
**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): November 7, 2019

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 November 7, 2019, Amphastar Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2019. 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 November 7, 2019, 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: November 7, 2019

Amphastar Pharmaceuticals, Inc.

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

EXHIBIT 99.1

Amphastar Pharmaceuticals Reports Financial Results for the Three Months Ended September 30, 2019

Reports Net Revenues of \$80.1 Million for the Three Months Ended September 30, 2019

RANCHO CUCAMONGA, CA – November 7, 2019 – Amphastar Pharmaceuticals, Inc. (NASDAQ: AMPH) (“Amphastar” or the “Company”) today reported results for the three months ended September 30, 2019.

Third Quarter Highlights

- Net revenues of \$80.1 million for the third quarter
- GAAP net income of \$1.3 million, or \$0.03 per share, for the third quarter
- Adjusted non-GAAP net income of \$5.2 million, or \$0.10 per share, for the third quarter

Dr. Jack Zhang, Amphastar’s Chief Executive Officer, commented: “A significant accomplishment in the third quarter was the successful ramp up of our marketing efforts for Primatene® Mist. We are pleased to announce we started shipping Primatene® Mist to Walmart in October. Meanwhile, our pipeline of both generic and proprietary candidates continues to move ahead. Additionally, we recently had another complex ANDA accepted for filing.”

	<u>Three Months Ended</u>		<u>Nine Months Ended</u>	
	<u>September 30,</u>		<u>September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
	(in thousands, except per share data)			
Net revenues	\$ 80,137	\$ 75,543	\$ 238,974	\$ 204,976
GAAP net income (loss) attributable to Amphastar	\$ 1,310	\$ 2,389	\$ 49,965	\$ (7,605)
Adjusted non-GAAP net income attributable to Amphastar*	\$ 5,169	\$ 5,721	\$ 14,171	\$ 4,168
GAAP diluted EPS attributable to Amphastar shareholders	\$ 0.03	\$ 0.05	\$ 1.00	\$ (0.16)
Adjusted non-GAAP diluted EPS attributable to Amphastar shareholders*	\$ 0.10	\$ 0.12	\$ 0.28	\$ 0.09

* Adjusted non-GAAP net income attributable to Amphastar and Adjusted non-GAAP diluted EPS attributable to Amphastar shareholders 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

	<u>Three Months Ended</u>		<u>Change</u>	
	<u>September 30,</u>		<u>Dollars</u>	<u>%</u>
	<u>2019</u>	<u>2018</u>		
	(in thousands)			
Net revenues:				
Lidocaine	\$ 11,670	\$ 9,875	\$ 1,795	18 %
Phytonadione	10,916	8,968	1,948	22 %
Naloxone	10,613	9,432	1,181	13 %
Enoxaparin	9,573	18,564	(8,991)	(48)%
Medroxyprogesterone	7,879	7,552	327	4 %
Epinephrine	3,756	1,881	1,875	100 %
Primatene® Mist	3,654	—	3,654	N/A
Other finished pharmaceutical products	17,668	15,495	2,173	14 %
Total finished pharmaceutical products net revenues	\$ 75,729	\$ 71,767	\$ 3,962	6 %
API	4,408	3,776	632	17 %

Total net revenues

\$ 80,137 \$ 75,543 \$ 4,594 6%

Changes in net revenues were primarily driven by:

- Lidocaine sales increases due to a higher average selling price, as well as higher unit volumes
- Phytonadione sales increases due to a higher average selling price
- Epinephrine and naloxone sales increases due to higher unit volumes
- Sales of Primatene[®] Mist, which launched in December 2018
- Increases in sales of other finished pharmaceutical products, including atropine, calcium chloride, and dextrose, which were in high demand due to market shortages

	Three Months Ended September 30,		Change	
	2019	2018	Dollars	%
	(in thousands)			
Net revenues	\$ 80,137	\$ 75,543	\$ 4,594	6 %
Cost of revenues	44,885	46,283	(1,398)	(3)%
Gross profit	\$ 35,252	\$ 29,260	\$ 5,992	20 %
<i>as % of net revenues</i>	<i>44%</i>	<i>39%</i>		

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

- Sales of Primatene[®] Mist, which has higher margins
- Increased sales of phytonadione, which has higher margins

	Three Months Ended September 30,		Change	
	2019	2018	Dollars	%
	(in thousands)			
Selling, distribution and marketing	\$ 3,221	\$ 1,963	\$ 1,258	64 %
General and administrative	11,021	13,407	(2,386)	(18)%
Research and development	18,606	11,340	7,266	64 %

- Selling, distribution and marketing expenses increased primarily due to increased marketing expenses related to Primatene[®] Mist, including the cost of a television and radio marketing campaign, which began in July 2019
- General and administrative expenses decreased primarily due to lower legal expenses
- Research and development expenses increased primarily due the development of active pharmaceutical ingredients and key components, and increased clinical trial expenses for our generic product pipeline, primarily for our inhalation abbreviated new drug applications, or ANDAs

Cash flow provided by operating activities for the nine months ended September 30, 2019, was \$36.1 million.

