
**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): May 6, 2021

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**

Not Applicable
(Former name or former address, if changed since last report)

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 May 6, 2021, Amphastar Pharmaceuticals, Inc. issued a press release announcing its financial results for the three months ended March 31, 2021. 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 May 6, 2021, issued by Amphastar Pharmaceuticals, Inc.

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: May 6, 2021

Amphastar Pharmaceuticals, Inc.

By: /s/ WILLIAM J. PETERS

William J. Peters

Chief Financial Officer and Senior Vice President

Amphastar Pharmaceuticals Reports Financial Results for the Three Months Ended March 31, 2021*Reports Net Revenues of \$103.0 Million for the Three Months Ended March 31, 2021*

RANCHO CUCAMONGA, CA – May 6, 2021 – Amphastar Pharmaceuticals, Inc. (NASDAQ: AMPH) (“Amphastar” or the “Company”) today reported results for the three months ended March 31, 2021.

First Quarter Highlights

- Net revenues of \$103.0 million for the first quarter
- GAAP net income of \$5.0 million, or \$0.10 per share, for the first quarter
- Adjusted non-GAAP net income of \$13.6 million, or \$0.27 per share, for the first quarter

Dr. Jack Zhang, Amphastar’s President and Chief Executive Officer commented: “The launch of glucagon, along with strong sales growth of Primatene Mist® and our epinephrine products, contributed to one of Amphastar’s strongest quarters in terms of sales growth to date. We expect that these core growth products will continue to drive growth for the remainder of the year, while we are confident in seeing our pipeline develop to diversify our portfolio.”

	Three Months Ended March 31,	
	2021	2020
	(in thousands, except per share data)	
Net revenues	\$ 103,020	\$ 84,688
GAAP net income attributable to Amphastar	\$ 5,041	\$ 3,949
Adjusted non-GAAP net income attributable to Amphastar*	\$ 13,553	\$ 8,383
GAAP diluted EPS attributable to Amphastar stockholders	\$ 0.10	\$ 0.08
Adjusted non-GAAP diluted EPS attributable to Amphastar stockholders*	\$ 0.27	\$ 0.17

* 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 March 31,		Change	
	2021	2020	Dollars	%
	(in thousands)			
Net revenues:				
Primatene Mist®	\$ 18,383	\$ 12,877	\$ 5,506	43 %
Epinephrine	15,578	3,990	11,588	290 %
Enoxaparin	10,658	9,168	1,490	16 %
Phytonadione	9,565	11,029	(1,464)	(13)%
Lidocaine	9,071	10,657	(1,586)	(15)%
Glucagon	7,984	—	7,984	N/A
Naloxone	6,341	8,875	(2,534)	(29)%
Other finished pharmaceutical products	20,302	24,702	(4,400)	(18)%
Total finished pharmaceutical products net revenues	\$ 97,882	\$ 81,298	\$ 16,584	20 %
API	5,138	3,390	1,748	52 %
Total net revenues	\$ 103,020	\$ 84,688	\$ 18,332	22 %

Changes in net revenues were primarily driven by:

- Primatene Mist® increased volumes resulting from:
 - The continued success of our nationwide television, radio, and digital marketing campaign
 - An increase in our distribution channels throughout 2020 and during the first quarter of 2021, including Target, which began selling Primatene Mist® in March 2021
- Glucagon for injection emergency kit launched in February 2021
- Epinephrine sales increased due to the launch of our approved epinephrine injection multi-dose vials during the second quarter of 2020 and a market shortage of the pre-filled syringes
- Naloxone sales decreased due to lower average selling price because of increased competition
- Other finished pharmaceutical product sales decreased due to lower demand, largely due to competitors returning to their normal distribution levels

	Three Months Ended March 31,		Change	
	2021	2020	Dollars	%
	(in thousands)			
Net revenues	\$ 103,020	\$ 84,688	\$ 18,332	22 %
Cost of revenues	58,074	47,865	10,209	21 %
Gross profit	\$ 44,946	\$ 36,823	\$ 8,123	22 %
as % of net revenues	44%	43%		

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 Primatene Mist®, epinephrine injection multi-dose vials, and glucagon
- Partially offset by increased sales of low margin enoxaparin and higher input cost

