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 12, 2019**

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**	**56623**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(218) 634-3500**

(Former name or former address, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	**Trading Symbol(s)**	**Name of each exchange on which registered:**
Common Stock	ANIP	Nasdaq Stock Market

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:

☐ 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 12, 2019, ANI Pharmaceuticals, Inc. (the “Company,” “we” or “us”) announced that Arthur Przybyl, President and CEO and Stephen Carey, Vice President and CFO, will present at the Raymond James Life Sciences and MedTech Conference, which presentation will be webcast live at http://wsw.com/webcast/rj115/anip/ at 8:00 AM ET on Tuesday, June 18, 2019. The live webcast will be archived and available for 7 days, through June 25, 2019.

On June 12, 2019, we posted to our website our June 2019 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 99.2 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 Exhibits 99.1 and 99.2, 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, 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 4, 2019. 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

No.	Description
99.1	Press release, dated June 12, 2019, issued by ANI Pharmaceuticals, Inc.
99.2	ANI Pharmaceuticals, Inc. Corporate Presentation, June 2019

SIGNATURE

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.

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

Dated: June 12, 2019

ANI Pharmaceuticals to Present at Raymond James Life Sciences and MedTech Conference

BAUDETTE, Minn., June 12, 2019 /PRNewswire/ -- ANI Pharmaceuticals, Inc. (NASDAQ: ANIP) will present on June 18, 2019 at Raymond James' Life Sciences and MedTech Conference in New York City. Arthur Przybyl, President and CEO and Stephen Carey, Vice President and CFO, will present at 8:00 AM ET on Tuesday, June 18, 2019. The presentation will be webcast live at http://wsw.com/webcast/rj115/anip/. The live webcast will be archived and available through the prior link for 7 days through June 25, 2019.

About ANI

ANI Pharmaceuticals, Inc. (the "Company" or "ANI") is an integrated specialty pharmaceutical company developing, manufacturing, and marketing branded and generic prescription pharmaceuticals. The Company's targeted areas of product development currently include narcotics, oncolytics (anti-cancers), hormones and steroids, and complex formulations involving extended release and combination products. For more information, please visit our website www.anipharmaceuticals.com.

Forward-Looking Statements

To the extent any statements made in this release 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 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 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; 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 news release speak only as of the date of this news release 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.

For more information about ANI, please contact:
Investor Relations
IR@anipharmaceuticals.com

ani Pharmaceuticals, Inc.

A Specialty Pharmaceutical Company

NASDAQ: ANIP

GENERIC AND BRANDED PRESCRIPTION DRUG PRODUCTS

Corporate Presentation

June 2019

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, statements regarding the Company's use of proceeds of the Company's credit facility in the manner currently anticipated, including the refinancing of the Convertible Notes, 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 Company's ability to meet its outstanding debt obligations; levels of indebtedness and restrictions on the Company's operations and activities imposed by the agreements governing the Company's outstanding indebtedness; the Company's sources of liquidity; changes in market conditions, including market factors affecting the price of debt and equity securities; the existence of alternative uses for the Company's cash; 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.

ani Pharmaceuticals, Inc.

Corporate Overview

- U.S. based specialty pharmaceutical company (NASDAQ: ANIP) with a commercial portfolio of 44 brand and generic Rx products
- Differentiated generic strategy including acquisition and re-commercialization of previously-approved products, as well as traditional development
- 311 employees; two manufacturing sites in Baudette, Minnesota and one in Oakville, Ontario

Generic Drugs

- 33 commercial products
- 100 pipeline products; 96 previously approved
- Total annual market size = $3.2B

Branded Drugs

- 11 commercial products
- 3 pipeline products previously approved
- Total annual market size = $1.1B

Contract Development & Manuf.

- 19 clients representing 31 products
- 177,000 ft^2 of U.S. based facilities
- 101,000 ft^2 Canadian facility
- Capabilities: Oral solids, 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

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

ani Pharmaceuticals, Inc.

