

Amphastar Pharmaceuticals Reports Financial Results for the Three Months Ended September 30, 2023

November 8, 2023

Reports Net Revenues of \$180.6 Million for the Three Months Ended September 30, 2023

RANCHO CUCAMONGA, CA / ACCESSWIRE / November 8, 2023 / Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) ("Amphastar" or the "Company") today reported results for the three months ended September 30, 2023.

Third Quarter Highlights

- Net revenues of \$180.6 million for the third quarter
- GAAP net income of \$49.2 million, or \$0.91 per share, for the third quarter
- Adjusted non-GAAP net income of \$61.9 million, or \$1.15 per share, for the third quarter

Dr. Jack Zhang, Amphastar's President and Chief Executive Officer, commented: "We are pleased to announce strong results driven by the success of our diabetes portfolio, particularly following the strategic acquisition of BAQSIMI[®] and the continued strength of our generic glucagon product. As we move forward, we anticipate that our strong pipeline will continue to drive growth in the future."

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2023	2022	2023	2022
	(in thousands, except per share data)			
Net revenues	\$ 180,556	\$ 120,129	\$ 466,290	\$ 363,964
GAAP net income	\$ 49,222	\$ 15,874	\$ 101,378	\$ 57,473
Adjusted non-GAAP net income*	\$ 61,898	\$ 20,232	\$ 128,823	\$ 65,548
GAAP diluted EPS	\$ 0.91	\$ 0.30	\$ 1.91	\$ 1.09
Adjusted non-GAAP diluted EPS*	\$ 1.15	\$ 0.38	\$ 2.43	\$ 1.24

* 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.

Third Quarter Results

	Three Months Ended		Change	
	September 30,		Dollars	%
	2023	2022		
	(in thousands)			

Product revenues:

Glucagon	\$ 29,514	\$ 14,224	\$ 15,290	107 %
Primatene MIST [®]	24,834	18,359	6,475	35 %
Epinephrine	20,199	19,502	697	4 %
Lidocaine	15,522	12,621	2,901	23 %
)	
Enoxaparin	7,702	7,983	(281)	(4 %)
)	
Phytonadione	7,449	13,978	(6,529)	(47 %)
)	
Naloxone	4,715	6,818	(2,103)	(31 %)
Other finished pharmaceutical products	<u>37,730</u>	<u>23,635</u>	<u>14,095</u>	<u>60 %</u>
Total finished pharmaceutical products net revenues	<u>\$ 147,665</u>	<u>\$ 117,120</u>	<u>\$ 30,545</u>	<u>26 %</u>
API	4,190	3,009	1,181	39 %
Other revenues	<u>28,701</u>	<u>-</u>	<u>28,701</u>	<u>N/A</u>
Total product revenues, net	<u><u>\$ 180,556</u></u>	<u><u>\$ 120,129</u></u>	<u><u>\$ 60,427</u></u>	<u><u>50 %</u></u>

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

- Glucagon sales increased primarily due to an increase in unit volumes, as a result of two suppliers discontinuing their glucagon injection products at the end of 2022
- Primatene MIST[®] sales increased due to an increase in unit volumes
- Lidocaine sales increased primarily due to an increase in unit volumes, as a result of supplier shortages
- Phytonadione sales decreased due to lower unit volumes, as a result of increased competition
- Sales of naloxone decreased due to lower unit volumes, as a result of increased competition
- Other finished pharmaceutical product sales increased primarily due to:
 - Higher unit volumes of dextrose, atropine, calcium chloride, and sodium bicarbonate, due to increased demand caused by supplier shortages during the quarter
 - A full quarter of sales for vasopressin, which was launched in August 2022
 - Launch of regadenoson in April 2023
- Active Pharmaceutical ingredient ("API") sales increased primarily due to the timing of customer purchases

Other revenues are comprised of net revenues from the sales of BAQSIMI[®] of \$28.7 million during the three months ended September 30, 2023, which was recognized on a net basis similar to a royalty and based on Eli Lilly & Company's ("Lilly") reported BAQSIMI[®] net sales of \$48.7 million. Currently, BAQSIMI[®] is being sold by Lilly on our behalf under the Transition Services Agreement ("TSA") with Lilly, whereby Lilly would provide certain services to support the transition of the BAQSIMI[®] operations to us. Once Amphastar takes over the distribution of BAQSIMI[®], Amphastar will recognize the entire revenue amount. This revenue recognition change is expected to be phased in by country during 2024.

