

Amphastar Pharmaceuticals Reports Financial Results for the Three Months Ended September 30, 2024

November 6, 2024

Reports Net Revenues of \$191.2 Million for the Three Months Ended September 30, 2024

RANCHO CUCAMONGA, CA / ACCESSWIRE / November 6, 2024 / Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) ("Amphastar" or the "Company") today reported results for the three months ended September 30, 2024.

Third quarter Highlights

- Net revenues of \$191.2 million for the third quarter
- GAAP net income of \$40.4 million, or \$0.78 per share, for the third quarter
- Adjusted non-GAAP net income of \$49.6 million, or \$0.96 per share, for the third quarter

Dr. Jack Zhang, Amphastar's President and Chief Executive Officer, commented: "Amphastar has continued its growth this quarter, highlighted by sales, particularly from BAQSIMI[®], which has become a cornerstone in our portfolio, and Primatene MIST[®], which is trending toward our goal of \$100 million in sales per year. Looking forward, we will focus on positioning our Company towards sustainable, long-term growth by pivoting to high-value and high-growth areas, particularly centered on developing proprietary products and biosimilars, which we expect will allow us to leverage our R&D expertise and technology."

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2024	2023	2024	2023
	(in thousands, except per share data)			
Net revenues	\$ 191,214	\$ 180,556	\$ 545,444	\$ 466,290
GAAP net income	\$ 40,429	\$ 49,222	\$ 121,555	\$ 101,378

Adjusted non-GAAP net income*	\$ 49,585	\$ 61,898	\$ 153,569	\$ 128,823
GAAP diluted EPS	\$ 0.78	\$ 0.91	\$ 2.32	\$ 1.91
Adjusted non-GAAP diluted EPS*	\$ 0.96	\$ 1.15	\$ 2.94	\$ 2.43

* 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

September 30,		Change	
2024	2023	Dollars	%

(in thousands)

Product revenues:

BAQSIMI [®]	\$ 40,409	\$ -	\$ 40,409	N/A
Glucagon	26,792	29,514	(2,722)	(9 %)
Primatene MIST [®]	26,055	24,834	1,221	5 %
Epinephrine	21,341	20,199	1,142	6 %
Lidocaine	15,884	15,522	362	2 %
Phytonadione	11,721	7,449	4,272	57 %

Enoxaparin	5,615	7,702	(2,087)	(27 %)
Naloxone	4,037	4,715	(678)	(14 %)
Other finished pharmaceutical products	35,503	37,730	(2,227)	(6 %)
Total finished pharmaceutical products net revenues	<u>\$ 187,357</u>	<u>\$ 147,665</u>	<u>\$ 39,692</u>	<u>27 %</u>
API	1,462	4,190	(2,728)	(65 %)
Other revenues	2,395	28,701	(26,306)	(92 %)
Total net revenues	<u><u>\$ 191,214</u></u>	<u><u>\$ 180,556</u></u>	<u><u>\$ 10,658</u></u>	<u><u>6 %</u></u>

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

- BAQSIMI[®] revenues consisting of \$40.4 million in sales made by the Company directly to its customers, which are recorded as part of product revenues, net, and \$6.4 million in sales made by Eli Lilly & Company, or Lilly, on behalf of the Company under a Transition Services Agreement, or TSA, which resulted in a net payment to the Company of \$2.4 million after deducting the cost of sales and other expenses and was recorded in other revenues
- Glucagon sales decreased due to a decrease in unit volumes as a result of a move to ready to use glucagon products such as BAQSIMI[®], as well as a decrease in average selling price
- Primatene MIST[®] sales increased primarily due to an increase in unit volumes
- Epinephrine sales increased primarily due to sales of epinephrine pre-filled syringes in Canada, which we began this quarter
- The increase in sales of phytonadione was primarily due to an increase in unit volume, as a result of an increase in demand during the quarter
- 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 sales of atropine and calcium chloride, as a result of other suppliers returning to their historical distribution levels

- These decreases were partially offset by:
 - Higher unit volumes of sodium bicarbonate due to an increase in capacity at our subsidiary, International Medication Systems, Limited
 - The launch of albuterol in August 2024

Between \$2.0 million and \$4.0 million in sales expected to be recognized in the third quarter were not recognized due to delayed shipments caused by the aftermath of Hurricane Helene. Revenues for these shipments are expected to be recognized in the fourth quarter.

