
**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 8, 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 August 8, 2017, ANI Pharmaceuticals, Inc. (the “Company,” “we” or “us”) posted to its website its August 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, August 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: August 8, 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

August 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.

Experienced Senior Management Team

		<u>With ANI Since</u>	<u>Previous Affiliation</u>
Arthur S Przybyl	President and CEO	2009	Akorn
Stephen Carey	VP, Finance and CFO	2016	Par Pharmaceutical
James Marken	SVP, Operations & Prod. Development	2007	Solvay
Robert Schrepfer	SVP, BD and Specialty Sales	2013	Healthcare Value Capital
David Sullivan, PhD	VP, Quality Operations	2014	Boston Scientific
Ellen Camos	VP, Regulatory Affairs	2012	Sandoz
Mark Ginski, PhD	VP, Corticotropin Development	2016	Mallinckrodt
Karen Quinn, PhD	VP, Corticotropin Regulatory Affairs	2017	Takeda

Building a Stable Base with Diversified Growth

What we do:

- Acquire, develop, manufacture and commercialize GENERIC Rx products
- Acquire, manufacture and commercialize MATURE BRAND Rx products
- Provide high quality CONTRACT MANUFACTURING services to select clients

Our strategy:

- Assemble a portfolio of limited competition / high barrier product opportunities
- Acquire previously approved A/NDA products to minimize development risk
- Control quality and own the manufacturing process when possible

ANI Objective

Create long term shareholder value by building a sustainable and growing base business in Generic and Mature Brand Rx products while advancing a transformational opportunity to re-commercialize Cortrophin® Gel and Cortrophin-Zinc®.

Three Platforms Form Strong Base Business

Generic Rx	<ul style="list-style-type: none">• 23 commercial products• 2Q17 net revenues: \$31.5M (+40% vs. PY; +19% vs.1Q17)• 71 Pipeline products – 40 previously approved and can be re-commercialized via CBE30 or Prior Approval Supplement• Addressable market of pipeline = \$2.1B
Brand Rx	<ul style="list-style-type: none">• 7 commercial products• 2Q17 net revenues: \$11.7M (+56% vs. PY; +45% vs. 1Q17)• 5 Pipeline products – Cortrophin Gel, Cortrophin-Zinc, Vancocin® Oral Solution, Brethine® tablets and Testosterone Gel• Addressable market of pipeline = \$1.6B
CMO	<ul style="list-style-type: none">• 4 customers / 7 products• 2Q17 net revenues: \$1.5M (+31% vs.PY; -15% vs. 1Q17)

Financial Highlights - 2Q and YTD 2017

(\$ in millions, except per share data)	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net revenues	\$ 44.8	\$ 31.3	\$ 81.4	\$ 51.9
Net income	\$ 2.7	\$ 1.1	\$ 3.8	\$ 2.5
GAAP earnings per diluted share	\$ 0.23	\$ 0.10	\$ 0.33	\$ 0.21
Adjusted non-GAAP EBITDA ⁽¹⁾	\$ 19.1	\$ 15.4	\$ 33.8	\$ 26.8
Adjusted non-GAAP diluted earnings per share ⁽¹⁾	\$ 0.98	\$ 0.75	\$ 1.72	\$ 1.28

Posted record quarterly Net Revenue, Adjusted non-GAAP EBITDA and Adjusted non-GAAP EPS

- 30 commercial product families as of June 30, 2017, up from 16 at the beginning of 2016
- Quarterly net revenues increased 43% from prior year
- Quarterly adjusted non-GAAP EBITDA increased 24% from prior year

(1) See Appendix A for US GAAP reconciliations

Financial Highlights - 2Q Net Revenues

(\$ in millions)	Three Months Ended		Variance	
	June 30,		to Prior Year	
	<u>2017</u>	<u>2016</u>	<u>\$</u>	<u>%</u>
Generic pharmaceutical products	\$ 31.5	\$ 22.5	\$ 9.0	40%
Branded pharmaceutical products	11.7	7.5	4.2	56%
Contract manufacturing	1.5	1.2	0.4	31%
Contract services and other income	0.1	0.2	(0.1)	-66%
Total net revenues	<u>\$ 44.8</u>	<u>\$ 31.3</u>	<u>\$ 13.4</u>	<u>43%</u>

