
**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): June 6, 2017

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

On June 6, 2017, ANI Pharmaceuticals, Inc. (the “Company,” “we” or “us”) posted to its website its June 2017 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 6, 2017. 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 June 2017

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: June 6, 2017

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

June 2017

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

		<u>With ANI Since</u>	<u>Yrs Industry Experience</u>	<u>Previous Affiliation</u>
Arthur Przybyl	President and CEO	2009	25+	Akorn
Stephen Carey	VP, Finance and CFO	2016	20+	Par Pharmaceutical
Robert Schrepfer	SVP, Business Development and Specialty Sales	2013	15	Healthcare Value Capital
James Marken	SVP, Operations and Product Development	2007	20+	Solvay
David Sullivan, PhD	VP, Quality Operations	2014	20	Boston Scientific
Ellen Camos	VP, Regulatory Affairs	2012	15	Sandoz
Mark Ginski, PhD	VP, Corticotropin Product Development	2016	20+	Mallinckrodt
Karen Quinn, PhD	VP, Corticotropin Regulatory Affairs	2017	30+	Takeda Pharmaceuticals

Financial Highlights - 1Q 2017

Three Months Ended March 31,

(\$ in millions, except per share data)

	<u>2017</u>	<u>2016</u>
Net revenues	\$ 36.6	\$ 20.6
Net income	\$ 1.2	\$ 1.3
GAAP earnings per diluted share	\$ 0.10	\$ 0.12
Adjusted non-GAAP EBITDA ⁽¹⁾	\$ 14.7	\$ 11.4
Adjusted non-GAAP diluted earnings per share ⁽¹⁾	\$ 0.74	\$ 0.53

Strong first quarter performance coming off of a record year of results in 2016:

- 27 commercial product families as of March 31, 2017, up from 16 at the beginning of 2016
- Quarterly net revenues increased 78% from prior year
- Quarterly adjusted non-GAAP EBITDA increased 29% from prior year



(1) See Appendix A for US GAAP reconciliations

Financial Highlights - 1Q Net Revenues

(\$ in millions)	Three Months Ended		Variance	
	March 31,		to Prior Year	
	2017	2016	\$	%
Generic pharmaceutical products	\$ 26.6	\$ 13.3	\$ 13.3	101%
Brand pharmaceutical products	8.0	5.6	2.4	44%
Contract manufacturing	1.8	1.4	0.4	30%
Contract services and other income	0.2	0.3	(0.1)	-31%
Total net revenues	\$ 36.6	\$ 20.6	\$ 16.1	78%

- Generic sales gains driven by eight products launched during 2016 (detailed on slide 11)
- Brand sales reflect April 2016 launch of Inderal® LA and the late February 2017 introduction of InnoPran XL® and Inderal® XL
- Contract manufacturing reflects timing and volume of customer orders

2017 Guidance

(\$ in millions except EPS figures)

	2016 <u>Actual</u>	2017 Guidance		% Increase	
		<u>Low</u>	<u>High</u>	<u>Low</u>	<u>High</u>
Net Revenues	\$ 128.6	\$ 181.0	\$ 190.0	41%	48%
Cost of sales as a percentage of revenues (excluding impact of inventory step-up)	33%	42%	44%	n/a	n/a
Sales, general and administrative	27.8	30.2	30.9	8%	11%
Research and development	2.9	6.5	6.8	125%	134%
Adjusted non-GAAP EBITDA ⁽¹⁾	61.1	73.1	77.2	20%	26%
Adjusted non-GAAP diluted earnings per share ⁽¹⁾	\$ 2.96	\$ 3.58	\$ 3.94	21%	33%

Forecast results projected to be driven by:

