

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event Reported): August 8, 2023

Amphastar Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

001-36509
(Commission File Number)

33-0702205
(I.R.S. Employer Identification
Number)

11570 6th Street
Rancho Cucamonga, California
(Address of Principal Executive Offices)

91730
(Zip Code)

Registrant's telephone number, including area code: **(909) 980-9484**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	AMPH	The NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On August 8, 2023, Amphastar Pharmaceuticals, Inc. issued a press release announcing its financial results for the three months ended June 30, 2023. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated August 8, 2023, issued by Amphastar Pharmaceuticals, Inc.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 8, 2023

Amphastar Pharmaceuticals, Inc.

By: /s/ WILLIAM J. PETERS
William J. Peters
Chief Financial Officer, Executive Vice President and
Treasurer

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

Reports Net Revenues of \$145.7 Million for the Three Months Ended June 30, 2023

RANCHO CUCAMONGA, CA – August 8, 2023 – Amphastar Pharmaceuticals, Inc. (NASDAQ: AMPH) (“Amphastar” or the “Company”) today reported results for the three months ended June 30, 2023.

Second Quarter Highlights

- Net revenues of \$145.7 million for the second quarter
- GAAP net income of \$26.1 million, or \$0.49 per share, for the second quarter
- Adjusted non-GAAP net income of \$34.8 million, or \$0.65 per share, for the second quarter

Dr. Jack Zhang, Amphastar’s President and Chief Executive Officer, commented: “We are pleased with the second quarter’s results, which are partially attributable to glucagon and phytonadione delivering strong sales growth along with sales from newer products such as regadenoson, ganirelix and vasopressin adding another layer of strength. Additionally, with the completion of our strategic acquisition of BAQSIMI® on June 30, we increased our proprietary products sales profile and continue to execute our strategic vision of advancing the Company with a durable portfolio of branded, biosimilar, and complex products.”

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	(in thousands, except per share data)			
Net revenues	\$ 145,712	\$ 123,467	\$ 285,734	\$ 243,835
GAAP net income	\$ 26,124	\$ 17,346	\$ 52,156	\$ 41,599
Adjusted non-GAAP net income*	\$ 34,782	\$ 20,730	\$ 66,925	\$ 45,316
GAAP diluted EPS	\$ 0.49	\$ 0.33	\$ 0.99	\$ 0.79
Adjusted non-GAAP diluted EPS*	\$ 0.65	\$ 0.39	\$ 1.27	\$ 0.86

* 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.

Second Quarter Results

	Three Months Ended June 30,		Change	
	2023	2022	Dollars	%
	(in thousands)			
Net revenues:				
Glucagon	\$ 27,276	\$ 11,795	\$ 15,481	131 %
Phytonadione	17,855	13,381	4,474	33 %
Epinephrine	16,714	18,119	(1,405)	(8)%
Primatene MIST®	16,520	18,974	(2,454)	(13)%
Lidocaine	14,006	16,042	(2,036)	(13)%
Enoxaparin	7,872	9,031	(1,159)	(13)%
Naloxone	5,102	7,193	(2,091)	(29)%
Other finished pharmaceutical products	37,521	25,588	11,933	47 %
Total finished pharmaceutical products net revenues	\$ 142,866	\$ 120,123	\$ 22,743	19 %
API	2,846	3,344	(498)	(15)%
Total net revenues	\$ 145,712	\$ 123,467	\$ 22,245	18 %

Changes in net revenues as compared to the second 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
- Phytonadione sales increased due to increased unit volumes, as a result of supplier shortages
- Primatene MIST® sales decreased due to a decrease in unit volumes, as a result of inventory drawdowns by retailers
- The decrease in sales of epinephrine and lidocaine was primarily due to a decrease in unit volumes, as a result of suppliers returning to their historical distribution levels
- The decrease in sales of enoxaparin and naloxone was primarily due to a decrease in unit volumes
- Other finished pharmaceutical product sales increased primarily due to:
 - An increase in unit volumes for dextrose, atropine, calcium chloride, and sodium bicarbonate, due to increasing demand caused by supplier shortages
 - A full quarter of sales for ganirelix and vasopressin, which were launched in June 2022 and August 2022, respectively
 - Launch of regadenoson in April 2023
- Active Pharmaceutical ingredient (“API”) sales increased primarily due to the timing of customer purchases