- Generic sales gains driven by eight products launched during 2016
- Brand sales gains reflect the late February 2017 introduction of InnoPran XL[®] and Inderal[®] XL
- Contract manufacturing reflects timing and volume of customer orders

Note: Figures may not foot / cross-foot due to rounding.

Financial Highlights - YTD Net Revenues

(\$ in millions)	Six Months Ended		Variance	
	June 30,		to Prior Year	
	2017	2016	\$	%
Generic pharmaceutical products	\$ 58.1	\$ 35.7	\$ 22.3	63%
Branded pharmaceutical products	19.7	13.1	6.6	51%
Contract manufacturing	3.3	2.6	0.8	30%
Contract services and other income	0.3	0.5	(0.2)	-45%
Total net revenues	<u>\$ 81.4</u>	<u>\$ 51.9</u>	<u>\$ 29.5</u>	57%

- Generic sales gains driven by eight products launched during 2016
- Brand sales gains 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

Note: Figures may not foot / cross-foot due to rounding.

2017 Guidance

(\$ in millions except EPS figures)

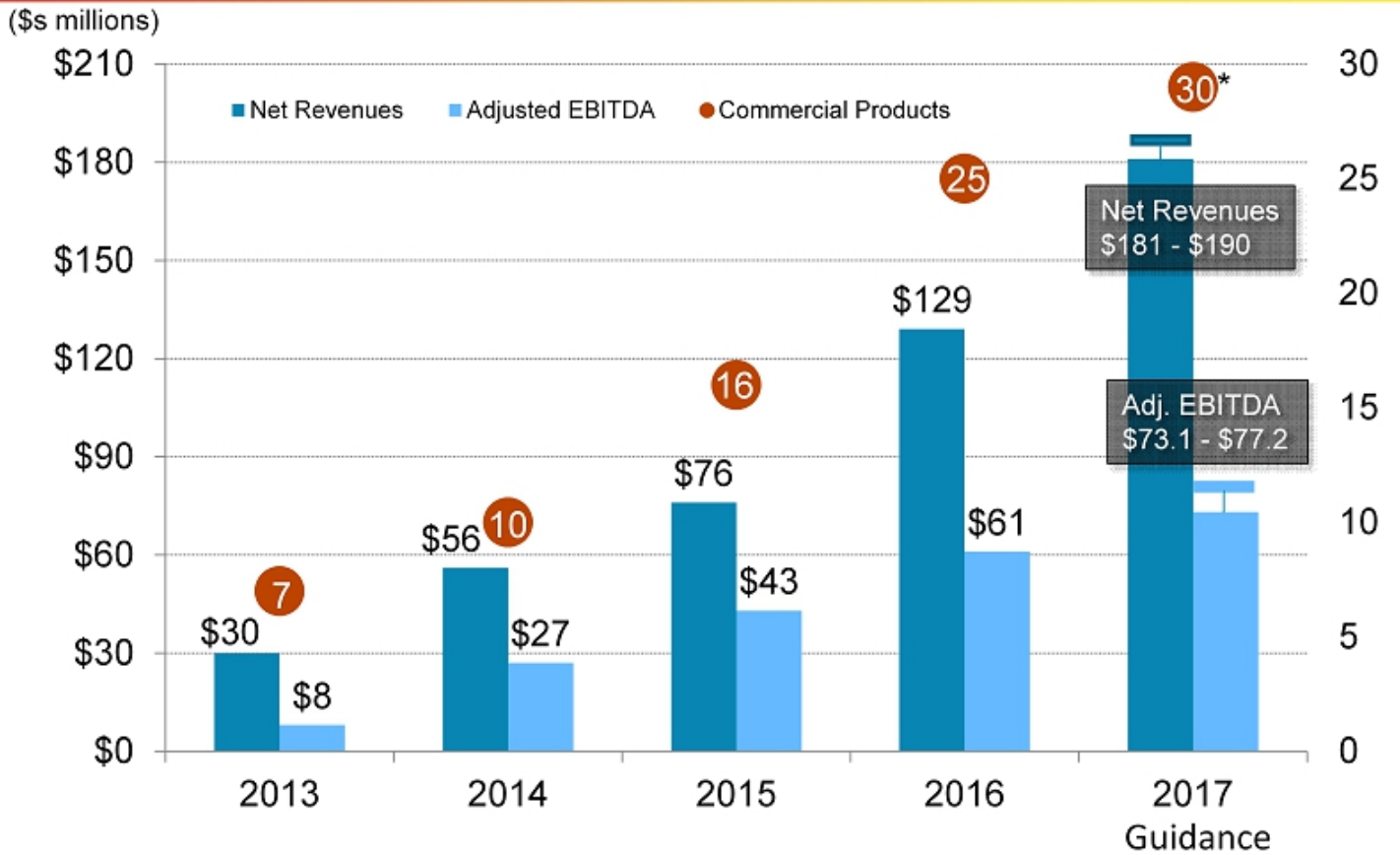
	2016 <u>Actual</u>	2017 Guidance		% Increase	
		<u>Low</u>	<u>High</u>	<u>Low</u>	<u>High</u>
Net Revenues	\$ 128.6	\$ 181.0	\$ 190.0	41%	48%
Cost of sales as a percentage of revenues (excluding impact of inventory step-up)	33%	42%	44%	n/a	n/a
Adjusted non-GAAP EBITDA ⁽¹⁾	61.1	73.1	77.2	20%	26%
Adjusted 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 in our Corticotropin re-commercialization project

