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 7, 2018

ANI PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-31812**	**58-2301143**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 7, 2018, ANI Pharmaceuticals, Inc. (the “Company,” “we” or “us”) posted to its website its August 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

Exhibit No.	Exhibit
99.1	ANI Pharmaceuticals, Inc. Corporate Presentation, August 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: August 7, 2018

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

Exhibit 99.1

ani Pharmaceuticals, Inc.

A Specialty Pharmaceutical Company

NASDAQ: ANIP

GENERIC AND BRANDED PRESCRIPTION DRUG PRODUCTS

Corporate Presentation

August 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 40 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: $195M - $205M Revenues / $82M - $88M Adjusted non-GAAP EBITDA

Generic Drugs

- 29 commercial products
- 71 pipeline products; 51 previously approved
- Total annual market size = $3.3B

Branded Drugs

- 11 commercial products
- 4 pipeline products previously approved
- Total annual market size = $1.2B

Contract Development & Manuf.

- 25 clients representing 38 products
- 177,000 ft^2 of US based facilities
- 101,000 ft^2 Canadian facility
- Capabilities: Solid oral, liquids, topicals 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
- Advancing a transformational opportunity to re-commercialize Cortrophin® Gel
- Expanding Contract Development and Manufacturing business

Experienced Senior Management Team

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

ani Pharmaceuticals, Inc.

Financial Highlights - 2Q and YTD 2018

($ in millions, except per share data)	Three Months Ended June 30, 2018	Three Months Ended June 30, 2017	Six Months Ended June 30, 2018	Six Months Ended June 30, 2017
Net revenues	$ 47.3	$ 44.8	$ 93.8	$ 81.4
Net income	$ 2.8	$ 2.7	$ 5.0	$ 3.8
GAAP earnings per diluted share	$ 0.23	$ 0.23	$ 0.42	$ 0.33
Adjusted non-GAAP EBITDA (1)	$ 19.0	$ 19.1	$ 40.8	$ 33.8
Adjusted non-GAAP diluted earnings per share (1)	$ 1.13	$ 0.98	$ 2.45	$ 1.72

- 2Q net revenues increased 6% from prior year
- 2Q adjusted non-GAAP EBITDA decreased slightly from prior year
- 2Q adjusted non-GAAP diluted earnings per share increased 15% from prior year

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(1) See Appendix A for US GAAP reconciliations

Financial Highlights - 2Q and YTD 2018

$ in millions	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Generic pharmaceutical products	$30.2	$31.5	$53.4	$58.1
Brand pharmaceutical products	$10.5	$11.7	$27.1	$19.7
Royalty and other income	$4.9	$0.1	$10.6	$0.3
Contract manufacturing	$1.7	$1.5	$2.6	$3.3
Total net revenues	$47.3	$44.8	$93.8	$81.4

Year-to-date results include:

- Generic sales declines driven by lower margin Fenofibrate and Propranolol ER, tempered by Q2 2018 product launches and full quarter impact of Diphenoxylate Hydrochloride & Atropine Sulfate
- Brand sales reflect the February 2018 re-launch of InnoPran XL® and Inderal® XL in the ANI label
- Royalty and other income includes $9.3 million of royalty associated with our December 2017 purchase of four brands from AstraZeneca and $0.9 million of royalty on sales of Yescarta®

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

Full Year 2018 Guidance

($ in millions except EPS figures)

	2018 Guidance Range					2017	2018 Guidance Growth	
	First Half	Second Half		Full Year		Full Year		
	Actual	Low	High	Low	High	Actual	Low	High
Net Revenues	$ 93.8	$ 101.2	$ 111.2	$ 195.0	$ 205.0	$ 176.8	10%	16%
Adjusted non-GAAP EBITDA (1)	40.8	41.2	47.2	82.0	88.0	74.2	11%	19%
Adjusted non-GAAP diluted earnings per share (1)	$ 2.45	$ 2.35	$ 2.92	$ 4.80	$ 5.27	$ 3.91	23%	35%

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 the Cortrophin® Gel re-commercialization program
- Combined Federal and State effective income tax rate of 23%
- Approximately 11.8 million shares outstanding

