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): **February 27, 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)

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 2.02 Results of Operations and Financial Condition.

On February 27, 2019, ANI Pharmaceuticals, Inc. ("ANI") issued a press release announcing its financial and operating results for the three months and year ended December 31, 2018. A copy of the press release is furnished as Exhibit 99.1 to this report.

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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

No.	Description
99.1	Press release, dated February 27, 2019, issued by ANI

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: February 27, 2019

Exhibit 99.1

ANI Pharmaceuticals Reports Record Full Year and Fourth Quarter 2018 Results and Provides 2019 Guidance

BAUDETTE, Minn., Feb. 27, 2019 /PRNewswire/ --

For the full year ended December 31, 2018:

- **Record net revenues of $201.6 million, an increase of 14% versus 2017**
- **GAAP net income of $15.5 million and diluted GAAP earnings per share of $1.30**
- **Adjusted non-GAAP EBITDA of $84.4 million**
- **Adjusted non-GAAP diluted earnings per share of $5.07**

For the fourth quarter 2018:

- **Record net revenues of $57.1 million, an increase of 21% versus 2017**
- **GAAP net income of $5.4 million and diluted GAAP earnings per share of $0.46**
- **Adjusted non-GAAP EBITDA of $22.2 million**
- **Adjusted non-GAAP diluted earnings per share of $1.32**

Guidance for 2019:

- **Net revenues of $231 million to $245 million**
- **Adjusted non-GAAP EBITDA of $95 million to $105 million**
- **Adjusted non-GAAP diluted earnings per share of $5.57 to $6.21**

ANI Pharmaceuticals, Inc. ("ANI") (NASDAQ: ANIP) today reported its financial results for the three and twelve months ended December 31, 2018 and provided its 2019 financial guidance. The Company will host its earnings conference call this morning, February 27, 2019, at 10:30 AM ET. Investors and other interested parties can join the call by dialing (866) 776-8875. The conference ID is 4655318.

Financial Summary

(in thousands, except per share data)	Q4 2018	Q4 2017	2018	2017
Net revenues	$ 57,122	$ 47,286	$ 201,576	$ 176,842
Net income/(loss)	$ 5,430	$ (9,629)	$ 15,494	$ (1,076)
GAAP earnings/(loss) per diluted share	$ 0.46	$ (0.83)	$ 1.30	$ (0.09)
Adjusted non-GAAP EBITDA[(a)]	$ 22,184	$ 19,672	$ 84,401	$ 74,175
Adjusted non-GAAP diluted earnings per share[(b)]	$ 1.32	$ 1.08	$ 5.07	$ 3.91

[(a)] See Table 3 for US GAAP reconciliation.
[(b)] See Table 4 for US GAAP reconciliation.

Arthur S. Przybyl, President and CEO, stated,

"ANI had a strong year, generating record net revenues, record adjusted non-GAAP EBITDA, and record adjusted non-GAAP diluted earnings per share. ANI's fourth quarter results also produced record net revenues, an increase of 21% over the prior year period, and record adjusted non-GAAP EBITDA, an increase of 13% of the prior year period. In 2018, adjusted non-GAAP EBITDA was 42% as a percent of net revenue and we generated $67.1 million of cash from operations during the year.

"Our record 2018 results exemplify ANI's role as a best-in-class specialty pharmaceutical company. We launched seven generic and four branded products during the year, increasing our commercial drug portfolio to 42 products. Our work has continued on our Cortrophin® re-commercialization project, and we intend to file the supplemental NDA in the first quarter of 2020. We continue to integrate our new Canadian operations and are working to use the facility for the tech transfer of several of our pipeline products and to grow our contract manufacturing business platform. With our new debt financing in place, we are in a strong position to not only refinance the convertible debt, but also have additional funds available to us for future acquisitions and provide ample opportunity to continue to grow."

2019 Financial Guidance

For the twelve months ending December 31, 2019, ANI is providing guidance on net revenue, adjusted non-GAAP EBITDA, and adjusted non-GAAP diluted earnings per share. The following table summarizes 2019 guidance as compared to 2018 actual results:

($ in millions except per share data)

	2018 Actual	2019 Guidance	% Increase from Prior Year
Net Revenues	$201.6	$231 to $245	15% to 22%
Adjusted non-GAAP EBITDA	$84.4	$95 to $105	13% to 24%

Adjusted non-GAAP diluted earnings per share	$5.07	$5.57 to $6.21	10% to 22%

ANI's 2019 financial guidance reflects management's current assumptions regarding customer relationships, product pricing, prescription trends, competition, inventory levels, cost of sales, operating costs, timing of research and development spend, taxes, and the anticipated timing of future product launches and other key events. 2019 guidance includes:

- full year revenues and expenses related to our August 6, 2018 acquisition of WellSpring Pharma Services Inc.;
- continued investment in our Cortrophin® Gel Re-Commercialization program. The above guidance ranges 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 and brands;
- a combined federal, state, and international effective income tax rate of 24%; and
- approximately 11.9 million shares of fully diluted common stock outstanding.

