

Amphastar Pharmaceuticals Reports Financial Results for the Three Months Ended March 31, 2023

May 9, 2023

Reports Net Revenues of \$140.0 Million for the Three Months Ended March 31, 2023

RANCHO CUCAMONGA, CA / ACCESSWIRE / May 9, 2023 / Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) ("Amphastar" or the "Company") today reported results for the three months ended March 31, 2023.

First Quarter Highlights

- Net revenues of \$140.0 million for the first quarter
- GAAP net income of \$26.0 million, or \$0.50 per share, for the first quarter
- Adjusted non-GAAP net income of \$32.1 million, or \$0.62 per share, for the first quarter

Dr. Jack Zhang, Amphastar's President and Chief Executive Officer, commented: "Strong sales of glucagon, Primatene MIST[®], and epinephrine played a key role in driving our quarterly sales growth. We expect similar growth trends in our key products to continue while we believe our newly-launched regadenoson and the approval of our intranasal naloxone will add another layer to our complex generics and proprietary products portfolio. Equally important, we expect our proposed BAQSIMI[®] acquisition will be the start of a transformative period for the Company - by adding to our diabetes portfolio and by expanding our branded products strategy. We are confident in this market as we believe this product aligns with our key focus areas."

	Three Months Ended March 31,	
	2023	2022
	(in thousands, except per share data)	
Net revenues	\$ 140,022	\$ 120,368
GAAP net income	\$ 26,032	\$ 24,253
Adjusted non-GAAP net income*	\$ 32,143	\$ 24,586
GAAP diluted EPS	\$ 0.50	\$ 0.47
Adjusted non-GAAP diluted EPS*	\$ 0.62	\$ 0.47

* 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

	<u>March 31,</u>		<u>Change</u>	
	<u>2023</u>	<u>2022</u>	<u>Dollars</u>	<u>%</u>
	<u>(in thousands)</u>			
Net revenues:				
Glucagon	\$ 25,696	\$ 10,984	\$ 14,712	134 %
)
Primatene MIST [®]	23,483	24,697	(1,214)	(5 %
Epinephrine	20,091	15,156	4,935	33 %
Lidocaine	13,646	10,590	3,056	29 %
)
Enoxaparin	9,867	10,124	(257)	(3 %
)
Phytonadione	7,713	10,475	(2,762)	(26 %
)
Naloxone	4,957	7,413	(2,456)	(33 %
Other finished pharmaceutical products	<u>30,557</u>	<u>27,107</u>	<u>3,450</u>	<u>13 %</u>
Total finished pharmaceutical products net revenues	<u>\$ 136,010</u>	<u>\$ 116,546</u>	<u>\$ 19,464</u>	<u>17 %</u>
API	<u>4,012</u>	<u>3,822</u>	<u>190</u>	<u>5 %</u>
Total net revenues	<u><u>\$ 140,022</u></u>	<u><u>\$ 120,368</u></u>	<u><u>\$ 19,654</u></u>	<u><u>16 %</u></u>

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

- Glucagon sales increased by \$14.7 million primarily due to an increase in unit volumes
- Primatene MIST[®] sales decreased \$3.6 million due to reduced unit volumes, which was partially offset by an increase in average selling price contributing \$2.4 million
- Epinephrine sales increased by \$4.9 million primarily due to an increase in unit volumes caused by shortages at other suppliers
- Lidocaine sales increased primarily due to an increase in unit volumes
- Phytonadione sales decreased due to decreased unit volumes as a new supplier commenced sales
- 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, which was in high demand due to shortages at other suppliers
 - Launches of ganirelix and vasopressin, in June 2022 and August 2022, respectively
- Active Pharmaceutical ingredient ("API") sales increased primarily due to the timing of customer purchases

	<u>Three Months Ended</u>		<u>Change</u>	
	<u>March 31,</u>	<u>March 31,</u>	<u>Dollars</u>	<u>%</u>
	<u>2023</u>	<u>2022</u>	<u>(in thousands)</u>	
Net revenues	\$ 140,022	\$ 120,368	\$ 19,654	16 %
Cost of revenues	<u>66,182</u>	<u>64,542</u>	<u>1,640</u>	3 %
Gross profit	<u><u>\$ 73,840</u></u>	<u><u>\$ 55,826</u></u>	<u><u>\$ 18,014</u></u>	32 %
<i>as % of net revenues</i>	53 %	46 %		

