
**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 10, 2015

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 November 10, 2015, ANI Pharmaceuticals, Inc. (the “Company,” “we” or “us”) posted to its website its November 2015 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 24, 2015. 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

<u>Exhibit No.</u>	<u>Exhibit</u>
99.1	ANI Pharmaceuticals, Inc. Corporate Presentation November 2015

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: November 10, 2015

By:

/s/ Charlotte C. Arnold

Charlotte C. Arnold

Vice President, Finance and Chief Financial Officer



A Specialty Pharmaceutical Company

NASDAQ: ANIP

GENERIC AND BRANDED PRESCRIPTION DRUG PRODUCTS

Corporate Presentation

November 2015

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.

We focus on niche and high barrier to entry opportunities including controlled substances, anti-cancer (oncolytics), hormones and steroids, and complex formulations.



ANI Overview – Positioned for Growth

● ANI Today

- Current business
 - For the quarter ended September 30, 2015: \$20.0 million total net revenues
 - ❖ \$15.1 million Generic Rx product revenues +48% y/y
 - ❖ \$2.3 million Brand Rx product revenues -53% y/y
 - ❖ \$2.6 million contract manufacturing/services revenues +9% y/y
 - ❖ Growth of 15% quarter/quarter
- Guidance for 2015⁽¹⁾
 - Net revenues of \$75.5 million to \$78.3 million
 - Adjusted non-GAAP EBITDA⁽²⁾ of \$43.3 to \$45.4 million
 - Adjusted non-GAAP net income per diluted share⁽²⁾ of \$2.83 to \$2.96
- 85 products in development; total current market \$4.6 billion⁽³⁾



(1) November 3, 2015 press release

(2) See Appendix A for US GAAP reconciliations

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

ANI History and Highlights

- 2015 Announced agreement to acquire two NDAs for Corticotrophin from Merck for \$75 million and a percentage of future gross profits, September 2015
- 2015 Acquired 22 previously marketed generic products from Teva for \$25 million and a percentage of future gross profits, July 2015
- 2015 Acquired approved NDA for Testosterone Gel from Teva, May 2015
- 2015 Acquired approved ANDA for Flecainide tablets from Teva for \$4.5 million and a percentage of future gross profits, March 2015
- 2014 Closed public offering of \$143.8 million of convertible debt with simultaneous bond hedge and warrant transactions, December 2014
- 2014 Acquired Vancocin® and related assets for \$11 million, August 2014
- 2014 Acquired Lithobid® for \$12 million, July 2014
- 2014 Closed public offering of common shares netting \$46.8 million, March 2014
- 2013 Announced agreement to acquire 31 previously marketed generic products from Teva for \$12.5 million and a percentage of future gross profits, December 2013
- 2013 Completed merger with BioSante Pharmaceuticals and obtains NASDAQ Global Market listing (NASDAQ: ANIP), June 2013