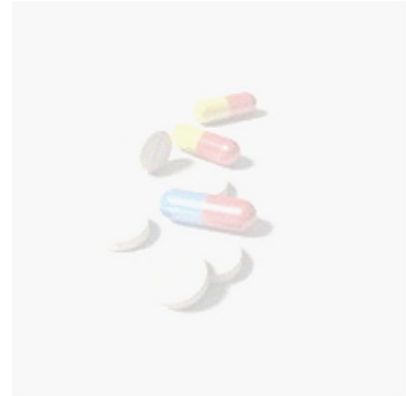
(1) See Appendix A for note regarding US GAAP reconciliations

Growth Led by New Product Introductions



* 30 Commercial Products as of August 3, 2017

Sales and Marketing Overview



Generic Rx Product Portfolio

2016 & 2017 Product Introductions

- Diphenoxylate Atropine (June 2017)
- 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-three generic product families encompassing 46 SKUs
- \$95.2 million of full year 2016 net sales (total Generic portfolio)
- \$58.1 million of first half 2017 net sales, up 63% vs. prior year

(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 net sales
- \$19.7 million first half 2017 net sales, up 51% vs. prior year

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



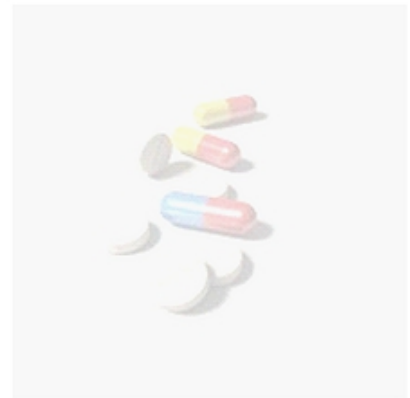
Two additional hypertension brands acquired in first quarter 2017:

- 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 was first full quarter of sales and gross profit contribution

Contract Manufacturing and Other

- Contract manufacturing
 - \$5.5 million of full year 2016 and \$3.3M of first half 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 \$0.3M of first half 2017 net revenues
 - Product development services, laboratory services, and royalties received