Financing Update

In December 2018, ANI refinanced its $125 million credit facility into a $265 million facility. As part of the refinancing, ANI extended the maturity of its currently outstanding $72.2 million term loan, increased its line of credit from $50 million to $75 million, and entered into a deferred draw term loan for $118 million. The deferred draw term loan is to be used only to retire the remaining convertible debt that matures in December 2019. The line of credit is currently undrawn.

Generic Pharmaceutical Products

Fourth Quarter Revenue Results and Update

Revenues from sales of generic pharmaceuticals increased 13%, to $33.7 million from $29.8 million in the prior period, primarily due to the second quarter 2018 launch of Ezetimibe-Simvastatin and other products launched in 2018, tempered by volume decreases for Fenofibrate and Nilutamide. ANI has launched seven generic products in 2018: Candesartan Hydrochlorothiazide (the authorized generic of Atacand HCT®), Terbutaline Sulfate (the authorized generic of Brethine®), Morphine Sulfate Oral Solution, Cholestyramine for Oral Suspension, Ezetimibe-Simvastatin, Desipramine, and Felbamate, increasing its generic commercialized product portfolio to a total of 31 products.

Key Generic Pipeline Products

Product	Reference Drug	Required Filing	Timing	Total Annual Market[(c)]
Methylphenidate ER Tablets	Concerta®	None (approved)	Launch Q1 2019	$1,300M
Aspirin/Dipyridamole ER Capsules	Aggrenox®	None (approved)	Launch no later than October 1, 2019	$ 178M
Undisclosed	Undisclosed	ANDA filed – priority review granted	GDUFA date: April 2019	$ 45M

[(c)] Based on data from IQVIA

Branded Pharmaceutical Products

Fourth Quarter Revenue Results and Update

Revenues from sales of branded pharmaceuticals increased 21%, to $18.8 million from $15.5 million in the prior period, primarily due to sales of Atacand® and Atacand HCT®, which were launched under the ANI label in October 2018 and sales of Casodex® and Arimidex®, which were launched under the ANI label in July 2018, tempered by lower unit sales and price of Inderal® LA and lower unit sales of Vancocin®. ANI sells eleven branded products under the ANI label.

Key Brand Pipeline Products

Product	Required Filing	Filing Date	Total Annual Market[(d)]
Vancocin® Oral Solution	PAS	Filed September 2018	$ 450M
Cortrophin® Gel	sNDA	By Q1 2020	$1,120M

[(d)] Based on data from IQVIA

Vancocin® Oral Solution Update

ANI is currently advancing a commercialization effort for Vancocin® oral solution. ANI filed a prior approval supplement ("PAS") in September 2018 and received a GDUFA date of March 2019. This product will be manufactured at ANI's site in Baudette, Minnesota and will compete in a market that currently exceeds $450 million annually.

Cortrophin® Gel Re-commercialization Update

In the fourth quarter of 2018, ANI completed its first commercial scale batch of Corticotropin API, which met specifications and was analytically-consistent with commercial API batches from the legacy API commercial manufacturer. ANI continues to manufacture additional commercial scale batches of Corticotropin API and is on track to initiate API process validation and registration batch manufacturing in the first quarter of 2019. ANI has completed validation for some API analytical methods to be used for API batch release and stability testing and will validate the remaining API release methods in the first quarter of 2019,

prior to initiation of process validation and registration batch manufacturing. Commercial scale registration batch manufacturing and process validation for Cortrophin® Gel is scheduled to begin in the second quarter of 2019.

ANI is on track to file a supplemental NDA by the first quarter of 2020.

For further details, please see ANI's Cortrophin® Gel Re-commercialization Milestone Update in Table 5.

