
**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 16, 2018

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 May 16, 2018, ANI Pharmaceuticals, Inc. (the “Company,” “we” or “us”) posted to its website its May 2018 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, 2018. 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, May 2018

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: May 16, 2018

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

May 2018



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.

Corporate Overview

- U.S. based specialty pharmaceutical company (NASDAQ: ANIP) with a commercial portfolio of 38 brand and generic Rx products
- Differentiated generic strategy including acquisition and re-commercialization of previously approved products, as well as traditional development
- Baudette, MN manufacturing footprint comprised of two sites and ~165 of our ~180 employees
- 2018 Financial Guidance: \$212M - \$228M Revenues / \$90M - \$100M Adjusted non-GAAP EBITDA

Generic Drugs

- 27 commercial products
- 72 pipeline products; 50 previously approved
- Addressable market of pipeline = \$3.4B

Branded Drugs

- 11 commercial products
- 4 pipeline products previously approved
- Addressable market of pipeline = \$1.2B

CMO / Manufacturing

- 4 CMO clients representing 7 products
- 177,000 ft² of US based facilities
- Significant capacity
- Capabilities: Solid oral, liquids, extended release, high containment

Core Strategic Focus

Create long term shareholder value by:

- Building a sustainable and growing portfolio of Brand and Generic Rx products via internal development and acquisition
- Leverage tech transfer team and manufacturing facilities to move acquired products to ANI sites
- Advancing a transformational opportunity to re-commercialize Cortrophin® Gel

Experienced Senior Management Team

Name	Role	Industry Experience	Joined ANI	Previous Affiliation
Arthur Przybyl	President and CEO	25+ years	2009	
Stephen Carey	VP, Finance and CFO	20	2016	
Robert Schrepfer	SVP, BD and Specialty Sales	15	2013	
James Marken	SVP, Operations & Prod. Development	20	2007	
David Sullivan, PhD	VP, Quality Operations	20	2014	
Ellen Camos	VP, Regulatory Affairs	15	2012	
Mark Ginski, PhD	VP, Corticotropin Development	20	2016	
Karen Quinn, PhD	VP, Corticotropin Regulatory Affairs	30	2017	



Financial Highlights - 1Q 2018

(\$ in millions, except per share data)	Three Months Ended	
	March 31	
	2018	2017
Net revenues	\$ 46.5	\$ 36.6
Net income	\$ 2.3	\$ 1.2
GAAP earnings per diluted share	\$ 0.19	\$ 0.10
Adjusted non-GAAP EBITDA ⁽¹⁾	\$ 21.8	\$ 14.7
Adjusted non-GAAP diluted earnings per share ⁽¹⁾	\$ 1.32	\$ 0.74

Posted record quarterly Adjusted non-GAAP EBITDA and Adjusted non-GAAP EPS

- Net revenues increased 27% from prior year
- Adjusted non-GAAP EBITDA increased 48% from prior year
- Adjusted non-GAAP diluted earnings per share increased 78% from prior year

Strong Capital Position

- \$52.0 million of cash as of March 31, 2018, up 67% from year end
 - 1Q 2018 cash flow from operations of \$22.9 million and free cash flow of \$20.6 million
- Net leverage of 1.75x based upon mid-point of 2018 guidance
- \$125 million senior secured credit facility includes undrawn \$50 million revolver
- Beneficiary of 2017 Tax Cuts and Jobs Act
 - Anticipated favorable impact of reduced cash tax burden worth approximately \$10 - \$13 million to 2018 cash flow

Improved ability to continue to invest in:

- value generating business development opportunities
- our U.S. based manufacturing and development capabilities
- research and development

Financial Highlights – 1Q 2018 Net Revenues

(\$ in millions)

	Three Months Ended March 31,		Variance to Prior Year	
	2018	2017	\$	%
Generic pharmaceutical products	\$ 23.2	\$ 26.6	\$ (3.3)	-13%
Branded pharmaceutical products	16.6	8.0	8.6	106%
Royalty and other income	5.7	0.2	5.5	n/m
Contract manufacturing	0.9	1.8	(0.8)	-47%
Total net revenues	\$ 46.5	\$ 36.6	\$ 9.9	27%

- Brand sales reflect the February 2018 re-launch of InnoPran XL® and Inderal® XL in the ANI label as well as increased sales of Inderal® LA which launched in Q2 2016
- Royalty and other income includes \$5.4 million of royalty associated with our December 2017 purchase of four brands from AstraZeneca
- Generic sales declines driven by lower margin Fenofibrate and Propranolol ER

Full Year 2018 Guidance

(\$ in millions except EPS figures)