Share Buyback Program

On November 4, 2019, the Company's Board of Directors authorized an increase of \$20 million 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 five ANDAs, filed with the FDA targeting products with a market size of approximately \$1.1 billion, three biosimilar products in development targeting products with a market size of approximately \$13 billion, and 11 generic products in development targeting products with a market size of approximately \$13 billion. This market information is based on IQVIA data for the 12 months ended September 30, 2019. The Company's proprietary pipeline includes a new drug application for intranasal naloxone. The Company is currently developing three other proprietary products, which include injectable and intranasal dosage forms.

Amphastar's Chinese subsidiary, ANP, currently has 14 Drug Master Files, or DMFs, on file with the FDA and is developing four additional DMFs.

Company Information

Amphastar is a specialty 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 Primatene[®], 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 shareholders, which exclude amortization expense, share-based compensation, impairment charges, 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, November 7, 2019, at 2:00 p.m. Pacific Time.

To access the conference call, dial toll-free (877) 881-2595 or (315) 625-3083 for international callers, five minutes before the conference. The passcode for the conference call is 8097493.

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 the Company's expectations regarding future financial performance, backlog, sales and marketing of its products, market size and growth, the timing of FDA filings or approvals, including the DMFs of ANP, the timing of product launches, acquisitions and other matters related to its pipeline of product candidates, its share buyback program and other future events. These statements are not historical facts but rather are based on Amphastar's historical performance and its current expectations, estimates, and projections regarding Amphastar's 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. You can locate these reports through the Company's website at <http://ir.amphastar.com> and on the SEC's website at www.sec.gov. Amphastar undertakes no obligation to revise or update information 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 Amphastar's 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		Nine Months Ended	
	September 30,		September 30,	
	2019	2018	2019	2018
Net revenues	\$ 80,137	\$ 75,543	\$ 238,974	\$ 204,976
Cost of revenues	44,885	46,283	140,432	132,680
Gross profit	35,252	29,260	98,542	72,296
Operating expenses:				
Selling, distribution, and marketing	3,221	1,963	9,354	5,560
General and administrative	11,021	13,407	39,774	36,074
Research and development	18,606	11,340	49,209	40,830
Total operating expenses	32,848	26,710	98,337	82,464
Income (loss) from operations	2,404	2,550	205	(10,168)
Non-operating (expense) income, net	(822)	24	58,837	(347)
Income (loss) before income taxes	1,582	2,574	59,042	(10,515)
Income tax provision (benefit)	598	958	13,292	(2,137)
Net income (loss)	<u>\$ 984</u>	<u>\$ 1,616</u>	<u>\$ 45,750</u>	<u>\$ (8,378)</u>
Net loss attributable to non-controlling interests	\$ (326)	\$ (773)	\$ (4,215)	\$ (773)
Net income (loss) attributable to Amphastar	<u>\$ 1,310</u>	<u>\$ 2,389</u>	<u>\$ 49,965</u>	<u>\$ (7,605)</u>
Net income (loss) per share attributable to Amphastar shareholders:				
Basic	\$ 0.03	\$ 0.05	\$ 1.06	\$ (0.16)
Diluted	\$ 0.03	\$ 0.05	\$ 1.00	\$ (0.16)
Weighted-average shares used to compute net income (loss) per share attributable to Amphastar shareholders:				
Basic	47,239	46,241	47,030	46,437
Diluted	50,075	48,281	50,128	46,437

