
**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 11, 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

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))
-
-

Item 7.01 Regulation FD Disclosure.

On August 11, 2016, ANI Pharmaceuticals, Inc. (the “Company,” “we” or “us”) posted to its website its August 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 99.1 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, acquisitions, contract manufacturing arrangements, 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 14, 2016. 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 August 2016

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: August 11, 2016

By: /s/ Stephen P. Carey
Stephen P. Carey
Vice President, Finance and Chief Financial Officer



A Specialty Pharmaceutical Company

NASDAQ: ANIP

GENERIC AND BRANDED PRESCRIPTION DRUG PRODUCTS

Corporate Presentation

August 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.

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 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.

Mission and Strategy

ANI Pharmaceuticals is an integrated specialty pharmaceutical company focused on delivering value to our customers by developing, manufacturing and marketing high quality branded and generic prescription pharmaceuticals.

Our dedicated team of R&D, business development, manufacturing, sales and regulatory compliance personnel focus on niche and high barrier to entry opportunities including controlled substances, anti-cancer (oncolytics), hormones and steroids, and complex formulations.

We manufacture diverse product offerings in two facilities with combined manufacturing, packaging, warehouse and laboratory space totaling 116,000 square feet.

Senior Management Team

		With ANI Since	Yrs Industry Experience
Arthur Przybyl	President and CEO	2009	25+
Steve Carey	VP, Finance and CFO	2016	20+
Robert Schrepfer	SVP, Business Development and Specialty Sales	2013	15
Jim Marken	SVP, Operations and Product Development	2007	20+
David Sullivan	VP, Quality Operations	2014	20
Ellen Camos	VP, Regulatory Affairs	2012	15
Mark Ginski	VP, Corticotropin Product Development	2016	20+

Financial Highlights – 2Q and YTD 2016

(\$ in millions, except per share data)	Three Months Ended		Year to Date	
	June 30,		June 30,	
	2016	2015	2016	2015
Net Revenues	\$ 31.3	\$ 19.5	\$ 51.9	\$ 38.3
Net Income	\$ 1.1	\$ 3.6	\$ 2.5	\$ 7.9
GAAP earnings per diluted share	\$ 0.10	\$ 0.31	\$ 0.21	\$ 0.68
Adjusted non-GAAP EBITDA ⁽¹⁾	\$ 15.4	\$ 10.9	\$ 26.8	\$ 22.3
Adjusted non-GAAP net income per diluted share ⁽¹⁾	\$ 1.11	\$ 0.68	\$ 1.87	\$ 1.40

- Record quarterly results on the strength of seven new product launches:
 - Net revenues up 61% from prior year and 52% from Q1 2016
 - Adjusted non-GAAP EBITDA up 42% from prior year and 36% from Q1 2016

Financial Highlights – 2Q Net Revenues

(\$ in millions)	Three Months Ended		Variance	
	June 30,		to Prior Year	
	2016	2015	\$	%
Generic pharmaceutical products	\$ 22.5	\$ 13.8	\$ 8.7	63%
Brand pharmaceutical products	7.5	2.1	5.4	251%
Contract manufacturing	1.2	1.1	0.1	7%
Contract services and other income	0.2	2.5	(2.3)	-91%
Total net revenues	\$ 31.3	\$ 19.5	\$ 11.8	61%

- Generic sales gains driven by April launches of Propranolol ER and Fenofibrate, as well as Vancomycin
- Brand sales reflect April launch of Inderal® LA
- Contract services previously reflected royalty income on authorized generic of Vancocin®, which is now sold directly by ANI and reflected in Generic sales

