

AMPHASTAR PHARMACEUTICALS, INC.

FORM 8-K (Current report filing)

Filed 08/09/17 for the Period Ending 08/09/17

Address	11570 SIXTH STREET RANCHO CUCAMONGA, CA 91730
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**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 9, 2017

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))

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 9, 2017, Amphastar Pharmaceuticals, Inc. issued a press release announcing its financial results for the three months ended June 30, 2017. 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 9, 2017, 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: August 9, 2017

Amphastar Pharmaceuticals, Inc.

By: /s/ WILLIAM J. PETERS

William J. Peters

Chief Financial Officer and Senior Vice President

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated August 9, 2017, issued by Amphastar Pharmaceuticals, Inc.

Amphastar Pharmaceuticals Reports Financial Results for the Three Months Ended June 30, 2017

Reports Net Revenues of \$65.2 Million for the Three Months Ended June 30, 2017

RANCHO CUCAMONGA, CA – August 9, 2017 – Amphastar Pharmaceuticals, Inc. (NASDAQ: AMPH) (“Amphastar” or the “Company”) today reported results for the three months ended June 30, 2017.

Second Quarter Highlights

- Net revenues of \$65.2 million for the second quarter
- GAAP net income of \$2.0 million, or \$0.04 per diluted share, for the second quarter
- Adjusted non-GAAP net income of \$5.4 million, or \$0.11 per diluted share, for the second quarter

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(in thousands, except per share data)			
Net revenues	\$ 65,187	\$ 68,033	\$ 121,857	\$ 127,399
GAAP net income	\$ 1,972	\$ 6,895	\$ 2,865	\$ 9,384
Adjusted non-GAAP net income*	\$ 5,430	\$ 10,347	\$ 9,905	\$ 15,906
GAAP diluted EPS	\$ 0.04	\$ 0.15	\$ 0.06	\$ 0.21
Adjusted non-GAAP diluted EPS *	\$ 0.11	\$ 0.23	\$ 0.21	\$ 0.35

* 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 II of this press release.

Second Quarter Results

For the three months ended June 30, 2017, the Company reported net revenues of \$65.2 million, a decrease of 4% compared to \$68.0 million for the three months ended June 30, 2016.

For the three months ended June 30, 2017, net revenues of enoxaparin were \$8.3 million, representing a decrease of 52% compared to \$17.3 million for the three months ended June 30, 2016. Of the decrease, \$7.1 million was due to lower unit volumes, while the remainder was due to lower pricing.

Other finished pharmaceutical product revenues were \$55.5 million for the three months ended June 30, 2017, representing an increase of 19% compared to \$46.4 million for the three months ended June 30, 2016. This was primarily due to an increase in sales of epinephrine to \$10.6 million from \$5.2 million resulting from increases in both average selling price and unit volumes. The FDA requested that the Company discontinue the manufacturing and distribution of its epinephrine injection, USP vial product, which had been marketed under the “grandfather” exception to the FDA’s “Prescription Drug Wrap-Up” program. The Company discontinued selling this product in the second quarter of 2017. Net revenues from this product were \$9.9 million for the three months ended June 30, 2017.

For the three months ended June 30, 2017, sales of lidocaine increased to \$9.3 million from \$8.2 million for the three months ended June 30, 2016, and sales of phytonadione increased to \$10.0 million from \$8.8 million for the three months ended June 30, 2016, both of which were primarily due to an increase in unit volumes. These increases were partially offset by a decrease in sales of naloxone to \$10.3 million for the three months ended June 30, 2017 from \$15.6 million for the three months ended June 30, 2016, primarily as a result of a decrease in unit volumes as well as a lower average selling price.

Sales of the Company's insulin active pharmaceutical ingredient, or API, products were \$1.4 million for the three months ended June 30, 2017, compared to \$4.3 million for the three months ended June 30, 2016, as the Company did not ship any API to MannKind in the second quarter of 2017.

Cost of revenues were \$38.4 million, or 59% of revenues, and \$36.3 million, or 53% of revenues, for the three months ended June 30, 2017 and 2016, respectively, representing an increase of \$2.1 million. Cost of revenues in the second quarter of 2017 included a charge of \$4.7 million to adjust certain inventory items to their net realizable value, including \$2.9 million for enoxaparin inventory.