	2017 <u>Actual</u>	2018 Guidance		% Increase	
		<u>Low</u>	<u>High</u>	<u>Low</u>	<u>High</u>
Net Revenues	\$ 176.8	\$ 212.0	\$ 228.0	20%	29%
Adjusted non-GAAP EBITDA ⁽¹⁾	74.2	90.0	100.0	21%	35%
Adjusted non-GAAP diluted earnings per share ⁽¹⁾	\$ 3.91	\$ 5.43	\$ 6.08	39%	55%

Forecast results assumes:

- Revenues and expenses related to our December 29, 2017 acquisition of the NDAs and U.S. product rights for Atacand®, Atacand HCT®, Arimidex®, and Casodex®
- Maximizing the potential of our currently commercialized product portfolio, 2018 generic launches, and integrating generic assets recently acquired from Impax
- Increased investment in R&D driven by our commitment to the Cortrophin® Gel re-commercialization program
- Combined Federal and State effective income tax rate of 23%
- Approximately 11.7 million shares outstanding



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

Growth Led by New Product Introductions

(\$'s in millions)



* 2017 products do not include the four products acquired from AstraZeneca on December 29, 2017, as net revenues from these products commenced in 2018.

** Midpoint of 2018 annual guidance, as presented in May 8, 2018 Earnings Release

Sales and Marketing Overview



Generic Rx Impax/Amneal Transaction

Commercialized:

- Ezetimibe-Simvastatin tablets
- Felbamate tablets
- Desipramine tablets

Approved ANDAs:

- Aspirin/Dipyridamole ER capsules
- Methylphenidate ER tablets

Pipeline:

- Erythromycin IR tablets
- Diclofenac-Misoprostol DR tablets*

Acquired six generic products, three of which are currently marketed, and a license, supply, and distribution agreement for a seventh product from Impax Laboratories, Inc. as part of an FTC-required divestiture required for the Impax/Amneal merger.

- Purchased on May 7, 2018 for consideration of \$2.3 million; the portfolio has a combined U.S. market of \$1.7 billion according to Iqvia/IMS Health data
- Portfolio includes two approved ANDAs requiring successful validation prior to launch and two pipeline products
- Portfolio includes option for date-certain launch of Aspirin/Dipyridamole ER capsules of no later than October 1, 2019

Generic Rx Product Portfolio

2016 & 2017 Product Introductions

- Diphenoxylate HCL and Atropine Sulfate
- Erythromycin Ethylsuccinate
- Fenofibrate Capsules (AG)
- HC Cream, for rectal use
- Indapamide
- Lithium Carbonate ER (AG)
- Mesalamine Enema (AG)
- Nilutamide Tablets
- Oxycodone Capsules
- Oxycodone Oral Solution (100 mg/5 mL)
- Pindolol
- Propranolol ER Capsules (AG)



Continued broadening of our product offerings

- Twenty-seven generic product families encompassing 67 SKUs
- Product offerings have more than doubled from twelve at the beginning of 2016



(AG) = Authorized Generic

Brand Rx AstraZeneca Transaction

Atacand
candesartan cilexetil

AtacandHCT
candesartan cilexetil hydrochlorothiazide

Arimidex
anastrozole 1mg tablets

Casodex
bicalutamide tablets

Acquired the NDAs and U.S. rights to four brands including two hypertension and two hormone based chemotherapy drugs

- Purchased on December 29, 2017, for approximately \$46.5 million
- Generated combined sales of \$19.0 million in U.S. gross market sales during the trailing twelve months ended October 31, 2017 according to IMS Health data
- Opportunity to further leverage our IDC road (hormone containment) facility

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

INDERAL[®] XL
propranolol HCl
EXTENDED RELEASE CAPSULES

INNOPRAN XL[®]
propranolol HCl $\frac{80\text{ mg}}{120\text{ mg}}$
EXTENDED RELEASE CAPSULES

Two additional hypertension brands acquired in first quarter 2017:

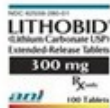
- Purchased on February 23, 2017, for approximately \$51 million
- Second quarter of 2017 was first full quarter of sales and gross profit contribution

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

- Number of branded product families has grown through acquisitions from four at the beginning of 2016 to eleven as of May 2018

Contract Manufacturing and Other

- Contract manufacturing
 - \$7.0 million of full year 2017 and \$0.9 of first quarter 2018 net revenues
 - Four customers
 - Seven products and seventeen SKUs
 - Contract manufacturing and contract packaging
- Royalty and other
 - \$0.4 million of full year 2017 and \$5.7 million of first quarter 2018 net revenues
 - First quarter 2018 primarily reflects royalties received on sales of Atacand[®], Atacand HCT[®], Arimidex[®], and Casodex[®]

