
**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): September 11, 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

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 (see *General Instruction A.2. below*):

- 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 7.01 Regulation FD Disclosure.

On September 11, 2014, ANI Pharmaceuticals, Inc. (the “Company,” “we” or “us”) posted to its website its September 2014 Corporate Presentation. We may use this presentation in our communications or at conferences. The presentation is available on our website, www.anipharmaceuticals.com, and is attached to this Current Report on Form 8-K as Exhibit 99.1 and incorporated into this Item 7.01 by reference.

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.

Forward-Looking Statements

Certain statements contained in the presentation slides furnished with this report contain forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about future operations, products, financial position, operating results, prospects, 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 our 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 we 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 (“FDA”), general business and economic conditions, market trends, product development, regulatory and other approvals and marketing.

More detailed information on these and additional factors that could affect our actual results are described in our filings with the Securities and Exchange Commission, including our most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as our proxy statement/prospectus, filed with the Securities and Exchange Commission on April 11, 2014. The forward-looking statements contained in this document are made only as of the date of this document. We undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.

Exhibit

99.1 ANI Pharmaceuticals, Inc. Corporate Presentation September 2014

SIGNATURES

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.

Date: September 11, 2014

By: /s/ Charlotte C. Arnold
Charlotte C. Arnold
Vice President and Chief Financial Officer

A Specialty Pharmaceutical Company
NASDAQ: ANIP

GENERIC AND BRANDED PRESCRIPTION DRUG PRODUCTS

Corporate Presentation

September 2014

Forward-Looking Statements

To the extent any statements made in this presentation 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 therefore, 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 presentation speak only as of the date of this presentation 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.

ANI Mission Statement

ANI Pharmaceuticals is an integrated specialty pharmaceutical company developing, manufacturing and marketing branded and generic prescription pharmaceuticals.

ANI's mission is to develop, manufacture, and market niche generic pharmaceuticals, focusing on opportunities in pain management (narcotics), anti-cancer (oncolytics), women's health (hormones and steroids), and complex formulations including extended release and combination products.

ANI Overview – Poised for Growth

● ANI Today

- Experienced management team
- Current business
 - For the six months ended June 30, 2014: \$17.5 million total net revenues
 - ❖ \$14.2 million ANI Rx product revenues
 - ❖ \$3.3 million contract manufacturing/services revenues
 - ❖ Organic growth 50% year/year
- Guidance for second half of 2014⁽¹⁾
 - Net revenues of \$28 million to \$30 million
 - Adjusted non-GAAP earnings per share of \$0.90 to \$1.00
- Potential future royalty stream from Teva's testosterone gel
- 50 products in development; total current market \$2.7 billion⁽²⁾
- Two manufacturing facilities: narcotics and potent compounds

(1) August 4, 2014 press release

(2) Based on Company estimates, and recent IMS and NSP Audit data 4

ANI Recent History and Highlights

- 2014 Acquires Vancocin® and related assets from Shire for \$11 million, August 2014
- 2014 Acquires Lithobid® from Noven for \$12 million, July 2014
- 2014 Closes public offering of common shares netting \$46.8 million, March 2014
- 2013 Announces agreement to acquire 31 previously marketed generic products from Teva for \$12.5 million and a percentage of future gross profits, December 2013
- 2013 ANI completes merger with BioSante Pharmaceuticals and obtains NASDAQ Global Market listing (NASDAQ: ANIP), June 2013
- 2011 ANI expands marketed Rx portfolio to seven products through internal development and acquisition
- 2010 Management implements strategy to expand ANI labeled Rx products
- 2009 New executive management team: Art Przybyl, CEO and Charlotte Arnold, CFO

