

**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 3, 2014**

ANI PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-31812

(Commission File Number)

58-2301143

(I.R.S. Employer
Identification Number)

210 Main Street West

Baudette, Minnesota

(Address of principal executive offices)

56623

(Zip Code)

Registrant's telephone number, including area code: **(218) 634-3500**

(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))
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Item 2.02 Results of Operations and Financial Condition.

On November 3, 2014, ANI Pharmaceuticals, Inc. (“ANI”) issued a press release announcing its financial and operating results for the three and nine months ended September 30, 2014. A copy of the press release is furnished as Exhibit 99.1 to this report.

In accordance with General Instruction B.2. of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be “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, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>No.</u>	<u>Description</u>
99.1	Press release, dated November 3, 2014, issued by ANI

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.

ANI PHARMACEUTICALS, INC.

By: /s/ Charlotte C. Arnold

Charlotte C. Arnold

Vice President and Chief Financial Officer

Dated: November 3, 2014

ANI Pharmaceuticals Reports Record Third Quarter 2014 Financial Results and Year-To-Date Highlights

- Record net revenues of \$17.4 million, an increase of 122% over third quarter 2013
- Record adjusted non-GAAP EBITDA of \$10.1 million
- Record adjusted non-GAAP diluted earnings per share of \$0.66

BAUDETTE, Minn., Nov. 3, 2014 /PRNewswire/ -- ANI Pharmaceuticals, Inc. ("ANI") (NASDAQ: ANIP) today reported financial results for the three and nine months ended September 30, 2014 and increased its revenue and non-GAAP EBITDA guidance for the fourth quarter of 2014.

Third quarter net revenues were \$17.4 million, an increase of 122% as compared to \$7.8 million for the same period in 2013. Third quarter adjusted non-GAAP EBITDA was \$10.1 million, an increase of 494% as compared to \$1.7 million in the same period in 2013. Third quarter operating income was \$8.2 million, an increase of 912% as compared to \$0.8 million in the same period in 2013. Third quarter adjusted non-GAAP diluted earnings per share was \$0.66. Third quarter diluted earnings per share was \$0.59, an increase of 354% as compared to \$0.13 in the same period in 2013. Also during the quarter, ANI acquired two mature brands, Lithobid[®] and Vancocin[®], for a combined \$23 million.

Arthur S. Przybyl, President and CEO, stated,

"ANI had a record third quarter across all major metrics of revenue, EBITDA, operating income, and earnings per share. Our third quarter financial results were the direct result of continued organic revenue growth, combined with the revenues from Lithobid and Vancocin, products we acquired in the third quarter. Third quarter results include two months of revenue from Vancocin and its authorized generic. We expect to launch Vancocin under our own label in the fourth quarter. We continue to advance our internal generic product development efforts while selectively pursuing acquisitions and partnerships for late stage ANDA products and mature brands."

ANI's Guidance for the Fourth Quarter of 2014

ANI's guidance for the fourth quarter of 2014 is based on management's current estimates of the Company's market share for its products, product pricing, cost of sales, and operating costs.

- Net revenues estimated to be between \$17 million and \$18 million.
- Adjusted non-GAAP EBITDA, excluding non-cash stock compensation expense, estimated to be between \$9.75 million and \$10.25 million.
- Adjusted non-GAAP earnings per share, excluding non-cash stock compensation expense, estimated to be between \$0.60 and \$0.65 per share, assuming 11,318,014 shares outstanding.
- An estimated effective tax rate of 18%.

The guidance above does not take into account additional product launches during the fourth quarter of 2014. ANI will provide initial 2015 guidance in conjunction with the announcement of its fourth quarter and year-end financial results.

Year-to-Date Highlights Include:

- Year-to-date net revenues of \$34.9 million, an increase of 79% as compared to \$19.6 million for the same period in 2013.
- Year-to-date adjusted non-GAAP EBITDA of \$14.5 million, an increase of 306% as compared to \$3.6 million for the same period in 2013.
- Year-to-date operating income of \$9.2 million, an increase of \$11.8 million as compared to an operating loss of \$2.6 million for the same period in 2013.
- Acquired Vancocin[®] NDA and related ANDAs from Shire on August 1, 2014.
- Acquired Lithobid[®] NDA from Noven Therapeutics on July 1, 2014.
- Acquired ANDAs for 31 generic products from Teva Pharmaceuticals.
- Filed an ANDA with the FDA for an anti-cancer drug, which was granted an expedited review.
- Entered into a collaborative arrangement for a second generic drug product with Sofgen Pharmaceuticals.
- Entered into a collaborative arrangement for a generic drug product with Dexcel Pharma Technologies Ltd.
- Entered into two development agreements for generic drugs with Sterling Pharmaceutical Services.
- Completed a follow-on public offering of common stock yielding net proceeds of \$46.7 million.