Three Months Ended**September 30,****Change**

	<u>2023</u>	<u>2022</u>	<u>Dollars</u>	<u>%</u>
	(in thousands)			
Net revenues	\$ 180,556	\$ 120,129	\$ 60,427	50%
Cost of revenues	<u>72,153</u>	<u>61,619</u>	<u>10,534</u>	17%
Gross profit	<u>\$ 108,403</u>	<u>\$ 58,510</u>	<u>\$ 49,893</u>	85%
<i>as % of net revenues</i>	60%	49%		

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

- Increased sales of higher-margin products such as glucagon and Primatene MIST[®], the sales of ganirelix and vasopressin that were launched in 2022, as well as the sales of regadenoson, which we launched in April 2023
- As a result of the TSA, the revenue relating to BAQSIMI[®] is recognized on a net basis within net revenues.

	Three Months Ended		Change	
	September 30,			
	<u>2023</u>	<u>2022</u>	<u>Dollars</u>	<u>%</u>
	(in thousands)			
Selling, distribution, and marketing	\$ 6,407	\$ 4,785	\$ 1,623	34 %
General and administrative	12,654	11,984	670	6% %
Research and development	16,664	18,514	(1,850)	(10) %
Non-operating income (expense), net	(9,041)	(632)	(8,409)	NM

- Selling, distribution, and marketing expenses increased primarily due to expenses related to the expansion of our sales force related to BAQSIMI[®], as well as an increase in advertising spending for Primatene MIST[®]
- General and administrative expenses increased primarily due to an increase in salary and personnel-related expenses, as well as costs related to the acquisition of BAQSIMI[®], which was partially offset by a decrease in legal fees
- Research and development expenses decreased due to:
 - Decrease in clinical trials expense
 - Decreases in materials and supply expense, as a result of a ramp-up of expenses in 2022 for AMP-018 and our insulin pipeline products
 - This decrease was partially offset by an increase in salary and personnel-related expenses
- The change in non-operating expenses, net is primarily a result of:
 - Foreign currency fluctuations
 - Costs incurred in connection with the syndicated credit agreement we entered into with Wells Fargo Bank, as syndication agent, to finance the acquisition of BAQSIMI[®]
 - Mark-to-market adjustments relating to our interest rate swap contracts

Cash flow provided by operating activities for the nine months ended September 30, 2023 was \$159.6 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 \$10 billion, and six generic products in development targeting products with a market size of over \$8 billion. This market information is based on IQVIA data for the 12 months ended September 30, 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[®], 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[®], 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, November 8, 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, ten 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, 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[®], and other future events, including potential contingent consideration amounts and terms related to the acquisition of BAQSIMI[®], the anticipated benefits of BAQSIMI[®] to our product portfolio, Amphastar's commitment to strategically maximizing the commercial potential 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, 2022, filed with the SEC on March 1, 2023, in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, filed with the SEC on May 9, 2023, and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, filed with the SEC on August 8, 2023. 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:

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Table I
Amphastar Pharmaceuticals, Inc.