First Quarter 2019 Financial Results

($ in millions, except per share data)	Three Months Ended March 31, 2019	2018
Net revenues	$ 52.9	$ 46.5
Net income	$ 0.4	$ 2.3
GAAP earnings per diluted share	$ 0.04	$ 0.19
Adjusted non-GAAP EBITDA (1)	$ 22.3	$ 21.8
Adjusted non-GAAP diluted earnings per share (1)	$ 1.30	$ 1.32

As compared with prior year:

- Net revenues increased 14%
- Adjusted non-GAAP EBITDA increased 2%
- Adjusted non-GAAP diluted earnings per share decreased 1.5%

ani Pharmaceuticals, Inc.

(1) See Appendix A for US GAAP reconciliations

First Quarter 2019 Revenues

($ in millions)	Three Months Ended March 31, 2019	2018
Generic pharmaceutical products	$ 31.6	$ 23.2
Branded pharmaceutical products	17.5	16.6
Contract manufacturing	2.4	0.9
Royalty and other income	1.3	5.7
Total net revenues	$ 52.9	$ 46.5

Results include:

- Generic sales increase primarily due to the launch of Ezetimibe-Simvastatin, Candesartan, and other products launched in 2018, as well as increased unit sales of Vancomycin
- Brand sales increase primarily due to 2018 launches of Atacand®, Atacand HCT®, Casodex® and Arimidex®, tempered by lower unit sales of Inderal ® LA and InnoPran XL®
- Contract manufacturing increase due to addition of ANI Pharmaceuticals Canada Inc. in Q3 2018
- Royalty and other income decreased primarily due to the launches of Atacand®, Atacand HCT®, Casodex®, and Arimidex® in 2018, tempered by product development and lab services revenue from ANI Canada, a royalty true-up from our former partner for Vancocin AG, and royalties on sales of Yescarta®

ani Pharmaceuticals, Inc.

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

2019 Guidance

($ in millions except EPS figures)

	2019 Guidance Range		2019 Guidance Growth	
	Low	High	Low	High
Net Revenues	$ 231.0	$ 245.0	15%	22%
Adjusted non-GAAP EBITDA (1)	$ 95.0	$ 105.0	13%	24%
Adjusted non-GAAP diluted earnings per share (1)	$ 5.57	$ 6.21	10%	22%

Forecast results assumes:

- Full year revenues and expenses related to our August 6th acquisition of WellSpring Pharma Services Inc.
- Continued investment in our Cortrophin® Gel re-commercialization program. The above guidance range include approximately $14.5 million to $16.5 million of total ANI Research and Development expense as compared to $15.4 million incurred in 2018
- Continued select investment in Selling, General, and Administrative expenses to support the continued growth of our business
- Combined Federal, State, and Foreign effective income tax rate of 24%
- Approximately 11.9 million shares outstanding