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 glucagon, epinephrine, and lidocaine, as well as the launches of ganirelix and vasopressin in 2022
- These factors were partially offset by overall increases in labor, material and overhead costs

	Three Months Ended			
	March 31,		Change	
	2023	2022	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	\$ 7,109	\$ 5,519	\$ 1,590	29 %
General and administrative	13,483	12,470	1,013	8 %
Research and development	19,815	16,223	3,592	22 %
Non-operating income (expense), net	136	7,419	(7,283)	(98 %)

- Selling, distribution, and marketing expenses increased primarily due to increased advertising expense for Primatene MIST[®]
- General and administrative expenses increased primarily due to an increase in legal expenses related to the planned purchase of BAQSIMI[®], as well as salary and personnel-related expenses
- Research and development expenses increased due to:
 - An increase in salary and personnel-related expenses
 - Increases in clinical trial expense as we continue to work on external studies related to our insulin and inhalation product pipeline
 - Increases in expenditure for raw materials and components, primarily for our insulin products
- The change in non-operating income, net is primarily a result of:
 - A \$5.4 million gain related to a settlement in connection with the regadenoson patent litigation during the three months ended March 31, 2022

Cash flow provided by operating activities for the three months ended March 31, 2023, was \$40.4 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 March 31, 2023. 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) and (ii) Adjusted non-GAAP diluted EPS, 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, May 9, 2023, at 2:00 p.m. Pacific Time.

To access the conference call, dial toll-free (888) 645-4404 or (862) 298-0702 for international callers, ten 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 forward-looking statements, including, among other things, statements relating to our expectations regarding future financial performance and business trends, our future growth, sales and marketing of our products, market size and expansion, product portfolio, 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 our expectations regarding our proposed acquisition of BAQSIMI[®], the prospective benefits of the proposed acquisition, potential contingent consideration amounts and terms, debt commitments related to the proposed acquisition, the anticipated occurrence, manner and timing of the proposed acquisition, and the benefits of BAQSIMI[®]. 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, 2022, filed with the SEC on March 1, 2023. In particular, there can be no guarantee that the proposed acquisition of BAQSIMI[®] will be completed in the anticipated timeframe or at all, that the conditions required to complete the proposed acquisition of BAQSIMI[®] will be met, that the debt commitments will be sufficient to effect the proposed acquisition of BAQSIMI[®], that any event, change or other circumstance that could give rise to the termination of the definitive agreement for the proposed acquisition of BAQSIMI[®] will not occur, that all or any of the contingent consideration potentially payable by the Company as a result of the proposed acquisition of BAQSIMI[®] will become payable on the terms described therein or at all or that Amphastar can reliably predict the impact of the proposed acquisition of BAQSIMI[®] on its financial results or financial guidance. 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:

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

	Three Months Ended	
	March 31,	
	2023	2022
Net revenues	\$ 140,022	\$ 120,368
Cost of revenues	66,182	64,542
Gross profit	73,840	55,826
Operating expenses:		
Selling, distribution, and marketing	7,109	5,519
General and administrative	13,483	12,470
Research and development	19,815	16,223
Total operating expenses	40,407	34,212

Income from operations	33,433	21,614
Non-operating income, net	<u>136</u>	<u>7,419</u>
Income before income taxes	33,569	29,033
Income tax provision	<u>6,752</u>	<u>4,077</u>
Net income before equity in losses of unconsolidated affiliate	26,817	24,956
Equity in losses of unconsolidated affiliate	(785)	(703)
Net income	<u>\$ 26,032</u>	<u>\$ 24,253</u>
Net income per share:		
Basic	\$ 0.54	\$ 0.50
Diluted	\$ 0.50	\$ 0.47
Weighted-average shares used to compute net income per share:		
Basic	48,000	48,138
Diluted	51,970	51,979

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

	March 31,	December
	2023	31,
	(unaudited)	2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 176,615	\$ 156,098
Restricted cash	235	235
Short-term investments	16,277	19,664
Restricted short-term investments	2,200	2,200
Accounts receivable, net	100,638	88,804
Inventories	103,647	103,584
Income tax refunds and deposits	731	171
Prepaid expenses and other assets	<u>7,327</u>	<u>7,563</u>
Total current assets	407,670	378,319
Property, plant, and equipment, net	243,479	238,266
Finance lease right-of-use assets	706	753