Condensed Consolidated Statement of Operations
(Unaudited; in thousands, except per share data)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2023	2022	2023	2022
Net revenues:				
Product revenues, net	\$ 151,855	\$ 120,129	\$ 437,589	\$ 363,964
Other revenues	28,701	-	28,701	-
Net revenues	<u>180,556</u>	<u>120,129</u>	<u>466,290</u>	<u>363,964</u>
Cost of revenues	<u>72,153</u>	<u>61,619</u>	<u>211,309</u>	<u>186,272</u>
Gross profit	108,403	58,510	254,981	177,692
Operating expenses:				
Selling, distribution, and marketing	6,407	4,784	20,234	16,059
General and administrative	12,654	11,984	38,418	34,433
Research and development	16,664	18,514	53,322	57,535
Total operating expenses	<u>35,725</u>	<u>35,282</u>	<u>111,974</u>	<u>108,027</u>
Income from operations	72,678	23,228	143,007	69,665
Non-operating income (expenses), net	<u>(9,041)</u>	<u>(632)</u>	<u>(12,993)</u>	<u>5,115</u>
Income before income taxes	63,637	22,596	130,014	74,780
Income tax provision	<u>14,025</u>	<u>6,559</u>	<u>27,160</u>	<u>16,187</u>
Net income before equity in losses of unconsolidated affiliate	49,612	16,037	102,854	58,593
Equity in losses of unconsolidated affiliate	<u>(390)</u>	<u>(163)</u>	<u>(1,476)</u>	<u>(1,120)</u>
Net income	<u>\$ 49,222</u>	<u>\$ 15,874</u>	<u>\$ 101,378</u>	<u>\$ 57,473</u>
Net income per share:				
Basic	\$ 1.01	\$ 0.32	\$ 2.10	\$ 1.18
Diluted	\$ 0.91	\$ 0.30	\$ 1.91	\$ 1.09
Weighted-average shares used to compute net income per share:				
Basic	48,701	48,904	48,368	48,635
Diluted	53,921	52,788	52,997	52,665

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

	September	December
	30,	31,
	2023	2022
	<u>(unaudited)</u>	<u>(unaudited)</u>
ASSETS		

Current assets:		
Cash and cash equivalents	\$ 266,778	\$ 156,098
Restricted cash	4,259	235
Short-term investments	33,098	19,664
Restricted short-term investments	2,200	2,200
Accounts receivable, net	118,990	88,804
Inventories	109,978	103,584
Income tax refunds and deposits	1,506	171
Prepaid expenses and other assets	6,196	7,563
Total current assets	<u>543,005</u>	<u>378,319</u>
Property, plant, and equipment, net	280,836	238,266
Finance lease right-of-use assets	610	753
Operating lease right-of-use assets	32,666	25,554
Investment in unconsolidated affiliate	1,026	2,414
Goodwill and intangible assets, net	619,351	37,298
Long-term investments	972	-
Other assets	25,299	20,856
Deferred tax assets	40,868	38,527
Total assets	<u>\$ 1,544,633</u>	<u>\$ 741,987</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable and accrued liabilities	\$ 222,719	\$ 84,242
Income taxes payable	31,092	4,571
Current portion of long-term debt	433	3,046
Current portion of operating lease liabilities	3,719	3,003
Total current liabilities	<u>257,963</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	638,206	72,839
Long-term operating lease liabilities, net of current portion	30,199	23,694
Deferred tax liabilities	201	144
Other long-term liabilities	15,699	14,565
Total liabilities	<u>949,493</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; 59,220,178 and 47,898,466 shares issued and outstanding as of September 30, 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	477,880	455,077

Retained earnings	373,102	271,723
Accumulated other comprehensive loss	(8,411)	(8,624)
Treasury stock	<u>(247,437)</u>	<u>(189,524)</u>
Total equity	<u>595,140</u>	<u>528,658</u>
Total liabilities and stockholders' equity	<u>\$ 1,544,633</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		Nine Months Ended	
	September 30,		September 30,	
	2023	2022	2023	2022
GAAP net income	\$ 49,222	\$ 15,874	\$ 101,378	\$ 57,473
Adjusted for:				
Intangible amortization	6,168	392	6,651	1,088
Share-based compensation	4,644	4,299	15,620	13,556
Impairment of long-lived assets	474	-	3,174	-
Expenses related to BAQSIMI ^{??} acquisition	2,182	-	3,682	-
Debt issuance costs	3,019	-	6,043	-
Litigation settlements	-	800	-	(4,929)
Income tax provision on pre-tax adjustments	<u>(3,811)</u>	<u>(1,133)</u>	<u>(7,725)</u>	<u>(1,640)</u>
Non-GAAP net income	<u>\$ 61,898</u>	<u>\$ 20,232</u>	<u>\$ 128,823</u>	<u>\$ 65,548</u>
Non-GAAP net income per share:				
Basic	\$ 1.27	\$ 0.41	\$ 2.66	\$ 1.35
Diluted	\$ 1.15	\$ 0.38	\$ 2.43	\$ 1.24
Weighted-average shares used to compute non-GAAP net income per share:				
Basic	48,701	48,904	48,368	48,635
Diluted	53,921	52,788	52,997	52,665

