

Amphastar Pharmaceuticals Reports Financial Results for the Three Months Ended March 31, 2024

May 8, 2024

Reports Net Revenues of \$171.8 Million for the Three Months Ended March 31, 2024

RANCHO CUCAMONGA, CA / ACCESSWIRE / May 8, 2024 / Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) ("Amphastar" or the "Company") today reported results for the three months ended March 31, 2024.

First Quarter Highlights

- Net revenues of \$171.8 million for the first quarter
- GAAP net income of \$43.2 million, or \$0.81 per share, for the first quarter
- Adjusted non-GAAP net income of \$55.3 million, or \$1.04 per share, for the first quarter

Dr. Jack Zhang, Amphastar's President and Chief Executive Officer, commented: "Amphastar's strong first quarter results were led by BAQSIMI[®] revenue growth of 22% over what Eli Lilly & Company ("Lilly") reported for the first quarter of 2023. This significant increase demonstrates a strong transition and the potential for continued growth of BAQSIMI[®]."

	Three Months Ended	
	March 31,	
	2024	2023
	(in thousands, except per share data)	
Net revenues	\$ 171,836	\$ 140,022
GAAP net income	\$ 43,177	\$ 26,032
Adjusted non-GAAP net income*	\$ 55,296	\$ 32,143
GAAP diluted EPS	\$ 0.81	\$ 0.50
Adjusted non-GAAP diluted EPS*	\$ 1.04	\$ 0.62

* 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		Change	
	March 31,			
	2024	2023	Dollars	%

	(in thousands)			
Product revenues:				
Glucagon	\$ 28,535	\$ 25,696	\$ 2,839	11 %
Epinephrine	26,110	20,091	6,019	30 %
Primatene MIST [®]	24,166	23,483	683	3 %
BAQSIMI [®]	13,843	-	13,843	N/A
)
Lidocaine	12,773	13,646	(873)	(6 %)
Phytonadione	9,973	7,713	2,260	29 %
)
Enoxaparin	7,096	9,867	(2,771)	(28 %)
)
Naloxone	4,287	4,957	(670)	(14 %)
)
Other finished pharmaceutical products	<u>29,154</u>	<u>30,557</u>	<u>(1,403)</u>	<u>(5 %)</u>
Total finished pharmaceutical products net revenues	<u>\$ 155,937</u>	<u>\$ 136,010</u>	<u>\$ 19,927</u>	<u>15 %</u>
)
API	1,692	4,012	(2,320)	(58 %)
Other revenues	<u>14,207</u>	<u>-</u>	<u>14,207</u>	<u>N/A</u>
Total net revenues	<u>\$ 171,836</u>	<u>\$ 140,022</u>	<u>\$ 31,814</u>	<u>23 %</u>

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

- BAQSIMI[®] sales consisting of \$13.8 million in sales made by the Company directly to its customers which are recorded as part of Product Revenues, net, and \$24.6 million in sales made by Lilly on behalf of the Company under the Transition Services Agreement ("TSA"), which resulted in a net payment to the Company of \$14.2 million after deducting cost of sales and other expenses and was recorded in Other Revenues
- Glucagon sales increased due to a growth in unit volumes, impacting sales by \$1.8 million as well as a higher average selling price, impacting sales by \$1.1 million as we launched glucagon in Canada
- Epinephrine and Phytonadione sales increased primarily due to an increase in unit volumes, as a result of other supplier shortages
- Primatene MIST[®] sales increased primarily due to an increase in unit volumes and a higher average selling price
- Lidocaine sales decreased primarily due to a decrease in unit volumes, as a result of other suppliers returning to their historical distribution levels
- Enoxaparin and Naloxone sales decreased primarily due to a decrease in unit volumes
- Other finished pharmaceutical product sales changes were primarily due to:
 - Lower unit volumes of MPA, as our Active Pharmaceutical Ingredient ("API") supplier discontinued making the active ingredient
 - This decrease was partially offset by higher unit volumes of dextrose and sodium bicarbonate caused by other supplier shortages during the quarter
 - Launch of regadenoson in April 2023
- API sales decreased primarily due to the timing of customer purchases