	Three Months Ended June 30,		Change	
	2023	2022 (in thousands)	Dollars	%
Net revenues	\$ 145,712	\$ 123,467	\$ 22,245	18 %
Cost of revenues	72,974	60,111	12,863	21 %
Gross profit	\$ 72,738	\$ 63,356	\$ 9,382	15 %
<i>as % of net revenues</i>	<i>50%</i>	<i>51%</i>		

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

- Increased sales of higher-margin products such as glucagon and epinephrine, the sales of ganirelix and vasopressin that were launched in 2022, as well as the sales of regadenoson, which we launched in April 2023
- These factors were partially offset by an impairment charge of \$2.7 million related to the impairment of the IMS (UK) international product rights, as well as charges included in cost of revenue to adjust our inventory and related purchase commitments to their net realizable value

	Three Months Ended June 30,		Change	
	2023	2022 (in thousands)	Dollars	%
Selling, distribution, and marketing	\$ 6,718	\$ 5,756	\$ 962	17 %
General and administrative	12,281	9,979	2,302	23 %
Research and development	16,843	22,798	(5,955)	(26)%
Non-operating income (expense), net	(4,088)	(1,672)	(2,416)	144 %

- Selling, distribution, and marketing expenses increased primarily due to increased advertising expenses 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®
- Research and development expenses decreased due to:
 - 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 and an increase in clinical trial expenses related to our insulin and inhalation product pipeline
- The change in non-operating income (expense), net is primarily a result of:
 - Foreign currency fluctuations
 - Mark-to-market adjustments relating to our interest rate swap contracts
 - 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®

Cash flow provided by operating activities for the six months ended June 30, 2023 was \$95.3 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 June 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®, 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, August 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 acquisition of BAQSIMI®, 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 and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, filed with the SEC on May 9, 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 of BAQSIMI® 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 the 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:

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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net revenues	\$ 145,712	\$ 123,467	\$ 285,734	\$ 243,835
Cost of revenues	72,974	60,111	139,156	124,653
Gross profit	72,738	63,356	146,578	119,182
Operating expenses:				
Selling, distribution, and marketing	6,718	5,756	13,827	11,275
General and administrative	12,281	9,979	25,764	22,449
Research and development	16,843	22,798	36,658	39,021
Total operating expenses	35,842	38,533	76,249	72,745
Income from operations	36,896	24,823	70,329	46,437
Non-operating income (expenses), net	(4,088)	(1,672)	(3,952)	5,747
Income before income taxes	32,808	23,151	66,377	52,184
Income tax provision	6,383	5,551	13,135	9,628
Net income before equity in losses of unconsolidated affiliate	26,425	17,600	53,242	42,556
Equity in losses of unconsolidated affiliate	(301)	(254)	(1,086)	(957)
Net income	<u>\$ 26,124</u>	<u>\$ 17,346</u>	<u>\$ 52,156</u>	<u>\$ 41,599</u>
Net income per share:				
Basic	\$ 0.54	\$ 0.35	\$ 1.08	\$ 0.86
Diluted	\$ 0.49	\$ 0.33	\$ 0.99	\$ 0.79
Weighted-average shares used to compute net income per share:				
Basic	48,404	48,864	48,202	48,501
Diluted	53,102	53,227	52,536	52,603