Three Months Ended September 30, 2023

	Cost of	Selling,	General	Research	Non-	Income
	revenue	distribution	and	and	operating	tax
		and	administrative	development	income	provision
		marketing			(expense),	
					net	
						
GAAP	\$ 72,153	\$ 6,407	\$ 12,654	\$ 16,664	\$ (9,041)	\$ 14,025
Intangible amortization	(6,149)	-	34	(53)	-	-
Share-based compensation	(1,004)	(213)	(2,975)	(452)	-	-
Impairment of long-lived assets	(470)	-	(4)	-	-	-

Expenses related to BAQSIMI [®] acquisition	-	-	(357)	-	1,825	-
Debt issuance costs	-	-	-	-	3,019	-
Income tax provision on pre-tax adjustments	-	-	-	-	-	3,811
Non-GAAP	<u>\$ 64,530</u>	<u>\$ 6,194</u>	<u>\$ 9,352</u>	<u>\$ 16,159</u>	<u>\$ (4,197)</u>	<u>\$ 17,836</u>

Three Months Ended September 30, 2022

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Non-operating income (expense), net	Income tax provision
GAAP	\$ 61,619	\$ 4,784	\$ 11,984	\$ 18,514	\$ (632)	\$ 6,559
Intangible amortization	(206)	-	(186)	-	-	-
Share-based compensation	(915)	(178)	(2,810)	(396)	-	-
Litigation settlements	-	-	(800)	-	-	-
Income tax provision on pre-tax adjustments	-	-	-	-	-	1,133
Non-GAAP	<u>\$ 60,498</u>	<u>\$ 4,606</u>	<u>\$ 8,188</u>	<u>\$ 18,118</u>	<u>\$ (632)</u>	<u>\$ 7,692</u>

Nine Months Ended September 30, 2023

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Non-operating income (expense), net	Income tax provision
GAAP	\$ 211,309	\$ 20,234	\$ 38,418	\$ 53,322	\$ (12,993)	\$ 27,160
Intangible amortization	(6,582)	-	(16)	(53)	-	-
Share-based compensation	(3,868)	(649)	(9,323)	(1,780)	-	-
Impairment of long-lived assets	(3,170)	-	(4)	-	-	-

Expenses related to BAQSIMI [®] acquisition	-	-	(1,857)	-	1,825	-
Debt issuance costs	-	-	-	-	6,043	-
Income tax provision on pre-tax adjustments	-	-	-	-	-	7,725
Non-GAAP	<u>\$ 197,689</u>	<u>\$ 19,585</u>	<u>\$ 27,218</u>	<u>\$ 51,489</u>	<u>\$ (5,125)</u>	<u>\$ 34,885</u>

Nine Months Ended September 30, 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	\$ 186,272	\$ 16,059	\$ 34,433	\$ 57,535	\$ 5,115	\$ 16,187
Intangible amortization	(660)	-	(428)	-	-	-
Share-based compensation	(3,238)	(540)	(8,389)	(1,389)	-	-
Litigation settlements	-	-	(800)	-	(5,729)	-
Income tax provision on pre-tax adjustments	-	-	-	-	-	1,640
Non-GAAP	<u>\$ 182,374</u>	<u>\$ 15,519</u>	<u>\$ 24,816</u>	<u>\$ 56,146</u>	<u>\$ (614)</u>	<u>\$ 17,827</u>

SOURCE: Amphastar Pharmaceuticals, Inc.

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