Amphastar Pharmaceuticals Reports Financial Results for the Three Months and Full-Year Ended December 31, 2022

February 28, 2023

Reports Net Revenues of \$135.0 Million for the Three Months Ended December 31, 2022

RANCHO CUCAMONGA, CA / ACCESSWIRE / February 28, 2023 / Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) ("Amphastar" or the "Company") today reported results for the three months and full-year ended December 31, 2022.

Fourth Quarter Highlights

- Net revenues of \$135.0 million for the fourth quarter
- GAAP net income of \$33.9 million, or \$0.66 per share, for the fourth quarter
- Adjusted non-GAAP net income of \$37.6 million, or \$0.73 per share, for the fourth quarter

Full-Year Highlights

- Net revenues of \$499.0 million for the fiscal year
- GAAP net income of \$91.4 million, or \$1.74 per share, for the fiscal year
- Adjusted non-GAAP net income of \$103.2 million, or \$1.97 per share, for the fiscal year

Dr. Jack Zhang, Amphastar's President and Chief Executive Officer, commented: "We are pleased to report our strongest quarter yet, driven by sales of epinephrine, Primatene MIST[®], glucagon, and other finished pharmaceutical products. Looking ahead to 2023, we anticipate launching multiple new products to continue driving our growth."

	Three Months Ended			Year Ended				
		Decem	ber	31,	December 31,			31,
		2022		2021	2022			2021
		(in the	ousa	ands, exc	ept per share data)			
Net revenues	\$	135,023	\$	120,887	\$	498,987	\$	437,768
GAAP net income attributable to Amphastar	\$	33,913	\$	19,760	\$	91,386	\$	62,116
Adjusted non-GAAP net income attributable to Amphastar*	\$	37,638	\$	20,833	\$	103,186	\$	67,999
GAAP diluted EPS attributable to Amphastar stockholders	\$	0.66	\$	0.39	\$	1.74	\$	1.25
Adjusted non-GAAP diluted EPS attributable to Amphastar stockholders*	\$	0.73	\$	0.42	\$	1.97	\$	1.37

^{*} 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

Total net revenues

	Three Months Ended December 31,					Chang	e.			
		2022 2021		Dollars		%				
	(in thousands)									
Net revenues:										
Primatene MIST®	\$	22,279	\$	21,489	\$	790	4 %			
Epinephrine		21,427		18,868		2,559	14 %			
Glucagon		18,319		15,335		2,984	19 %			
Lidocaine		13,286		12,099		1,187	10 %			
Phytonadione		11,666		13,921		(2,255)) (16 %			
Enoxaparin		7,812		7,942		(130)	(2 %			
Naloxone		4,845		6,546		(1,701)) (26 %			
Other finished pharmaceutical products	_	33,082		21,776	_	11,306	52 %			
Total finished pharmaceutical products net revenues	<u>\$</u>	132,716	\$	117,976	\$	14,740	12 %			
API	_ .	2,307	_ -	2,911		(604)	(21 %			

Changes in net revenues as compared to fourth quarter in prior year were primarily driven by:

- Primatene MIST[®] sales increased primarily due to an increase in unit volumes
- Epinephrine sales increased by \$1.8 million due to an increase in average selling price, with the remainder of the increase due to increased unit volumes as a result of competitor shortages

\$ 135,023

\$ 120,887

\$ 14,136

12 %

- Glucagon sales increased primarily due to an increase in unit volumes
- Phytonadione sales decreased due to decreased unit volumes
- Naloxone sales decreased primarily due to a lower average selling price
- Other finished pharmaceutical product sales changes were primarily due to:
 - An increase in unit volumes for dextrose and sodium bicarbonate, which were in high demand due to competitor shortages
 - Higher unit volumes of isoproterenol
 - Launches of ganirelix and vasopressin, in June 2022 and August 2022, respectively
- Active Pharmaceutical ingredient ("API") sales decreased primarily due to the timing of customer purchases