	Three Months Ended		Change	
	March 31,		Dollars	%
	2024	2023		
		(in thousands)		
Net revenues	\$ 171,836	\$ 140,022	\$ 31,814	\$ 23
Cost of revenues	81,736	66,182	15,554	24 %
Gross profit	<u>\$ 90,100</u>	<u>\$ 73,840</u>	<u>\$ 16,260</u>	<u>\$ 22 %</u>
as % of net revenues	52.4 %	52.7 %		

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

- Increase in depreciation and amortization expense related to the acquired BAQSIMI[®] assets
- Increases in labor costs and certain component costs
- Charges included in cost of revenues to adjust our inventory and related purchase commitments to their net realizable value
- These factors were partially offset by increased sales of higher-margin products:
 - BAQSIMI[®] which was acquired in June 2023
 - Glucagon, Primatene MIST[®], and epinephrine
 - Regadenoson launched in April 2023

	Three Months Ended		Change	
	March 31,		Dollars	%
	2024	2023		
		(in thousands)		
Selling, distribution, and marketing	\$ 9,371	\$ 7,109	\$ 2,262	32 %
General and administrative	15,676	13,483	2,193	16 %
Research and development	17,043	19,815	(2,772)	(14) %
Non-operating (expenses) income, net	(134)	136	(270)	NM

- Selling, distribution, and marketing expenses increased primarily due to the expansion of our sales and marketing efforts related to BAQSIMI[®]
- General and administrative expenses increased primarily due to an increase in expenses related to BAQSIMI[®]
- Research and development expenses decreased due to the timing of clinical trial expenses, as well as a decrease in materials and supply expenses, primarily related to our insulin and inhalation pipeline products, as a result of a ramp-up in 2023

Cash flow provided by operating activities for the three months ended March 31, 2024, was \$55.3 million.

Pipeline Information

The Company currently has four abbreviated new drug applications ("ANDAs") on file with the U.S. Food and Drug Administration (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 \$7 billion, and four generic products in development targeting products with a market size of over \$3

billion. This market information is based on IQVIA data for the 12 months ended March 31, 2024. The Company is developing multiple proprietary products with injectable and intranasal dosage forms.

Amphastar's Chinese subsidiary, Amphastar Nanjing Pharmaceuticals, Co., Ltd. ("ANP"), currently has multiple Drug Master Files ("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[®], BAQSIMI[®], Primatene MIST[®], REXTOVY[™], 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, expenses related to our acquisition of BAQSIMI[®], certain debt issuance costs, 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 8, 2024, 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, 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, the prospective benefits of the acquisition of BAQSIMI[®], including its potential for continued revenue growth, the success of our integration of BAQSIMI[®], and other future events. 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, 2023, filed with the SEC on February 29, 2024. In particular, there can be no guarantee that the acquisition of BAQSIMI[®] will be beneficial to our business, that any event, change or other circumstance could cause the results of the acquisition and integration of BAQSIMI[®] into our product portfolio to differ from Amphastar's expectation, that all or any of the contingent consideration will be payable on the terms described herein or at all, or that Amphastar can reliably predict the impact 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:

Amphastar Pharmaceuticals, Inc.
Bill Peters
Chief Financial Officer
(909) 476-3416

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

	Three Months Ended	
	March 31,	
	2024	2023
Net revenues:		
Product revenues, net	\$ 157,629	\$ 140,022

Other revenues	14,207	-
Total net revenues	<u>171,836</u>	<u>140,022</u>
Cost of revenues	<u>81,736</u>	<u>66,182</u>
Gross profit	90,100	73,840
Operating expenses:		
Selling, distribution, and marketing	9,371	7,109
General and administrative	15,676	13,483
Research and development	<u>17,043</u>	<u>19,815</u>
Total operating expenses	<u>42,090</u>	<u>40,407</u>
Income from operations	48,010	33,433
Non-operating (expenses) income, net	<u>(134)</u>	<u>136</u>
Income before income taxes	47,876	33,569
Income tax provision	<u>4,126</u>	<u>6,752</u>
Net income before equity in losses of unconsolidated affiliate	43,750	26,817
Equity in losses of unconsolidated affiliate	<u>(573)</u>	<u>(785)</u>
Net income	<u>\$ 43,177</u>	<u>\$ 26,032</u>
Net income per share:		
Basic	\$ 0.90	\$ 0.54
Diluted	\$ 0.81	\$ 0.50
Weighted-average shares used to compute net income per share:		
Basic	48,212	48,000
Diluted	53,013	51,970

