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

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**

Baudette, Minnesota (February 27, 2019) – 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.

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