Selling, distribution, and marketing expenses were \$1.6 million and \$1.3 million for the three months ended June 30, 2017 and 2016, respectively. For the three months ended June 30, 2017, general and administrative expenses increased to \$12.2 million from \$9.5 million for the three months ended June 30, 2016, primarily due to an increase in legal fees, in preparation for the Company's patent trial in July 2017.

For the three months ended June 30, 2017, research and development expenses increased by 1% to \$10.7 million from \$10.5 million for the three months ended June 30, 2016. Expenditures on clinical trials and materials related to our pipeline products increased, which were partially offset by a decrease in FDA fees pertaining to the NDA filing of our intranasal naloxone product candidate that was submitted in the second quarter of 2016.

The Company recorded an income tax expense of \$1.2 million for the three months ended June 30, 2017, compared to an income tax expense of \$2.9 million for the three months ended June 30, 2016.

The Company recognized net income of \$2.0 million, or \$0.04 per fully diluted share, for the three months ended June 30, 2017, compared to a net income of \$6.9 million, or \$0.15 per fully diluted share, for the three months ended June 30, 2016. The Company's adjusted non-GAAP quarterly net income was \$5.4 million, or \$0.11 per fully diluted share, for the three months ended June 30, 2017, compared to an adjusted non-GAAP net income of \$10.3 million, or \$0.23 per fully diluted share, for the three months ended June 30, 2016. Please see the discussion in the section entitled "Non-GAAP Financial Measures" and the reconciliation of GAAP to non-GAAP measures in Table II of this press release.

The Company's cash and cash equivalents, short-term investments, and unrestricted short-term investments were \$87.4 million as of June 30, 2017. Cash flow provided by operating activities for the six months ended June 30, 2017, was \$27.0 million.

Share buyback program

On August 7, 2017, the Company's Board of Directors authorized an increase of \$20.0 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.

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 six abbreviated new drug applications, or ANDAs, filed with the FDA targeting products with a market size of over \$1.1 billion, three biosimilar products in development targeting products with a market size of \$15.0 billion, and 11 generic products in development targeting products with a market

size of over \$12.0 billion. This market information is based on IMS Health data for the 12 months ended June 30, 2017. The Company's proprietary pipeline includes NDAs for Primatene[®] Mist and intranasal naloxone. The Company is currently developing four other proprietary products, which include injectable, inhalation and intranasal dosage forms.

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 is available at the Company's website at www.amphastar.com.

Amphastar's logo and other trademarks or service marks of Amphastar Pharmaceuticals, Inc., including, but not limited to Primatene[®], Amphadase[®] and Cortrosyn[®], are the property of Amphastar Pharmaceuticals, Inc.

Non-GAAP Financial Measures

To supplement its consolidated financial statements, which are prepared and presented in accordance with U.S. generally accepted accounting principles, or 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, that exclude amortization expense, share-based compensation, and impairment charges 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 9, 2017, 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 62348267.

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, acquisitions and other matters related to its pipeline of product

candidates, the timing for completion of construction at the Company's IMS facility, 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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net revenues	\$ 65,187	\$ 68,033	\$ 121,857	\$ 127,399
Cost of revenues	38,440	36,319	72,282	70,783
Gross profit	<u>26,747</u>	<u>31,714</u>	<u>49,575</u>	<u>56,616</u>
Operating (income) expenses:				
Selling, distribution, and marketing	1,596	1,332	3,075	2,684
General and administrative	12,234	9,458	23,572	20,328
Research and development	10,732	10,594	21,982	19,199
Gain on sale of intangible assets	—	—	(2,643)	—
Total operating expenses	<u>24,562</u>	<u>21,384</u>	<u>45,986</u>	<u>42,211</u>
Income from operations	2,185	10,330	3,589	14,405
Non-operating income (expense), net	<u>988</u>	<u>(578)</u>	<u>1,088</u>	<u>(837)</u>
Income before income taxes	3,173	9,752	4,677	13,568
Income tax expense	1,201	2,857	1,812	4,184
Net income	<u>\$ 1,972</u>	<u>\$ 6,895</u>	<u>\$ 2,865</u>	<u>\$ 9,384</u>
Net income per share:				
Basic	\$ 0.04	\$ 0.15	\$ 0.06	\$ 0.21
Diluted	\$ 0.04	\$ 0.15	\$ 0.06	\$ 0.21
Weighted-average shares used to compute net income per share:				
Basic	46,025	44,957	46,047	44,999
Diluted	47,866	45,968	47,962	45,712

