
**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): **May 18, 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 May 18, 2016, ANI Pharmaceuticals, Inc. (the "Company," "we" or "us") announced that Arthur S. Przybyl, President and CEO, will present at the UBS Global Healthcare Conference, which presentation will be webcast live at https://cc.talkpoint.com/ubsx001/052316a_ae/?entity=62_R53VV6X at 2:00 PM ET on Monday, May 23, 2016. The live webcast will be archived and available for 90 days, through August 21, 2016.

On May 18, 2016, we posted to our website our May 2016 Corporate Presentation. We may use this presentation in our communications or at conferences. The presentation is available on our website, www.anipharma.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 risk that we may face with respect to importing raw materials, acquisitions, contract manufacturing arrangements, 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 most recent proxy statement/prospectus. 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 May 18, 2016, issued by ANI Pharmaceuticals, Inc.
99.2	ANI Pharmaceuticals, Inc. Corporate Presentation, May 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/ Stephen P. Carey
Stephen P. Carey
Vice President and Chief Financial Officer

Dated: May 18, 2016

ANI Pharmaceuticals to Present at the UBS Global Healthcare Conference

BAUDETTE, Minn., May 18, 2016 /PRNewswire/ -- ANI Pharmaceuticals, Inc. (NASDAQ: ANIP) announced today that it will present on May 23, 2016 at the UBS Global Healthcare Conference at the Grand Hyatt in New York City. On Monday, May 23, 2016 at 2:00 PM ET, 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. The presentation will be webcast live at https://cc.talkpoint.com/ubsx001/052316a_ae/?entity=62_R53VV6X, and will be archived and available through the link through August 21, 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; contract manufacturing arrangements; 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

May 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 Senior Management Team

		<u>At ANI Since</u>	<u>Yrs Industry Experience</u>
Arthur Przybyl	President and CEO	2009	25+
Stephen Carey	VP and CFO	2016	20+
Robert Schrepfer	VP of Bus. Development	2013	15
Jim Marken	VP of Operations	2007	20+
David Sullivan	VP of Quality Operations	2014	20

ANI Overview – Positioned for Growth

● ANI Today

- Current business
 - For the quarter ended March 31, 2016: \$20.6 million total net revenues
 - ❖ \$13.3 million Generic Rx product revenues
 - ❖ \$5.6 million Brand Rx product revenues
 - ❖ \$1.7 million contract manufacturing/services revenues
 - ❖ Growth of 9% quarter/quarter
- Guidance for 2016⁽¹⁾
 - Net revenues of \$119 million to \$134 million
 - Adjusted non-GAAP EBITDA⁽²⁾ of \$55 million to \$63 million
 - Adjusted non-GAAP net income per diluted share⁽²⁾ of \$3.54 to \$3.91
- 81 products in development; total current market \$4.1 billion⁽³⁾

(1) May 5, 2016 press release

(2) See Appendix A for US GAAP reconciliations

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



ANI Financial Highlights

First Quarter 2016 Results

(\$ in millions)

	Quarter ended		% Growth
	<u>March 31, 2016</u>	<u>March 31, 2015</u>	
Net revenues	\$ 20.6	\$ 18.8	9%
Adjusted non-GAAP EBITDA ⁽¹⁾	\$ 11.4	\$ 11.5	-

2015 Results

(\$ in millions)