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

	March 31,	December
	2024	31,
	(unaudited)	2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 201,148	\$ 144,296
Restricted cash	235	235
Short-term investments	88,407	112,510
Restricted short-term investments	2,200	2,200
Accounts receivable, net	138,114	114,943
Inventories	115,494	105,833
Income tax refunds and deposits	784	526
Prepaid expenses and other assets	<u>8,696</u>	<u>9,057</u>

Total current assets	555,078	489,600
Property, plant, and equipment, net	288,523	282,746
Finance lease right-of-use assets	516	564
Operating lease right-of-use assets	31,352	32,333
Investment in unconsolidated affiliate	-	527
Goodwill and intangible assets, net	607,064	613,295
Long-term investments	15,163	14,685
Other assets	23,369	25,910
Deferred tax assets	53,252	53,252
Total assets	<u>\$ 1,574,317</u>	<u>\$ 1,512,912</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 116,697	\$ 93,366
Accrued payments for BAQSIMI [®]	128,245	126,090
Income taxes payable	5,857	1,609
Current portion of long-term debt	428	436
Current portion of operating lease liabilities	3,942	3,906
Total current liabilities	<u>255,169</u>	<u>225,407</u>
Long-term reserve for income tax liabilities	6,066	6,066
Long-term debt, net of current portion and unamortized debt issuance costs	594,006	589,579
Long-term operating lease liabilities, net of current portion	28,739	29,721
Other long-term liabilities	17,981	22,718
Total liabilities	<u>901,961</u>	<u>873,491</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; 60,160,459 and 48,841,343 shares issued and outstanding as of March 31, 2024 and 59,390,194 and 48,068,881 shares issued and outstanding as of December 31, 2023, respectively	6	6
Additional paid-in capital	476,072	486,056
Retained earnings	452,445	409,268
Accumulated other comprehensive loss	(8,769)	(8,478)
Treasury stock	(247,398)	(247,431)
Total equity	<u>672,356</u>	<u>639,421</u>
Total liabilities and stockholders' equity	<u>\$ 1,574,317</u>	<u>\$ 1,512,912</u>

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

	Three Months Ended March 31,	
	<u>2024</u>	<u>2023</u>
GAAP net income	\$ 43,177	\$ 26,032
Adjusted for:		
Intangible asset amortization	6,167	241
Share-based compensation	7,360	6,111
Expenses related to BAQSIMI [®] acquisition	1,826	1,217
Income tax provision on pre-tax adjustments	<u>(3,234)</u>	<u>(1,458)</u>
Adjusted non-GAAP net income	<u>\$ 55,296</u>	<u>\$ 32,143</u>
Adjusted non-GAAP net income per share:		
Basic	\$ 1.15	\$ 0.67
Diluted	\$ 1.04	\$ 0.62
Weighted-average shares used to compute adjusted non-GAAP net income per share:		
Basic	48,212	48,000
Diluted	53,013	51,970

Three Months Ended March 31, 2024

	<u>Cost of revenue</u>	<u>Selling, distribution and marketing</u>	<u>General and administrative</u>	<u>Research and development</u>	<u>Non- operating (expenses) income, net</u>	<u>Income tax provision</u>
GAAP	\$ 81,736	\$ 9,371	\$ 15,676	\$ 17,043	\$ (134)	\$ 4,126
Intangible asset amortization	(6,147)	-	(3)	(17)	-	-
Share-based compensation	(2,125)	(260)	(3,876)	(1,099)	-	-
Expenses related to BAQSIMI [®] acquisition	-	-	-	-	1,826	-
Income tax provision on pre-tax adjustments	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>3,234</u>
Non-GAAP	<u>\$ 73,464</u>	<u>\$ 9,111</u>	<u>\$ 11,797</u>	<u>\$ 15,927</u>	<u>\$ 1,692</u>	<u>\$ 7,360</u>

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 (expenses) income, net</u>	<u>Income tax provision</u>
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GAAP	\$ 66,182	\$ 7,109	\$ 13,483	\$ 19,815	\$ 136	\$ 6,752
Intangible asset amortization	(211)	-	(30)	-	-	-
Share-based compensation	(1,706)	(209)	(3,357)	(839)	-	-
Expenses 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>

SOURCE: Amphastar Pharmaceuticals, Inc.

View the original [press release on accesswire.com](#)