Contract Manufacturing

Fourth Quarter Revenue Results and Update

Contract manufacturing revenue increased by 94% to $3.7 million from $1.9 million in the prior year period, primarily due to the impact of contract manufacturing revenue from our Canadian subsidiary, ANI Pharmaceuticals Canada Inc. ("ANI Canada"). Through the ANI Canada subsidiary, ANI acquired WellSpring Pharma Services Inc. ("WellSpring"), a Canadian company located in Oakville, Ontario that performs contract development and manufacturing of pharmaceutical products, in August 2018. ANI has continued the integration of the ANI Canada operations in the fourth quarter.

Royalty and Other Income

Fourth Quarter Revenue Result and Update

Royalty and other income increased to $0.9 million from $41 thousand, primarily due to the $0.3 million of royalties from sales related to Gilead's Yescarta® product, as further described below and the impact of product development services and laboratory services revenue from our ANI Canada subsidiary.

Key Royalty Product: Yescarta®

ANI is entitled to a percentage of global Yescarta® net sales as well as a portion of certain product milestones, such as the recent positive opinion issued by the European Medicines Agency ("EMA") Committee for Medicinal Products for Human Use ("CHMP").

Fourth Quarter Results

Net Revenues (in thousands)	**Three Months Ended December 31,**			
	2018	**2017**	**Change**	**% Change**
Generic pharmaceutical products	$ 33,735	$ 29,829	$ 3,906	13%
Branded pharmaceutical products	18,840	15,521	3,319	21%
Contract manufacturing	3,669	1,895	1,774	94%
Royalty and other income	878	41	837	NM(1)
Total net revenues	$ 57,122	$ 47,286	$ 9,836	21%

(1) Not Meaningful

For the three months ended December 31, 2018, ANI reported net revenues of $57.1 million, an increase of 21% from $47.3 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals increased 13%, to $33.7 million from $29.8 million in the prior period, primarily due to the second quarter 2018 launch of Ezetimibe-Simvastatin and other products launched in 2018, tempered by volume decreases for Fenofibrate and Nilutamide.
- Revenues from sales of branded pharmaceuticals increased 21%, to $18.8 million from $15.5 million in the prior period, primarily due to sales of Atacand® and Atacand HCT®, which were launched under the ANI label in October 2018 and sales of Casodex® and Arimidex®, which were launched under the ANI label in July 2018, tempered by lower unit sales and price of Inderal® LA and lower unit sales of Vancocin®.
- Contract manufacturing revenue increased by 94% to $3.7 million from $1.9 million in the prior year period, primarily due to the results of the ANI Canada subsidiary.
- Royalty and other income increased to $0.9 million from $41 thousand, due to the royalties from Yescarta® sales, as well as the impact of product development services and laboratory services revenue from our ANI Canada subsidiary.

Operating expenses increased to $45.7 million for the three months ended December 31, 2018, from $39.9 million in the prior year period. The increase was primarily due to a $4.5 million increase in selling, general, and administrative expense as compared with the prior period, as a result of increases in personnel and related costs. In addition, depreciation and amortization increased by $1.7 million due to the amortization of the product rights for Atacand®, Atacand HCT®, Arimidex®, and Casodex®, which were acquired in December 2017.

Cost of sales as a percentage of net revenues decreased to 35% during the three months ended December 31, 2018, from 37% during same period in 2017, excluding $2.9 million of net inventory step-up costs related to sales of Inderal® XL, InnoPran XL®, and Inderal® LA in the fourth quarter of 2017. The decrease was primarily due to change in product mix towards higher-margin brand products and lower sales of products subject to profit-sharing arrangements.

Net income was $5.4 million for the three months ended December 31, 2018, as compared to a net loss of $9.6 million in the prior year period. The effective tax rate for the three months ended December 31, 2018 was 26%.

Diluted earnings per share for the three months ended December 31, 2018 was $0.46, based on 11,785 thousand diluted shares outstanding, as compared to diluted loss per share of $0.83 in the prior year period. Adjusted non-GAAP diluted earnings per share was $1.32, as compared to adjusted non-GAAP diluted earnings per share of $1.08 in the prior year period. For a reconciliation of adjusted non-GAAP diluted earnings per share to the most directly comparable GAAP financial measure, please see Table 4.