Business and Product Development Overview



Business Development Activity – Generic Products

		NOTES	DATE	ANI MANUF	APPROVED	COST (\$M)
G e n e r i c s	Rowasa® AG (Partnership with Meda)	Commercial	May-16	✓	✓	\$0.0
	Lipofen® AG & 1% and 2.5% HC Cream	Commercial	Jan-16		✓	\$10.0
	IDT Partnership (18 previously approved ANDAs)	to date, 1 product commercialized	Aug-15	✓	✓	\$1.0
	ANDA Basket 2 (22 previously approved ANDAs)	to date, 3 products commercialized	Jul-15	✓	✓	\$25.0
	Flecainide (flecainide tablets)	Commercial	Mar-15	✓	✓	\$4.5
	ANDA Basket 1 (31 previously approved ANDAs)	to date, 3 products commercialized	Jan-14	✓	✓	\$12.5
	Nimodipine & Omega (Partnership with Sofgen)	Nimodipine Commercial Omega in pipeline	Aug-13 and Apr-14			\$1.1
					Total	\$54.1

Business Development Activity – Brand Products

		NOTES	DATE	ANI MANUF	APPROVED	COST (\$M)
B r a n d s	Inderal® XL (propranolol ER capsules)	Commercial	Feb-17		✓	\$20.0
	InnoPran XL® (propranolol ER capsules)	Commercial	Feb-17		✓	\$31.0
	Brethine® (terbutaline tablets)	Pipeline	Dec-16	✓	✓	\$0.0
	Inderal® LA (propranolol ER capsules)	Commercial	Apr-16		✓	\$60.0
	Cortrophin® Assets (corticotropin)	Pipeline	Jan-16		✓	\$75.0
	Testosterone Gel (testosterone gel satchets)	Pipeline	May-15		✓	\$0.0
	Vancocin® Assets (vancomycin HCl capsules, injectable, solution)	Capsules Commercial Inj & Solution in Pipeline	Aug-14		✓	\$11.0
	Lithobid® (lithium carbonate tablets)	Commercial	Jul-14	✓	✓	\$12.0
					Total	\$209.0

Product Development Pipeline

- 76 products in development
- ANI believes 45 can be commercialized via CBE30 or PAS
- Total combined market value: \$3.7 billion⁽¹⁾

Generic Product Pipeline

- 71 products – 40 can be re-commercialized via CBE30 or Prior Approval Supplement
- Addressable market of pipeline = \$2.1B

Brand Product Pipeline

- 5 products – Cortrophin Gel, Cortrophin-Zinc, Vancocin® Oral Solution, Brethine® tablets and Testosterone Gel; all are approved and can be re-commercialized via sNDA filing
- Addressable market of pipeline = \$1.6B

Cortrophin Assets

- NDA #008975 Purified Cortrophin Gel, 40 units/mL and 80 units/mL
- NDA #009854 Cortrophin-Zinc, 40 units/mL
- Drug Master File 4181 for corticotropin (*withdrawn*); API Process “know-how”

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

Cortrophin - A Compelling Strategic Opportunity

Regulatory and Development Considerations

- Approved NDAs/Discontinued Marketing: Clear and abbreviated pathway to re-commercialization
- Acquired: NDAs, DMF* and other documentation (e.g. batch records, historical data)

