

**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): **March 9, 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 7.01 Regulation FD Disclosure.

On March 9, 2016, ANI Pharmaceuticals, Inc. (the "Company," "we" or "us") announced that Arthur S. Przybyl, President and CEO, will present at the 28th Annual ROTH Conference, which presentation will be webcast live at <http://wsw.com/webcast/roth30/anip> at 11:30 AM PT on Monday, March 14, 2016. The live webcast will be archived and available for 90 days, through June 12, 2016.

On March 9, 2016, we posted to our website our March 2016 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 99.2 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 Exhibits 99.1 and 99.2, 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 risks that we may face with respect to importing raw materials, acquisitions, 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

No.	Description
99.1	Press release, dated March 9, 2016, issued by ANI Pharmaceuticals, Inc.
99.2	ANI Pharmaceuticals, Inc. Corporate Presentation, March 2016

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, Finance and Chief Financial Officer

Dated: March 9, 2016

ANI Pharmaceuticals to Present at 28th Annual ROTH Conference

BAUDETTE, Minn., March 9, 2016 /PRNewswire/ -- ANI Pharmaceuticals, Inc. (NASDAQ: ANIP) announced today that it will present at the 28th Annual ROTH Conference at the Ritz-Carlton at Laguna Niguel, California. On March 14, 2016 at 11:30 AM PT Arthur S. Przybyl, President and CEO, will give the Company's presentation, which is posted on the Investor section of ANI's website at www.anipharmaceuticals.com. Mr. Przybyl's presentation will be webcast live at <http://wsw.com/webcast/roth30/anip>, and archived and available through the link through June 12, 2016.

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 risks that the Company may face with respect to importing raw materials; increased competition; acquisitions; 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
IR@anipharmaceuticals.com



A Specialty Pharmaceutical Company

NASDAQ: ANIP

GENERIC AND BRANDED PRESCRIPTION DRUG PRODUCTS

Corporate Presentation

March 2016

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.

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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 year ended December 31, 2015: \$76.3 million total net revenues
 - ❖ \$55.2 million Generic Rx product revenues
 - ❖ \$11.0 million Brand Rx product revenues
 - ❖ \$10.1 million contract manufacturing/services revenues
 - ❖ Growth of 36% year/year
- Guidance for 2016⁽¹⁾
 - Net revenues of \$105 million to \$120 million
 - Adjusted non-GAAP EBITDA⁽²⁾ of \$45 to \$53 million
 - Adjusted non-GAAP net income per diluted share⁽²⁾ of \$2.94 to \$3.31
- 85 products in development; total current market \$4.5 billion⁽³⁾