	Three Months Ended			
	September 30,		Change	
	2024	2023	Dollars	%
	(in thousands)			
Net revenues	\$ 191,214	\$ 180,556	\$ 10,658	6 %
Cost of revenues	89,273	72,153	17,120	24 %
Gross profit	\$ 101,941	\$ 108,403	\$ (6,462)	(6 %)
<i>as % of net revenues</i>	53.3%	60.0%		

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

- Increased labor costs and certain component costs, as well as charges included in cost of revenues to adjust our inventory and related purchase commitments to their net realizable value
- Decrease in other revenues related to Lilly's sales of BAQSIMI[®] under the TSA, which are recorded net of cost of sales and other expenses as we assumed distribution of BAQSIMI[®] to our customers and are now recording those sales in product revenues and cost of sales separately
- This was partially offset by:
 - Increase in sales of Primatene MIST[®] and epinephrine, which are higher-margin products

Three Months Ended

	September 30,		Change	
	2024	2023	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	\$ 8,995	\$ 6,407	\$ 2,588	40 %
General and administrative	14,821	12,654	2,167	17 %
Research and development	21,077	16,664	4,413	26 %

- Selling, distribution, and marketing expenses increased primarily due to the expenses related to the expansion of our sales and marketing efforts related to BAQSIMI[®]
- General and administrative expenses increased primarily due to an increase in salary and personnel-related expenses and expenses related to BAQSIMI[®]
- Research and development expenses increased due to expenditure on raw materials and components for our insulin pipeline products, as well as an increase in salary and personnel-related expenses, which was partially offset by a decrease in clinical trial expenses due to the timing of clinical trials

Three Months Ended

	September 30,		Change	
	2024	2023	Dollars	%
	(in thousands)			
Non-operating income (expenses)				
Interest income	\$ 2,427	\$ 1,202	\$ 1,225	102 %

Interest expense	(6,698)	(13,702)	7,004	(51 %)
Other income (expenses), net	(5,094)	3,459	(8,553)	(247 %)
Total non-operating income (expenses), net	<u>\$ (9,365)</u>	<u>\$ (9,041)</u>	<u>\$ (324)</u>	4 %

The change in non-operating income (expenses), net is primarily a result of:

- An increase in interest income resulting from an increase in cash and investments
- A decrease in interest expense was primarily due to the \$250.0 million repayment of the principal balance of the Wells Fargo Term Loan in September 2023, along with the write-off of unamortized debt issuance costs related to the Term Loan in 2023
- A change to other income (expenses), net primarily as a result of foreign currency fluctuation, as well as mark-to-market adjustments relating to our interest rate swap contracts

Cash flow provided by operating activities for the nine months ended September 30, 2024, was \$184.4 million.

Share Buyback Program

On November 4, 2024, the Company's Board of Directors authorized a \$50 million increase to the Company's share buyback program, which is expected to continue for an indefinite period of time. The primary goal of the program is to offset dilution created by the Company's equity compensation programs.

Purchases may be made through the open market and private block transactions pursuant to Rule 10b5-1 plans, privately negotiated transactions, or other means, as determined by the Company's management and in accordance with the requirements of the Securities and Exchange Commission and applicable laws.

The timing and actual number of shares repurchased will depend on a variety of factors including price, corporate and regulatory requirements, and other conditions.

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 \$2.4 billion, four biosimilar products in development targeting products with a market size of over \$8 billion, and three generic products in development targeting products with a market size of approximately \$2 billion. This market information is based on IQVIA data for the 12 months ended September 30, 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, November 6, 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 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 benefits of the acquisition of BAQSIMI[®], including its potential for continued revenue growth, the success of our integration of BAQSIMI[®], the transition of our pipeline towards branded products, proprietary products, and biosimilars, our ability to leverage our existing expertise and technology, 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 our Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, filed with the SEC on May 10, 2024, and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, filed with the SEC on August 9, 2024. In particular, there can be no guarantee that our pivoting towards high-value and high-growth areas market will be successful, that demand will be sufficient for us to meet our sales goal for Primatene MIST[®] or that we will continue to experience significant sales of BAQSIMI[®]. 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
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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,	
2024	2023	2024	2023

Net revenues:

Product revenues, net	\$ 188,819	\$ 151,855	\$ 525,836	\$ 437,589
Other revenues	2,395	28,701	19,608	28,701
Total net revenues	<u>191,214</u>	<u>180,556</u>	<u>545,444</u>	<u>466,290</u>
Cost of revenues	<u>89,273</u>	<u>72,153</u>	<u>258,237</u>	<u>211,309</u>
Gross profit	101,941	108,403	287,207	254,981
Operating expenses:				
Selling, distribution, and marketing	8,995	6,407	27,378	20,234
General and administrative	14,821	12,654	43,782	38,418
Research and development	21,077	16,664	55,772	53,322
Total operating expenses	<u>44,893</u>	<u>35,725</u>	<u>126,932</u>	<u>111,974</u>
Income from operations	57,048	72,678	160,275	143,007
Non-operating income (expenses):				
Interest income	2,427	1,202	8,320	3,156
Interest expense	(6,698)	(13,702)	(23,918)	(17,702)
Other income (expenses), net	<u>(5,094)</u>	<u>3,459</u>	<u>1,125</u>	<u>1,553</u>
Total non-operating income (expenses), net	<u>(9,365)</u>	<u>(9,041)</u>	<u>(14,473)</u>	<u>(12,993)</u>

Income before income taxes	47,683	63,637	145,802	130,014
Income tax provision	<u>7,254</u>	<u>14,025</u>	<u>23,674</u>	<u>27,160</u>
Net income before equity in losses of unconsolidated affiliate	40,429	49,612	122,128	102,854
Equity in losses of unconsolidated affiliate	-	(390)	(573)	(1,476)
Net income	<u>\$ 40,429</u>	<u>\$ 49,222</u>	<u>\$ 121,555</u>	<u>\$ 101,378</u>
Net income per share:				
Basic	\$ 0.83	\$ 1.01	\$ 2.50	\$ 2.10
Diluted	\$ 0.78	\$ 0.91	\$ 2.32	\$ 1.91
Weighted-average shares used to compute net income per share:				
Basic	48,621	48,701	48,580	48,368
Diluted	51,862	53,921	52,307	52,997

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

September	December
30,	31,
2024	2023
<u> </u>	<u> </u>

(unaudited)

ASSETS

Current assets:

Cash and cash equivalents	\$ 192,116	\$ 144,296
Restricted cash	235	235
Short-term investments	58,375	112,510
Restricted short-term investments	2,200	2,200
Accounts receivable, net	139,635	114,943
Inventories	130,316	105,833
Income tax refunds and deposits	5,349	526
Prepaid expenses and other assets	17,723	9,057
Total current assets	<u>545,949</u>	<u>489,600</u>
Property, plant, and equipment, net	295,384	282,746
Finance lease right-of-use assets	426	564
Operating lease right-of-use assets	31,708	32,333
Investment in unconsolidated affiliate	-	527
Goodwill and intangible assets, net	594,796	613,295
Long-term investments	-	14,685

Other assets	23,663	25,910
Deferred tax assets	53,252	53,252
	<u> </u>	<u> </u>
Total assets	\$ 1,545,178	\$ 1,512,912
	<u> </u>	<u> </u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable and accrued liabilities	\$ 153,268	\$ 93,366
Accrued payments for BAQSIMI [®]	-	126,090
Income taxes payable	1,281	1,609
Current portion of long-term debt	252	436
Current portion of operating lease liabilities	4,209	3,906
	<u> </u>	<u> </u>
Total current liabilities	159,010	225,407

Long-term reserve for income tax liabilities	6,066	6,066
Long-term debt, net of current portion and unamortized debt issuance costs	596,446	589,579
Long-term operating lease liabilities, net of current portion	28,941	29,721
Other long-term liabilities	27,037	22,718
	<u> </u>	<u> </u>
Total liabilities	817,500	873,491
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; 60,690,076 and 48,372,997 shares issued and outstanding, respectively, as of September 30, 2024 and 59,390,194 and 48,068,881 shares issued and outstanding, respectively, as of December 31, 2023	6	6
Additional paid-in capital	496,427	486,056
Retained earnings	530,823	409,268
Accumulated other comprehensive loss	(8,821)	(8,478)
Treasury stock	(290,757)	(247,431)
Total equity	<u>727,678</u>	<u>639,421</u>
Total liabilities and stockholders' equity	<u>\$ 1,545,178</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		Nine Months Ended	
	September 30,		September 30,	
	2024	2023	2024	2023
GAAP net income	\$ 40,429	\$ 49,222	\$ 121,555	\$ 101,378
Adjusted for:				
Intangible asset amortization	6,179	6,168	18,539	6,651
Share-based compensation	5,596	4,644	18,736	15,620