Commercial Considerations

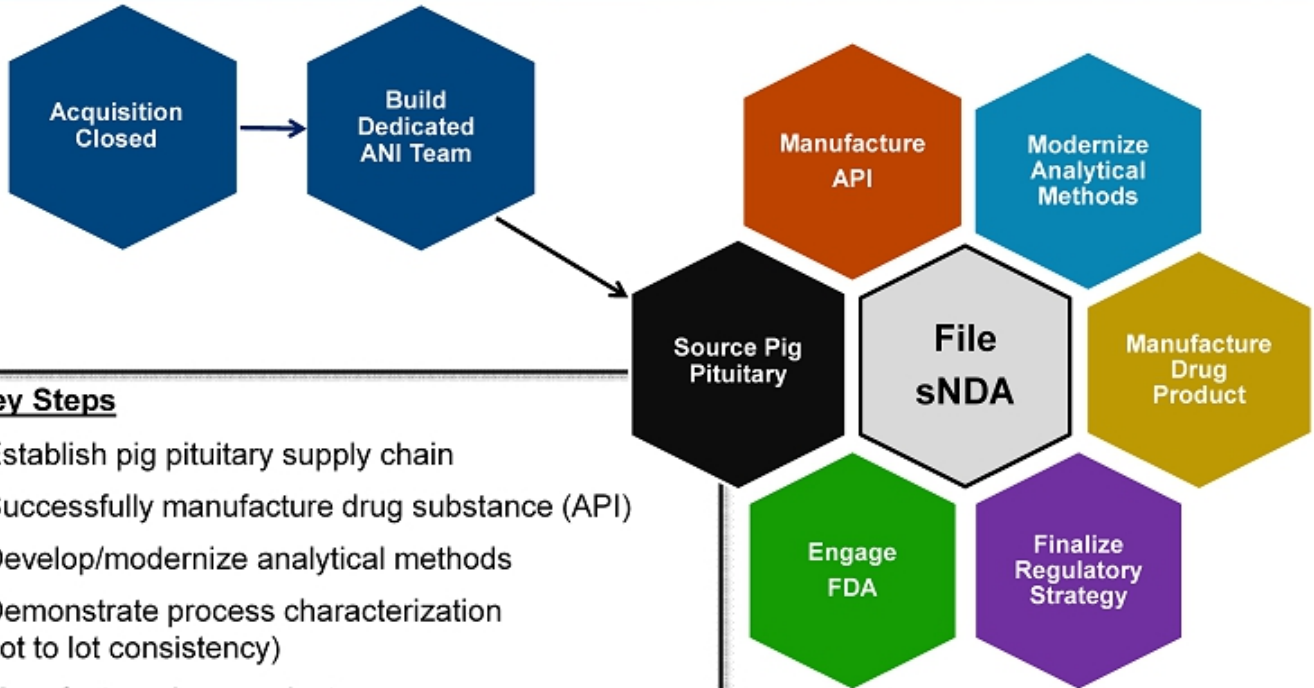
- \$1B+ U.S. market opportunity today and growing
- Provides patients, prescribers and payors with valuable therapeutic alternative
- Broad label / concentrated prescriber base
- Durable assets: high barrier to generic entry, ANI's products represent the last of the dormant corticotropin filings that were not withdrawn via Federal Register

Value Creation

- Provides patients, payors and physicians with valuable therapeutic option
- Potential to generate substantial revenues and cash flow
- High risk-adjusted ROI and NPV

* DMF = drug master file

Cortrophin - Path to Re-Commercialization



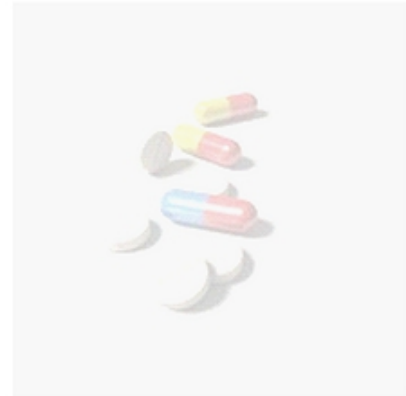
Key Steps

- Establish pig pituitary supply chain
- Successfully manufacture drug substance (API)
- Develop/modernize analytical methods
- Demonstrate process characterization (lot to lot consistency)
- Manufacture drug product
- Demonstrate comparability to historically manufactured product