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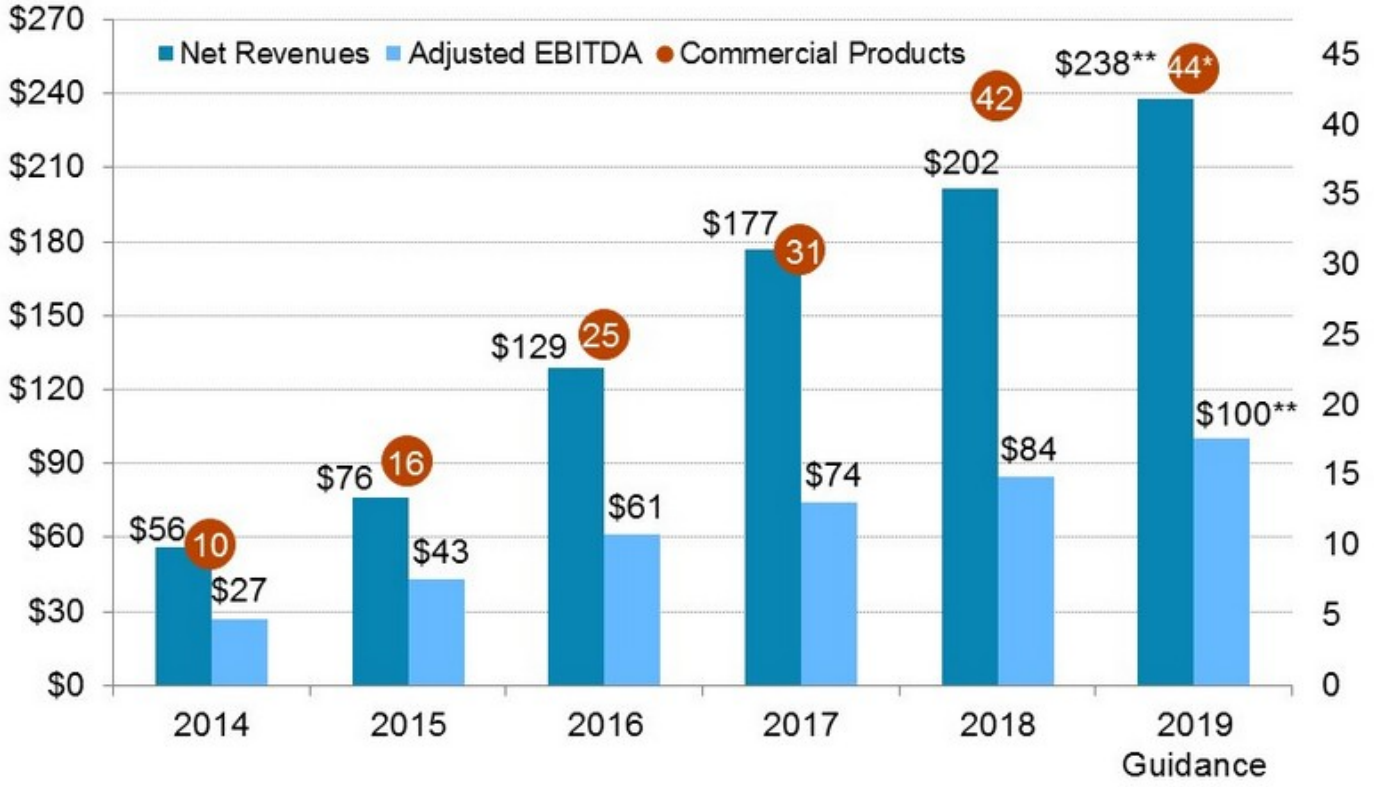
(1) See Appendix A for note regarding US GAAP reconciliations

Revenue & Adjusted EBITDA Growth

($'s in millions)



* Products as of May 9, 2019

** Midpoint of 2019 annual guidance, as presented in May 9, 2019 Earnings Release

Balance Sheet: Strong Capital Position

- $38.2 million of cash as of March 31, 2019, down 11% from year end
  - 1Q cash flow from operations of $14.3 million and free cash flow of $12.5 million
  - $18.5 million utilized to acquire ANDA related intangible assets in Q1 2019
- Net leverage of 1.5x as of March 31, 2019, based upon mid-point of 2019 guidance
- Recently completed 5-year, $265 million senior secured credit facility includes:
  - Undrawn $118 million delayed draw term loan to address December 2019 maturity of 3.00% convertible notes
  - Undrawn $75 million revolver

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 - $31.6M Net Sales for 1Q 2019

33 Commercial products, 79 SKUs

Two products added to commercial portfolio in 2019

- Strong market share position – top 10 products average approximately 51% share as of March 29, 2019
- Substantial Authorized Generic portfolio of 9 commercial products
- Contracts with all 3 major buying consortia – Red Oak, WBAD, and ClarusONE
- To date, ANI has re-launched 11 products from its pipeline of acquired ANDAs that require a tech transfer prior to re-commercialization
- 23 of the 33 commercial products are currently manufactured at ANI's sites

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Generic Rx – Pipeline

Total annual market size: $3.2 billion[1]

- ANDA Pipeline includes 100 products
  - At least 52 can be re-commercialized via CBE-30 or Prior Approval Supplement
  - Leverage ANI's three manufacturing sites to re-launch acquired ANDAs

Key Pipeline Products

- Methylphenidate ER Tablets (36mg & 54mg)
  - $563M market
- Aspirin/Dipyridamole ER Capsules
  - $117M market
- Undisclosed product – via development partner
  - $45M market

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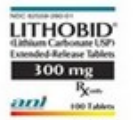
(1) Based on Company estimates and IQVIA data