Net revenues and Adjusted Non-GAAP EBITDA (in thousands)

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Net revenues	\$ 17,387	\$ 7,836	\$ 34,933	\$ 19,550
Adjusted Non-GAAP EBITDA ^(a)	\$ 10,078	\$ 1,696	\$ 14,549	\$ 3,582

^(a) See Table 2 for US GAAP reconciliation.

Third Quarter Results

For the three months ended September 30, 2014, ANI reported net revenues of \$17.4 million, an increase of 122% from \$7.8 million in the prior year period. The increase in revenues was due to a 135% increase in net prescription sales from \$6.4 million to \$15.0 million, primarily as a result of sales of ANI's newly acquired products, Lithobid and Vancocin, as well as price increases for the Company's existing products. Contract sales, development services, and royalty revenues increased from \$1.5 million to \$2.4 million, primarily due to royalties received on sales of the authorized generic of Vancocin.

Adjusted non-GAAP EBITDA was \$10.1 million for the three months ended September 30, 2014, compared to \$1.7 million in the prior year period, an increase of 494%. For a reconciliation of adjusted non-GAAP EBITDA to GAAP operating income, please see Table 2.

Cost of sales decreased as a percentage of net revenues to 18% from 35%, primarily due to higher margin sales of the newly acquired Lithobid and Vancocin branded products, as well as price increases for the Company's existing products.

Research and development costs were \$0.9 million and \$0.5 million for the three months ended September 30, 2014 and 2013, respectively. The increase was due to work on new development projects, including the Teva products and the collaborations with Sterling and Sofgen.

Selling, general and administrative expenses increased to \$4.1 million for the three months ended September 30, 2014, from \$3.5 million in the prior year period. The increase was primarily due to \$692 thousand in non-cash stock-based compensation expense recognized during the quarter.

Operating income was \$8.2 million for the three months ended September 30, 2014, as compared to \$0.8 million in the prior year period. The third quarter 2013 operating income included \$0.5 million of merger-related expenses.

Net income was \$6.7 million for the three months ended September 30, 2014, as compared to \$1.2 million in the prior year period. Diluted earnings per share for the three months ended September 30, 2014 was \$0.59, based on 11,302,319 diluted shares outstanding, as compared with earnings per share of \$0.13 in the prior year period.

Adjusted non-GAAP diluted earnings per share, excluding non-cash stock compensation expense, was \$0.66. For a reconciliation of adjusted non-GAAP diluted earnings per share to GAAP net income, please see Table 3.

Results for Nine Months Ended September 30, 2014

For the nine months ended September 30, 2014, ANI reported net revenues of \$34.9 million, an increase of 79% from \$19.5 million in the prior year period. The increase in revenues was due to a 111% increase in net prescription sales from \$13.8 million to \$29.2 million, primarily as a result of increased existing product sales, as well as sales of ANI's newly acquired products, Lithobid and Vancocin. Contract sales, development services, and royalty revenues were \$5.7 million, consistent with the prior year period. Royalties received on sales of the authorized generic of Vancocin fully offset decreased contract manufacturing revenue during the quarter.

Adjusted non-GAAP EBITDA was \$14.5 million for the nine months ended September 30, 2014, as compared to \$3.6 million in the prior year period, an increase of 306%. For a reconciliation of adjusted non-GAAP EBITDA to GAAP operating income, please see Table 2.

Cost of sales decreased as a percentage of net revenues to 22% from 37%, primarily due to price increases for the Company's existing products, as well as higher margin sales of the newly acquired Lithobid and Vancocin branded products.

Research and development costs were \$2.1 million and \$1.2 million for the nine months ended September 30, 2014 and 2013, respectively. The increase was due to work on new development projects, including the Teva products, the new collaborations with Sterling and Sofgen, and a filing fee for an ANDA submission of an anti-cancer drug.

