39	\$ (0.13) \$	1.25	\$	0.03
Weighted-average shares used to compute net income (loss) per share attributable to Amphastar stockholders:					
Basic	47,836	47,496	47,777		47,038
Diluted	50,057	47,496	49,784		49,124

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

	D	ecember 31, 2021	December 31, 2020		
ASSETS					
Current assets:					
Cash and cash equivalents	\$	126,353	\$	92,642	
Restricted cash		235		1,865	
Short-term investments		10,320		12,977	
Restricted short-term investments		2,200		2,200	
Accounts receivable, net		78,804		66,005	
Inventories		92,807		96,831	
Income tax refunds and deposits		126		385	
Prepaid expenses and other assets	_	7,274	_	6,777	
Total current assets		318,119		279,682	
Property, plant, and equipment, net		244,244		260,055	
Finance lease right-of-use assets		353		612	
Operating lease right-of-use assets		26,894		20,042	
Equity method investment		3,985		-	
Goodwill and intangible assets, net		38,870		40,615	
Other assets		16,665		5,250	
Deferred tax assets	_	22,399	_	24,980	
Total assets	\$	671,529	\$	631,236	
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current liabilities:					
Accounts payable and accrued liabilities	\$	89,545	\$	95,504	
Income taxes payable		9,081		1,077	
Current portion of long-term debt		2,202		12,263	
Current portion of operating lease liabilities	_	2,982	_	3,357	

Total current liabilities	103,810	112,201
Long-term reserve for income tax liabilities	6,531	4,709
Long-term debt, net of current portion and unamortized debt issuance costs	74,776	34,186
Long-term operating lease liabilities, net of current portion	24,703	17,464
Deferred tax liabilities	534	741
Other long-term liabilities	15,653	13,212
Total liabilities	226,007	182,513
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; 56,440,202 and 47,714,912 shares issued and outstanding as of December 31, 2021 and 54,760,922 and 47,495,439 shares issued	C	5
and outstanding as of December 31, 2020, respectively	6	
Additional paid-in capital	422,423	410,061
Retained earnings	180,337	117,773
Accumulated other comprehensive loss	(6,765)	(3,721)
Treasury stock	(150,479)	(121,812)
Total Amphastar Pharmaceuticals, Inc. stockholders' equity	445,522	402,306
Non-controlling interests		46,417
Total equity	445,522	448,723
Total liabilities and stockholders' equity	\$ 671,529	\$ 631,236

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

	\mathbf{T}	hree Mon	ths	Ended		Year E	ed		
		Decem	ber	31,		Decemb	ber 31,		
		2021	2020			2021		2020	
GAAP net income (loss)	\$	19,760	\$	(5,792)	\$	63,301	\$	1,097	
Adjusted for:									
Intangible amortization		360		265		1,290		1,036	
Share-based compensation		3,850		4,334		18,687		18,180	
Impairment of long-lived assets		9		81		348		241	
Gain on ANP Restructuring		-		-		(13,587)		-	
Expense related to executive separation									
agreement		-		-		-		4,869	
Reserves for litigation and settlements		(2,717)		13,780		274		13,780	
Income tax benefit on pre-tax adjustments		(429)	_	(4,090)	_	(2,043)	_	(7,482)	
Non-GAAP net income	\$	20,833	\$	8,578	\$	68,270	\$	31,721	

