**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

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**FORM 8-K**

**Current Report**
**Pursuant to Section 13 or 15(d) of the**
**Securities Exchange Act of 1934**

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Date of Report (Date of earliest event reported): **December 27, 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**<br>**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)

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 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 1.01. Entry into a Material Definitive Agreement.**

On December 27, 2018, ANI Pharmaceuticals, Inc. (the "Company," "we" or "us") and its subsidiaries entered into an amended and restated five-year senior secured credit facility (the "Amended Credit Agreement") with Citizens Bank, N.A. as a lender and as administrative agent, and the other lenders party thereto, which amends and restates the Company's previous credit facility dated as of December 29, 2017, as amended (the "Previous Credit Agreement").

The Amended Credit Agreement, among other things, (i) adds a delayed draw term loan facility in an amount up to $118.0 million, (ii) increases the borrowing capacity under the revolving line of credit by $25.0 million to $75.0 million and (iii) extends the maturity of the credit facility, including the outstanding $72.2 million initial term loan, to December 27, 2023, from the Previous Credit Agreement maturity date of December 29, 2022. Subject to the satisfaction of certain conditions, the Company may borrow the delayed draw term loans at any time prior to December 1, 2019, at which time any portion of the delayed draw term loan facility that remains undrawn will be automatically cancelled. The total size of the Amended Credit Agreement is $265.2 million following the amendment and restatement thereof.

The Amended Credit Facility continues to be secured by the assets of the Company and guaranteed by certain subsidiaries of the Company.

The Company may repay borrowings under the term loans, including the initial term loan and any delayed draw term loans, and the revolving credit facility without any premium or penalty, and so long as the Company meets certain conditions by August 30, 2019 relating to its total net leverage ratio and liquidity or to the repayment or refinancing of its outstanding 3.00% Convertible Senior Notes due 2019 (the "Notes") as set forth in the Amended Credit Agreement, all borrowings thereunder shall be repaid by December 27, 2023. The Company may use the proceeds of revolving loans for working capital and other general corporate purposes and may only use the proceeds from the delayed draw term loans, if borrowed, to refinance the Company's outstanding Notes.

Term loans under the Amended Credit Agreement bear interest at a rate per annum of, at the Company's option, either (i) the Alternative Base Rate, as defined in the Amended Credit Agreement, plus an applicable Base Rate Margin, which varies within a range of 0.50% to 1.75% depending on the Company's total leverage ratio (as determined under the Amended Credit Agreement), or (ii) the LIBOR Rate, as defined in the Amended Credit Agreement, plus an applicable LIBOR Margin and L/C Fee, which varies within a range of 1.50% to 2.75% depending on the Company's total leverage ratio (as determined under the Amended Credit Agreement). The Company is required to pay a Commitment Fee under the Amended Credit Agreement in consideration of the revolving line of credit at a rate per annum that varies within a range of 0.25% to 0.50% depending on the Company's total leverage ratio (as determined under the Amended Credit Agreement). The Company is also required to pay a Delayed Draw Ticking Fee under the Amended Credit Agreement at a rate per annum that varies within a range of 0.25% to 0.50% depending on the Company's total leverage ratio (as determined under the Amended Credit Agreement) on the average daily unused amount of the Delayed Draw Term Loan from the date of the Amended Credit Agreement until December 1, 2019.

The Amended Credit Agreement contains customary representations and affirmative, negative and financial covenants that are similar to the Previous Credit Agreement. The primary financial covenants under the Amended Credit Agreement consist of a maximum total net leverage ratio, which initially shall be no greater than 3.75 to 1.00, and a minimum fixed charge coverage ratio which shall be greater than or equal to 1.25 to 1.00. The primary non-financial covenants under the Amended Credit Agreement limit, subject to various exceptions, the Company's ability to incur future indebtedness, to place liens on assets, to pay dividends or make other distributions on the Company's capital stock, to repurchase the Company's capital stock, to conduct acquisitions, to alter its capital structure and to dispose of assets.