Results for Year Ended December 31, 2018

Net Revenues (in thousands)	**Year Ended December 31,**			
	2018	**2017**	**Change**	**% Change**
Generic pharmaceutical products	$ 117,451	$ 118,437	$ (986)	(1)%
Branded pharmaceutical products	60,554	50,919	9,635	19%
Contract manufacturing	9,119	7,046	2,073	29%
Royalty and other income	14,452	440	14,012	NM[(1)]
Total net revenues	$ 201,576	$ 176,842	$ 24,734	14%

[(1)] Not Meaningful

For the year ended December 31, 2018, ANI reported net revenues of $201.6 million, an increase of 14% from $176.8 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals decreased 1%, to $117.5 million from $118.4 million in the prior period, primarily due to volume decreases for Fenofibrate and Nilutamide, as well as sales decreases for Propranolol ER driven by price, tempered by the impact of the second quarter 2017 launch of Diphenoxylate Hydrochloride and Atropine Sulfate, as well as the second quarter 2018 launch of Ezetimibe-Simvastatin and other products launched in 2018.
- Revenues from sales of branded pharmaceuticals increased 19%, to $60.6 million from $50.9 million in the prior period, primarily due to sales of Arimidex® and Casodex®, which were launched under the ANI label in July 2018, sales of Atacand® and Atacand HCT®, which were launched under the ANI label in October 2018, as well as sales of Inderal® XL and InnoPran XL®, both of which were acquired in the first quarter of 2017, and which were re-launched under our label in the first quarter of 2018. These increases were tempered by lower unit sales of Inderal® LA and Vancocin®.
- Contract manufacturing revenue increased by 29% to $9.1 million from $7.0 million in the prior year period, primarily due to the impact of contract manufacturing sales from our ANI Canada subsidiary.
- Royalty and other income increased to $14.5 million from $0.4 million, primarily due to the royalties received on sales of Atacand®, Atacand HCT®, Arimidex®, and Casodex®, as well as royalties from Yescarta® sales and milestones.

Operating expenses increased to $166.2 million for the year ended December 31, 2018, from $148.5 million in the prior year period. The increase was primarily due to a $12.5 million increase in selling, general, and administrative expense as compared with the prior period, as a result of increases in personnel and related costs and $1.4 million of costs associated with the WellSpring acquisition and integration. Research and development expense increased by $6.3 million as compared with the prior period, primarily as a result of $1.3 million of acquired in-process research and development, which was recognized as research and development expense in relation to the asset acquisition from Impax/Amneal, as well as increased work on development projects, primarily the Cortrophin® Gel re-commercialization project and work on the ANDAs acquired in the asset purchase agreement with Impax/Amneal. In addition, depreciation and amortization increased by $5.8 million due primarily to the amortization of the product rights for Atacand®, Atacand HCT®, Arimidex®, and Casodex®, which were acquired in December 2017.

Excluding the $5.6 million of net inventory step-up, primarily related to the sales and write off Inderal® XL and InnoPran XL® in the year ended December 31, 2018 and $10.4 million of net inventory step-up costs related to sales of Inderal® XL, InnoPran XL®, and Inderal® LA in the year ended December 31, 2017, cost of sales as a percentage of net revenues decreased to 33% during the year ended December 31, 2018, from 39% in the year ended December 31, 2017, primarily due to increased royalty revenues, change in product mix towards higher-margin brand products, and lower sales of products subject to profit-sharing arrangements.

Net income was $15.5 million for the year ended December 31, 2018, as compared to a net loss of $1.1 million in the prior year period. The effective tax rate for the year ended December 31, 2018 was 23%.

Diluted earnings per share for the year ended December 31, 2018 was $1.30, based on 11,772 thousand diluted shares outstanding, as compared to diluted loss per share of $0.09 in the prior year period. Adjusted non-GAAP diluted earnings per share was $5.07, as compared to adjusted non-GAAP diluted earnings per share of $3.91 in the prior year period. For a reconciliation of adjusted non-GAAP diluted earnings per share to the most directly comparable GAAP financial measure, please see Table 4.

Selected Balance Sheet Data

(in thousands)

	December 31, 2018	**December 31, 2017**
Cash	$ 43,008	$ 31,144
Accounts receivable, net	$ 64,842	$ 58,788
Inventory, net	$ 40,503	$ 37,727
Current assets	$ 152,877	$ 131,605
Current liabilities	$ 165,549	$ 39,228

Non-current debt	$	67,296	$	198,154

ANI generated $67.1 million of positive cash flows from operations in the year ended December 31, 2018.