Three Mor	nths Ended		
Decem	ber 31,	Chan	ige
2022	2021	Dollars	%
(in thousand	s)	

Net revenues	\$ 135,023	\$ 120,887	\$ 14,136	12 %
)
Cost of revenues	63,855	64,653	(798)	(1%
Gross profit	<u>\$ 71,168</u>	\$ 56,234	<u>\$ 14,934</u>	27 %
as % of net revenues	53%	47%		

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

- Increased sales of higher-margin products such as Primatene MIST[®], epinephrine, and glucagon, as well as the launches of ganirelix and vasopressin in 2022
- These factors were partially offset by overall increases in labor and input costs

	Three Months Ended							
	December 31,					Change		
	2022		2021		Dollars		%	
		((in t	housands	s)			
Selling, distribution, and marketing	\$	5,472	\$	4,075	\$	1,397	34 %	
General and administrative		10,628		10,621		7	0 %	
Research and development		17,236		17,286		(50)	0 %	
Non-operating income (expense), net		3,428		2,910		518	18 %	

- Selling, distribution, and marketing expenses increased primarily due to increased advertising and freight expenses
- Research and development expenses remained flat during the quarter as a result of a decrease in expenditure for materials and components, which was partially offset by an increase in clinical trial expense for our insulin and inhalation product pipeline

Voor Ended

• The change in non-operating income, net is primarily a result of foreign currency gains

Year-End Results

		Year I						
		Decem	ber	31,		Change		
		2022 2021		Dollars		%		
		(in t	housands	s) _		_	
Net revenues:								
Primatene MIST [®]	\$	84,309	\$	73,113	\$	11,196	15 %	
Epinephrine		74,204		57,530		16,674	29 %	
Glucagon		55,322		47,639		7,683	16 %	
Lidocaine		52,539		44,413		8,126	18 %	
Phytonadione		49,500		45,498		4,002	9 %	
)	
Enoxaparin		34,950		35,962		(1,012)	(3 %	
)	
Naloxone		26,269		27,540		(1,271)	(5 %	
Other finished pharmaceutical products	_	109,412		87,875	_	21,537	<u>25</u> %	

Total finished pharmaceutical products net revenues	\$ 486,505	<u>\$ 419,570</u>	\$ 66,935	<u>16</u> %
API	12,482	18,198	(5,716)	(31 %
Total net revenues	\$ 498,987	\$ 437,768	\$ 61,219	14 %

Changes in net revenues were primarily driven by:

- Primatene MIST[®] sales increased primarily due to increased unit volumes, which was primarily a result of the continued success of our advertising campaign throughout the year
- Epinephrine sales increased primarily due to an increase in unit volumes, arising from high demand due to competitor shortages, contributing \$9.0 million in sales, as well as a higher average selling price, which contributed \$7.7 million to the increase in sales
- Glucagon sales increased due to an increase in unit volumes as the prior year period did not include a full year of sales due to glucagon's launch in the first quarter of 2021
- Lidocaine sales increased due to an increase in unit volumes, which contributed \$4.4 million, as well as a higher average selling price, which contributed \$3.8 million to the increase in sales
- Phytonadione sales increased due to a higher average selling price
- Other finished pharmaceutical product sales changes were primarily due to:
 - Higher unit volumes of calcium chloride, dextrose, and sodium bicarbonate, which were in high demand due to competitor shortages
 - Launches of ganirelix and vasopressin in June 2022 and August 2022, respectively
- API sales decreased primarily due to the timing of customer purchases

	Year l			
	Decem	ber 31,	Char	ige
	2022	2021	Dollars	<u>%</u>
	(in thousands	5)	
Net revenues	\$ 498,987	\$ 437,768	\$ 61,219	14 %
Cost of revenues	250,127	238,029	12,098	5 %
Gross profit	<u>\$ 248,860</u>	<u>\$ 199,739</u>	\$ 49,121	25 %
as % of net revenues	50%	46%		

