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): **December 3, 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 December 3, 2019, ANI Pharmaceuticals, Inc. (the “Company,” “we” or “us”) posted to its website its December 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, 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	ANI Pharmaceuticals, Inc. Corporate Presentation, December 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: December 3, 2019

Exhibit 99.1

ani Pharmaceuticals, Inc.

A Specialty Pharmaceutical Company

NASDAQ: ANIP

GENERIC AND BRANDED PRESCRIPTION DRUG PRODUCTS

Corporate Presentation

December 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 47 brand and generic Rx products
- Differentiated generic strategy including acquisition and re-commercialization of previously-approved products, as well as traditional development
- Approximately 340 employees; two manufacturing sites in Baudette, Minnesota and one in Oakville, Ontario

Generic Drugs

- 36 commercial products
- 107 pipeline products (92 previously approved) with total annual market size = $4.3B

Branded Drugs

- 11 commercial products
- 2 pipeline products previously approved with total annual market size = $1.0B

Contract Development & Manuf.

- 18 clients representing 29 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 Connolly	VP, Regulatory Affairs	15+	2012	SANDOZ
Mark Ginski, PhD	VP, Corticotropin Development	20+	2016	Mallinckrodt

ani Pharmaceuticals, Inc.

Financial Highlights - 3Q and YTD 2019

($ in millions, except per share data)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Net revenues	$ 51.3	$ 50.7	$ 158.6	$ 144.5
Net income / (loss)	$ 3.9	$ 5.0	$ 10.9	$ 10.1
GAAP earnings / (loss) per diluted share	$ 0.32	$ 0.42	$ 0.89	$ 0.85
Adjusted non-GAAP EBITDA (1)	$ 19.8	$ 21.4	$ 65.8	$ 62.2
Adjusted non-GAAP diluted earnings per share (1)	$ 1.23	$ 1.29	$ 3.98	$ 3.74

As compared with prior year:

- Net revenues increased 10% YTD
- Adjusted non-GAAP EBITDA increased 6% YTD
- Adjusted non-GAAP diluted earnings per share increased 6% YTD

ani Pharmaceuticals, Inc.

(1) See Appendix A for US GAAP reconciliations

Third Quarter and YTD 2019 Revenues

($ in millions)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Generic pharmaceutical products	$ 31.8	$ 30.3	$ 99.5	$ 83.7
Branded pharmaceutical products	16.6	14.6	48.3	41.7
Contract manufacturing	2.4	2.8	8.5	5.5
Royalty and other income	0.6	3.0	2.3	13.6
Total net revenues	$ 51.3	$ 50.7	$ 158.6	$ 144.5

Year-to-date results include:

- Generic sales increased primarily due to the launch of four products during 2019 as well as continued strength in certain 2018 launch products.
- Brand sales increased primarily due to 2018 launches of Atacand®, Atacand HCT®, Casodex® and Arimidex®, tempered by lower unit sales of InnoPran XL®, Lithobid, and Vancocin®.
- Contract manufacturing increased primarily 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® under our own label in 2018.

ani Pharmaceuticals, Inc.

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

2019 Guidance

($ in millions except EPS figures)

	2019 Guidance Range Low	High
Net Revenues	$ 209.0	$ 212.0
Adjusted non-GAAP EBITDA (1)	$ 84.7	$ 86.8
Adjusted non-GAAP diluted earnings per share (1)	$ 5.06	$ 5.23