Selling, general and administrative expenses increased to \$13.2 million for the nine months ended September 30, 2014 from \$13.0 million in the prior year period. The slight increase was due to increases in personnel and consulting, legal, and other fees related to becoming a public company, as well as \$2.7 million of non-cash stock compensation expense, of which \$1.3 million was a catch-up charge recognized upon shareholder approval of an increase in shares available for issuance under ANI's stock compensation plan. These increases were partially offset by the lack of \$5.5 million of merger-related expenses incurred in the first nine months of 2013.

Operating income was \$9.2 million for the nine months ended September 30, 2014, as compared to a \$2.6 million operating loss in the prior year period. The year-to-date 2013 operating loss included \$5.5 million of merger-related expenses.

Net income was \$7.7 million for the nine months ended September 30, 2014, as compared to a \$3.1 million loss in the prior year period. Diluted earnings per share for the nine months ended September 30, 2014 was \$0.70, based on 10,865,142 diluted shares outstanding and an effective tax rate of 17%.

Selected Balance Sheet Data *(in thousands)*

	September 30, 2014	December 31, 2013
Cash	\$ 35,050	\$ 11,105

Accounts Receivable	\$	14,570	\$	12,513
Inventory	\$	7,346	\$	3,518
Current Assets	\$	57,565	\$	27,716
Current Liabilities	\$	8,145	\$	3,538

ANI generated \$4.2 million and \$11.3 million of positive cash flows from operations in the third quarter and in the first nine months of 2014, respectively. As a result of these cash flows from operations and a follow-on public offering completed during the first quarter, net of \$34.6 million of payments for product acquisitions, ANI had \$35.1 million of cash at September 30, 2014. Accounts receivable increased from \$12.5 million to \$14.6 million. ANI's inventory increased from \$3.5 million to \$7.3 million as a direct result of raw materials acquired for key products, and inventories related to Lithobid and Vancocin. ANI's total current assets increased by \$29.9 million to \$57.6 million at September 30, 2014, from \$27.7 million at December 31, 2013.

Total shares issued and outstanding at September 30, 2014 were 11,318,014.

ANI Product Development Pipeline

<u>Products</u>	<u>ANI</u>	<u>Partnered</u>	<u>Total</u>
At FDA	6	3	9
Development	4	5	9
Teva Products	31	0	31

ANI's product development pipeline includes extended-release products, narcotics, anti-cancers, oral solutions, suspensions and solid dosage forms. These forty-nine generic products address a total annual market size of approximately \$2.7 billion, based on data from IMS Health.

Non-GAAP Financial Measures

Adjusted Non-GAAP EBITDA

ANI's management considers adjusted non-GAAP EBITDA to be an important financial indicator of ANI's operating performance, providing investors and analysts with a useful measure of operation results unaffected by non-cash stock-based compensation, merger-related expenses, and differences in capital structures, tax structures, capital investment cycles, ages of related assets and compensation structures among otherwise comparable companies. Management uses adjusted non-GAAP EBITDA when analyzing Company performance.

Adjusted non-GAAP EBITDA is defined as operating income/(loss), excluding depreciation, amortization, stock-based compensation expense, and merger-related operating expenses. Adjusted non-GAAP EBITDA should be considered in addition to, but not in lieu of, net income or loss reported under GAAP. A reconciliation of adjusted non-GAAP EBITDA to the most directly comparable GAAP financial measure is provided in Table 2.

Adjusted non-GAAP Diluted Earnings per Share

ANI's management considers adjusted non-GAAP diluted earnings per share to be an important financial indicator of ANI's operating performance, providing investors and analysts with a useful measure of operation results unaffected by non-cash stock-based compensation. Management uses adjusted non-GAAP diluted earnings per share when analyzing Company performance.

Adjusted non-GAAP diluted earnings per share is defined as net income/(loss), excluding stock-based compensation expense, divided by the diluted weighted average shares outstanding during the period. Adjusted non-GAAP diluted earnings per share should be considered in addition to, but not in lieu of, earnings or loss per share reported under GAAP. A reconciliation of adjusted non-GAAP diluted earnings per share to the most directly comparable GAAP financial measure is provided in Table 3.

About ANI

ANI Pharmaceuticals, Inc. (the "Company" or "ANI") is an integrated specialty pharmaceutical company developing, manufacturing, and marketing branded and generic prescription pharmaceuticals. The Company's targeted areas of product development currently include narcotics, oncolytics (anti-cancers), hormones and steroids, and complex formulations involving extended release and combination products. For more information, please visit our website www.anipharmaceuticals.com.