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

- Increased sales of higher-margin products such as Primatene MIST[®], epinephrine, and glucagon, as well as the launches of ganirelix and vasopressin in 2022
- These factors were partially offset by overall increases in labor and input costs

		Ended ber 31,	Change						
	2022 2021		Dollars	%					
	(in thousands)								
Selling, distribution, and marketing	\$ 21,531	\$ 17,486	\$ 4,045	23 %					
General and administrative	45,061	51,434	(6,373)) (12 %					

Research and development	74,771	60,932	13,839	23 %
)
Non-operating income (expense), net	8,543	14,252	(5,709)	(40 %

- Selling, distribution, and marketing expenses increased due to increased freight expense and advertising expense for Primatene MIST[®]
- General and administrative expenses decreased primarily due to a decrease in legal expenses and a decrease in expenses in China due to the restructuring of Amphastar's Chinese subsidiary, Amphastar Nanjing Pharmaceutical, Co., Ltd. ("ANP"), in 2021
- Research and development expenses increased due to:
 - Increases in expenditures for materials and components, primarily for our AMP-018 and insulin products candidates
 - An increase in clinical trial expense primarily due to external studies related to our insulin and inhalation product pipeline
 - This was partially offset by a decrease in expenses in China due to the completion of the restructuring of ANP in 2021
- The change in non-operating income, net is primarily due to:
 - \$5.4 million litigation settlement received in January 2022 in connection with the Regadenoson patent litigation
 - \$13.6 million gain on the deconsolidation of Hanxin Pharmaceutical Technology Co.,
 Ltd related to the ANP restructuring in 2021

Cash flow provided by operating activities for the year ended December 31, 2022 was \$89.2 million.

Pipeline Information

The Company currently has three ANDAs on file with the FDA targeting products with a market size of over \$3 billion, three biosimilar products in development targeting products with a market size of over \$11 billion, and six generic products in development targeting products with a market size of over \$9 billion. This market information is based on IQVIA data for the 12 months ended December 31, 2022. 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, 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, February 28, 2023, 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 and business trends, our future growth, backlog, sales and marketing of our products, market size and expansion, 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, and other future events, such as the impact of the COVID-19 pandemic including its variants, the Russia-Ukraine conflict and resulting macroeconomic conditions, such as inflation and rising interest rates, and related responses of business and governments to the pandemic and international conflict 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, 2021, filed with the SEC on March 11, 2022, in our Ouarterly Report on Form 10-O for the guarter ended March 31, 2022, filed with the SEC on May 10, 2022, in our Quarterly Report on Form 10-Q for the guarter ended June 30, 2022, filed with the SEC on August 9, 2022, and in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, filed with the SEC on November 7, 2022. In particular, the extent of COVID-19 including its variants, the Russia-Ukraine conflict and resulting macroeconomic conditions, such as inflation and rising interest rates, impacts on our business will depend on several factors, including the actions taken by governments, businesses, and consumers in response, which continues 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 Mo	nths Ended	Year Ended			
	Decem	ber 31,	Decem	ber 31,		
	2022	2022 2021		2021		
Net revenues	\$ 135,023	\$ 120,887	\$ 498,987	\$ 437,768		
Cost of revenues	63,855	64,653	250,127	238,029		
Gross profit	71,168	56,234	248,860	199,739		
Operating expenses:						
Selling, distribution, and marketing	5,472	4,075	21,531	17,486		
General and administrative	10,628	10,621	45,061	51,434		
Research and development	17,236	17,286	74,771	60,932		
Total operating expenses	33,336	31,982	_141,363	_129,852		
Income from operations	37,832	24,252	107,497	69,887		
Non-operating income (expense), net	3,428	2,910	8,543	14,252		
Income before income taxes	41,260	27,162	116,040	84,139		
Income tax provision	7,290	7,194	23,477	20,630		