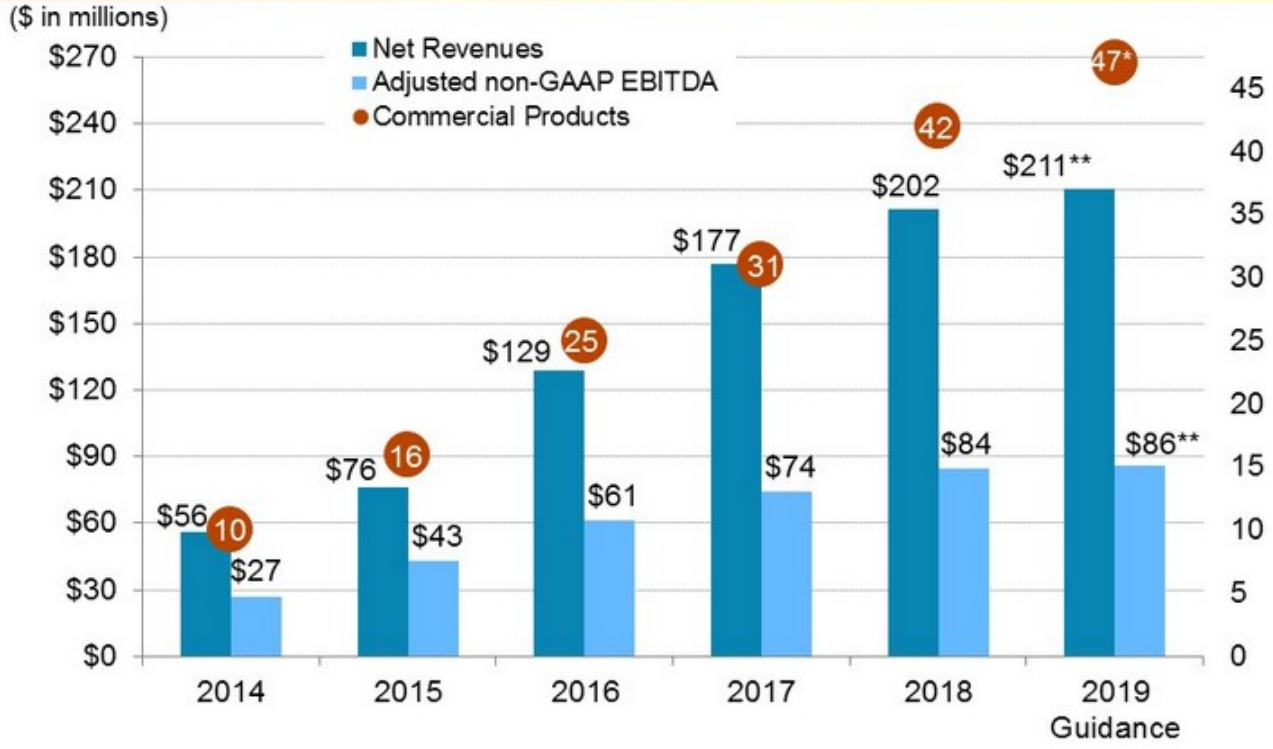
Forecast results assumes:

- Continued investment in our Cortrophin® Gel re-commercialization program. The above guidance range includes approximately $18.0 million to $18.5 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 growth of our business
- Combined Federal, State, and Foreign marginal income tax rate of 24%
- Approximately 12.0 million shares outstanding

ani Pharmaceuticals, Inc.

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

Revenue & Adjusted non-GAAP EBITDA Growth



* Products as of November 6, 2019
** Midpoint of 2019 annual guidance, as presented in November 6, 2019 Earnings Release

Balance Sheet: Strong Capital Position

- $59.7 million of cash as of September 30, 2019, up 39% from year end
  - YTD cash flow from operations of $40.8 million and free cash flow of $35.9 million
  - $21.2 million utilized to acquire ANDA related intangible assets, product rights, and IPR&D
- Net leverage of 1.5x as of September 30, 2019, based upon mid-point of 2019 guidance
- Retired $118.75 million convertible notes on December 2, 2019
- 5-year, $265 million senior secured credit facility:
  - Drawn $187.5 million Term Loan A
  - 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

ani Pharmaceuticals, Inc.

Generic Rx - $99.5M Net Sales YTD

36 Commercial products, 86 SKUs

Five products added to commercial portfolio in 2019

- Strong market share position – top 10 products average approximately 43% share as of September 30, 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
- 25 of the 36 commercial products are currently manufactured at ANI's sites

ani Pharmaceuticals, Inc.

Generic Rx – Key New Product Launch

- Vancomycin Oral Solution 250mg/5ml
  - Launched September 2019
  - ANI sells the only FDA approved generic product
  - Convenient pre-flavored single bottle format
  - Launch supported by broad marketing/awareness program
  - Annual U.S. vancomycin market exceeds $450M (1)
  - Heavily compounded dosage form
    - ANI actively targeting removal of compounded product
  - Manufactured at ANI facility in Baudette, MN

Vancomycin is used in treating antibiotic-associated pseudomembranous colitis caused by Clostridium difficile colitis (commonly referred to as "C-diff") and for staphylococcal enterocolitis in particular, methicillin resistant staphylococcus aureus (MRSA).