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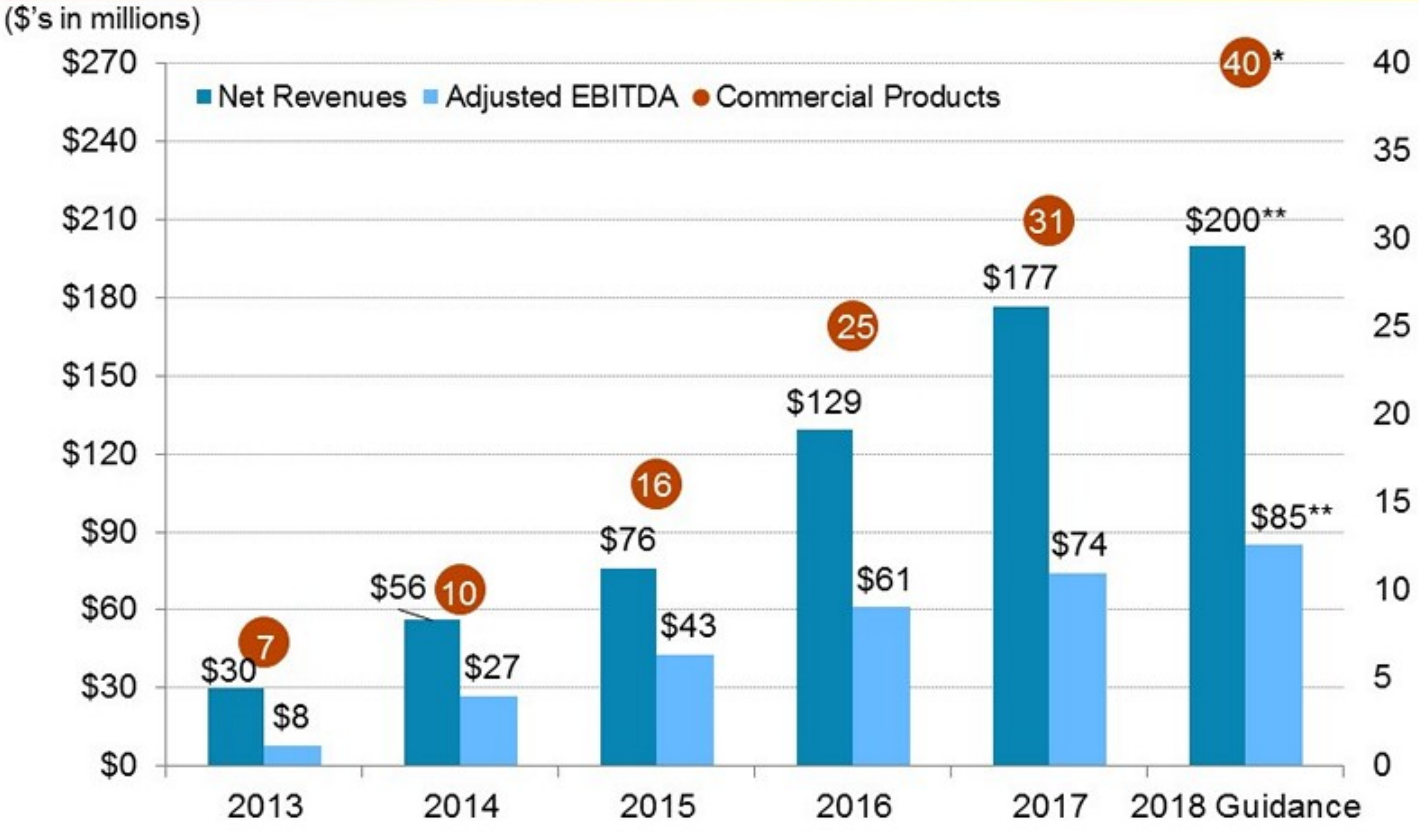
(1) See Appendix A for note regarding US GAAP reconciliations

Growth Led by New Product Introductions



* Products as of August 7, 2018
** Midpoint of 2018 annual guidance, as presented in August 7, 2018 Earnings Release

Strong Capital Position

- $55.0 million of cash as of June 30, 2018, up 77% from year end
  - 2Q 2018 cash flow from operations of $8.6 million and free cash flow of $7.5 million
- Net leverage of 1.92x 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 over $10 million to 2018 cash flow

Improved ability to continue to invest in:

- value generating business development opportunities
- our North American based manufacturing and development capabilities
- research and development

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Generic Rx - $53.4M Net Sales YTD