Brand Rx - $17.5M Net Sales for 1Q 2019

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
- Launched Atacand® and Atacand HCT® in ANI label in October 2018



INDERAL XL propranolol HCl EXTENDED RELEASE CAPSULES

Arimidex anastrozole 1 mg tablets

Atacand candesartan cilexetil

INNOPRAN XL propranolol HCl 80 mg 120 mg EXTENDED RELEASE CAPSULES

Casodex bicalutamide tablets

AtacandHCT candesartan cilexetil-hydrochlorothiazide

Inderal LA (propranolol hydrochloride) Long-Acting Capsules

ani Pharmaceuticals, Inc.

Brand Rx – Pipeline

Total annual market size: $1.1 billion+(1)

- Brand Pipeline includes three products
  - Cortrophin® Gel, Cortrophin-Zinc®, and Vancocin® Oral Solution
  - All are FDA approved and can be re-commercialized via sNDA filing

Pipeline Products

- Cortrophin® Gel
  - $1.11B market
  - Target sNDA filing by 1Q 2020
- Vancocin® Oral Solution
  - $450M addressable market
  - Filed Prior Approval Supplement Sept. 2018

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(1) Based on Company estimates and IQVIA data

Cortrophin® Gel Re-commercialization Milestones

Manufacture Commercial Scale API

- ✓ 5X scale up to commercial scale
- ✓ Finalize API manufacturing process and initiate process validation
- ✓ Method development for API characterization methods
- ✓ Method validation for API release / stability methods
- Viral clearance validation

Manufacture Commercial Scale Drug Product

- ✓ Finalize drug product manufacturing process
- Initiate process validation
- Method validation for API release / stability methods

Manufacture Three Registration Batches

- Manufacture API and drug product registration batches
- Initiate registration stability studies and demonstrate six-months of accelerated and real-time stability prior to sNDA submission

sNDA Submission

- Target date: 1Q 2020
- Four-month PDUFA date

'✓' Work complete / substantially complete
'–' Work in process

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Contract Manufacturing - $2.4M Net Sales for Q1 2019

- Contract manufacturing – Baudette, Minnesota
  - Four customers
    - Seven products and seventeen SKUs
    - Contract manufacturing and contract packaging
- Contract manufacturing – Oakville, Ontario
  - Currently generating approximately $10M in annual revenues
  - 17 customers
    - 12 commercial products
    - 12 products in development
    - Contract development, manufacturing, and packaging

ani Pharmaceuticals, Inc.

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, Ontario

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 & Other Income - $1.3M Net Revenues for Q1 2019

- Royalty income primarily reflects:
  - $0.2 million for sales and milestones on Yescarta®
  - $0.5 million related to one-time royalty true-up
- Yescarta® Royalty
  - ANI recognized $0.2 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®

ani Pharmaceuticals, Inc.

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
- 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.

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, 2019	2018
Net Income	$ 449	$ 2,250
Add back		
Interest expense, net	3,354	3,634
Other expense, net	130	61
Provision for income taxes	469	592
Depreciation and amortization	16,103	8,195
Add back		
Stock-based compensation	1,710	1,377
Excess of fair value over cost of acquired inventory	-	5,645
Transaction and integration expenses	84	-
Adjusted non-GAAP EBITDA	$ 22,299	$ 21,754

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 March 31, 2019	2018
Net Income	$ 449	$ 2,250
Add back		
Non-cash interest expense	1,799	1,914
Depreciation and amortization expense	16,103	8,195
Stock-based compensation	1,710	1,377
Excess of fair value over cost of acquired inventory	-	5,645
Transaction and integration expenses	84	-
Less		
Tax impact of adjustments	(4,727)	(3,940)
Adjusted non-GAAP Net Income	$ 15,418	$ 15,441
Diluted Weighted-Average Shares Outstanding	11,823	11,706
Adjusted non-GAAP Diluted Earnings per Share	$ 1.30	$ 1.32

ani Pharmaceuticals, Inc.

U.S. GAAP Reconciliations

Non-GAAP Financial Measures included in 2019 Guidance

The Company's fiscal 2019 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.