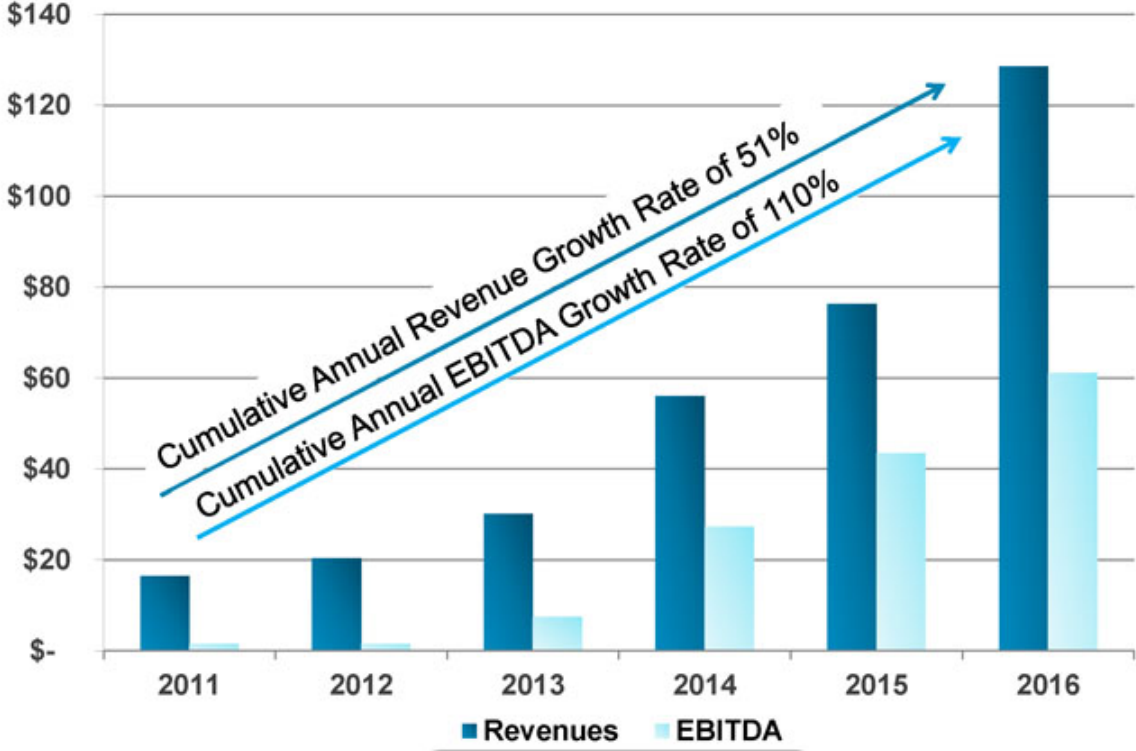
- Annualization and continued operational focus on maximizing 2016 launches
- Expansion of our brand revenues with the addition of InnoPran XL[®] and Inderal[®] XL
- Execution of 2017 generic product launches
- Increasing the investment behind our Corticotropin re-commercialization project



(1) See Appendix A for note regarding US GAAP reconciliations

Historical 5-Year Revenue and Adjusted EBITDA Growth

\$s in millions



Sales and Marketing Overview



Generic Rx Product Portfolio

2016 & 2017 Product Introductions

- Erythromycin Ethylsuccinate
- Fenofibrate Capsules (AG)
- HC Cream, for rectal use
- Indapamide (April 2017)
- Lithium Carbonate ER (AG)
- Mesalamine Enema (AG)
- Nilutamide Tablets
- Oxycodone Capsules
- Pindolol (May 2017)
- Propranolol ER Capsules (AG)



Continued broadening of our product offerings

- Twenty-two generic product families encompassing 44 SKUs
- \$95.2 million of full year 2016 and \$26.6 million of first quarter 2017 generic net sales



(AG) = Authorized Generic

Generic Rx Product Portfolio

Foundational Products (launched prior to 2016)

- EE/MT Tablets
- Etodolac Capsules
- Flecainide Tablets
- Fluvoxamine Maleate Tablets (AG)
- HC Enema (AG)
- Methazolamide Tablets
- Metoclopramide Solution
- Nimodipine Capsules
- Opium Tincture
- Oxycodone Oral Solution
- Propafenone Tablets
- Vancomycin Capsules (AG)



(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

- \$26.4 million of full year 2016 and \$8.0M of first quarter 2017 brand net sales
- Inderal® LA launched April 2016

Brand Rx InnoPran XL[®] and Inderal[®] XL



Once Daily at Bedtime

INDERAL[®] XL

propranolol HCl

EXTENDED RELEASE CAPSULES

Visit www.InderalXL.com



INNOPRAN[®] XL

propranolol HCl $\frac{80 \text{ mg}}{120 \text{ mg}}$

EXTENDED RELEASE CAPSULES

Two additional hypertension brands acquired in first quarter 2017:

- Purchased on February 23, 2017, for approximately \$51 million
- Generated combined sales of \$23.3 million in 2016 according to IMS Health data (gross sales basis)
- Second quarter of 2017 will be first full quarter of sales and gross profit contribution

Contract Manufacturing and Other

- Contract manufacturing
 - \$5.5 million of full year 2016 and \$1.8M of first quarter 2017 net revenues
 - Four customers
 - Seven products and seventeen SKUs
 - Contract manufacturing and contract packaging
- Contract services and other
 - \$1.4 million of full year 2016 and \$0.2M of first quarter 2017 net revenues
 - Product development services, laboratory services, and royalties received

Business and Product Development Overview



Business Development Activity - Generics

		STRUCTURE	SOURCE	STRATEGY	ANI MANUF	APPROVED	COST (\$M)
G e n e r i c s	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	\$54.1