In August 2018, ANI acquired WellSpring, a Canadian company that performs contract development and manufacturing of pharmaceutical products for a purchase price of $18.0 million, subject to certain customary adjustments. Pursuant to these customary adjustments, the total purchase consideration was $16.7 million. The consideration was paid entirely from cash on hand. As a result of the transaction, ANI acquired WellSpring's pharmaceutical manufacturing facility, laboratory, and offices, current book of commercial business, as well as an organized workforce. In April 2018, ANI purchased from IDT Australia, Limited the ANDAs for 23 previously-marketed generic drug products and API for four of the acquired products for $2.7 million in cash and a single-digit royalty on net profits from sales of one of the products. ANI made the $2.7 million payment using cash on hand. In May 2018, ANI purchased from Impax Laboratories, Inc. (now Amneal) the approved ANDAs for three previously-commercialized generic drug products, the approved ANDAs for two generic drug products that have not yet been commercialized, the development package for one generic drug product, and a license, supply, and distribution agreement for a generic drug product with an ANDA that is pending approval, and certain manufacturing equipment required to manufacture one of the products, for $2.3 million in cash. ANI made the $2.3 million payment using cash on hand.

ANI Product Development Pipeline

ANI's pipeline consists of 75 products, addressing a total annual market size of $4.5 billion, based on data from IQVIA. Of these 75 products, 70 were acquired and of these acquired products, ANI expects that 54 can be commercialized based on either CBE-30s or prior approval supplements filed with the FDA.

Non-GAAP Financial Measures

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 release.

Adjusted non-GAAP EBITDA

ANI's management considers adjusted non-GAAP EBITDA to be an important financial indicator of ANI's operating performance, providing investors and analysts with a useful measure of operating results unaffected by non-cash stock-based compensation and differences in capital structures, tax structures, capital investment cycles, ages of related assets, and compensation structures among otherwise comparable companies. Management uses adjusted non-GAAP EBITDA when analyzing Company performance.

Adjusted non-GAAP EBITDA is defined as net income/(loss), excluding tax expense, interest expense, depreciation, amortization, the excess of fair value over cost of acquired inventory, stock-based compensation expense, expense from acquired in-process research and development, gains, losses, and expenses related to the repurchase of convertible debt, expenses related to debt financing, transaction and integration expenses, and other income / expense. Adjusted non-GAAP EBITDA should be considered in addition to, but not in lieu of, net income or loss reported under GAAP. A reconciliation of adjusted non-GAAP EBITDA to the most directly comparable GAAP financial measure is provided in Table 3.

Adjusted non-GAAP Net Income

ANI's management considers adjusted non-GAAP net income to be an important financial indicator of ANI's operating performance, providing investors and analysts with a useful measure of operating results unaffected by purchase accounting adjustments, non-cash stock-based compensation, non-cash interest expense, depreciation and amortization, and non-cash impairment charges. Management uses adjusted non-GAAP net income when analyzing Company performance.

Adjusted non-GAAP net income is defined as net income/(loss), plus the excess of fair value over cost of acquired inventory, stock-based compensation expense, transaction and integration expenses, gains, losses, and expenses related to the repurchase of convertible debt, expenses related to debt financing, non-cash interest expense, depreciation and amortization expense, expense from acquired in-process research and development, and non-cash impairment charges, less the tax impact of these adjustments calculated using an estimated statutory tax rate. Management will continually analyze this metric and may include additional adjustments in the calculation in order to provide further understanding of ANI's results. Adjusted non-GAAP net income should be considered in addition to, but not in lieu of, net income reported under GAAP. A reconciliation of adjusted non-GAAP net income to the most directly comparable GAAP financial measure is provided in Table 4.

Adjusted non-GAAP Diluted Earnings per Share

ANI's management considers adjusted non-GAAP diluted earnings per share to be an important financial indicator of ANI's operating performance, providing investors and analysts with a useful measure of operating results unaffected by purchase accounting adjustments, non-cash stock-based compensation, non-cash interest expense, depreciation and amortization, and non-cash impairment charges.

Management uses adjusted non-GAAP diluted earnings per share when analyzing Company performance.

Adjusted non-GAAP diluted earnings per share is defined as adjusted non-GAAP net income, as defined above, divided by the diluted weighted average shares outstanding during the period. Management will continually analyze this metric and may include additional adjustments in the calculation in order to provide further understanding of ANI's results. Adjusted non-GAAP diluted earnings per share should be considered in addition to, but not in lieu of, diluted earnings or loss per share reported under GAAP. A reconciliation of adjusted non-GAAP diluted earnings per share to the most directly comparable GAAP financial measure is provided in Table 4.