Key Re-commercialization Milestones

	Duration	Status	Additional Details
Manufacture small-scale batch of corticotropin API	4 mos.	Complete	<ul style="list-style-type: none"> Initial batch yields similar to historical yields Analytical method development and testing ongoing Initiate stability testing
Select drug product CMO	6 mos.	Ongoing	<ul style="list-style-type: none"> Drug product CMO has been identified
Manufacture intermediate-scale batches of corticotropin API	2-3 mos. per batch	Ongoing	<ul style="list-style-type: none"> Demonstrate lot to lot consistency Further refine/modernize analytical methods and process Establish API specifications
Type C meeting with FDA		Target 2H2017	<ul style="list-style-type: none"> Present re-commercialization plan Preliminary batch characterization and comparability data Updated analytical methods
Manufacture demo batches of Cortrophin Gel	TBD	Target 2H2017	<ul style="list-style-type: none"> Initiate formulation / fill / finish of drug product
Manufacture commercial-scale batches of corticotropin API	2-3 mos. per batch	Not started	<ul style="list-style-type: none"> Process validation Registration / Commercial batches Initiate registration-enabling ICH stability studies
Manufacture registration batches of Cortrophin Gel	TBD	Not started	<ul style="list-style-type: none"> Process validation Registration / Commercial batches Initiate registration-enabling ICH stability studies
Initiate registration stability for sNDA	6 mos.	Not started	<ul style="list-style-type: none"> Six months of accelerated stability from drug substance and drug product batches at time of submission
sNDA submission	TBD	TBD	<ul style="list-style-type: none"> PAS filing - PDUFA four month review time

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
- 5,500 square foot warehouse expansion includes additional schedule CII vault and CIII cage space (expected completion: September 2017)
- 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 IIN capability
- Adding a low-humidity suite for processing and encapsulating moisture-sensitive compounds



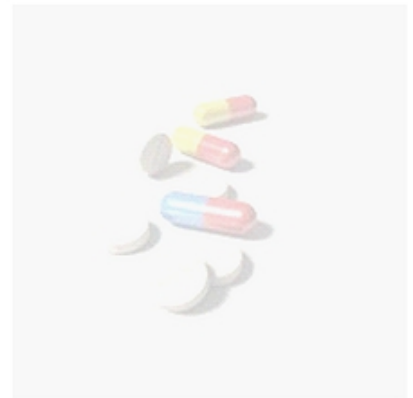
Summary

- 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) August 3, 2017 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,	
	2017	2016	2017	2016
Net Income	\$ 2,681	\$ 1,125	\$ 3,833	\$ 2,471
Add back				
Interest expense, net	3,025	2,830	5,957	5,612
Other expense, net	19	12	37	10
Provision for income taxes	1,269	1,227	1,792	2,767
Depreciation and amortization	7,101	5,956	13,807	10,565
Add back				
Stock-based compensation	1,807	2,217	3,193	3,322
Excess of fair value over cost of acquired inventory	3,210	2,078	4,745	2,078
Expenses related to transaction not consummated	-	-	477	-
Adjusted non-GAAP EBITDA	\$ 19,112	\$ 15,445	\$ 33,841	\$ 26,825

U.S. GAAP Reconciliations

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net Income	\$ 2,681	\$ 1,125	\$ 3,833	\$ 2,471
Add back				
Non-cash interest expense	1,774	1,757	3,566	3,482
Depreciation and amortization expense	7,101	5,956	13,807	10,565
Stock-based compensation	1,807	2,217	3,193	3,322
Excess of fair value over cost of acquired inventory	3,210	2,078	4,745	2,078
Expenses related to transaction not consummated	-	-	477	-
Less				
Tax impact of adjustments	(5,140)	(4,443)	(9,542)	(7,195)
Adjusted non-GAAP Net Income	\$ 11,433	\$ 8,690	\$ 20,079	\$ 14,723
Diluted Weighted-Average Shares Outstanding	11,667	11,541	11,659	11,514
Adjusted non-GAAP Diluted Earnings per Share	\$ 0.98	\$ 0.75	\$ 1.72	\$ 1.28

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.