(1) February 23, 2016 press release

(2) See Appendix A for US GAAP reconciliations

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



ANI Acquisition Highlights

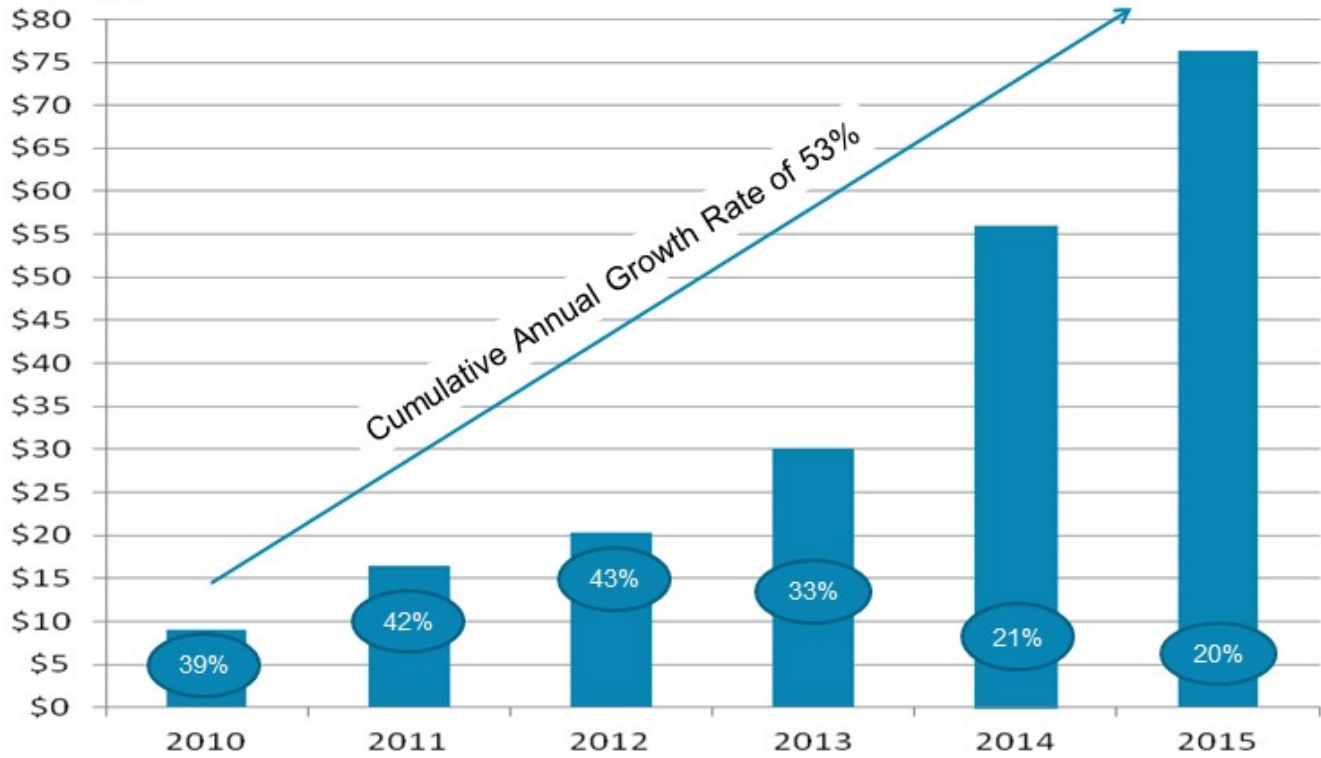
- 2016 Acquired exclusive rights to market three products and an early stage development injectable product from H2-Pharma for \$10 million, January 2016
- 2016 Acquired two NDAs for Corticotrophin from Merck for \$75 million and a percentage of future net sales, January 2016
- 2015 Acquired 22 previously 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 Acquired Vancocin® and related assets for \$11 million, August 2014
- 2014 Acquired Lithobid® for \$12 million, July 2014
- 2014 Acquired 31 previously marketed generic products from Teva for \$12.5 million and a percentage of future gross profits, January 2014
- 2013 Completed merger with BioSante Pharmaceuticals and obtains NASDAQ Global Market listing (NASDAQ: ANIP), June 2013

Sales and Marketing Overview



ANI 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	50%	3
Fluvoxamine Tablets	56%	3
HC Enema	90%	2
Metoclopramide Solution	26%	2
Opium Tincture	70%	3
Methazolamide Tablets	29%	3
Etodolac Capsules	21%	3
Propafenone Tablets	5%	4
Oxycodone Solution	Launched 10/15	4
Vancomycin Capsules	Launched 11/15	6
Nimodipine Capsules	Launched 12/15	3
Flecainide Tablets	Launched 12/15	5