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	Generic Products & Assets (5 ANDAs / 1 distribution partnership / 1 in-development)	3 Commercial, 2 Approved and 2 Development ANDAs	Apr-18	✓	✓	\$2.3
	ANDA Basket 3 (23 previously approved ANDAs)	Acquisition of ANDAs from IDT Australia	Apr-18	✓	✓	\$2.6
	Rowasa® AG (Partnership with Meda)	Commercial	May-16	✓	✓	\$0.0
	Lipofen® AG & 1% and 2.5% HC Cream (feno fibrate capsules & hydrocortison cream)	Commercial	Jan-16		✓	\$10.0
	ANDA Partnership (Partnership with IDT Australia)	to date, 1 product re-commercialized	Aug-15	✓	✓	\$1.0
	ANDA Basket 2 (22 previously approved ANDAs)	to date, 3 products re- commercialized	Jul-15	✓	✓	\$25.0
	Flecainide (flecainide tablets)	Commercial	Mar-15	✓	✓	\$4.5
	ANDA Basket 1 (31 previously approved ANDAs)	to date, 3 products re- commercialized	Jan-14	✓	✓	\$12.5
	Nimodipine & Omega (Partnership with Sofgen)	Nimodipine Commercial Omega in pipeline	Aug-13 and Apr-14			\$1.1
					Total	\$59.0

Business Development Activity – Brand Products

	NOTES	DATE	ANI MANUF	APPROVED	COST (\$M)	
B r a n d s	Atacand® & Atacand HCT® (candesartan cilexetil & candesartan cilexetil- hydrochlorothiazide)	Commercial	Dec-17	✓	\$28.0	
	Casodex® & Arimidex® (bicalutamide & anastrozole)	Commercial	Dec-17	✓	\$18.5	
	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
	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	\$255.5	

Product Development Pipeline

- 76 products in development
- ANI believes 54 can be commercialized via CBE30 or PAS
- Total combined market value: \$4.6 billion⁽¹⁾

Generic Product Pipeline

- 72 products – 50 can be re-commercialized via CBE30 or Prior Approval Supplement
- Addressable market of pipeline = \$3.4B⁽¹⁾

Brand Product Pipeline

- 4 products – Cortrophin® Gel, Cortrophin-Zinc®, Vancocin® Oral Solution, and Brethine® tablets; all are approved and can be re-commercialized via sNDA filing
- Addressable market of pipeline = \$1.2B⁽¹⁾

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

- \$1.2B U.S. market opportunity today
- 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