Net income before equity in losses of unconsolidated affiliate	33,970	19,968	92,563	63,509
Equity in losses of unconsolidated affiliate	(57)	(208)	(1,177)	(208)
Net income	\$ 33,913	\$ 19,760	\$ 91,386	\$ 63,301
Net income attributable to non-controlling interests	\$ -	\$ -	\$ -	\$ 1,185
Net income attributable to Amphastar	\$ 33,913	\$ 19,760	\$ 91,386	\$ 62,116
Net income per share attributable to Amphastar stockholders:				
Basic	\$ 0.70	\$ 0.41	\$ 1.88	\$ 1.30
Diluted	\$ 0.66	\$ 0.39	\$ 1.74	\$ 1.25
Weighted-average shares used to compute net income per share attributable to Amphastar stockholders:				
Basic	48,298	47,836	48,551	47,777
Diluted	51,716	50,057	52,427	49,784

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

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 156,098	\$ 126,353
Restricted cash	235	235
Short-term investments	19,664	10,320
Restricted short-term investments	2,200	2,200
Accounts receivable, net	88,804	78,804
Inventories	103,584	92,807
Income tax refunds and deposits	171	126
Prepaid expenses and other assets	7,563	7,274
Total current assets	378,319	318,119
Property, plant, and equipment, net	238,266	244,244
Finance lease right-of-use assets	753	353
Operating lease right-of-use assets	25,554	26,894

Investment in unconsolidated affiliate Goodwill and intangible assets, net Other assets Deferred tax assets Total assets	2,414 37,298 20,856 38,527 \$ 741,987	3,985 38,870 16,665 22,399 \$ 671,529
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 84,242	\$ 89,545
Income taxes payable	4,571	9,081
Current portion of long-term debt	3,046	2,202
Current portion of operating lease liabilities	3,003	2,982
Total current liabilities	94,862	103,810
Long-term reserve for income tax liabilities Long-term debt, net of current portion and unamortized debt issuance	7,225	6,531
costs	72,839	74,776
Long-term operating lease liabilities, net of current portion	23,694	24,703
Deferred tax liabilities	144	534
Other long-term liabilities	14,565	15,653
Total liabilities	213,329	226,007
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; 58,110,231 and 48,112,069 shares issued and outstanding as of December 31, 2022 and 56,440,202 and 47,714,912 shares issued and outstanding as of December		
31, 2021, respectively	6	6
Additional paid-in capital	455,077	422,423
Retained earnings	271,723	180,337
Accumulated other comprehensive loss	(8,624)	(6,765)
Treasury stock	_(189,524)	_(150,479)
Total equity	528,658	445,522
Total liabilities and stockholders' equity	<u>\$ 741,987</u>	<u>\$ 671,529</u>

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

Three Mor	nths Ended	Year Ended					
Decem	ber 31,	December 31,					
2022	2022 2021		2021				

GAAP net income	\$	33,913	\$	19,760	\$	91,386	\$ 63,301
Adjusted for:							
Intangible amortization		331		360		1,419	1,290
Share-based compensation		4,304		3,850		17,860	18,687
Impairment of long-lived assets		-		9		-	348
Gain on ANP Restructuring		-		-		-	(13,587)
Reserves for litigation and settlements Income tax provision on pre-tax		-		(2,717)		(4,929)	274
adjustments		(910)		(429)		(2,550)	(2,043)
Non-GAAP net income	\$	37,638	\$	20,833	\$	103,186	\$ 68,270
Non-GAAP net income attributable to non-controlling interests	\$	-	\$	-	\$	-	\$ 271
Non-GAAP net income attributable to Amphastar	\$	37,638	\$	20,833	\$ =	103,186	\$ 67,999
Non-GAAP net income per share attributable to Amphastar stockholders:							
Basic	\$	0.78	\$	0.44	\$	2.13	\$ 1.42
Diluted	\$	0.73	\$	0.42	\$	1.97	\$ 1.37
Weighted-average shares used to compute non-GAAP net income per share attributable to Amphastar stockholders:							
Basic		48,298		47,836		48,551	47,777
Diluted		51,716		50,057		52,427	49,784
Th	ree	Months E	nd	ed Decem	bei	31, 2022	