Forward-Looking Statements

To the extent any statements made in this release deal with information that is not historical, these are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about price increases, the Company's future operations, products financial position, operating results and prospects, the Company's pipeline or potential markets therefor, and other statements that are not historical in nature, particularly those that utilize terminology such as "anticipates," "will," "expects," "plans," "potential," "future," "believes," "intends," "continue," other words of similar meaning, derivations of such words and the use of future dates.

Uncertainties and risks may cause the Company's actual results to be materially different than those expressed in or implied by such forward-looking statements. Uncertainties and risks include, but are not limited to, the risk that the Company may face with respect to importing raw materials; increased competition; delays or failure in obtaining product approval from the U.S. Food and Drug Administration; general business and economic conditions; market trends; products development; regulatory and other approvals and marketing.

More detailed information on these and additional factors that could affect the Company's actual results are described in the Company's filings with the Securities and Exchange Commission, including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as its proxy statement. All forward-looking statements in this news release speak only as of the date of this news release and are based on the Company's current beliefs, assumptions, and expectations. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

For more information about ANI, please contact:

Investor Relations

(218) 634-3608

IR@anipharma.com

ANI Pharmaceuticals, Inc. and Subsidiary
Table 1: US GAAP Income Statement
(unaudited, in thousands, except per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Net Revenues	\$ 17,387	\$ 7,836	\$ 34,933	\$ 19,550
Operating Expenses				
Cost of sales (excl. depreciation and amortization)	3,061	2,710	7,800	7,290
Research and development	883	454	2,110	1,188
Selling, general and administrative	4,057	3,480	13,193	12,961
Depreciation and amortization	1,187	382	2,596	673
Total Operating Expenses	9,188	7,026	25,699	22,112
Operating (Loss)/Income	8,199	810	9,234	(2,562)
Other Income/(Expense)				
Interest income/(expense)	10	-	13	(467)
Other expense	82	148	72	(336)
(Loss)/Income Before Income Tax Benefit/(Provision)	8,291	958	9,319	(3,365)
Income tax benefit/(provision)	(1,545)	83	(1,577)	83
Net Income/(Loss) from Continuing Operations	6,746	1,041	7,742	(3,282)
Gain on discontinued operation, net of provision (benefit) for income taxes	-	150	0	150
Net Income/(Loss)	6,746	1,191	7,742	(3,132)
Basic Earnings (Loss) Per Share				
Continuing Operations	\$ 0.59	\$ 0.11	\$ 0.71	\$ (2.31)
Discontinued Operations	-	0.02	-	0.04
Basic Earnings/(Loss) Per Share	\$ 0.59	\$ 0.13	\$ 0.71	\$ (2.27)
Basic Weighted-Average Shares Outstanding	11,235	9,480	10,824	3,577
Diluted Earnings (Loss) Per Share				
Continuing Operations	\$ 0.59	\$ 0.11	\$ 0.70	\$ (2.31)
Discontinued Operations	-	0.02	-	0.04
Diluted Earnings/(Loss) Per Share	\$ 0.59	\$ 0.13	\$ 0.70	\$ (2.27)
Diluted Weighted-Average Shares Outstanding	11,302	9,480	10,865	3,577

ANI Pharmaceuticals, Inc. and Subsidiary
Table 2: Adjusted non-GAAP EBITDA Calculation and US GAAP to Non-GAAP Reconciliation
(unaudited, in thousands)

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Operating (Loss)/Income	\$8,199	\$810	\$9,234	(\$2,562)
Add back				
Depreciation and amortization	1,187	382	2,596	673

Add back				
Stock-based compensation	692	3	2,719	3
Merger-related expenses, not already added back	<u>-</u>	<u>501</u>	<u>-</u>	<u>5,468</u>
Adjusted EBITDA	\$10,078	\$1,696	\$14,549	\$3,582

ANI Pharmaceuticals, Inc. and Subsidiary
Table 3: Adjusted non-GAAP Diluted Earnings Per Share Reconciliation
(unaudited, in thousands, except per share amounts)

	<u>Three months ended September 30, 2014</u>
Net Income	6,746
Add back	
Stock-based compensation	<u>692</u>
Adjusted Net Income Used in Calculating Adjusted non-GAAP Diluted Earnings Per Share	\$ 7,438
Diluted Weighted-Average Shares Outstanding	11,302
Adjusted non-GAAP Diluted Earnings Per Share	<u>\$ 0.66</u>