Impairment of long-lived assets	-	474	-	3,174
Expenses related to BAQSIMI [®] acquisition	-	2,182	3,651	3,682
Debt issuance costs	-	3,019	-	6,043
Income tax provision on pre-tax adjustments	(2,619)	(3,811)	(8,912)	(7,725)
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Adjusted non-GAAP net income	<u>\$ 49,585</u>	<u>\$ 61,898</u>	<u>\$ 153,569</u>	<u>\$ 128,823</u>
Adjusted non-GAAP net income per share:				
Basic	\$ 1.02	\$ 1.27	\$ 3.16	\$ 2.66
Diluted	\$ 0.96	\$ 1.15	\$ 2.94	\$ 2.43
Weighted-average shares used to compute adjusted non-GAAP net income per share:				
Basic	48,621	48,701	48,580	48,368
Diluted	51,862	53,921	52,307	52,997

Three Months Ended September 30, 2024

	Selling, Cost of revenue	distribution and marketing	General and administrative	Research and development	Non- operating (expenses) income, net	Income tax provision
	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
GAAP	\$ 89,273	\$ 8,995	\$ 14,821	\$ 21,077	\$ (9,365)	\$ 7,254

Intangible asset amortization	(6,159)	-	(1)	(19)	-	-
Share-based compensation	(1,133)	(249)	(3,710)	(504)	-	-
Income tax provision on pre-tax adjustments	-	-	-	-	-	2,619
Non-GAAP	<u>\$ 81,981</u>	<u>\$ 8,746</u>	<u>\$ 11,110</u>	<u>\$ 20,554</u>	<u>\$ (9,365)</u>	<u>\$ 9,873</u>

Three Months Ended September 30, 2023

	Selling, Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Non- operating (expenses) income, net	Income tax provision
GAAP	\$ 72,153	\$ 6,407	\$ 12,654	\$ 16,664	\$ (9,041)	\$ 14,025
Intangible asset 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	\$ 64,530	\$ 6,194	\$ 9,352	\$ 16,159	\$ (4,197)	\$ 17,836
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Nine Months Ended September 30, 2024

	Cost of	Selling,	General	Research	Non-	Income
	revenue	distribution	and	and	operating	(expenses)
	and	and	administrative	development	income,	tax
	marketing	marketing	development	development	net	provision
	and	and	development	development	net	provision
GAAP	\$ 258,237	\$ 27,378	\$ 43,782	\$ 55,772	\$ (14,473)	\$ 23,674
Intangible asset amortization	(18,479)	-	(4)	(56)	-	-
Share-based compensation	(4,583)	(777)	(11,239)	(2,137)	-	-
Expenses related to BAQSIMI [®] acquisition	-	-	-	-	3,651	-
Income tax provision on pre-tax adjustments	-	-	-	-	-	8,912
Non-GAAP	\$ 235,175	\$ 26,601	\$ 32,539	\$ 53,579	\$ (10,822)	\$ 32,586

Nine Months Ended September 30, 2023

	Cost of	Selling,	General	Research	Non-	Income
	revenue	distribution	and	and	operating	(expenses)
	and	and	administrative	development	income,	tax
	marketing	marketing	development	development	net	provision
	and	and	development	development	net	provision

	<u>revenue</u>	<u>and marketing</u>	<u>administrative</u>	<u>development</u>	<u>income, net</u>	<u>tax provision</u>
	\$ 211,309	\$ 20,234	\$ 38,418	\$ 53,322	\$ (12,993)	\$ 27,160
GAAP						
Intangible asset 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
	<u>\$ 197,689</u>	<u>\$ 19,585</u>	<u>\$ 27,218</u>	<u>\$ 51,489</u>	<u>\$ (5,125)</u>	<u>\$ 34,885</u>
Non-GAAP						

SOURCE: Amphastar Pharmaceuticals, Inc.

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