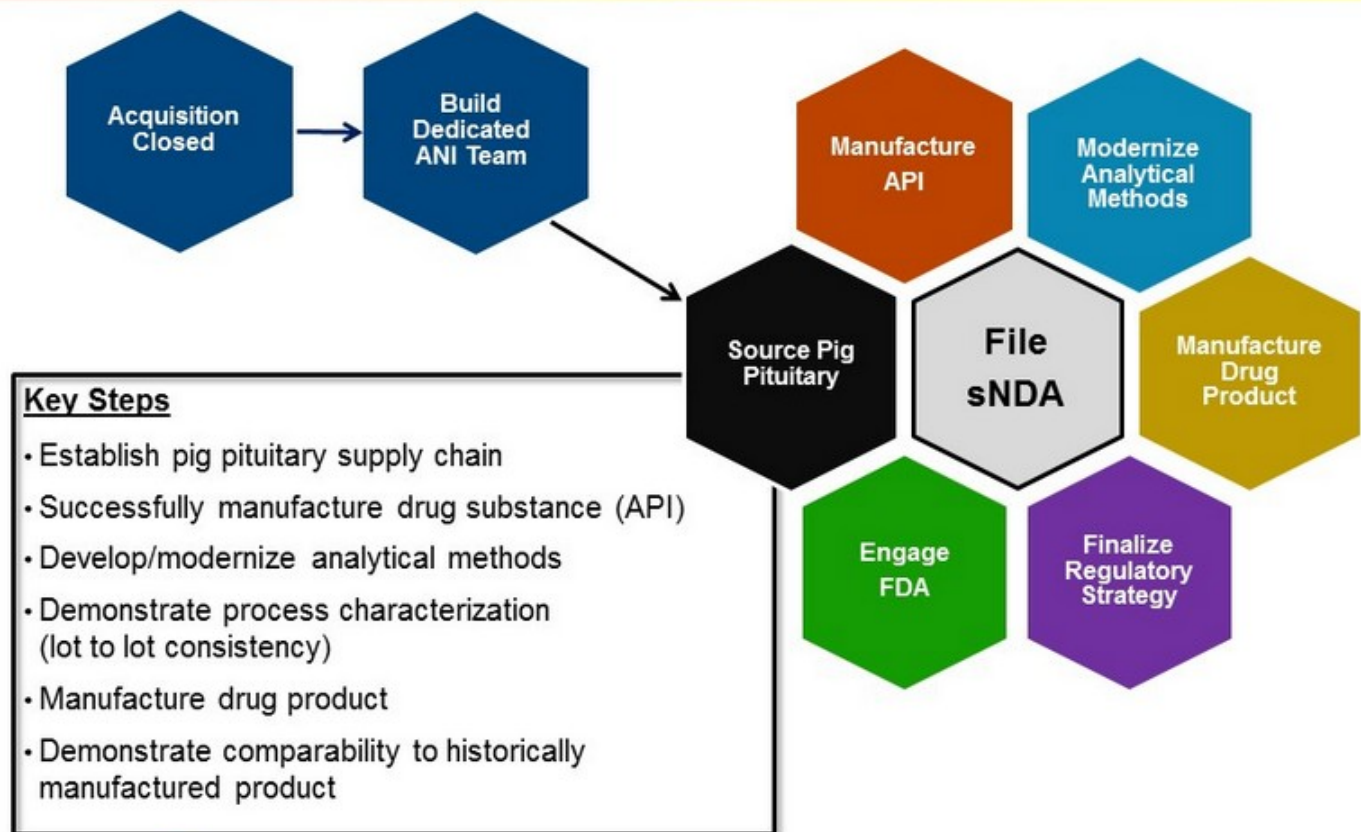
Value Creation

- 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 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
Select drug product CMO	6 mos.	Complete	<ul style="list-style-type: none"> Drug product CMO has been selected
Manufacture intermediate-scale batches of corticotropin API	4-6 mos.	Complete	<ul style="list-style-type: none"> Three intermediate-scale batches successfully completed Further refined/modernized analytical methods & process Demonstrated lot-to-lot consistency
Type C meeting with FDA		Communications with FDA on-going	<ul style="list-style-type: none"> Meeting Request submitted 4Q17; FDA granted Type C Meeting Information provided on ANI's regulatory plan for re-commercialization Initial FDA response received March 2018 with additional communications expected 2nd Quarter 2018
Manufacture demo batches of Cortrophin® Gel	TBD	Target Q3 2018	<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	Target H1 2018	<ul style="list-style-type: none"> Scale-up manufacturing process 5x Manufacture API under cGMPs Finalize API manufacturing process in preparation for process validation/registration batches
Manufacture registration batches of Cortrophin® Gel	2-3 mos. per batch	Target end 2018	<ul style="list-style-type: none"> Process validation Registration / Commercial batches Initiate registration-enabling ICH stability studies
Initiate registration stability for sNDA	6 mos.	TBD	<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 Overview

Main Street Facility – 130K ft²



IDC Road Facility – 47K ft²



Overview

- 57,000 ft² of manufacturing, packaging, and warehouse
- Recently completed 5,500 ft² warehouse expansion includes additional schedule CII vault & CIII cage space
- 17,000 ft² of laboratory space for product development and analytical testing
- 32,000 ft² of manufacturing, packaging, and warehouse
- 100 nano-gram per eight-hour time weighted average maximum exposure limit to ensure employee safety
- Adding a low-humidity suite for processing and encapsulating moisture-sensitive compounds

Capabilities

- Rx solutions, suspensions, topicals, tablets, capsules and powder for suspension
- DEA-licensed for Schedule II controlled substances
- Fully-contained high potency facility with capabilities to manufacture hormone, steroid, and oncolytic products
- DEA Schedule III capability

Capacity

- **Solid Dose** - ~1.2 billion doses/yr
- **Liquids** - ~53 million bottles/yr
- **Liquid Unit Dose** - ~23 million doses/yr
- **Powder** - ~12 million bottles/yr
- **Tablets** - ~2.5 billion doses/yr
- **Capsules** - ~150 million doses/yr

Manufacturing and Packaging Capabilities by Site

Main Street Facility

Solid Dose Manufacturing

- Particle Size Control
 - Sieving, Oscillating Granulators, Fitzmills, Comils
- Blending / Granulating – Wet and Dry capability
 - Marion Paddle Mixers, V-Blender, Gemco Slant Cone
 - Collette Gral 600 High Shear Granulator (100 – 200kg)
 - Collette Gral 75 (also explosion proof) (12 – 25kg)
 - Hobart Planetary Mixer
- Drying – Gruenberg Ovens, Vector FL-3N Fluid Bed Dryer
- Encapsulating Machine (pilot scale / small batch)
 - Zanasi, MG Suprema
- Rotary Tablet Presses
 - Courtoy R100, Killian Synthesis 300
- Coating – Film / Sugar coating, Solvent & Aqueous
 - ACCELA-COTA and Vector Hi Coater Pans