Business Development Activity - Brands

		STRUCTURE	SOURCE	STRATEGY	ANI MANUF	APPROVED	COST (\$M)
B r a n d s	Inderal® XL (propranolol ER capsules)	Acquisition	Private	✓		✓	\$20.0
	InnoPran XL® (propranolol ER capsules)	Acquisition	Private	✓		✓	\$31.0
	Brethine® (terbutaline tablets)	Acquisition	Private	✓	✓	✓	\$0.0
	Inderal® LA (propranolol ER capsules)	Acquisition	Private	✓		✓	\$60.0
	Corticotrophin® (corticotropin injectable)	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	\$209.0

Product Development Pipeline

● ANI Pipeline

- 77 products in development, total combined current market: \$3.8 billion⁽¹⁾
- 53 products were acquired and of those, ANI believes 46 can be commercialized based on either a CBE-30 or PAS

● Corticotropin Re-commercialization Update

- Identified, initiated, and continuing to make substantial progress toward the development of analytical methods required for the sNDA filing
- Accomplishments to date in 2017:
 - successfully manufactured a development lot of API
 - initiated the scale-up of the API manufacturing process and process characterization, which is the next step prior to commercial scale API manufacturing
- Second half 2017 goals:
 - Select finished dose form contract manufacturer
 - Secure and conduct initial regulatory meeting with FDA



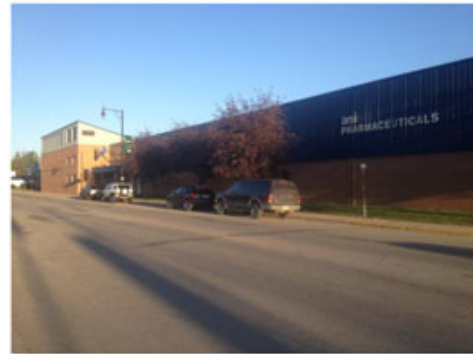
(1) Based on Company estimates, and recent IMS and NSP Audit data

Manufacturing Overview



Manufacturing – Main Street Facility

- Location: Baudette, Minnesota
 - 52,000 sq. ft. 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
 - Expanding the warehouse by 5,500 square feet and adding additional schedule CII vault and CIII cage space
 - 2017 cap ex also includes powder fill line, liquid unit dose filling line, liquid packaging line, machinery and equipment upgrades and serialization capabilities



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 time weighted average maximum exposure limit to ensure employee safety
- DEA Schedule IIIN capability
- Adding a low-humidity suite for processing and encapsulating moisture-sensitive compounds



Summary

- ANI is an integrated specialty generic pharmaceutical company with:
 - Profitable base business generating organic growth
 - Strong capital position
 - Experienced management team
 - US-based manufacturing assets and expertise
 - 2017 Annual guidance⁽¹⁾
 - Net revenues of \$181 million to \$190 million
 - Adjusted non-GAAP EBITDA⁽²⁾ of \$73.1 million to \$77.2 million
 - Adjusted non-GAAP diluted earnings per share⁽²⁾ of \$3.58 to \$3.94
- ANI is focused on delivering value through:
 - Partnerships and strategic alliances
 - Accretive acquisitions
 - Internal product development



(1) March 2, 2017 press release

(2) See Appendix A for note regarding US GAAP reconciliations

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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 March 31,	
	2017	2016
Net Income	\$ 1,152	\$ 1,346
Add back		
Interest expense, net	2,932	2,782
Other income/(expense), net	18	(2)
Provision for income taxes	523	1,540
Depreciation and amortization	6,706	4,609
Add back		
Stock-based compensation	1,386	1,105
Excess of fair value over cost of acquired inventory	1,535	-
Expenses related to transaction not consummated	477	-
Adjusted non-GAAP EBITDA	\$ 14,729	\$ 11,380

U.S. GAAP Reconciliations

ANI Pharmaceuticals, Inc. and Subsidiaries
Adjusted non-GAAP Net Income and Adjusted non-GAAP Diluted Earnings per Share
(unaudited, in thousands, except per share amounts)

	Three Months Ended March 31,	
	2017	2016
Net Income	\$ 1,152	\$ 1,346
Add back		
Non-cash interest expense	1,792	1,725
Depreciation and amortization expense	6,706	4,609
Stock-based compensation	1,386	1,105
Excess of fair value over cost of acquired inventory	1,535	-
Expenses related to transaction not consummated	477	-
Less		
Tax impact of adjustments	(4,402)	(2,752)
Adjusted non-GAAP Net Income	\$ 8,646	\$ 6,033
Diluted Weighted-Average Shares Outstanding	11,653	11,489
Adjusted non-GAAP Diluted Earnings per Share	\$ 0.74	\$ 0.53

U.S. GAAP Reconciliations

Non-GAAP Financial Measures included in 2017 Guidance

The Company's fiscal 2017 guidance for adjusted non-GAAP EBITDA and adjusted non-GAAP diluted earnings per 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.