The Amended Credit Agreement also includes customary events of default that are similar to the Previous Credit Agreement, the occurrence of which, following any applicable grace period, would permit the lenders to, among other things, accelerate repayment of the loans under the Amended Credit Agreement.

On December 27, 2018, the Company issued a press release with respect to the Amended Credit Agreement, which is attached as Exhibit 99.1 hereto and is incorporated herein by reference.

The foregoing description of the Amended Credit Agreement does not purport to be complete and is qualified in its entirety by reference to the Amended Credit Agreement, which will be filed as an exhibit to the Company's Annual Report on Form 10-K for its fiscal year ending December 31, 2018.

**Item 2.03 Creation of a Direct Financial Obligation or an Obligation Under an Off-Balance Sheet Arrangement of a Registrant.**

The information set forth in Item 1.01 above is incorporated by reference into this Item 2.03.

**Item 7.01 Regulation FD Disclosure.**

On December 27, 2018, we posted to our website our December 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 99.2 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 Exhibit 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 price increases, the Company's future operations, products financial position, operating results and prospects, the Company's pipeline or potential markets therefor, 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.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

| No. | Description |
|---|---|
| 99.1 | Press release, dated December 27, 2018. |
| 99.2 | ANI Pharmaceuticals, Inc. Corporate Presentation, December 2018. |

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 27, 2018

# ANI Pharmaceuticals Secures Refinancing for Convertible Debt Due December 2019 and Enters Amended Five-Year $265 Million Senior Secured Credit Facility

BAUDETTE, Minn., Dec. 27, 2018 /PRNewswire/ -- ANI Pharmaceuticals, Inc. ("ANI" or the "Company") (Nasdaq: ANIP) today announced that it has entered an amended and restated five-year Senior Secured Credit Facility (the "Facility") for up to $265.2 million with its existing syndicate of bank lenders (the "Bank Group"). The Facility amends ANI's current $125 million Senior Secured Credit Facility and is structured to provide ANI flexibility in refinancing its 3.00% Convertible Senior Notes due 2019 ("the Convertible Notes"). The principal feature of the Facility is a new $118.0 million Delayed Draw Term Loan available to refinance ANI's Convertible Notes maturing in December 2019. The Delayed Draw Term Loan is fully committed by the Bank Group and can be accessed by ANI at any time and in multiple tranches through December 1, 2019, subject to satisfaction of certain conditions precedent. The second feature is the extension of $72.2 million of Term Loan-A debt currently outstanding under the existing facility. In addition, the Facility increases the existing $50.0 million Senior Secured Revolving Credit Facility to $75.0 million. Both the Delayed Draw Term Loan and Senior Secured Revolving Credit Facility are undrawn as of this time. Interest on the Facility is LIBOR based and generally consistent with ANI's current borrowing arrangements with the Bank Group. The Facility is secured by the assets and equity interests of ANI and guaranteed by certain of its subsidiaries.

The Lead Arranger and Administrative Agent for the Facility is Citizens Bank, N.A. The Bank of Tokyo-Mitsubishi UFJ, Ltd. and The Huntington National Bank acted as Joint Lead Arrangers, while Regions Bank acted as Documentation Agent. The Facility is also funded by U.S. Bank National Association and J.P. Morgan Chase Bank, N.A.

Arthur S. Przybyl, ANI's President and CEO stated, "The expansion of our existing credit facility is a testament to the financial strength of ANI and signals our intent to refinance our Convertible Notes in a shareholder friendly manner." Stephen P. Carey, ANI's Vice President and CFO added, "Today's amendment provides ANI maximum flexibility in approaching the refinancing of our Convertible Notes maturing in December 2019, with the security of fully committed capital from our Bank Group. In addition, the expansion of the revolver portion of the Facility coupled with our cash on-hand, continued cash flow from operations, and on-going support of our Bank Group will continue to support our future growth."

