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): March 15, 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** **(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 March 15, 2019, ANI Pharmaceuticals, Inc. (the “Company,” “we” or “us”) posted to its website its March 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 99.1 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. 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, March 2019

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: March 15, 2019

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

March 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 42 brand and generic Rx products
- Differentiated generic strategy including acquisition and re-commercialization of previously-approved products, as well as traditional development
- 304 employees; two manufacturing sites in Baudette, Minnesota and one in Oakville, Ontario
- 2019 Financial Guidance: $231M - $245M Revenues / $95M - $105M Adjusted non-GAAP EBITDA

Generic Drugs

- 31 commercial products
- 103 pipeline products; 98 previously approved
- Total annual market size = $4.1B

Branded Drugs

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

Contract Development & Manuf.

- 21 clients representing 31 products
- 177,000 ft^2 of US 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

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
Russell Miller	Sr. Director, Contract Sales	15	2019	Catalent

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Financial Highlights - 4Q and Full Year 2018

($ in millions, except per share data)	Three Months Ended December 31, 2018	Three Months Ended December 31, 2017	Year Ended December 31, 2018	Year Ended December 31, 2017
Net revenues	$ 57.1	$ 47.3	$ 201.6	$ 176.8
Net income / (loss)	$ 5.4	$ (9.6)	$ 15.5	$ (1.1)
GAAP earnings / (loss) per diluted share	$ 0.46	$ (0.83)	$ 1.30	$ (0.09)
Adjusted non-GAAP EBITDA (1)	$ 22.2	$ 19.7	$ 84.4	$ 74.2
Adjusted non-GAAP diluted earnings per share (1)	$ 1.32	$ 1.08	$ 5.07	$ 3.91

As compared with prior year:

- Net revenues increased 21% in 4Q and 14% YTD
- Adjusted non-GAAP EBITDA increased 13% in 4Q and 14% YTD
- Adjusted non-GAAP diluted earnings per share increased 22% in 4Q and 30% YTD

ani Pharmaceuticals, Inc.

(1) See Appendix A for US GAAP reconciliations

Financial Highlights - 4Q and Full Year 2018

($ in millions)	Three Months Ended December 31, 2018	Three Months Ended December 31, 2017	Year Ended December 31, 2018	Year Ended December 31, 2017
Generic pharmaceutical products	$ 33.7	$ 29.8	$ 117.4	$ 118.4
Branded pharmaceutical products	18.8	15.5	60.6	50.9
Royalty and other income	0.9	0.1	14.5	0.5
Contract manufacturing	3.7	1.9	9.1	7.0
Total net revenues	$ 57.1	$ 47.3	$ 201.6	$ 176.8

Year-to-date results include:

- Generic sales declines driven by volume decreases for Fenofibrate and Nilutamide, as well as sales decreases for Propranolol ER driven by price, tempered by 2018 product launches and impact of the Q2 2017 launch of Diphenoxylate Hydrochloride & Atropine Sulfate
- Brand sales reflect launches of InnoPran XL®, Inderal® XL, Arimidex®, Casodex®, Atacand®, and Atacand HCT® in the ANI label, tempered by lower unit sales of Inderal ® LA and Vancocin®
- Royalty and other income includes $10.7 million of royalty associated with our December 2017 purchase of four brands from AstraZeneca and $1.8 million of royalty on sales of Yescarta®

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

Full Year 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

Growth Led by New Product Introductions

($'s in millions)

* Midpoint of 2019 annual guidance, as presented in February 27, 2019 Earnings Release

Strong Capital Position

- $43.0 million of cash as of December 31, 2018, up 38% from prior year
  - YTD 2018 cash flow from operations of $67.1 million and free cash flow of $61.3 million
- Net leverage of 1.5x as of December 31, 2018, 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 - $117.4M Net Sales for Full Year 2018

31 Commercial products, 76 SKUs

Seven products added to commercial portfolio in 2018

- Strong market share position – top 10 products average approximately 50% share as of February 28, 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 10 products from its pipeline of acquired ANDAs that require a tech transfer prior to re-commercialization
- 22 of the 31 commercial products are currently manufactured at ANI's sites

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Generic Rx - Recent Transactions

Impax / Amneal

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

- **Commercialized:** Ezetimibe-Simvastatin, Felbamate, and Desipramine tablets
- **Approved ANDAs:** Aspirin/Dipyridamole ER capsules, Methylphenidate ER tablets
- **Pipeline:** Erythromycin IR tablets, Diclofenac-Misoprostol DR tablets*