Table II
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,	
	2017	2016	2017	2016
GAAP net income	\$ 1,972	\$ 6,895	\$ 2,865	\$ 9,384
Adjusted for:				
Intangible amortization	705	570	1,426	1,050
Share-based compensation	4,298	4,198	8,749	8,049
Impairment of long-lived assets	—	114	—	331
Income tax expense on pre-tax adjustments	(1,545)	(1,430)	(3,135)	(2,908)
Non-GAAP net income	<u>\$ 5,430</u>	<u>\$ 10,347</u>	<u>\$ 9,905</u>	<u>\$ 15,906</u>
Non-GAAP net income per share:				
Basic	\$ 0.12	\$ 0.23	\$ 0.22	\$ 0.35
Diluted	\$ 0.11	\$ 0.23	\$ 0.21	\$ 0.35
Weighted-average shares used to compute non-GAAP net income per share:				
Basic	46,025	44,957	46,047	44,999
Diluted	47,866	45,968	47,962	45,712

	Three Months Ended June 30, 2017				
	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Income tax expense (benefit)
GAAP	\$ 38,440	\$ 1,596	\$ 12,234	\$ 10,732	\$ 1,201
Intangible amortization	(669)	—	(36)	—	—
Share-based compensation	(897)	(65)	(2,985)	(351)	—
Income tax expense on pre-tax adjustments	—	—	—	—	1,545
Non-GAAP	<u>\$ 36,874</u>	<u>\$ 1,531</u>	<u>\$ 9,213</u>	<u>\$ 10,381</u>	<u>\$ 2,746</u>

	Three Months Ended June 30, 2016				
	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Income tax expense (benefit)
GAAP	\$ 36,319	\$ 1,332	\$ 9,458	\$ 10,594	\$ 2,857
Intangible amortization	(535)	—	(35)	—	—
Share-based compensation	(771)	(65)	(3,100)	(262)	—
Impairment of long-lived assets	—	—	—	(114)	—
Income tax expense on pre-tax adjustments	—	—	—	—	1,430
Non-GAAP	<u>\$ 35,013</u>	<u>\$ 1,267</u>	<u>\$ 6,323</u>	<u>\$ 10,218</u>	<u>\$ 4,287</u>

Reconciliation of Non-GAAP Measures (continued)

	Six Months Ended June 30, 2017				
	Cost of	Selling,	General	Research	Income
	revenue	distribution	and	and	tax expense
		and	administrative	development	(benefit)
		marketing			
GAAP	\$ 72,282	\$ 3,075	\$ 23,572	\$ 21,982	\$ 1,812
Intangible amortization	(1,354)	—	(72)	—	—
Share-based compensation	(2,028)	(149)	(5,768)	(804)	—
Income tax expense on pre-tax adjustments	—	—	—	—	3,135
Non-GAAP	<u>\$ 68,900</u>	<u>\$ 2,926</u>	<u>\$ 17,732</u>	<u>\$ 21,178</u>	<u>\$ 4,947</u>

	Six Months Ended June 30, 2016				
	Cost of	Selling,	General	Research	Income
	revenue	distribution	and	and	tax expense
		and	administrative	development	(benefit)
		marketing			
GAAP	\$ 70,783	\$ 2,684	\$ 20,328	\$ 19,199	\$ 4,184
Intangible amortization	(981)	—	(69)	—	—
Share-based compensation	(1,570)	(131)	(5,746)	(602)	—
Impairment of long-lived assets	—	—	—	(331)	—
Income tax expense on pre-tax adjustments	—	—	—	—	2,908
Non-GAAP	<u>\$ 68,232</u>	<u>\$ 2,553</u>	<u>\$ 14,513</u>	<u>\$ 18,266</u>	<u>\$ 7,092</u>