
**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 4, 2016**

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 August 4, 2016, ANI Pharmaceuticals, Inc. (“ANI”) issued a press release announcing its financial and operating results for the three and six months ended June 30, 2016. 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

No.	Description
99.1	Press release, dated August 4, 2016, 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/ Stephen P. Carey
Stephen P. Carey
Vice President and Chief Financial Officer

Dated: August 4, 2016

ANI Pharmaceuticals Reports Record Second Quarter Results and Increases Full-year 2016 Guidance

For the second quarter 2016:

- Record net revenues of \$31.3 million, an increase of 61% as compared to the same period in 2015
- GAAP net income of \$1.1 million and diluted GAAP earnings per share of \$0.10
- Adjusted non-GAAP EBITDA of \$15.4 million
- Adjusted non-GAAP net income per diluted share of \$1.11

BAUDETTE, Minn., Aug. 4, 2016 /PRNewswire/ -- ANI Pharmaceuticals, Inc. ("ANI") (NASDAQ: ANIP) today reported financial results for the three and six months ended June 30, 2016, and increased its financial guidance for 2016. The Company will host its earnings conference call this morning, August 4, 2016, at 10:30 AM ET. Investors and other interested parties can join the call by dialing (866) 776-8875. The conference ID is 47510730.

Financial Summary

(in thousands, except per share data)

	<u>Q2 2016</u>	<u>Q2 2015</u>	<u>YTD 2016</u>	<u>YTD 2015</u>
Net revenues	\$31,337	\$19,516	\$51,892	\$38,315
Net income	\$ 1,125	\$ 3,571	\$ 2,471	\$ 7,940
GAAP earnings per diluted share	\$ 0.10	\$ 0.31	\$ 0.21	\$ 0.68
Adjusted non-GAAP EBITDA^(a)	\$15,445	\$10,858	\$26,825	\$22,320
Adjusted non-GAAP net income per diluted share^(b)	\$ 1.11	\$ 0.68	\$ 1.87	\$ 1.40

(a) See Table 2 for US GAAP reconciliation.

(b) See Table 3 for US GAAP reconciliation.

Arthur S. Przybyl, President and CEO, stated,

"ANI had a record second quarter, with revenues, adjusted non-GAAP EBITDA, and adjusted non-GAAP net income per diluted share increasing 61%, 42%, and 63%, respectively, as a result of seven product launches.

In July, we received FDA approval for and immediately launched our generic anti-cancer product, Nilutamide. We look forward to launching our anti-infective product in the third quarter and continue to guide to approximately \$20 million of combined annualized EBITDA from these two important products."

ANI Increases Full Year 2016 Guidance

ANI's estimates are based on projected results for the twelve months ending December 31, 2016 and reflect management's current beliefs about product pricing, prescription trends, inventory levels, cost of sales, operating costs, and the anticipated timing of future product launches and events.

- Net revenues for 2016 to be between \$119 million and \$134 million.
- Reported (US GAAP) diluted EPS to be between \$0.60 and \$0.85, assuming 11,514 thousand weighted average shares outstanding.
- Adjusted non-GAAP EBITDA to be between \$58 million and \$66 million.
- Adjusted non-GAAP net income per diluted share to be between \$4.00 and \$4.25.

Second Quarter Results

Net Revenues (in thousands)	Three Months Ended June 30,		Change	% Change
	<u>2016</u>	<u>2015</u>		
Generic pharmaceutical products	\$ 22,463	\$ 13,764	\$ 8,669	63%
Branded pharmaceutical products	7,488	2,136	5,352	251%
Contract manufacturing	1,166	1,091	75	7%
Contract services and other income	220	2,525	(2,305)	(91)%
Total net revenues	<u>\$ 31,337</u>	<u>\$ 19,516</u>	<u>\$ 11,821</u>	61%

For the three months ended June 30, 2016, ANI reported net revenues of \$31.3 million, an increase of 61% from \$19.5 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals increased 63%, to \$22.5 million from \$13.8 million in the prior period, primarily due to sales of Propranolol ER and other products launched in Q2 2016, as well as sales of Vancomycin, which was launched in the ANI label in Q4 2015.
- Revenues from sales of branded pharmaceuticals increased 251%, to \$7.5 million from \$2.1 million in the prior period, primarily due to sales of Inderal® LA, which was launched in Q2 2016.
- Contract manufacturing revenue increased by 7% to \$1.2 million from \$1.1 million in the prior year period, primarily as a result of the timing of customer orders.
- Contract services and other income decreased by 91%, to \$0.2 million from \$2.5 million, primarily because sales of Vancomycin in the ANI label have replaced the royalties received on the product previously.