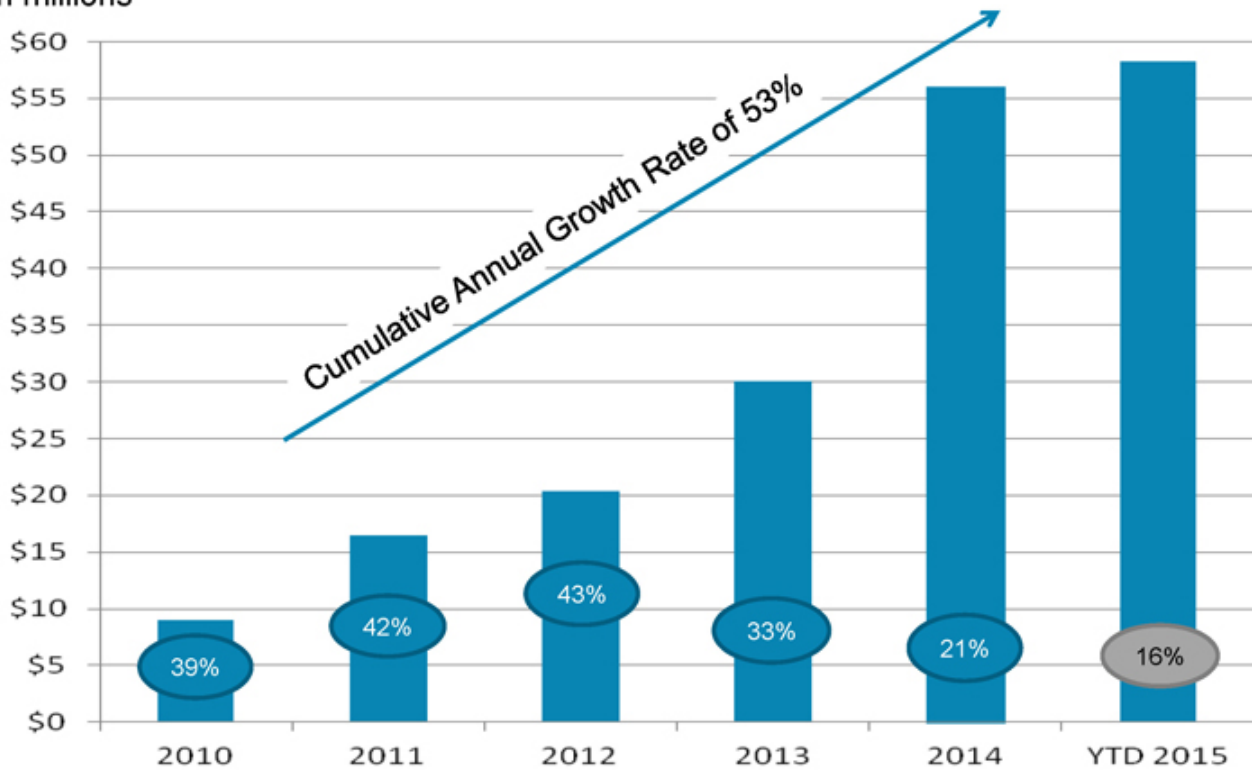


Sales and Marketing Overview



ANI Historical Revenue Growth

\$s in millions



Cost of sales as a percentage of net revenues, excluding depreciation and amortization

ANI Generic Rx Product Portfolio

<u>Generic Products</u>	<u>Market Share⁽¹⁾</u>	<u>Competitors⁽²⁾</u>
EE/MT Tablets	49%	3
Fluvoxamine Tablets	55%	3
HC Enema	80%	2
Metoclopramide Solution	22%	2
Opium Tincture	74%	3
Methazolamide Tablets	40%	3
Etodolac Capsules	19%	3
Propafenone Tablets	3%	4
Oxycodone Solution	Launched 10/15	4
Vancomycin Capsules	Launched 11/15	5

3Q 2015 Net Sales: \$15.1M

(1) Based on Company estimates, and recent IMS and NSP Audit data
(2) Including ANI Pharmaceuticals



ANI Brand Rx Product Portfolio



Lithobid[®] Tablets

Bipolar Disorder



Vancocin[®] Capsules

C. difficile-Associated Diarrhea



Cortenema[®]

Ulcerative Colitis



Reglan[®]

Gastroesophageal Reflux

3Q 2015 Net Sales: \$2.3M

ANI Contract Manufacturing and Other

- Current Business
 - Four customers
 - Seven products and seventeen SKUs
 - Contract manufacturing and contract packaging