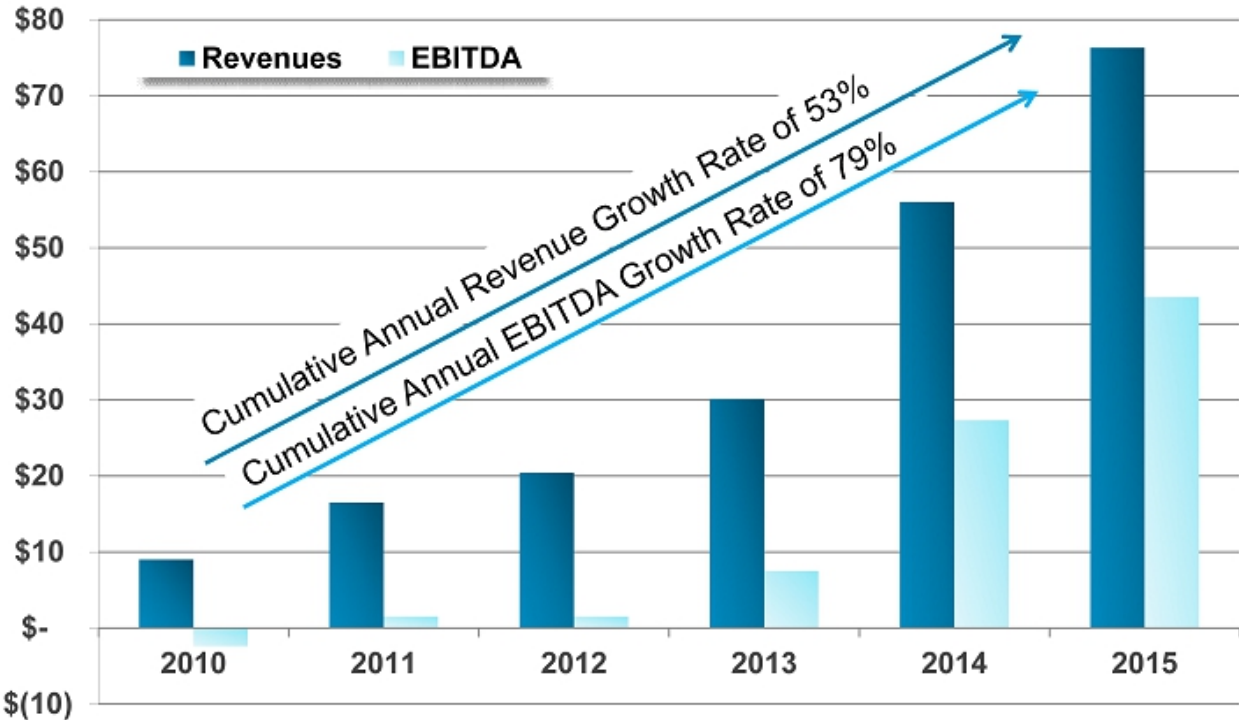
Revised 2016 Guidance

(\$ in millions except EPS figures)	Previous Guidance		Revised Guidance (8/4/2016)	
	Low	High	Low	High
Net Revenues	\$ 119.0	\$ 134.0	\$ 119.0	\$ 134.0
Adjusted non-GAAP EBITDA ⁽¹⁾	\$ 55.0	\$ 63.0	\$ 58.0	\$ 66.0
GAAP Earnings per Diluted Share	\$ 0.30	\$ 0.65	\$ 0.60	\$ 0.85
Adjusted non-GAAP net income per diluted share ⁽¹⁾	\$ 3.54	\$ 3.91	\$ 4.00	\$ 4.25

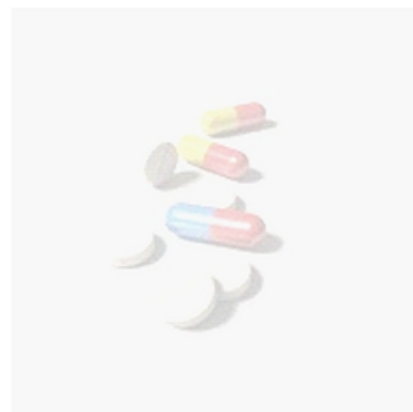
- Second half catalysts include:
 - Continued execution of 2Q product launches
 - July launch of Nilutamide
 - Late-September launch of an anti-infective product

Historical 5-Year Revenue and Adjusted EBITDA Growth

\$s in millions



Sales and Marketing Overview



Generic Rx Product Portfolio

- EE/MT Tablets
- Etodolac Capsules
- Fenofibrate Capsules (AG)
- Flecainide Tablets
- Fluvoxamine Maleate Tablets (AG)
- HC Cream, for rectal use
- HC Enema (AG)
- Hydroxyprogesterone Caproate Injection USP
- Mesalamine Enema (AG)
- Methazolamide Tablets
- Metoclopramide Solution
- Nilutamide Tablets
- Nimodipine Capsules
- Opium Tincture
- Oxycodone Capsules
- Oxycodone Oral Solution
- Propafenone Tablets
- Propranolol ER Capsules (AG)
- Vancomycin Capsules (AG)



- Continued broadening of our product offerings

- Nineteen generic product families
- \$22.5M of Q2 2016 net sales



(AG) = Authorized Generic

Brand Rx Product Portfolio

Inderal® LA
(propranolol hydrochloride)
Long-Acting Capsules

Inderal® LA Capsules

Hypertension



Lithobid® Tablets

Bipolar Disorder



Vancocin® Capsules

C. difficile-Associated Diarrhea



Cortenema®

Ulcerative Colitis



Reglan® Tablets

Gastroesophageal Reflux

● \$13.1 million of Q2 2016 net sales

Contract Manufacturing and Other

- Contract manufacturing
 - \$1.2 million of Q2 2016 net revenues
 - Four customers
 - Seven products and seventeen SKUs
 - Contract manufacturing and contract packaging
- Contract services and other
 - \$0.2 million of Q2 2016 net revenues
 - Product development services, laboratory services, and royalties received

Business Development / Product Development Overview



Business Development Activity - Generics

	STRUCTURE	SOURCE	STRATEGY	ANI MANUF	APPROVED	COST (\$M)
Undisclosed Product (Partnership with Aspen)	US Distr Rights	Private	✓		✓	\$0.0
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
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

Product Development Pipeline

- 79 products in development, total combined current market: \$3.9 billion⁽¹⁾
 - 54 products were acquired and of those, ANI believes 47 can be commercialized based on either a CBE-30 or PAS
 - New product introductions:

Product	Total Annual Market Size ⁽¹⁾	Estimated Launch	FDA Status
Anti-infective	\$77M	Sept 2016	CBE-30
IDT product	\$11M	Q1 2017	CBE-30
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 Target Action Date, per FDA communications

Manufacturing Overview



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



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, packaging, and warehouse facilities
- 100 nano-gram per eight-hour weighted average maximum exposure limit to ensure employee safety
- DEA Schedule IIIN capability



Summary

- ANI is an integrated specialty generic pharmaceutical company 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 \$58 million to \$66 million
 - ❖ Adjusted non-GAAP Net Income Per Diluted Share⁽²⁾ of \$4.00 to \$4.25
 - Strong capital position
 - Experienced management team
- ANI is focused on delivering value through:
 - Partnerships / strategic alliances
 - Accretive acquisitions
 - Internal product development



(1) August 4, 2016 press release

(2) See Appendix A for note regarding 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 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

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 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	(1,563)	(1,937)	(3,183)	(4,175)
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	\$ 1.11	\$ 0.68	\$ 1.87	\$ 1.40



U.S. GAAP Reconciliations

Non-GAAP Financial Measures included in 2016 Guidance

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 presentation.