	Three Months Ended March 31,		Change	
	2021	2020	Dollars	%
	(in thousands)			
Selling, distribution, and marketing	\$ 4,537	\$ 3,294	\$ 1,243	38 %
General and administrative	15,338	10,746	4,592	43 %
Research and development	14,765	15,303	(538)	(4)%
Non-operating expense, net	5,192	1,675	3,517	NM

- Selling, distribution, and marketing expenses increased due to the cost of our ongoing national television, radio, and digital marketing campaign for Primatene Mist®
- General and administrative expenses increased primarily due to increased legal expenses, including a reserve of \$1.3 million related to the settlement of employment litigation
- Research and development expenses decreased due to lower clinical trial expenses, which was partially offset by an increase in salaries and personnel-related expenses as well as an increase in depreciation expense
- We recorded an additional \$4.4 million of expense relating to the litigation with Aventis

Cash flow provided by operating activities for the three months ended March 31, 2021, was \$22.8 million.

Pipeline Information

The Company currently has five ANDAs on file with the FDA targeting products with a market size of approximately \$2.4 billion, three biosimilar products in development targeting products with a market size of

approximately \$13 billion, and seven generic products in development targeting products with a market size of approximately \$10 billion. This market information is based on IQVIA data for the 12 months ended March 31, 2021. The Company is currently 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) attributed to Amphastar and (ii) Adjusted non-GAAP diluted EPS attributed to Amphastar's stockholders, which exclude amortization expense, share-based compensation, impairment charges, executive severance expense, and legal settlements, 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 6, 2021, at 2:00 p.m. Pacific Time.

To access the conference call, dial toll-free (877) 876-9177 or (785) 424-1672 for international callers, five 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, backlog, sales and marketing of our products, market size and growth, 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, our share buyback program and other future events, such as the impact of the COVID-19 pandemic and related responses of business and governments to the pandemic on our operations and personnel, and on commercial activity and demand across our business operations and results of operations. 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, 2020, filed with the SEC on March 15, 2021. In particular, the extent of COVID-19's impact on our business will depend on several factors, including the severity, duration and extent of the pandemic, as well as actions taken by governments, businesses, and consumers in response to the pandemic, all of which continue to evolve and remain uncertain at this time. 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) 980-9484

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

	Three Months Ended March 31,	
	2021	2020
Net revenues	\$ 103,020	\$ 84,688
Cost of revenues	58,074	47,865
Gross profit	44,946	36,823
Operating expenses:		
Selling, distribution, and marketing	4,537	3,294
General and administrative	15,338	10,746
Research and development	14,765	15,303
Total operating expenses	34,640	29,343
Income from operations	10,306	7,480
Non-operating expense, net	(5,192)	(1,675)
Income before income taxes	5,114	5,805
Income tax provision	1,155	2,280
Net income	\$ 3,959	\$ 3,525
Net loss attributable to non-controlling interests	\$ (1,082)	\$ (424)
Net income attributable to Amphastar	\$ 5,041	\$ 3,949
Net income per share attributable to Amphastar stockholders:		
Basic	\$ 0.11	\$ 0.09
Diluted	\$ 0.10	\$ 0.08
Weighted-average shares used to compute net income per share attributable to Amphastar stockholders:		
Basic	47,520	46,408
Diluted	49,518	48,248