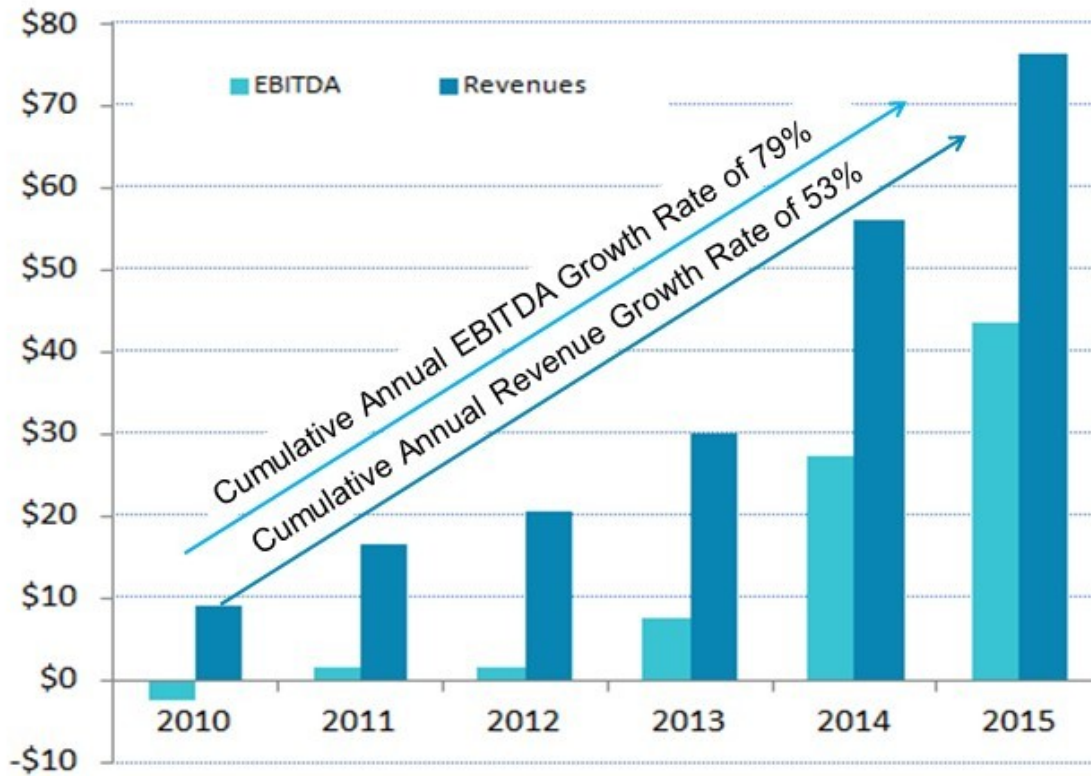
	Year ended		% Growth
	<u>December 31, 2015</u>	<u>December 31, 2014</u>	
Net Revenues	\$ 76.3	\$ 56.0	36%
Adjusted non-GAAP EBITDA ⁽¹⁾	\$ 43.5	\$ 27.3	59%

(1) Please see Appendix A for US GAAP reconciliation



ANI Revenue and EBITDA Historical Growth

\$s in millions



Sales and Marketing Overview



ANI Generic Rx Product Portfolio

Generic Products

16

Q1 2016 Net Sales

\$13.3M

Total IMS Market Value

\$672M

EE/MT Tablets

Etodolac Capsules

Fenofibrate Capsules (AG) → **Launched 2Q 2016**

Flecainide Tablets

Fluvoxamine Tablets (AG)

HC Cream, for rectal use → **Launched 2Q 2016**

HC Enema (AG)

Mesalamine Enema (AG) → **Launched 2Q 2016**

Methazolamide Tablets

Metoclopramide Solution

Nimodipine Capsules

Opium Tincture

Oxycodone Solution

Propafenone Tablets

Propranolol ER Caps (AG) → **Launched 2Q 2016**

Vancomycin Capsules (AG)



(AG) = Authorized Generic

ANI Brand Rx Product Portfolio



Lithobid® Tablets

Bipolar Disorder

Vancocin® Capsules

C. difficile-Associated Diarrhea

Cortenema®

Ulcerative Colitis

Reglan®

Gastroesophageal Reflux

Q1 2016 Net Sales: \$5.6M



Inderal® LA

Hypertension

Launched April 2016

ANI Contract Manufacturing and Other

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

Q1 2016 Net Sales: \$1.7M

Business Development / Product Development Overview



Business Development Activity - Generics

	STRUCTURE	SOURCE	STRATEGY	ANI MANUF	APPROVED	COST (\$M)
HPC Injectable (Partnership with Aspen)	US Distr Rights	Private	✓		✓	\$0.0
Rowasa AG (Partnership with Meda)	US Distr Rights	Private	✓	✓	✓	\$0.0
Lipofen AG & 1% and 2.5% HC Cream	Acquisition of US Distr Rights	Private	✓		✓	\$10.0
IDT Partnership (18 previously approved ANDAs)	US Distr Rights	Private	✓	✓	✓	\$1.0
Nimodipine & Omega (Partnership with Sofgen)	US Distr Rights	Private	✓			\$1.1
Donepezil (Partnership with Dexcel)	US Distr Rights	Private				\$0.1
Flecainide (flecainide tablets)	Acquisition	Private	✓	✓	✓	\$4.5
ANDA Basket 1 (31 previously approved ANDAs)	Acquisition	Public	✓	✓	✓	\$12.5
ANDA Basket 2 (22 previously approved ANDAs)	Acquisition	Public	✓	✓	✓	\$25.0
					Total	\$54.2