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

	September 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 85,611	\$ 86,337
Restricted cash	1,865	1,865
Short-term investments	12,666	2,831
Restricted short-term investments	2,290	2,290
Accounts receivable, net	45,255	52,163
Inventories	109,854	69,322
Income tax refunds and deposits	890	49
Prepaid expenses and other assets	10,472	5,485
Total current assets	<u>268,903</u>	<u>220,342</u>
Property, plant, and equipment, net	222,158	210,418
Finance lease right-of-use assets	896	—
Operating lease right-of-use assets	19,463	—
Goodwill and intangible assets, net	41,139	42,267
Other assets	12,331	9,918
Deferred tax assets	20,746	30,618
Total assets	<u>\$ 585,636</u>	<u>\$ 513,563</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 75,137	\$ 87,418
Income taxes payable	1,400	1,187
Current portion of long-term debt	6,969	18,229
Current portion of operating lease liabilities	3,090	—
Total current liabilities	<u>86,596</u>	<u>106,834</u>
Long-term reserve for income tax liabilities	415	415
Long-term debt, net of current portion	38,079	31,984
Long-term operating lease liabilities, net of current portion	16,940	—
Deferred tax liabilities	976	1,031
Other long-term liabilities	8,977	8,940
Total liabilities	<u>151,983</u>	<u>149,204</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; 52,399,044 and 47,199,907 shares issued and outstanding as of September 30, 2019 and 51,438,675 and 46,631,118 shares issued and outstanding as of December 31, 2018, respectively	5	5
Additional paid-in capital	361,705	344,434
Retained earnings	117,396	67,485
Accumulated other comprehensive loss	(5,848)	(4,013)
Treasury stock	(83,853)	(75,476)
Total Amphastar Pharmaceuticals, Inc. stockholders' equity	<u>389,405</u>	<u>332,435</u>
Non-controlling interests	44,248	31,924
Total equity	<u>433,653</u>	<u>364,359</u>
Total liabilities and stockholders' equity	<u>\$ 585,636</u>	<u>\$ 513,563</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
GAAP net income (loss)	\$ 984	\$ 1,616	\$ 45,750	\$ (8,378)
Adjusted for:				
Intangible amortization	251	271	777	1,722
Share-based compensation	4,294	3,908	13,000	12,770
Impairment of long-lived assets	11	10	194	390
Gain on litigation settlement	—	—	(59,900)	—
Income tax provision (benefit) on pre-tax adjustments	(598)	(788)	10,422	(3,040)
Non-GAAP net income (loss)	<u>\$ 4,942</u>	<u>\$ 5,017</u>	<u>\$ 10,243</u>	<u>\$ 3,464</u>
Non-GAAP net loss attributable to non-controlling interests	\$ (227)	\$ (704)	\$ (3,928)	\$ (704)
Non-GAAP net income attributable to Amphastar	<u>\$ 5,169</u>	<u>\$ 5,721</u>	<u>\$ 14,171</u>	<u>\$ 4,168</u>
Non-GAAP net income per share attributable to Amphastar shareholders:				
Basic	\$ 0.11	\$ 0.12	\$ 0.30	\$ 0.09
Diluted	\$ 0.10	\$ 0.12	\$ 0.28	\$ 0.09
Weighted-average shares used to compute non-GAAP net income per share attributable to Amphastar shareholders:				
Basic	47,239	46,241	47,030	46,437
Diluted	50,075	48,281	50,128	48,713

Three Months Ended September 30, 2019

	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Non- operating income (expense), net	Income tax provision (benefit)	Non- controlling interest adjustment
GAAP	\$ 44,885	\$ 3,221	\$ 11,021	\$ 18,606	\$ (822)	\$ 598	\$ (326)
Intangible amortization	(216)	—	(35)	—	—	—	12
Share-based compensation	(701)	(96)	(3,138)	(359)	—	—	107
Impairment of long-lived assets	(4)	—	(11)	4	—	—	6
Gain on litigation settlement	—	—	—	—	—	—	—
Income tax provision (benefit) on pre-tax adjustments	—	—	—	—	—	598	(26)
Non-GAAP	<u>\$ 43,964</u>	<u>\$ 3,125</u>	<u>\$ 7,837</u>	<u>\$ 18,251</u>	<u>\$ (822)</u>	<u>\$ 1,196</u>	<u>\$ (227)</u>

Reconciliation of Non-GAAP Measures (continued)

Three Months Ended September 30, 2018							
	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Non-operating income (expense), net	Income tax provision (benefit)	Non-controlling interest adjustment
GAAP	\$ 46,283	\$ 1,963	\$ 13,407	\$ 11,340	\$ 24	\$ 958	\$ (773)
Intangible amortization	(230)	—	(41)	—	—	—	11
Share-based compensation	(884)	(86)	(2,615)	(323)	—	—	68
Impairment of long-lived assets	—	—	—	(10)	—	—	1
Income tax provision (benefit) on pre-tax adjustments	—	—	—	—	—	788	(11)
Non-GAAP	\$ 45,169	\$ 1,877	\$ 10,751	\$ 11,007	\$ 24	\$ 1,746	\$ (704)

Nine Months Ended September 30, 2019							
	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Non-operating income (expense), net	Income tax provision (benefit)	Non-controlling interest adjustment
GAAP	\$140,432	\$ 9,354	\$ 39,774	\$ 49,209	\$ 58,837	\$ 13,292	\$ (4,215)
Intangible amortization	(669)	—	(108)	—	—	—	34
Share-based compensation	(2,939)	(285)	(8,577)	(1,199)	—	—	257
Impairment of long-lived assets	(69)	—	(23)	(102)	—	—	55
Gain on litigation settlement	—	—	—	—	(59,900)	—	—
Income tax provision (benefit) on pre-tax adjustments	—	—	—	—	—	(10,422)	(59)
Non-GAAP	\$136,755	\$ 9,069	\$ 31,066	\$ 47,908	\$ (1,063)	\$ 2,870	\$ (3,928)

Nine Months Ended September 30, 2018							
	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Non-operating income (expense), net	Income tax provision (benefit)	Non-controlling interest adjustment
GAAP	\$132,680	\$ 5,560	\$ 36,074	\$ 40,830	\$ (347)	\$ (2,137)	\$ (773)
Intangible amortization	(1,602)	—	(120)	—	—	—	11
Share-based compensation	(3,025)	(297)	(8,251)	(1,197)	—	—	68
Impairment of long-lived assets	(77)	—	(4)	(309)	—	—	1
Income tax provision (benefit) on pre-tax adjustments	—	—	—	—	—	3,040	(11)
Non-GAAP	\$127,976	\$ 5,263	\$ 27,699	\$ 39,324	\$ (347)	\$ 903	\$ (704)