2015 Net Sales: \$55.2M

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

(2) Including ANI



ANI Brand Rx Product Portfolio



Lithobid® Tablets

Bipolar Disorder



Vancocin® Capsules

C. difficile-Associated Diarrhea



Cortenema®

Ulcerative Colitis



Reglan®

Gastroesophageal Reflux

2015 Net Sales: \$11.0M

ANI Contract Manufacturing and Other

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

2015 Net Sales: \$10.1M

Business Development / Product Development Overview



Business Development Activity

		DEAL STRUCTURE	DEAL SOURCE	STRATEGY STATEMENT	ANI MANUFACTURED	PREVIOUSLY APPROVED	ACQUISITION COST (\$M)	
B r a n d s	CORTICOTROPIN (corticotropin)	Acquisition	Public	✓		✓	\$75.0	
	TESTOSTERONE GEL (testosterone gel sachets)	Acquisition	Private	✓		✓	\$0.0	
	VANCOGIN (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	
	DONEPEZIL (Partnership with Dexcel)	FDF Partnership	Private				\$0.1	
	H2-Pharma (Lipofen, AG, 1% & 2.5% HC Cream)	Acquisition US Distribution Rights	Private	✓		✓	\$10.0	
	IDT Partnership (18 previously approved ANDAs)	US Distribution 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

ANI Product Development Pipeline

- 85 products in development, total combined current market: \$4.5 billion⁽¹⁾
 - 57 products were acquired and of those, ANI believes 48 can be commercialized based on either a CBE-30 or PAS
 - ANI anticipates launching 12 products by the end of 2016:

Product	Total Annual Market Size ⁽¹⁾	Estimated Launch	FDA Approvals Required
Hydrocortisone rectal cream, 1% and 2.5%	\$73M	Q2 2016	Approved
Anti-cancer drug, (TAD ⁽²⁾ 6/7/2016)	Undisclosed	Q2 2016	ANDA
Dexcel product	\$44M	Q3 2016	Approved
Anti-infective	\$69M	Q3 2016	CBE-30
Three IDT products	\$97M	Q3 2015	CBE-30s
Four C-II products	\$46M	Q4 2016	ANDAs

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

(2) FDA's Revised TargetAction 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
 - 2016 Annual guidance⁽¹⁾
 - ❖ Net revenues of \$105 million to \$120 million
 - ❖ Adjusted non-GAAP EBITDA of \$45 million to \$53 million
 - ❖ Adjusted non-GAAP Net Income Per Diluted Share of \$2.94 to \$3.31
 - Well capitalized balance sheet with \$75 million in cash
 - Experienced management team
- ANI is focused on:
 - Partnerships/strategic alliances
 - Accretive acquisitions
 - Internal product development



(1) February 23, 2016 press release

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Appendix A



U.S. GAAP Reconciliations

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

	Three months ended December 31,		Year ended December 31,	
	2015	2014	2015	2014
Operating Income	\$6,268	\$10,772	\$32,700	\$20,006
Add back				
Depreciation and amortization	2,111	1,282	6,900	3,878
Add back				
Stock-based compensation	1,139	704	3,856	3,423
Adjusted non-GAAP EBITDA	<u>\$9,518</u>	<u>\$12,758</u>	<u>\$43,456</u>	<u>\$27,307</u>

U.S. GAAP Reconciliations

ANI Pharmaceuticals, Inc. and Subsidiaries
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 December 31,		Year ended December 31,	
	2015	2014	2015	2014
Net Income	\$ 2,876	21,006	\$ 15,375	\$ 28,747
Add back				
Tax provision	625	(10,946)	6,358	(9,368)
Depreciation and amortization expense	2,111	1,282	6,900	3,878
Non-cash interest expense	1,722	560	6,831	560
Stock-based compensation	1,139	704	3,856	3,423
Excess of Fair Value over Cost of Acquired Inventory	-	10	-	29
Less				
Current portion of tax provision	(2,431)	(3,163)	(7,875)	(4,307)
Adjusted non-GAAP Net Income	\$ 6,042	\$ 9,453	\$ 31,445	\$ 22,962
Diluted Weighted-Average Shares Outstanding	11,552	11,476	11,557	11,053
Adjusted non-GAAP Net Income Per Diluted Share	\$ 0.52	\$ 0.82	\$ 2.72	\$ 2.08