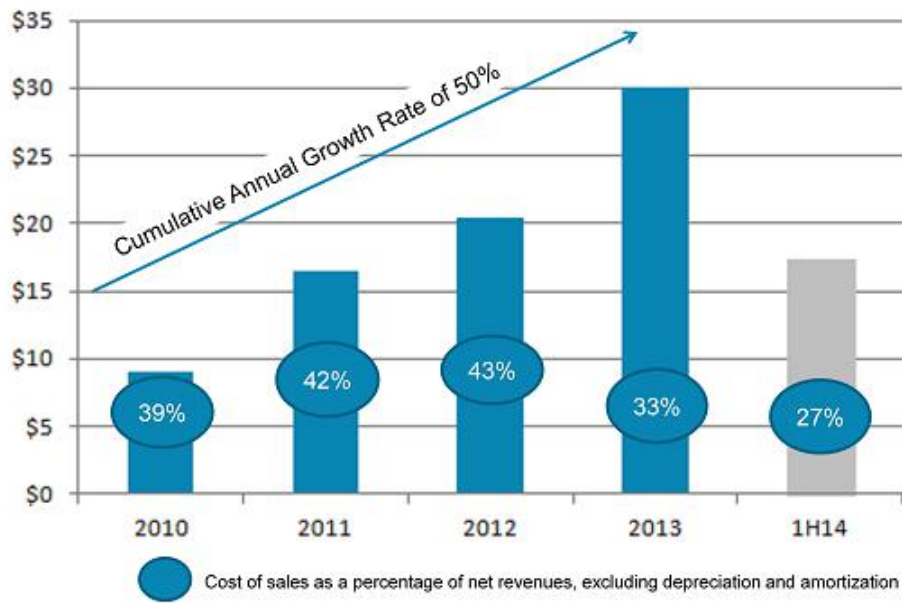


Sales and Marketing / Financial Overview



ANI Historical Revenue Growth

\$s in millions



ANI Current Rx Product Portfolio

<u>Generic Products</u>	<u>Position</u>	<u>Market Share⁽¹⁾</u>
EE/MT Tablets	#1	50%
Fluvoxamine Tablets	#1	55%
HC Enema	#1	85%
Metoclopramide Solution	#2	31%
Opium Tincture	#1	75%

Branded Products

Lithobid® tablets

Vancocin® capsules



Cortenema®

Reglan® tablets



(1) Based on Company estimates, and recent IMS and NSP Audit data 8

ANI Contract Manufacturing Revenues

- Current Business
 - \$3.3 million in contract manufacturing and services revenues during the six-month period ended June 30, 2014
 - Four customers
 - Seven products and fourteen SKUs

- Future Opportunities
 - Potential future royalty: Teva's testosterone gel

ANI Financial Highlights

First Half Results – 2014

(\$ in millions)

	Six months ended		<u>% Growth</u>
	<u>June 30, 2014</u>	<u>June 30, 2013</u>	
Net revenues	\$17.5	\$11.7	50%
Adjusted non-GAAP EBITDA ⁽¹⁾	\$4.5	\$1.9	136%

Second Half Guidance – 2014⁽²⁾

(\$ in millions, except earnings per share)

Net revenues	\$28.0 to \$30.0
Adjusted non-GAAP EBITDA	\$14.0 to \$15.0
Adjusted non-GAAP earnings per share	\$0.90 to \$1.00

(1) Please see page 19 for US GAAP reconciliation

(2) August 4, 2014 press release

Product Development / Business Development Overview



ANI Product Development Pipeline

- Development Pipeline: 50 products in development
 - Ten filed products
 - One ANDA granted expedited review
 - Development collaborations: Ricon, Sofgen, Sterling
 - Total combined current market: \$2.7 billion⁽¹⁾

Products	ANI	Partnered	Total
At FDA	7	3	10
Development	4	5	9
Acquired Products	<u>31</u>	-	<u>31</u>
Totals	42	8	50

(1) Based on Company estimates, and recent IMS and NSP Audit data 12

ANI Business Development Highlights

- Acquired Vancocin® and related assets from Shire, August 2014
- Acquired Lithobid® from Noven, July 2014
- Acquired 31 generic products from Teva, December 2013
- Product development partnership with Sofgen, August 2013; expanded, April 2014
- Acquired royalty arrangement with Teva, June 2013
- Product development partnership with Ricon, June 2011
- Acquired Reglan® tablets, June 2011

Business Development Focus

- In-licensing/acquisitions/alliances for development stage ANDAs, revenue generating products
- Enhancing generic product pipeline through development partnerships
- Company acquisitions



Manufacturing Overview



ANI Manufacturing – Main Street Facility

- Location: Baudette, Minnesota
 - 52,000 square feet of manufacturing, packaging, and warehouse facilities
 - Rx solutions, suspensions, topicals, tablets, and capsules
 - DEA-licensed for Schedule II controlled substances
 - 17,000 square feet of laboratory space for product development and analytical testing



ANI Manufacturing – IDC Road Facility

- Location: Baudette, Minnesota
 - Fully-contained high potency facility with capabilities to manufacture hormone, steroid, and oncolytic products
 - 47,000 square feet of manufacturing and packaging, and warehouse facilities
 - 100 nano-gram per eight-hour weighted average maximum exposure limit to ensure employee safety
 - DEA Schedule IIIN capability



ANI Summary

- ANI is an integrated specialty generic pharmaceutical firm with:
 - Profitable base business generating organic growth
 - Second half 2014 guidance⁽¹⁾
 - ❖ Net revenues of \$28 million to \$30 million
 - ❖ Adjusted non-GAAP EBITDA of \$14 million to \$15 million
 - ❖ Adjusted non-GAAP EPS of \$0.90 to \$1.00
 - Well capitalized balance sheet, no debt
 - Experienced management team
- ANI is focused on:
 - Internal product development
 - Partnerships/strategic alliances
 - Accretive acquisitions

(1) August 4, 2014 press release

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U.S. GAAP Reconciliation

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

	Six months ended June 30,	
	2014	2013
Operating (Loss)/Income	\$1,035	(\$3,372)
Add back		
Depreciation and amortization	1,409	291
Add back		
Stock-based compensation	2,026	-
Merger-related expenses, not already added back	-	4,967
Adjusted EBITDA	<u>\$4,470</u>	<u>\$1,886</u>