Liquid Manufacturing

- Liquids / Syrups
- Solutions / Suspensions / Emulsions
- Lotions / Ointments

Solid Dose Packaging – 7 to 1,000 units/container

- Tablets – Mass: 60mg – 1050mg
- Capsules – Mass: 100mg – 600mg

Liquid Dose Packaging Capabilities

- Solutions, Suspensions, Enemas

Unit Dose Cup Blisters

Powder Filling Capability

- 1" – 5" Diameter containers



Manufacturing and Packaging Capabilities by Site

IDC Road Facility

Solid Dose Manufacturing

- Particle Size Control
 - Sieving, Oscillating Granulators, Fitzmills, Comils
 - Alpine Pin Mill (1Q18)
- Blending / Granulating – Wet and Dry capability
 - Marion Paddle Mixers, V-Blender, Gemco Cone Blenders
 - Gemco Formulator (jacketed)
 - Collette Gra1 75 (also explosion proof)
 - Vector Granumeist GMX 600L high shear granulator
 - Hobart Planetary Mixer
- Drying – Gruenberg Ovens, Vector FL-N-15 Fluid Bed Dryer
- Rotary Tablet Presses
 - Two Courtoy R190
 - Korsch XL 200
 - Two Korsch XL 400
- Encapsulation
 - Bosch 1400L for hotmelt capsule filling (1Q18)

Solid Dose Packaging – 7 to 1,000 units/container

- Tablets – Mass: 60mg – 1050mg
- Capsules – Mass: 100mg – 600mg

Blister Packaging (Klockner CP-2 and Klockner CP-8)

- Physician sample / clinical size Klockner Blister Forming Machines
 - Multiple base material options
 - 4, 7, or 10 tablet blister
 - Cold form capable



Recently Expanded Warehouse Capacity

	Pallet Spaces
Main Street Facility	
Approved Rack Spaces	1,471
Quarantine Rack Spaces	136
Reject Spaces	14
CIII (Cage Spaces)	180
CII (Vault Spaces)	116
Containment Facility	
Approved Rack Spaces	216
Building 5 (Bulk Materials / Equipment Storage)	
Approved Rack Spaces	50
Total Pallet Spaces	2,183



New controlled substance vault expansion



Main St. warehouse

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
 - 2018 Annual guidance⁽¹⁾
 - Net revenues of \$212 million to \$228 million
 - Adjusted non-GAAP EBITDA⁽²⁾ of \$90 million to \$100 million
 - Adjusted non-GAAP diluted earnings per share⁽²⁾ of \$5.43 to \$6.08
- ANI is focused on delivering value through:
 - Partnerships, strategic alliances and accretive acquisitions
 - Internal product development and leveraging manufacturing capabilities
 - Advancing the re-commercialization of Cortrophin[®] Gel



(1) May 8, 2018 earnings release

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

Appendix A



U.S. GAAP Reconciliations

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

	Three Months Ended March 31,	
	2018	2017
Net Income	\$ 2,250	\$ 1,152
Add back		
Interest expense, net	3,634	2,932
Other expense, net	61	18
Provision for income taxes	592	523
Depreciation and amortization	8,195	6,706
Add back		
Stock-based compensation	1,377	1,386
Excess of fair value over cost of acquired inventory	5,645	1,535
Expenses related to transaction not consummated	-	477
Adjusted non-GAAP EBITDA	\$ 21,754	\$ 14,729

U.S. GAAP Reconciliations

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

	Three Months Ended March 31,	
	2018	2017
Net Income	\$ 2,250	\$ 1,152
Add back		
Excess of fair value over cost of acquired inventory	5,645	1,535
Non-cash interest expense	1,914	1,792
Stock-based compensation	1,377	1,386
Depreciation and amortization expense	8,195	6,706
Expenses related to transaction not consummated	-	477
Less		
Tax impact of adjustments	(3,940)	(4,402)
Adjusted non-GAAP Net Income	\$ 15,441	\$ 8,646
Diluted Weighted-Average Shares Outstanding	11,706	11,653
Adjusted non-GAAP Diluted Earnings per Share	\$ 1.32	\$ 0.74

U.S. GAAP Reconciliations

Non-GAAP Financial Measures included in 2018 Guidance

The Company's fiscal 2018 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.