29 Commercial products, 70 SKUs

Five products added to commercial portfolio YTD 2018

- Strong market share position – top 10 products average 47% share
- Substantial Authorized Generic portfolio of 7 commercial products
- Contracts with all 3 major buying consortia – Red Oak, WBAD, and ClarusOne
- To date, ANI has re-launched 10 products from its pipeline of acquired ANDAs that require a tech transfer prior to re-commercialization
- 21 of the 29 commercial products are currently manufactured at ANI's sites

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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
- Two approved ANDAs require successful validation prior to launch
- Option for date-certain launch of Aspirin/Dipyridamole ER capsules of no later than October 1, 2019

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* License, supply, and distribution agreement

Generic Rx – Pipeline

Total annual market size: $3.3 billion[1]

- Large ANDA Pipeline includes 71 products
  - 51 can be re-commercialized via CBE30 or Prior Approval Supplement
  - Leverage ANI's three manufacturing sites to re-launch acquired ANDAs

Key Pipeline Products

- Methylphenidate ER Tablets
  - $1.3B market
  - est. launch date 1Q 2019
- Aspirin/Dipyridamole ER Capsules
  - $176M market
  - Launch by Oct. 2019
- Undisclosed product – via development partner
  - $47M market
  - Priority Review with GDUFA date of April 2019

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(1) Based on Company estimates and Iqvia data

Brand Rx - $27.1M Net Sales YTD

Commercial Portfolio includes 11 Brand Products

- Inderal® XL and InnoPran XL® supported by active sampling, patient awareness campaigns and physician sales and marketing effort
- Launched Arimidex ® and Casodex ® in ANI label in July 2018
- Target launch of Atacand ® and Atacand HCT ® in ANI label in October 2018
- Target completion of manufacturing and packaging site transfer of Atacand ® and Atacand HCT ® to Baudette by 2020
- Vancocin ® capsules manufacturing site transfer ongoing

Brand Rx – Pipeline

Total annual market size: $1.2 billion+[1]

- Brand Pipeline includes four products
  - Cortrophin® Gel, Cortrophin-Zinc®, Vancocin® Oral Solution, Brethine® tablets
  - All are FDA approved and can be re-commercialized via sNDA filing
  - Vancocin® Oral Solution and Brethine® tablets to be manufactured at ANI sites

Pipeline Products

- Cortrophin® Gel
  - $1.2B market
  - Target sNDA filing by 1Q 2020
- Vancocin® Oral Solution
  - $450M addressable market
  - Target Prior Approval Supplement filing in Sept. 2018
- Brethine® tablets
  - $11M market
  - Manufacturing site transfer underway

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(1) Based on Company estimates and Iqvia data

Cortrophin® Gel Re-commercialization Milestones

	Duration	Status	Additional Details
Manufacture small-scale batch of corticotropin API	4 mos.	Complete	• Initial batch yields similar to historical yields • Analytical method development and testing ongoing
Select drug product CMO	6 mos.	Complete	• Drug product CMO has been selected
Manufacture intermediate-scale batches of corticotropin API	4-6 mos.	Complete	• Four intermediate-scale batches successfully completed • Further refined/modernized analytical methods & process • Demonstrated lot-to-lot consistency
Type C meeting with FDA		Complete	• Meeting Request submitted 4Q17; FDA granted as Type C Meeting • Information provided on ANI's regulatory plan for re-commercialization • Initial FDA response received March 2018 with additional communication in 2nd Quarter 2018
Manufacture demo batch of Cortrophin® Gel	1 mo.	Q3 2018	• Initiate non-GMP formulation/fill/finish of drug product at commercial scale
Manufacture commercial-scale batches of corticotropin API	2-3 mos. per batch	Ongoing	• Scale-up manufacturing process 5x to projected commercial scale • Manufacture API under cGMPs • Finalize API manufacturing process and initiate process validation/registration batches
Manufacture registration batches of Cortrophin® Gel	1-2 mos. per batch	1H 2019	• Process validation • Registration / Commercial batches • Initiate registration-enabling ICH stability studies
Initiate registration stability for sNDA	6 mos.	1H 2019	• Six months of accelerated stability from drug substance and drug product batches at time of submission
sNDA submission		By 1Q 2020	• Filing - four month PDUFA date

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Contract Manufacturing - $2.6M Net Sales YTD