Non-GAAP ne		tributable to 1		5	- \$	584	\$	271	\$	10)5	
Non-GAAP ne Amphastar	et income at	tributable to	9	\$ 20,83	33 <u>\$</u>	7,994	\$	67,999	<u>\$</u>	31,61	.6	
Non-GAAP not to Amphastar s	-		utable									
Basic			9	5 0.4	4 \$	0.17	\$	1.42	\$	0.6	57	
Diluted			9	5 0.4	12 \$	0.16	\$	1.37	\$	0.6	64	
Weighted-aver GAAP net inco Amphastar sto	ome per sha											
Basic				47,83	86	47,496		47,777		47,03	88	
Diluted			50,057 49,730 49,7			49,784		49,12	24			
		T	hree Mon	ths End	led D	ecember 3	31, 2	2021				
		Selling, distribution	1		Re	esearch	op	Non- erating icome			Noi	n- trolling
	Cost of	and		ral and and				kpense),		ovision		0
	revenue	marketing	adminis	trative	deve	elopment		net	<u>(be</u>	enefit)	adjı	ustment
GAAP	\$ 64,653	\$ 4,075	\$	10,621	\$	17,286	\$	2,910	\$	7,194	\$	-
Intangible												
amortization	(235)	-		(125)		-		-		-		-
Share-based compensation Impairment of long-lived	(811)	(158))	(2,553))	(328)	1	-		-		-
assets	(9)	-		-		-		-		-		-

Reserves for litigation and

settlements Income tax provision

(benefit) on pre-tax

adjustments

Non-GAAP

\$ 63,598

3,917

Three	Months	Ended	December 3	1	2020
Inree	VIANTING	r.naea	December 3		/U/U

16,958

(2,717)

193

429

\$ 7,623 \$

	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 adjustmen	
GAAP	\$ 59,089	\$	3,787	\$	12,033	\$	18,133	\$	(9,621)	\$	(950)	\$	481
Intangible amortization	(232))	-		(33)		-		-		-	11	
Share-based compensation	(972))	(106)		(2,920)		(336)		-		-		114

7,943

Impairment of long-lived assets Loss on litigation settlement Income tax provision (benefit) on	(40) -	-	(12) (975)		(29)	- 12,805	-	5 -
pre-tax adjustments	-	-	-		-	-	4,090	(27)
	57,845 \$	3,681 \$	8,093	\$	17,768 \$	3,182 \$	3,140 \$	584
==			Year Er	==== nded De	======================================	=: 2021		
	Cost of revenue	Selling, distributior and marketing		R	Research and velopment	Non- operating income (expense), net	Income tax provision (benefit)	Non- controllir interest adjustme
GAAP	\$ 238,029	\$ 17,486	\$ 51,4		60,932	\$ 14,252	\$ 20,630	
Intangible amortization Share-based	(963)	-	(3	327)	-	-	-	2
compensation	(3,778)	(596) (12,6	522)	(1,691)	-	-	87
Impairment of long-lived assets Gain on ANP	(93)	-	((33)	(222)	-	-	
Restructuring Reserves for	-	-		-	-	(13,587)	-	(2,06
litigation and settlements Income tax provision	-	-	(1,2	295)	-	(1,021)	-	
(benefit) on pre- tax adjustments	_	_		_	_	_	2,043	24
Non-GAAP	\$ 233,195	\$ 16,890	\$ 37,1	\$	59,019	\$ (356)	\$ 22,673	\$ 27
			Year End	— == led Dec	======= ember 31, 2	020		
	Cost of revenue	Selling, distribution and marketing	General an administrat	d ive <u>dev</u>	esearch and velopment	Non- operating income (expense), net	Income tax provision (benefit)	
GAAP Intangible amortization	\$ 206,506 (902)	\$ 14,780	\$ 50,3	77 \$ 34)	67,229	\$ (6,317)	\$ 3,540	\$ (306 45
Share-based compensation	(4,248)	(456)	·	ŕ	(1,705)	-	-	444

Impairment										
of long-lived		`		(1.40.)		(20.)				20
assets	(72))	-	(140))	(29)	1	-	-	20
Expense										
related to										
executive										
separation				(4.000.)						
agreement	-		-	(4,869))	-		-	-	-
Loss on										
litigation										
settlement	-		-	(975))	-		12,805	-	-
Income tax										
provision										
(benefit) on										
pre-tax										
adjustments				 			_		7,482	 (98
Non-GAAP	<u>\$ 201,284</u>	\$	14,324	\$ 32,488	\$	65,495	\$	6,488	\$ 11,022	\$ 105

SOURCE: Amphastar Pharmaceuticals, Inc.

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