"At Citizens, we try to think about the needs of our clients from their point of view and offer holistic solutions," said Daniel K. Fitzpatrick, Executive President of Mid-Atlantic Region and Head of National Industry Verticals for Citizens Bank. "Leading flexible credit facilities so valued clients such as ANI Pharmaceuticals can grow is just one of the ways that Citizens delivers substantial value for our clients at every stage of their business life cycle."

**About ANI**

ANI Pharmaceuticals, Inc. 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.

**About Citizens Financial Group, Inc.**

Citizens Financial Group, Inc. is one of the nation's oldest and largest financial institutions, with $158.6 billion in assets as of September 30, 2018. Headquartered in Providence, Rhode Island, Citizens offers a broad range of retail and commercial banking products and services to individuals, small businesses, middle-market companies, large corporations and institutions. Citizens helps its customers reach their potential by listening to them and by understanding their needs in order to offer tailored advice, ideas and solutions. In Consumer Banking, Citizens provides an integrated experience that includes mobile and online banking, a 24/7 customer contact center and the convenience of approximately 2,900 ATMs and approximately 1,150 branches in 11 states in the New England, Mid-Atlantic and Midwest regions. Consumer Banking products and services include a full range of banking, lending, savings, wealth management and small business offerings. In Commercial Banking, Citizens offers corporate, institutional and not-for-profit clients a full range of wholesale banking products and services, including lending and deposits, capital markets, treasury services, foreign exchange and interest rate products and asset finance. More information is available at www.citizensbank.com or visit us on Twitter, LinkedIn or Facebook.

**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 regarding the Company's use of proceeds of the Facility in the manner currently anticipated, including the refinancing of the Convertible Notes, in addition 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 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 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

**Exhibit 99.2**

ani Pharmaceuticals, Inc.

A Specialty Pharmaceutical Company

NASDAQ: ANIP

GENERIC AND BRANDED PRESCRIPTION DRUG PRODUCTS

# Corporate Presentation

December 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, 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.

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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
- 305 employees; two manufacturing sites in Baudette, Minnesota and one in Oakville, Ontario
- 2018 Financial Guidance: $195M - $205M Revenues / $82M - $88M Adjusted non-GAAP EBITDA

### Generic Drugs

- 31 commercial products
- 72 pipeline products; 50 previously approved
- Total annual market size = $3.3B

### Branded Drugs

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

### Contract Development & Manuf.

- 24 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 - 3Q and YTD 2018

| *($ in millions, except per share data)* | Three Months Ended September 30, 2018 | Three Months Ended September 30, 2017 | Nine Months Ended September 30, 2018 | Nine Months Ended September 30, 2017 |
|---|---|---|---|---|
| Net revenues | $ 50.7 | $ 48.2 | $ 144.5 | $ 129.6 |
| Net income | $ 5.0 | $ 4.7 | $ 10.1 | $ 8.6 |
| GAAP earnings per diluted share | $ 0.42 | $ 0.40 | $ 0.85 | $ 0.73 |
| Adjusted non-GAAP EBITDA (1) | $ 21.4 | $ 20.7 | $ 62.2 | $ 54.5 |
| Adjusted non-GAAP diluted earnings per share (1) | $ 1.29 | $ 1.11 | $ 3.74 | $ 2.83 |

As compared with prior year:

- Net revenues increased 5% in 3Q and 10% YTD
- Adjusted non-GAAP EBITDA increased 4% in 3Q and 14% YTD
- Adjusted non-GAAP diluted earnings per share increased 16% in 3Q and 32% YTD

ani Pharmaceuticals, Inc.