Operating lease right-of-use assets	25,801	25,554
Investment in unconsolidated affiliate	1,758	2,414
Goodwill and intangible assets, net	37,179	37,298
Other assets	18,536	20,856
Deferred tax assets	38,527	38,527
Total assets	<u>\$ 773,656</u>	<u>\$ 741,987</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable and accrued liabilities	\$ 88,886	\$ 84,242
Income taxes payable	11,590	4,571
Current portion of long-term debt	2,168	3,046
Current portion of operating lease liabilities	2,991	3,003
Total current liabilities	<u>105,635</u>	<u>94,862</u>

Long-term reserve for income tax liabilities	7,225	7,225
Long-term debt, net of current portion and unamortized debt issuance costs	72,872	72,839
Long-term operating lease liabilities, net of current portion	23,994	23,694
Deferred tax liabilities	178	144
Other long-term liabilities	15,175	14,565
Total liabilities	<u>225,079</u>	<u>213,329</u>

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; 58,440,531 and 48,179,238 shares issued and outstanding as of March 31, 2023 and 58,110,231 and 48,112,069 shares issued and outstanding as of December 31, 2022, respectively	6	6
Additional paid-in capital	456,623	455,077
Retained earnings	297,755	271,723
Accumulated other comprehensive loss	(8,268)	(8,624)
Treasury stock	<u>(197,539)</u>	<u>(189,524)</u>

Total equity	<u>548,577</u>	<u>528,658</u>
Total liabilities and stockholders' equity	<u>\$ 773,656</u>	<u>\$ 741,987</u>

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

Three Months Ended
March 31,

	<u>2023</u>	<u>2022</u>
GAAP net income	\$ 26,032	\$ 24,253
Adjusted for:		
Intangible amortization	241	352
Share-based compensation	6,111	5,022
Legal fees related to BAQSIMI [®] acquisition	1,217	-
Litigation settlements	-	(5,346)
Income tax provision on pre-tax adjustments	(1,458)	305
Non-GAAP net income	<u>\$ 32,143</u>	<u>\$ 24,586</u>

Non-GAAP net income per share:

Basic	\$ 0.67	\$ 0.51
Diluted	\$ 0.62	\$ 0.47

Weighted-average shares used to compute non-GAAP net income per share:

Basic	48,000	48,138
Diluted	51,970	51,979

Three Months Ended March 31, 2023

	<u>Cost of revenue</u>	<u>Selling, distribution and marketing</u>	<u>General and administrative</u>	<u>Research and development</u>	<u>Non-operating income (expense), net</u>	<u>Income tax provision</u>
GAAP	\$ 66,182	\$ 7,109	\$ 13,483	\$ 19,815	\$ 136	\$ 6,752
Intangible amortization	(211)	-	(30)	-	-	-
Share-based compensation	(1,706)	(209)	(3,357)	(839)	-	-
Legal fees related to BAQSIMI [®] acquisition	-	-	(1,217)	-	-	-
Income tax provision on pre-tax adjustments	-	-	-	-	-	1,458
Non-GAAP	<u>\$ 64,265</u>	<u>\$ 6,900</u>	<u>\$ 8,879</u>	<u>\$ 18,976</u>	<u>\$ 136</u>	<u>\$ 8,210</u>

Three Months Ended March 31, 2022

	<u>Cost of revenue</u>	<u>Selling, distribution and marketing</u>	<u>General and administrative</u>	<u>Research and development</u>	<u>Non-operating income (expense), net</u>	<u>Income tax provision</u>
GAAP	\$ 64,542	\$ 5,519	\$ 12,470	\$ 16,223	\$ 7,419	\$ 4,077

Intangible amortization	(235)	-	(117)	-	-	-
Share-based compensation	(1,385)	(168)	(2,861)	(608)	-	-
Litigation settlements	-	-	-	-	(5,346)	-
Income tax provision on pre-tax adjustments	-	-	-	-	-	(305)
Non-GAAP	<u>\$ 62,922</u>	<u>\$ 5,351</u>	<u>\$ 9,492</u>	<u>\$ 15,615</u>	<u>\$ 2,073</u>	<u>\$ 3,772</u>

SOURCE: Amphastar Pharmaceuticals, Inc.

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