Operating expenses increased to \$26.1 million for the three months ended June 30, 2016, from \$11.1 million in the prior year period. The increase was primarily due to an \$8.7 million increase in cost of sales as compared with the prior period, as a result of increased volume, higher mix of sales of products with profit-sharing arrangements, as well as \$2.1 million of cost of sales related to the inventory step-up on Inderal® LA and Propranolol ER inventory. In addition, depreciation and amortization increased by \$4.5 million as compared with the prior period driven by amortization of a higher intangible asset base. Selling, general, and administrative expenses for the period includes \$1.3 million of principally non-cash expense, representing the entire cost of ANI's CFO transition.

Excluding the \$2.1 million of costs related to the Inderal® LA inventory step-up, cost of sales increased as a percentage of net revenues to 31% from 16%, primarily as a result of increased sales of products with profit-sharing arrangements.

Net income was \$1.1 million for the three months ended June 30, 2016, as compared to net income of \$3.6 million in the prior year period. The effective tax rate for the three months ended June 30, 2016 was 52%, including a 66% rate for current taxes partially offset by a 14% rate benefit for deferred taxes.

Diluted earnings per share for the three months ended June 30, 2016 was \$0.10, based on 11,541 thousand diluted shares outstanding, as compared to diluted earnings per share of \$0.31 in the prior year period. Adjusted non-GAAP net income per diluted share was \$1.11, as compared to adjusted non-GAAP net income per diluted share of \$0.68 in the prior year period. For a reconciliation of adjusted non-GAAP net income per diluted share to the most directly comparable GAAP financial measure, please see Table 3.

Results for Six Months Ended June 30, 2016

Net Revenues (in thousands)	Six Months Ended June 30,		Change	% Change
	2016	2015		
Generic pharmaceutical products	\$ 35,715	\$ 26,021	\$ 9,694	37%
Branded pharmaceutical products	13,084	6,408	6,676	104%
Contract manufacturing	2,550	2,295	255	11%
Contract services and other income	543	3,591	(3,048)	(85)%
Total net revenues	<u>\$ 51,892</u>	<u>\$ 38,315</u>	<u>\$ 13,577</u>	35%

For the six months ended June 30, 2016, ANI reported net revenues of \$51.9 million, an increase of 35% from \$38.3 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals increased 37%, to \$35.7 million from \$26.0 million in the prior period, primarily due to sales of Propranolol ER and other products launched in Q2 2016, as well as sales of Vancomycin, which was launched in the ANI label in Q4 2015.
- Revenues from sales of branded pharmaceuticals more than doubled to \$13.1 million as compared to \$6.4 million in the prior period, primarily due to sales of Inderal® LA, which was launched in Q2 2016.
- Contract manufacturing revenue increased by 11% to \$2.6 million from \$2.3 million in the prior year period, primarily as a result of the timing of customer orders.
- Contract services and other income decreased by 85%, to \$0.5 million from \$3.6 million, primarily because sales of Vancomycin in the ANI label have replaced the royalties received on the product previously, partially offset by royalty income on sales of Fenofibrate, the authorized generic of Lipofen®. ANI received royalties on sales of Fenofibrate during a brief transition period prior to launching under the ANI label.

Operating expenses increased to \$41.0 million for the six months ended June 30, 2016, from \$20.3 million in the prior year period. The increase was primarily due to a \$9.3 million increase in cost of sales as compared with the prior period, as a result of increased volumes, higher mix of sales of products with profit-sharing arrangements, as well as \$2.1 million of cost of sales related to the inventory step-up on Inderal® LA and Propranolol ER inventory. In addition, depreciation and amortization increased by \$7.8 million as compared with the prior period driven by amortization of a higher intangible asset base. Selling, general, and administrative expenses for the period includes \$1.3 million of principally non-cash expense, representing the entire cost of ANI's CFO transition.

Excluding the \$2.1 million of costs related to the Inderal® LA inventory step-up, cost of sales increased as a percentage of net revenues to 25% from 15%, primarily as a result of increased sales of products with profit-sharing arrangements.

Net income was \$2.5 million for the six months ended June 30, 2016, as compared to net income of \$7.9 million in the prior year period. The effective tax rate for the six months ended June 30, 2016 was 53%, including a 61% rate for current taxes partially offset

by an 8% rate benefit for deferred taxes.