(1) See Appendix A for US GAAP reconciliations

# Financial Highlights - 3Q and YTD 2018

| *($ in millions)* | Three Months Ended September 30, 2018 | Three Months Ended September 30, 2017 | Nine Months Ended September 30, 2018 | Nine Months Ended September 30, 2017 |
|---|---|---|---|---|
| Generic pharmaceutical products | $ 30.3 | $ 30.6 | $ 83.7 | $ 88.6 |
| Branded pharmaceutical products | 14.6 | 15.7 | 41.7 | 35.4 |
| Royalty and other income | 3.0 | 0.1 | 13.6 | 0.4 |
| Contract manufacturing | 2.8 | 1.8 | 5.5 | 5.2 |
| Total net revenues | $ 50.7 | $ 48.2 | $ 144.5 | $ 129.6 |

Year-to-date results include:

- Generic sales declines driven by volume decreases for Fenofibrate, EEMT, and Nilutamide and price decreases for Propranolol ER, tempered by Q2 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®, and Casodex® in the ANI label
- Royalty and other income includes $11.1 million of royalty associated with our December 2017 purchase of four brands from AstraZeneca and $1.4 million of royalty on sales of Yescarta®

ani Pharmaceuticals, Inc.

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

# Full Year 2018 Guidance

*($ in millions except EPS figures)*

| | 2018 Guidance Range | | 2018 Guidance Growth | |
|---|---|---|---|---|
| | Low | High | Low | High |
| Net Revenues | $ 195.0 | $ 205.0 | 10% | 16% |
| Adjusted non-GAAP EBITDA (1) | $ 82.0 | $ 88.0 | 11% | 19% |
| Adjusted non-GAAP diluted earnings per share (1) | $ 4.80 | $ 5.27 | 23% | 35% |

Forecast results assumes:

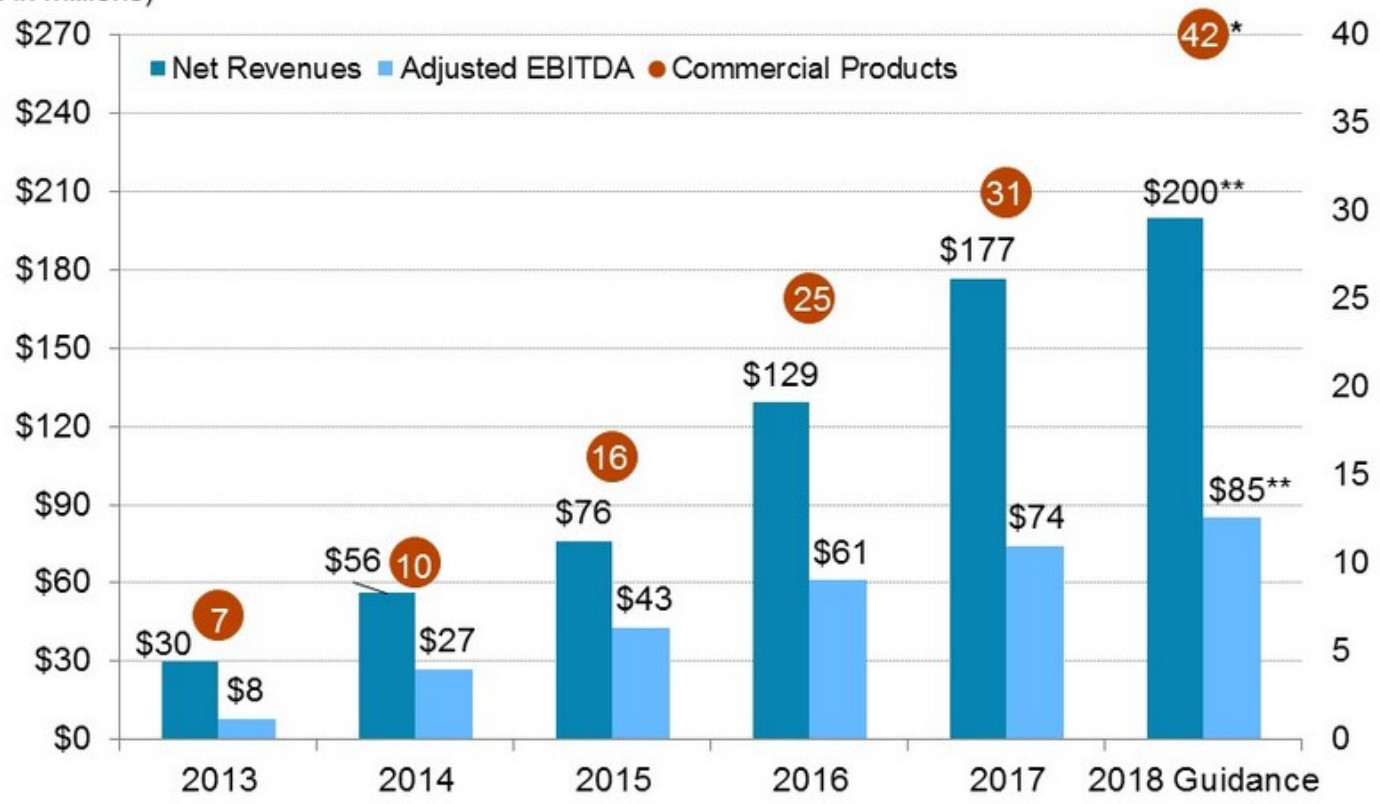
- Revenues and expenses related to our December 29, 2017 acquisition of the NDAs and U.S. product rights for Atacand®, Atacand HCT®, Arimidex®, and Casodex® and August 6th acquisition of WellSpring Pharma Services
- Maximizing the potential of our currently commercialized product portfolio, 2018 generic launches, and integrating generic assets 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