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

	March 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 101,601	\$ 92,642
Restricted cash	235	1,865
Short-term investments	13,531	12,977
Restricted short-term investments	2,200	2,200
Accounts receivable, net	77,938	66,005
Inventories	97,110	96,831
Income tax refunds and deposits	800	385
Prepaid expenses and other assets	6,749	6,777
Total current assets	<u>300,164</u>	<u>279,682</u>
Property, plant, and equipment, net	253,265	260,055
Finance lease right-of-use assets	594	612
Operating lease right-of-use assets	19,280	20,042
Goodwill and intangible assets, net	40,243	40,615
Other assets	7,212	5,250
Deferred tax assets	24,980	24,980
Total assets	<u>\$ 645,738</u>	<u>\$ 631,236</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 108,545	\$ 95,504
Income taxes payable	2,676	1,077
Current portion of long-term debt	12,173	12,263
Current portion of operating lease liabilities	3,702	3,357
Total current liabilities	<u>127,096</u>	<u>112,201</u>
Long-term reserve for income tax liabilities	4,709	4,709
Long-term debt, net of current portion	32,334	34,186
Long-term operating lease liabilities, net of current portion	16,464	17,464
Deferred tax liabilities	755	741
Other long-term liabilities	13,420	13,212
Total liabilities	<u>194,778</u>	<u>182,513</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; 55,184,000 and 47,718,003 shares issued and outstanding as of March 31, 2021 and 54,760,922 and 47,495,439 shares issued and outstanding as of December 31, 2020, respectively	6	5
Additional paid-in capital	413,926	410,061
Retained earnings	122,814	117,773
Accumulated other comprehensive loss	(5,642)	(3,721)
Treasury stock	(125,546)	(121,812)
Total Amphastar Pharmaceuticals, Inc. stockholders' equity	<u>405,558</u>	<u>402,306</u>
Non-controlling interests	45,402	46,417
Total equity	<u>450,960</u>	<u>448,723</u>
Total liabilities and stockholders' equity	<u>\$ 645,738</u>	<u>\$ 631,236</u>

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

	Three Months Ended March 31,	
	2021	2020
GAAP net income	\$ 3,959	\$ 3,525
Adjusted for:		
Intangible amortization	276	258
Share-based compensation	4,834	5,282
Impairment of long-lived assets	6	14
Reserves for litigation and settlements	5,695	—
Income tax (benefit) provision on pre-tax adjustments	(2,229)	(1,004)
Non-GAAP net income	<u>\$ 12,541</u>	<u>\$ 8,075</u>
Non-GAAP net loss attributable to non-controlling interests	\$ (1,012)	\$ (308)
Non-GAAP net income attributable to Amphastar	<u>\$ 13,553</u>	<u>\$ 8,383</u>
Non-GAAP net income per share attributable to Amphastar stockholders:		
Basic	\$ 0.29	\$ 0.18
Diluted	\$ 0.27	\$ 0.17
Weighted-average shares used to compute non-GAAP net income per share attributable to Amphastar stockholders:		
Basic	47,520	46,408
Diluted	49,518	48,248

	Three Months Ended March 31, 2021						
	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Non-operating expense, net	Income tax provision (benefit)	Non-controlling interest adjustment
GAAP	\$ 58,074	\$ 4,537	\$ 15,338	\$ 14,765	\$ 5,192	\$ 1,155	\$ (1,082)
Intangible amortization	(242)	—	(34)	—	—	—	11
Share-based compensation	(1,146)	(127)	(2,968)	(593)	—	—	71
Impairment of long-lived assets	—	—	(6)	—	—	—	2
Reserves for litigation and settlements	—	—	(1,295)	—	(4,400)	—	—
Income tax provision (benefit) on pre-tax adjustments	—	—	—	—	—	2,229	(14)
Non-GAAP	<u>\$ 56,686</u>	<u>\$ 4,410</u>	<u>\$ 11,035</u>	<u>\$ 14,172</u>	<u>\$ 792</u>	<u>\$ 3,384</u>	<u>\$ (1,012)</u>

Three Months Ended March 31, 2020

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Non-operating expense, net	Income tax provision (benefit)	Non-controlling interest adjustment
GAAP	\$ 47,865	\$ 3,294	\$ 10,746	\$ 15,303	\$ 1,675	\$ 2,280	\$ (424)
Intangible amortization	(224)	—	(34)	—	—	—	11
Share-based compensation	(1,359)	(107)	(3,219)	(597)	—	—	127
Impairment of long-lived assets	(10)	—	(4)	—	—	—	1
Income tax provision (benefit) on pre-tax adjustments	—	—	—	—	—	1,004	(23)
Non-GAAP	<u>\$ 46,272</u>	<u>\$ 3,187</u>	<u>\$ 7,489</u>	<u>\$ 14,706</u>	<u>\$ 1,675</u>	<u>\$ 3,284</u>	<u>\$ (308)</u>