Diluted earnings per share for the six months ended June 30, 2016 was \$0.21, based on 11,514 thousand diluted shares outstanding, as compared to diluted earnings per share of \$0.68 in the prior year period. Adjusted non-GAAP net income per diluted share was \$1.87, as compared to adjusted non-GAAP net income per diluted share of \$1.40 in the prior year period. For a reconciliation of adjusted non-GAAP net income per diluted share to the most directly comparable GAAP financial measure, please see Table 3.

Year-to-Date Highlights Include:

- Record year-to-date net revenues of \$51.9 million, an increase of 35% as compared to the same period in 2015.
- Year-to-date net income of \$2.5 million and year-to-date diluted earnings per share of \$0.21, each a decrease of 69% as compared to the same period in 2015.
- Year-to-date adjusted non-GAAP EBITDA of \$26.8 million, an increase of 20% as compared to the same period in 2015.
- Year-to-date adjusted non-GAAP diluted earnings per share of \$1.87, an increase of 34% as compared to the same period in 2015.
- Acquired NDAs for Corticotropin and Corticotropin-Zinc.
- Acquired exclusive rights to distribute an authorized generic of Lipofen® and 1% and 2.5% hydrocortisone rectal cream.
- Acquired the NDA for Inderal® LA.
- Received ANDA approval for Oxycodone capsules and PAS approval for Oxcarbazepine tablets.
- Received ANDA approval for and immediately launched Nilutamide tablets.
- Entered into a distribution and supply agreement with Aspen Global Incorporated to market and distribute Hydroxyprogesterone Caproate Injection in the U.S.

Selected Balance Sheet Data

(in thousands)

	<u>June 30, 2016</u>	<u>December 31, 2015</u>
Cash	\$ 15,014	\$ 154,684
Accounts receivable, net	\$ 35,562	\$ 21,932
Inventory, net	\$ 25,052	\$ 13,387
Current assets	\$ 79,824	\$ 192,583
Current liabilities	\$ 24,730	\$ 11,756

ANI generated \$14.3 million of positive cash flows from operations in the six months ended June 30, 2016. In January 2016, ANI purchased from Merck the NDAs for Corticotropin and Corticotropin-Zinc for \$75.0 million and a percentage of future net sales on products sold under the NDAs. Also in January 2016, ANI purchased from H2-Pharma, LLC the exclusive U.S. distribution rights for two products, as well as an early stage development project for a generic injectable drug product, for \$8.8 million in cash and the assumption of an accrued royalty of \$1.2 million. In April 2016, ANI purchased from Cranford Pharmaceuticals, LLC the rights, title, and interest in the NDA for Inderal® LA, as well as certain documentation, trademark rights, and finished goods for \$60 million in cash and milestone payments based on future gross profits from sales of products under the NDA. ANI also transferred \$5.0 million to an escrow account to secure the future milestone payments. As a result of the net effect of these sources and uses of cash, ANI had \$15.0 million of cash at June 30, 2016.

New Product Introductions

<u>Product</u>	<u>Total Annual Market Size^(c)</u>	<u>Estimated Launch</u>	<u>FDA Approvals Required</u>
Nilutamide	\$23M	Launched July 2016	Approved
Anti-Infective	\$77M	Q3 2016	CBE-30
IDT product	\$11M	Q1 2017	CBE-30
Three additional C-II products (TADs ^(d))	\$39M	Q1 2017	ANDAs

(c) Per IMS Health

(d) FDA's Target Action Date, per FDA communications

ANI Product Development Pipeline

ANI's pipeline consists of 79 products, addressing a total annual market size of \$3.9 billion, based on data from IMS Health. Of these 79 products, 54 were acquired and of these acquired products, ANI expects that 47 can be commercialized based on either CBE-30s or prior approval supplements filed with the FDA.

Non-GAAP Financial Measures

The Company's fiscal 2016 guidance for adjusted non-GAAP EBITDA and adjusted non-GAAP net income per diluted share is not reconciled to the most comparable GAAP measure. This is due to the inherent difficulty of forecasting the timing or amount of items that would be included in a reconciliation to the most directly comparable forward-looking GAAP financial measures. Because a reconciliation is not available without unreasonable effort, it is not included in this release.

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 operating results unaffected by non-cash stock-based compensation 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 net income/(loss), excluding depreciation, amortization, the excess of fair value over cost of acquired inventory, and stock-based compensation expense. 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 Net Income

ANI's management considers adjusted non-GAAP net income to be an important financial indicator of ANI's operating performance, providing investors and analysts with a useful measure of operating results unaffected by non-cash stock-based compensation, non-cash interest expense, depreciation amortization, and deferred tax expenses and benefits. Management uses adjusted non-GAAP net income when analyzing Company performance.