- 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 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

Teva

Acquired a basket of active and discontinued generic ANDAs which increase ANI's pipeline product portfolio by 31

- Purchased on March 8, 2019 for consideration of $2.5 million; the portfolio has a combined U.S. market of approximately $800 million according to IQVIA data

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* License, supply, and distribution agreement

Generic Rx – Pipeline

Total annual market size: $4.1 billion[1]

- ANDA Pipeline includes 103 products
  - At least 57 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
  - $1.3B market
  - Estimated launch date March 2019
- Aspirin/Dipyridamole ER Capsules
  - $178M market
  - Launch October 2019
- Undisclosed product – via development partner
  - $45M market
  - Priority Review with GDUFA date of April 2019

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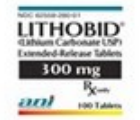
(1) Based on Company estimates and IQVIA data

Brand Rx - $60.6M Net Sales for Full Year 2018

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
- Target completion of manufacturing and packaging site transfer of Atacand® and Atacand HCT® to Baudette by 2020
- Vancocin® capsules manufacturing site transfer in progress



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
  - Vancocin® Oral Solution to be manufactured at ANI sites

Pipeline Products

- Cortrophin® Gel
  - $1.12B 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

	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, additional communication in 2Q18
Manufacture demo batch of Cortrophin® Gel	1 mo.	Ongoing	• 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	• Analytical Method Validation for API Release/Stability • 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 mo. per batch	Q2 2019	• Analytical Method Validation for drug product Release/Stability • 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		Q1 2020	• Filing - four month PDUFA date

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Contract Manufacturing - $9.1M Net Sales for Full Year 2018

- 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 Income - $14.5M Net Revenues for fiscal 2018

- YTD Royalty income primarily reflects:
  - $10.7 million on sales of Atacand®, Atacand HCT®, Arimidex®, and Casodex®
  - $1.8 million for sales and milestones on Yescarta®
- Yescarta® Royalty
  - YTD 2018, ANI recognized $1.8 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
  - 2019 Annual guidance[1]
    - Net revenues of $231 million to $245 million
    - Adjusted non-GAAP EBITDA[2] of $95 million to $105 million
    - Adjusted non-GAAP diluted earnings per share[2] of $5.57 to $6.21
- 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) February 27, 2019 earnings 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 December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Net Income/(Loss)	$ 5,430	$ (9,629)	$ 15,494	$ (1,076)
Add back				
Interest expense, net	3,626	3,026	14,758	12,035
Other (income)/expense, net, less loss on and expense on repurchase of convertible debt	(90)	3	(19)	(55)
Provision for income taxes	1,910	13,979	4,557	17,425
Depreciation and amortization	8,686	7,022	33,742	27,928
Intangible asset impairment charge	-	903	-	903
Add back				
Stock-based compensation	1,828	1,422	6,782	6,090
Acquired IPR&D expense	-	-	1,335	-
Excess of fair value over cost of acquired inventory	-	2,946	5,689	10,448
Loss on and expense on repurchase of convertible debt and expense on debt refinancing	691	-	691	-
Transaction and integration expenses	103	-	1,372	477
Adjusted non-GAAP EBITDA	$ 22,184	$ 19,672	$ 84,401	$ 74,175

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 December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Net Income/(Loss)	$ 5,430	$ (9,629)	$ 15,494	$ (1,076)
Add back				
Non-cash interest expense	1,903	1,758	7,741	7,113
Depreciation and amortization expense	8,686	7,022	33,742	27,928
Acquired IPR&D expense	-	-	1,335	-
Stock-based compensation	1,828	1,422	6,782	6,090
Excess of fair value over cost of acquired inventory	-	2,946	5,689	10,448
Intangible asset impairment charge	-	903	-	903
Loss on and expense on repurchase of convertible debt and expense on debt refinancing	691	-	691	-
Transaction and integration expenses	103	-	1,372	477
Less				
Tax impact of adjustments	(3,039)	(5,199)	(13,191)	(19,595)
Add back				
Impact of Tax Cuts and Jobs Act of 2017 on Deferred Tax Assets	-	13,394	-	13,394
Adjusted non-GAAP Net Income	$ 15,602	$ 12,617	$ 59,655	$ 45,682
Diluted Weighted-Average Shares Outstanding	11,785	11,723	11,772	11,680
Adjusted non-GAAP Diluted Earnings per Share	$ 1.32	$ 1.08	$ 5.07	$ 3.91

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.

ani Pharmaceuticals, Inc.