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

	June 30, 2023 (unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 148,595	\$ 156,098
Restricted cash	2,685	235
Short-term investments	14,541	19,664
Restricted short-term investments	2,200	2,200
Accounts receivable, net	104,715	88,804
Inventories	104,617	103,584
Income tax refunds and deposits	1,329	171
Prepaid expenses and other assets	5,872	7,563
Total current assets	<u>384,554</u>	<u>378,319</u>
Property, plant, and equipment, net	278,526	238,266
Finance lease right-of-use assets	657	753
Operating lease right-of-use assets	26,327	25,554
Investment in unconsolidated affiliate	1,462	2,414
Goodwill and intangible assets, net	625,603	37,298
Other assets	20,269	20,856
Deferred tax assets	40,868	38,527
Total assets	<u>\$ 1,378,266</u>	<u>\$ 741,987</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 217,536	\$ 84,242
Income taxes payable	17,696	4,571
Current portion of long-term debt	12,920	3,046
Current portion of operating lease liabilities	3,133	3,003
Total current liabilities	<u>251,285</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	488,280	72,839
Long-term operating lease liabilities, net of current portion	24,407	23,694
Deferred tax liabilities	201	144
Other long-term liabilities	17,633	14,565
Total liabilities	<u>789,031</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; 59,068,477 and 48,818,806 shares issued and outstanding as of June 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	471,110	455,077
Retained earnings	323,880	271,723
Accumulated other comprehensive loss	(8,324)	(8,624)
Treasury stock	(197,437)	(189,524)
Total equity	<u>589,235</u>	<u>528,658</u>
Total liabilities and stockholders' equity	<u>\$ 1,378,266</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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
GAAP net income	\$ 26,124	\$ 17,346	\$ 52,156	\$ 41,599
Adjusted for:				
Intangible amortization	242	344	483	696
Share-based compensation	4,865	4,235	10,976	9,257
Impairment of long-lived assets	2,700	—	2,700	—
Expenses related to BAQSIMI® acquisition	3,307	—	4,524	—
Litigation settlements	—	(383)	—	(5,729)
Income tax provision on pre-tax adjustments	(2,456)	(812)	(3,914)	(507)
Non-GAAP net income	<u>\$ 34,782</u>	<u>\$ 20,730</u>	<u>\$ 66,925</u>	<u>\$ 45,316</u>
Non-GAAP net income per share:				
Basic	\$ 0.72	\$ 0.42	\$ 1.39	\$ 0.93
Diluted	\$ 0.65	\$ 0.39	\$ 1.27	\$ 0.86
Weighted-average shares used to compute non-GAAP net income per share:				
Basic	48,404	48,864	48,202	48,501
Diluted	53,102	53,227	52,536	52,603

	Three Months Ended June 30, 2023					
	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Non-operating income (expense), net	Income tax provision
GAAP	\$ 72,974	\$ 6,718	\$ 12,281	\$ 16,843	\$ (4,088)	\$ 6,383
Intangible amortization	(222)	—	(20)	—	—	—
Share-based compensation	(1,158)	(227)	(2,991)	(489)	—	—
Impairment of long-lived assets	(2,700)	—	—	—	—	—
Expenses related to BAQSIMI® acquisition	—	—	(283)	—	(3,024)	—
Income tax provision on pre-tax adjustments	—	—	—	—	—	2,456
Non-GAAP	<u>\$ 68,894</u>	<u>\$ 6,491</u>	<u>\$ 8,987</u>	<u>\$ 16,354</u>	<u>\$ (7,112)</u>	<u>\$ 8,839</u>

	Three Months Ended June 30, 2022					
	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Non-operating income (expense), net	Income tax provision
GAAP	\$ 60,111	\$ 5,756	\$ 9,979	\$ 22,798	\$ (1,672)	\$ 5,551
Intangible amortization	(219)	—	(125)	—	—	—
Share-based compensation	(938)	(194)	(2,718)	(385)	—	—
Litigation settlements	—	—	—	—	(383)	—
Income tax provision on pre-tax adjustments	—	—	—	—	—	812
Non-GAAP	<u>\$ 58,954</u>	<u>\$ 5,562</u>	<u>\$ 7,136</u>	<u>\$ 22,413</u>	<u>\$ (2,055)</u>	<u>\$ 6,363</u>

Six Months Ended June 30, 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	\$ 139,156	\$ 13,827	\$ 25,764	\$ 36,658	\$ (3,952)	\$ 13,135
Intangible amortization	(433)	—	(50)	—	—	—
Share-based compensation	(2,864)	(436)	(6,348)	(1,328)	—	—
Impairment of long-lived assets	(2,700)	—	—	—	—	—
Expenses related to BAQSIMI® acquisition	—	—	(1,500)	—	(3,024)	—
Income tax provision on pre-tax adjustments	—	—	—	—	—	3,914
Non-GAAP	<u>\$ 133,159</u>	<u>\$ 13,391</u>	<u>\$ 17,866</u>	<u>\$ 35,330</u>	<u>\$ (6,976)</u>	<u>\$ 17,049</u>

Six Months Ended June 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	\$ 124,653	\$ 11,275	\$ 22,449	\$ 39,021	\$ 5,747	\$ 9,628
Intangible amortization	(454)	—	(242)	—	—	—
Share-based compensation	(2,323)	(362)	(5,579)	(993)	—	—
Litigation settlements	—	—	—	—	(5,729)	—
Income tax provision on pre-tax adjustments	—	—	—	—	—	507
Non-GAAP	<u>\$ 121,876</u>	<u>\$ 10,913</u>	<u>\$ 16,628</u>	<u>\$ 38,028</u>	<u>\$ 18</u>	<u>\$ 10,135</u>