Adjusted non-GAAP net income is defined as net income/(loss), plus tax expense, the excess of fair value over cost of acquired inventory, stock-based compensation expense, non-cash interest expense, depreciation and amortization expense, less the current portion of the tax provision. Adjusted non-GAAP net income should be considered in addition to, but not in lieu of, net income reported under GAAP. A reconciliation of adjusted non-GAAP net income to the most directly comparable GAAP financial measure is provided in Table 3.

Adjusted non-GAAP Net Income per Diluted Share

ANI's management considers adjusted non-GAAP net income per diluted share to be an important financial indicator of ANI's operating performance, providing investors and analysts with a useful measure of operating results unaffected by non-cash stock-based compensation, non-cash interest expense, depreciation, amortization, and deferred tax expenses and benefits. Management uses adjusted non-GAAP net income per diluted share when analyzing Company performance.

Adjusted non-GAAP net income per diluted share is defined as adjusted non-GAAP net income, as defined above, divided by the diluted weighted average shares outstanding during the period. Adjusted non-GAAP net income per diluted 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 net income per diluted 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 controlled substances, oncolytics (anti-cancers), hormones and steroids, and complex formulations involving extended release and combination products. For more information, please visit the Company's 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; acquisitions; contract manufacturing arrangements; delays or failure in obtaining product approvals 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

IR@anipharmaceuticals.com

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Net Revenues	\$31,337	\$19,516	\$51,892	\$38,315
Operating Expenses				
Cost of sales (excl. depreciation and amortization)	11,795	3,141	15,205	5,892
Research and development	764	995	1,730	1,398
Selling, general, and administrative	7,628	5,551	13,532	10,302
Depreciation and amortization	5,956	1,415	10,565	2,742
Total Operating Expenses	26,143	11,102	41,032	20,334
Operating Income	5,194	8,414	10,860	17,981
Other Expense, Net				
Interest expense, net	(2,830)	(2,749)	(5,612)	(5,474)
Other expense/income, net	(12)	-	(10)	68
Income Before Provision for Income Taxes	2,352	5,665	5,238	12,575
Provision for Income Taxes	(1,227)	(2,094)	(2,767)	(4,635)
Net Income	\$ 1,125	\$ 3,571	\$ 2,471	\$ 7,940
Basic Earnings Per Share				
Basic Earnings Per Share	\$ 0.10	\$ 0.31	\$ 0.22	\$ 0.70
Diluted Earnings Per Share	\$ 0.10	\$ 0.31	\$ 0.21	\$ 0.68
Basic Weighted-Average Shares Outstanding	11,402	11,344	11,398	11,335
Diluted Weighted-Average Shares Outstanding	11,541	11,549	11,514	11,556

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Net Income	\$ 1,125	\$ 3,571	\$ 2,471	\$ 7,940
Add back				
Interest expense, net	2,830	2,749	5,612	5,474
Other expense/income, net	12	-	10	(68)
Provision for income taxes	1,227	2,094	2,767	4,635
Depreciation and amortization	5,956	1,415	10,565	2,742
Add back				
Stock-based compensation	2,217	1,029	3,322	1,597
Excess of fair value over cost of acquired inventory	2,078	-	2,078	-
Adjusted non-GAAP EBITDA	\$15,445	\$10,858	\$26,825	\$22,320

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Net Income	\$ 1,125	\$3,571	\$ 2,471	\$ 7,940
Add back				
Tax provision	1,227	2,094	2,767	4,635

Depreciation and amortization expense	5,956	1,415	10,565	2,742
Non-cash interest expense	1,757	1,705	3,482	3,388
Stock-based compensation	2,217	1,029	3,322	1,597
Excess of fair value over cost of acquired inventory	2,078	-	2,078	-
Less				
Current portion of tax provision	<u>(1,563)</u>	<u>(1,937)</u>	<u>(3,183)</u>	<u>(4,175)</u>
Adjusted non-GAAP Net Income	\$12,797	\$7,877	\$21,502	\$16,127
Diluted Weighted-Average				
Shares Outstanding	11,541	11,549	11,514	11,556
Adjusted non-GAAP				
Net Income Per Diluted Share	<u>\$ 1.11</u>	<u>\$ 0.68</u>	<u>\$ 1.87</u>	<u>\$ 1.40</u>