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(1) Based on Company estimates and IQVIA data

Generic Rx – Key New Product Launch

- Bretylium Tosylate Injection, 500mg/10ml
  - ANI's launch re-introduces this critical care drug to the U.S. market
  - ANI will support launch with educational programs and broad awareness campaign
  - 180,000 crash carts in U.S. with recommendation for two vials per crash cart (1)
  - Drug previously included in Advanced Cardiac Life Support (ACLS) guidelines

Indicated for ventricular fibrillation and life-threatening ventricular arrhythmias, such as ventricular tachycardia

(1) Based on Company estimates

Generic Rx – Pipeline

Total annual market size: $4.3 billion(1)

- Generic pipeline includes 107 products
  - At least 53 can be re-commercialized via CBE-30 or Prior Approval Supplement
  - Approved ANDAs allow ANI to rapidly respond to changing market dynamics
- Growing injectable pipeline of five products with total annual market size of $769M (1)
- Leverage ANI's three manufacturing sites to re-launch acquired ANDAs
- Dosage forms include:
  - solid orals,
  - solutions/suspensions and
  - injectables
- Ability to launch unit-dose presentation

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(1) Based on Company estimates and IQVIA data

Brand Rx - $48.3M 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
- Launched Atacand® and Atacand HCT® in ANI label in October 2018

INDERAL XL propranolol HCl EXTENDED RELEASE CAPSULES

INNOPRAN XL propranolol HCl 80 mg 120 mg EXTENDED RELEASE CAPSULES

Inderal LA (propranolol hydrochloride) Long-Acting Capsules

Arimidex anastrozole 1 mg tablets

Casodex bicalutamide tablets

Atacand candesartan cilexetil

AtacandHCT candesartan cilexetil-hydrochlorothiazide

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Brand Rx – Pipeline

Total annual market size: $1.0 billion(1)

- Brand pipeline includes two products:
  - Cortrophin® Gel and Cortrophin-Zinc®
  - Both are FDA approved and can be re-commercialized via sNDA filing

Key Pipeline Product

- Cortrophin® Gel, 80 USP units/ml
  - $1.0B market
  - Target sNDA filing in March 2020
  - Commercial launch will occur immediately upon FDA approval of sNDA
  - Launch will be supported by a dedicated sales force
  - Target 50% market share
  - Drug substance and drug product sourced and manufactured in U.S.

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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
- Demonstrate six-months of accelerated and real-time stability prior to sNDA submission

sNDA Submission

- Target date: March 2020
- Four-month PDUFA date

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

ani Pharmaceuticals, Inc.

Contract Manufacturing - $8.5M Net Sales YTD

- Experienced contract manufacturer since 2007
  - Quality focus at our three North American manufacturing facilities
  - Broad scientific and regulatory expertise
  - Solid oral, liquids, topicals, potent compounds, DEA schedule 2 products
  - Launched ANI Global Source brand in October 2019

- Currently serve 18 customers
  - Brand and generic customers
  - 19 commercial products
  - 10 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 ▪ 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
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

ani Pharmaceuticals, Inc.

Other Revenue Generating Assets

- Yescarta® Royalty
  - 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®

Summary

- ANI is an integrated specialty generic pharmaceutical company with:
  - Profitable base business with substantial pipeline opportunities
  - 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net Income	$ 3,895	$ 5,037	$ 10,929	$ 10,064
Add back				
Interest expense, net	3,336	3,768	10,096	11,132
Other expense/(income), net	33	(20)	117	71
(Provision)/Benefit for income taxes	64	1,329	(120)	2,647
Depreciation and amortization	9,473	8,548	35,048	25,056
Cortrophin pre-launch charges	195	-	195	-
Expensed FDA approval milestone payment	329	-	329	-
Add back				
Stock-based compensation	2,470	1,795	6,773	4,954
Acquired IPR&D expense	-	-	2,324	1,335
Excess of fair value over cost of acquired inventory	-	44	-	5,689
Transaction and integration expenses	-	928	84	1,269
Adjusted non-GAAP EBITDA	$ 19,795	$ 21,429	$ 65,775	$ 62,217

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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net Income	$ 3,895	$ 5,037	$ 10,929	$ 10,064
Add back				
Non-cash interest expense	1,871	1,980	5,525	5,839
Depreciation and amortization expense	9,473	8,548	35,048	25,056
Cortrophin pre-launch charges	195	-	195	-
Expensed FDA approval milestone payment	329	-	329	-
Acquired IPR&D expense	-	-	2,324	1,335
Stock-based compensation	2,470	1,795	6,773	4,954
Excess of fair value over cost of acquired inventory	-	44	-	5,689
Transaction and integration expenses	-	928	84	1,269
Less				
Tax impact of add back items	(3,441)	(3,058)	(12,067)	(10,153)
Discrete tax benefit related to ANI Canada transfer pricing agreement	-	-	(1,653)	-
Adjusted non-GAAP Net Income	$ 14,792	$ 15,274	$ 47,487	$ 44,053
Diluted Weighted-Average Shares Outstanding	12,085	11,804	12,060	11,767
Less dilutive effect of notes	(78)	-	(128)	-
Adjusted Diluted Weighted-Average Shares Outstanding	12,007	11,804	11,932	11,767
Adjusted non-GAAP Diluted Earnings per Share	$ 1.23	$ 1.29	$ 3.98	$ 3.74

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.