3Q 2015 Net Sales: \$2.6M

Business Development / Product Development Overview



Business Development Activity

		DEAL STRUCTURE	DEAL SOURCE	STRATEGY STATEMENT	ANI MANUF	PREVIOUSLY APPROVED	ACQUISITION COST (\$M)
B r a n d s	CORTICOTROPIN (corticotropin)	Acquisition	Public	✓		✓	\$75.0
	TESTOSTERONE GEL (testosterone gel satchets)	Acquisition	Private	✓		✓	\$0.0
	VANCOCIN (vancomycin hydrochloride capsules)	Acquisition	Private	✓		✓	\$11.0
	LITHOBID (lithium carbonate tablets)	Acquisition	Private		✓	✓	\$12.0
G e n e r i c s	NIMODIPINE & GENERIC PRODUCT (Partnership with Sofgen)	FDF Partnership	Private	✓			\$1.1
	GENERIC PRODUCT (Partnership with Dexcel)	FDF Partnership	Private				\$0.1
	IDT PARTNERSHIP (18 previously approved ANDAs)	US Distr Rights	Private	✓	✓	✓	\$1.0
	FLECAINIDE (flecainide tablets)	Acquisition	Private	✓	✓	✓	\$4.5
	TEVA ANDA BASKET 1 (31 previously approved ANDAs)	Acquisition	Public	✓	✓	✓	\$12.5
	TEVA ANDA BASKET 2 (22 previously approved ANDAs)	Acquisition	Public	✓	✓	✓	\$25.0
						Total	\$142.2

ANI Product Development Pipeline

- 85 products in development, total combined current market: \$4.6 billion⁽¹⁾
 - 54 products were acquired and of those, ANI believes 47 can be commercialized based on either a CBE-30 or PAS
 - ANI anticipates launching ten products by the end of 2016:

Product	Total Annual Market Size ⁽¹⁾	Estimated Launch	FDA Approvals Required
Nimodipine capsules (partnered with Sofgen)	\$24M	Q4 2015	Approved
Flecainide tablets	\$79M	Q4 2015	CBE-30
Dexcel product	\$47M	Q2 2016	ANDA
Anti-cancer drug, (TAD ⁽²⁾ 2/26/2016)	Undisclosed	Q1 2016	ANDA
Five ANDAs acquired in July	\$264M	Q4 2016	CBE-30
Testosterone 1% gel	\$370M	Q4 2016	CBE-30

(1) Based on Company estimates, and recent IMS and NSP Audit data
 (2) FDA's Target Action Date, per FDA communications



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
 - 2015 Annual guidance⁽¹⁾
 - ❖ Net revenues of \$75.5 million to \$78.3 million
 - ❖ Adjusted non-GAAP EBITDA of \$43.3 million to \$45.4 million
 - ❖ Adjusted non-GAAP Net Income Per Diluted Share of \$2.83 to \$2.96
 - Well capitalized balance sheet with \$151 million in cash
 - Experienced management team
- ANI is focused on:
 - Partnerships/strategic alliances
 - Accretive acquisitions
 - Internal product development



(1) November 3, 2015 press release

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Appendix A



U.S. GAAP Reconciliations

ANI Pharmaceuticals, Inc. and Subsidiary
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,	
	2015	2014	2015	2014
Operating Income	\$8,451	\$8,199	\$26,432	\$9,234
Add back				
Depreciation and amortization	2,047	1,187	4,789	2,596
Add back				
Stock-based compensation	1,120	692	2,717	2,719
Adjusted non-GAAP EBITDA	<u>\$11,618</u>	<u>\$10,078</u>	<u>\$33,938</u>	<u>\$14,549</u>

U.S. GAAP Reconciliations

ANI Pharmaceuticals, Inc. and Subsidiary

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 September 30, 2015	Nine months ended September 30, 2015
Net Income	\$ 4,559	\$ 12,499
Add back		
Tax provision	1,098	5,733
Depreciation and amortization expense	2,047	4,789
Non-cash interest expense	1,721	5,109
Stock-based compensation	1,120	2,717
Less		
Current portion of tax provision	(1,252)	(5,444)
Adjusted non-GAAP Net Income	\$ 9,293	\$ 25,403
Diluted Weighted-Average Shares Outstanding	11,563	11,559
Adjusted non-GAAP Net Income Per Diluted Share	\$ 0.80	\$ 2.20