ani Pharmaceuticals, Inc.

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

# Growth Led by New Product Introductions

($'s in millions)




* Products as of November 6, 2018

** Midpoint of 2018 annual guidance, as presented in November 6, 2018 Earnings Release

# Strong Capital Position

- $44.1 million of cash as of September 30, 2018, up 40% from year end
  - YTD 2018 cash flow from operations of $39.8 million and free cash flow of $35.1 million
- Net leverage of 2.0x as of September 30, 2018, based upon mid-point of 2018 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

ani Pharmaceuticals, Inc.

# Generic Rx - $83.7M Net Sales YTD

**31 Commercial products, 76 SKUs**

**Seven products added to commercial portfolio YTD 2018**

- Strong market share position – top 10 products average approximately 48% share as of October 29, 2018
- 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

ani Pharmaceuticals, Inc.

# 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 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

ani Pharmaceuticals, Inc.

* License, supply, and distribution agreement

# Generic Rx – Pipeline

**Total annual market size: $3.3 billion[1]**

- ANDA Pipeline includes 72 products
  - 51 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 1Q 2019
- Aspirin/Dipyridamole ER Capsules
  - $176M market
  - Launch October 2019
- Undisclosed product – via development partner
  - $46M market
  - Priority Review with GDUFA date of April 2019

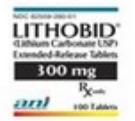
ani Pharmaceuticals, Inc.

(1) Based on Company estimates and IQVIA data

# Brand Rx - $41.7M 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
- 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 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
  - $1.2B market
  - Target sNDA filing by 1Q 2020
- Vancocin ® Oral Solution
  - $450M addressable market
  - Filed Prior Approval Supplement Sept. 2018

ani Pharmaceuticals, Inc.

(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<br>• 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<br>• Further refined/modernized analytical methods & process<br>• Demonstrated lot-to-lot consistency |
| **Type C meeting with FDA** | | Complete | • Meeting Request submitted 4Q17; FDA granted as Type C Meeting<br>• Information provided on ANI's regulatory plan for re-commercialization<br>• 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<br>• Scale-up manufacturing process 5x to projected commercial scale<br>• Manufacture API under cGMPs<br>• Finalize API manufacturing process and initiate process validation/registration batches |
| **Manufacture registration batches of Cortrophin® Gel** | 1 mo. per batch | 1Q 2019 | • Analytical Method Validation for drug product Release/Stability<br>• Process validation<br>• Registration / Commercial batches<br>• 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** | | 1Q 2020 | • Filing - four month PDUFA date |

ani Pharmaceuticals, Inc.