- Contract manufacturing
  - Four customers
    - Seven products and seventeen SKUs
    - Contract manufacturing and contract packaging
- Recently acquired WellSpring Pharma Services - CDMO
  - Currently generating approximately $15M in annual revenues
  - 21 customers
    - 17 commercial products
    - 14 products in development
    - Contract development, manufacturing and packaging

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WellSpring Pharma Services Acquisition

Transaction Details - $18 million, cash at close

- Location: Oakville, Canada (near Toronto)
- Employee base: ~100

Strategic Rationale – Scale and Synergy

- Additional tech transfer site to accelerate re-commercialization of ANI's pipeline of approved generic ANDAs
- Expand ANI's legacy contract manufacturing business
- Broaden ANI manufacturing capability and provide redundant capacity

Current WellSpring CMO Business and Pipeline

17 Commercial Products	14 Additional Products	3 Dosage Forms
6 ANDA 11 NDA * Includes one ANI product	In development / Filed 9 ANDA 5 NDA	18 Solids 10 Semi-solids 3 Non-Sterile Liquids

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Manufacturing Overview – Baudette, Minnesota

	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

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Manufacturing Overview – Oakville, Canada

Canadian Facility – 101K ft²

Overview

- 101,000 ft² of manufacturing, packaging, lab, warehouse, and administrative space
- US FDA and Health Canada inspected
- Controlled drugs and substance license
- Ability to expand footprint

Capabilities

- Rx solutions, suspensions, topicals, tablets, and capsules
- Serialization-ready

Capacity

- **Tablets** ~1 billion doses/yr
- **Capsules** ~340 million doses/yr
- **Liquids** ~3 million bottles/yr
- **Topicals** ~2 million tubes/yr

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ANI Royalty Income - $10.6M Net Revenues YTD

- YTD Royalty Income Primarily Reflects:
  - $9.3 million received on sales of Atacand®, Atacand HCT®, Arimidex®, and Casodex®
  - $0.9 million received on sales and for milestones on Yescarta®
- Yescarta® Royalty
  - In 2Q 2018 ANI recognized $0.9 million in royalties and milestones
  - Originates from assets acquired in Biosante transaction
  - Entitled to percentage of global Yescarta® net sales and certain milestones
  - In June 2018 European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion on the Marketing Authorization Application (MAA) for Yescarta®

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Summary

- ANI is an integrated specialty generic pharmaceutical company with:
  - Profitable base business generating organic growth
  - Strong capital position
  - Experienced management team
  - North American based manufacturing assets and expertise
  - 2018 Annual guidance[1]
    - Net revenues of $195 million to $205 million
    - Adjusted non-GAAP EBITDA[2] of $82 million to $88 million
    - Adjusted non-GAAP diluted earnings per share[2] of $4.80 to $5.27
- 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

ani Pharmaceuticals, Inc.

(1) August 7, 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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net Income	$ 2,777	$ 2,681	$ 5,027	$ 3,833
Add back				
Interest expense, net	3,730	3,025	7,364	5,957
Other expense, net	30	19	91	37
Provision for income taxes	726	1,269	1,318	1,792
Depreciation and amortization	8,313	7,101	16,508	13,807
Add back				
Stock-based compensation	1,782	1,807	3,159	3,193
Acquired IPR&D expense	1,335	-	1,335	-
Excess of fair value over cost of acquired inventory	-	3,210	5,645	4,745
Transaction expenses	341	-	341	477
Adjusted non-GAAP EBITDA	$ 19,034	$ 19,112	$ 40,788	$ 33,841

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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net Income	$ 2,777	$ 2,681	$ 5,027	$ 3,833
Add back				
Non-cash interest expense	1,945	1,774	3,859	3,566
Depreciation and amortization expense	8,313	7,101	16,508	13,807
Acquired IPR&D expense	1,335	-	1,335	-
Stock-based compensation	1,782	1,807	3,159	3,193
Excess of fair value over cost of acquired inventory	-	3,210	5,645	4,745
Transaction expenses	341	-	341	477
Less				
Tax impact of adjustments	$ (3,155)	(5,140)	(7,095)	(9,542)
Adjusted non-GAAP Net Income	$ 13,338	$ 11,433	$ 28,779	$ 20,079
Diluted Weighted-Average Shares Outstanding	11,789	11,667	11,748	11,659
Adjusted non-GAAP Diluted Earnings per Share	$ 1.13	$ 0.98	$ 2.45	$ 1.72

ani Pharmaceuticals, Inc.

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.