	Cost of	distril	Selling, listribution		General and		Research and	op i	Non- perating income	I	ncome	Non- controllii interest	
	revenue		and marketing		administrative		development		(expense), net		tax covision	adjustme	
GAAP	\$ 63,855	\$	5,472	\$	10,628	\$	17,236	\$	3,428	\$	7,290	\$	
Intangible amortization Share-based	(205)		-		(126)		-		-		-		
compensation	(941)		(186)		(2,791)		(386))	-		-		
Income tax provision on pre-tax											010		
adjustments								_		_	910		
Non-GAAP	\$ 62,709	\$	5,286	\$	7,711	\$	16,850	\$	3,428	\$	8,200	\$	
				Th	ree Months	End	ed Decembe	<u>er 3</u>	1, 2021				

	Cost of	Selling, distribution	General and	Research and	Non- operating income	Income	Non- controlli interes	
		and	- 1	J	(expense),	tax		
	revenue	marketing	administrative	development	<u>net</u>	provision	adjustm	
GAAP	\$ 64,653	\$ 4,075	\$ 10,621	\$ 17,286	\$ 2,910	\$ 7,194	\$	
Intangible amortization Share-based	(235)	-	(125)	-	-	-		
compensation	(811)	(158)	(2,553)	(328)) -	_		
Impairment of long-lived assets Reserves for	(9)	,	-	-	-	-		
litigation and settlements Income tax provision on	-	-	-	-	(2,717)	-		
pre-tax adjustments	_	_	_	_	_	429		
,	\$ 63,598	\$ 3,917	\$ 7,943	\$ 16,958	\$ 193	\$ 7,623	\$	
Non-GAAP	<u>=</u>	<u> </u>		ed December 31	-	ψ /,023	<u>Ψ</u> =	

	Cost of	Selling, distribution	General and	Research and	Non- operating income	Income	Non control inter
	revenue	and marketing	administrative	development	(expense), net	tax provision	adjustr
GAAP	\$ 250,127	\$ 21,531	\$ 45,061	\$ 74,771	\$ 8,543	\$ 23,477	\$
Intangible	. ,			,	, ,		·
amortization	(865)	-	(554	-	-	-	
Share-based	(4.450.)	(FDC)	(11.100	\			
compensation	(4,179)	(726)	(11,180) (1,775)	-	-	
Reserves for litigation and							
settlements	_	-	(800) -	(5,729)	_	
Income tax			`	,			
provision on							
pre-tax						2,550	
adjustments							
Non-GAAP	\$ 245,083	\$ 20,805	\$ 32,527	\$ 72,996	\$ 2,814	\$ 26,027	\$
			Year End	ed December 31,	2021		

General

and

Selling,

distribution

Cost of

Non-

operating

income

Research

and

Non

contro

Income

inter

			and arketing	ng administrative		dev	elopment	(e	xpense), net	tax provision		adjustr
GAAP	\$ 238,029	\$	17,486	\$	51,434	\$	60,932	\$	14,252	\$	20,630	
Intangible amortization Share-based	(963)		-		(327)		-		-		-	
compensation	(3,778)		(596)		(12,622)		(1,691)		-		-	
Impairment of long-lived assets	(93)		-		(33)		(222)		-		-	
Gain on ANP Restructuring Reserves for	-		-		-		-		(13,587)		-	(2
litigation and settlements Income tax	-		-		(1,295)		-		(1,021)		-	
provision on pre-tax adjustments			<u> </u>					_		_	2,043	
Non-GAAP	<u>\$ 233,195</u>	\$	16,890	\$	37,157	\$	59,019	\$	<u>(356</u>)	\$	22,673	\$

SOURCE: Amphastar Pharmaceuticals, Inc.

View source version on accesswire.com:

https://www.accesswire.com/741090/Amphastar-Pharmaceuticals-Reports-Financial-Results-for-the-Three-Months-and-Full-Year-Ended-December-31-2022