About ANI

ANI Pharmaceuticals, Inc. (the "Company" or "ANI") is an integrated specialty pharmaceutical company developing, manufacturing, and marketing high quality branded and generic prescription pharmaceuticals. The Company's targeted areas of product development currently include controlled substances, oncolytics (anti-cancers), hormones and steroids, and complex formulations involving extended release and combination products. For more information, please visit the Company's 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; acquisitions; contract manufacturing arrangements; delays or failure in obtaining product approvals from the U.S. Food and Drug Administration; general business and economic conditions; market trends; regulatory environment; 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. and Subsidiaries
Table 1: US GAAP Income Statement
(unaudited, in thousands, except per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Net Revenues	$57,122	$47,286	$201,576	$176,842
Operating Expenses				
Cost of sales (excl. depreciation and amortization)	20,133	20,446	73,024	79,032
Research and development	3,482	2,651	15,388	9,070
Selling, general, and administrative	13,376	8,885	44,063	31,580
Depreciation and amortization	8,686	7,022	33,742	27,928
Intangible asset impairment charge	-	903	-	903
Total Operating Expenses	45,677	39,907	166,217	148,513
Operating Income	11,445	7,379	35,359	28,329
Other Expense, Net				
Interest expense, net	(3,626)	(3,026)	(14,758)	(12,035)
Other (expense)/income, net	(479)	(3)	(550)	55
Income Before Provision for Income Taxes	7,340	4,350	20,051	16,349
Provision for Income Taxes	(1,910)	(13,979)	(4,557)	(17,425)

Net Income/(Loss)	$ 5,430	$ (9,629)	$ 15,494	$ (1,076)
Earnings Per Share				
Basic Earnings/(Loss) Per Share	$ 0.46	$ (0.83)	$ 1.31	$ (0.09)
Diluted Earnings/(Loss) Per Share	$ 0.46	$ (0.83)	$ 1.30	$ (0.09)
Basic Weighted-Average Shares Outstanding	11,730	11,560	11,677	11,547
Diluted Weighted-Average Shares Outstanding	11,785	11,560	11,772	11,547

ANI Pharmaceuticals, Inc. and Subsidiaries
Table 2: US GAAP Balance Sheets
(in thousands)

	December 31, 2018	December 31, 2017
Current Assets		
Cash and cash equivalents	$ 43,008	$ 31,144
Accounts receivable, net	64,842	58,788
Inventories, net	40,503	37,727
Prepaid income taxes, net	-	1,162
Prepaid expenses and other current assets	4,524	2,784
Total Current Assets	152,877	131,605
Property and equipment, net	38,090	20,403
Restricted cash	5,021	5,006
Deferred tax assets, net of deferred tax liabilities and valuation allowance	27,964	22,667
Intangible assets, net	201,604	229,790
Goodwill	3,580	1,838
Other long-term assets	1,468	829
Total Assets	$ 430,604	$ 412,138
Current Liabilities		
Current component of long-term borrowing, net of deferred financing costs	$ 3,256	$ 3,353
Convertible notes, net of discount and deferred financing costs	112,463	-
Accounts payable	8,884	3,630
Accrued expenses and other	1,707	1,571
Accrued royalties	8,456	12,164
Accrued compensation and related expenses	3,524	2,306
Current income taxes payable, net	5,022	-
Accrued government rebates	8,974	7,930
Returned goods reserve	12,552	8,274
Deferred revenue	711	-
Total Current Liabilities	165,549	39,228
Long-term borrowing, net of deferred financing costs and current borrowing component	67,296	69,946
Convertible notes, net of discount and deferred financing costs	-	128,208
Other long-term liabilities	496	-
Total Liabilities	233,341	237,382
Stockholders' Equity		
Common stock	1	1
Treasury stock	(659)	(259)
Additional paid-in capital	186,812	179,020
Retained earnings/(accumulated deficit)	11,488	(4,006)
Accumulated other comprehensive loss, net of tax	(379)	-
Total Stockholders' Equity	197,263	174,756
Total Liabilities and Stockholders' Equity	$ 430,604	$ 412,138

ANI Pharmaceuticals, Inc. and Subsidiaries
Table 3: 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

ANI Pharmaceuticals, Inc. and Subsidiaries
Table 4: 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

ANI Pharmaceuticals, Inc. and Subsidiaries
Table 5: Cortrophin® Gel Re-Commercialization Milestone Update

Step	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 and process • Demonstrated lot-to-lot consistency
Type C meeting with FDA		Complete	• Meeting Request submitted 4Q17; FDA granted as Type C Meeting • Information provided on ANI's regulatory plan for re-commercialization • Initial FDA response received March 2018 with additional communications in 2nd Quarter 2018
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
Initiate manufacture of 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