# Contract Manufacturing - $5.5M 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 $11M in annual revenues
  - 20 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 |
|---|---|---|
| 5 ANDA<br>12 NDA | In development / Filed<br>9 ANDA<br>5 NDA | 17 Solids<br>11 Semi-solids<br>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<br>▪ Recently completed 5,500 ft² warehouse expansion includes additional schedule CII vault & CIII cage space<br>▪ 17,000 ft² of laboratory space for product development and analytical testing | ▪ 32,000 ft² of manufacturing, packaging, and warehouse<br>▪ 100 nano-gram per eight-hour time weighted average maximum exposure limit to ensure employee safety<br>▪ Adding a low-humidity suite for processing and encapsulating moisture-sensitive compounds |
| **Capabilities** | ▪ Rx solutions, suspensions, topicals, tablets, capsules, and powder for suspension<br>▪ DEA-licensed for Schedule II controlled substances | ▪ Fully-contained high potency facility with capabilities to manufacture hormone, steroid, and oncolytic products<br>▪ DEA Schedule III capability |
| **Capacity** | ▪ **Solid Dose** - ~1.2 billion doses/yr<br>▪ **Liquids** - ~53 million bottles/yr<br>▪ **Liquid Unit Dose** - ~23 million doses/yr<br>▪ **Powder** - ~12 million bottles/yr | ▪ **Tablets** - ~2.5 billion doses/yr<br>▪ **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 - $13.6M Net Revenues YTD

- YTD Royalty income primarily reflects:
  - $11.1 million on sales of Atacand®, Atacand HCT®, Arimidex®, and Casodex®
  - $1.4 million for sales and milestones on Yescarta®
- Yescarta® Royalty
  - YTD 2018, ANI recognized $1.4 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

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(1) November 6, 2018 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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Net Income | $ 5,037 | $ 4,720 | $ 10,064 | $ 8,553 |
| Add back | | | | |
| Interest expense, net | 3,768 | 3,052 | 11,132 | 9,009 |
| Other income/(expense), net | (20) | (95) | 71 | (58) |
| Provision for income taxes | 1,329 | 1,654 | 2,647 | 3,446 |
| Depreciation and amortization | 8,548 | 7,099 | 25,056 | 20,906 |
| Add back | | | | |
| Stock-based compensation | 1,795 | 1,475 | 4,954 | 4,668 |
| Acquired IPR&D expense | - | - | 1,335 | - |
| Excess of fair value over cost of acquired inventory | 44 | 2,757 | 5,689 | 7,502 |
| Transaction and integration expenses | 928 | - | 1,269 | 477 |
| Adjusted non-GAAP EBITDA | $ 21,429 | $ 20,662 | $ 62,217 | $ 54,503 |

# 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, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Net Income | $ 5,037 | $ 4,720 | $ 10,064 | $ 8,553 |
| Add back | | | | |
| Non-cash interest expense | 1,980 | 1,789 | 5,839 | 5,355 |
| Depreciation and amortization expense | 8,548 | 7,099 | 25,056 | 20,906 |
| Acquired IPR&D expense | - | - | 1,335 | - |
| Stock-based compensation | 1,795 | 1,475 | 4,954 | 4,668 |
| Excess of fair value over cost of acquired inventory | 44 | 2,757 | 5,689 | 7,502 |
| Transaction and integration expenses | 928 | - | 1,269 | 477 |
| Less | | | | |
| Tax impact of adjustments | (3,058) | (4,854) | (10,153) | (14,396) |
| Adjusted non-GAAP Net Income | $ 15,274 | $ 12,986 | $ 44,053 | $ 33,065 |
| Diluted Weighted-Average Shares Outstanding | 11,804 | 11,677 | 11,767 | 11,666 |
| Adjusted non-GAAP Diluted Earnings per Share | $ 1.29 | $ 1.11 | $ 3.74 | $ 2.83 |

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# 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.