Business Development Activity - Brands

	STRUCTURE	SOURCE	STRATEGY	ANI MANUF	APPROVED	COST (\$M)
Inderal LA (propranolol ER capsules)	Acquisition	Private	✓		✓	\$60.0
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
					Total	\$158.0

ANI Product Development Pipeline

- 81 products in development, total combined current market: \$4.1 billion⁽¹⁾
 - 55 products were acquired and of those, ANI believes 48 can be commercialized based on either a CBE-30 or PAS
 - New product introductions:

Product	Total Annual Market Size ⁽¹⁾	Estimated Launch	FDA Status
Oxycodone capsules	\$7.5M	June 2016	Approved
Anti-cancer drug	Undisclosed	June 2016	ANDA
Hydroxyprogesterone Caproate Injection	NA	June 2016	Approved
Donepezil	\$41M	Q3 2016	Approved
Anti-infective	\$78M	Q3 2016	CBE-30
Three IDT products	\$86M	Q3 2016/ Q4 2016	CBE-30s
Three C-II products (TADs ⁽²⁾ 1/2/2017 & 2/15/17)	\$39M	Q1 2017	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 \$119 million to \$134 million
 - ❖ Adjusted non-GAAP EBITDA⁽²⁾ of \$55 million to \$63 million
 - ❖ Adjusted non-GAAP Net Income Per Diluted Share⁽²⁾ of \$3.54 to \$3.91
 - Strong capital position
 - Experienced management team
- ANI is focused on:
 - Partnerships/strategic alliances
 - Accretive acquisitions
 - Internal product development



(1) May 5, 2016 press release

(2) See Appendix A for US GAAP reconciliations

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	
	March 31,	
	2016	2015
Operating Income	\$ 5,666	\$ 9,567
Add back		
Depreciation and amortization	4,609	1,327
Add back		
Stock-based compensation	1,105	568
Adjusted non-GAAP EBITDA	\$ 11,380	\$ 11,462

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 March 31,	
	2016	2015
Net Income	\$ 1,346	4,369
Add back		
Tax provision	1,540	2,541
Depreciation and amortization expense	4,609	1,327
Non-cash interest expense	1,725	1,683
Stock-based compensation	1,105	568
Excess of Fair Value over Cost of Acquired Inventory	-	-
Less		
Current portion of tax provision	(1,620)	(2,238)
Adjusted non-GAAP Net Income	\$ 8,705	\$ 8,250
Diluted Weighted-Average Shares Outstanding	11,489	11,562
Adjusted non-GAAP Net Income Per Diluted Share	\$ 0.76	\$ 0.71

U.S. GAAP Reconciliations

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

	Year ended December 31,	
	2015	2014
Operating Income	\$32,700	\$20,006
Add back		
Depreciation and amortization	6,900	3,878
Add back		
Stock-based compensation	3,856	3,423
Adjusted non-GAAP EBITDA	<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)

	Year ended December 31,	
	2015	2014
Net Income	\$ 15,375	\$ 28,747
Add back		
Tax provision	6,358	(9,368)
Depreciation and amortization expense	6,900	3,878
Non-cash interest expense	6,831	560
Stock-based compensation	3,856	3,423
Excess of Fair Value over Cost of Acquired Inventory	-	29
Less		
Current portion of tax provision	(7,875)	(4,307)
Adjusted non-GAAP Net Income	\$ 31,445	\$ 22,962
Diluted Weighted-Average Shares Outstanding	11,557	11,053
Adjusted non-GAAP Net Income Per Diluted Share	\$ 2.72	\$ 2.08