ANI Pharmaceuticals Reports First Quarter 2019 Results and Reaffirms Guidance

For the first quarter 2019:

- **Net revenues of $52.9 million, an increase of 14% versus 2018**
- **GAAP net income of $0.4 million and diluted GAAP earnings per share of $0.04**
- **Record adjusted non-GAAP EBITDA of $22.3 million**
- **Adjusted non-GAAP diluted earnings per share of $1.30**

Baudette, Minnesota (May 9, 2019) – ANI Pharmaceuticals, Inc. ("ANI") (NASDAQ: ANIP) today reported its financial results for the three months ended March 31, 2019 and reaffirmed its 2019 financial guidance. The Company will host its earnings conference call this morning, May 9, 2019, at 10:30 AM ET. Investors and other interested parties can join the call by dialing (866) 776-8875. The conference ID is 5649987.

Financial Summary

(in thousands, except per share data)	**Q1 2019**	**Q1 2018**
Net revenues	$ 52,887	$ 46,483
Net income	$ 449	$ 2,250
GAAP earnings per diluted share	$ 0.04	$ 0.19
Adjusted non-GAAP EBITDA[(a)]	$ 22,299	$ 21,754
Adjusted non-GAAP diluted earnings per share[(b)]	$ 1.30	$ 1.32

[(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 start to the year, generating record adjusted non-GAAP EBITDA of $22.3 million in the first quarter. Our first quarter results also generated net revenues of $52.9 million, an increase of 14% over the prior year period. In addition, product development expense increased by $2.3 million, or 108%, over the prior year period as we continue to advance the re-commercialization of Cortrophin® gel.
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> Generic product revenue increased 36% over the prior year period and we launched two generic products in late March: 400 mg/5mL Erythromycin Ethylsuccinate for oral suspension and 18 mg and 27 mg Methylphenidate Hydrochloride extended-release tablets. The full effect of these launches will be realized throughout the remainder of the year. The Methylphenidate Hydrochloride launch included two of the strengths recently acquired, and we intend to launch the remaining strengths later in the year."

ANI Reaffirms Guidance for the Full Year 2019

ANI's estimates are based upon actual results for the three months ending March 31, 2019 and projected results for the remaining nine months of the year. ANI's full year 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. 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:

($ in millions except per share data)

	2019 Guidance
Net Revenues	$231 to $245
Adjusted non-GAAP EBITDA	$95 to $105
Adjusted non-GAAP diluted earnings per share	$5.57 to $6.21

First Quarter Results

Net Revenues (in thousands)	**Three Months Ended March 31,**			
	2019	**2018**	**Change**	**% Change**
Generic pharmaceutical products	$ 31,599	$ 23,227	$ 8,372	36%
Branded pharmaceutical products	17,543	16,595	948	6%
Contract manufacturing	2,437	945	1,492	158%
Royalty and other income	1,308	5,716	(4,408)	(77%)
Total net revenues	$ 52,887	$ 46,483	$ 6,404	14%

Generic Pharmaceutical Products

First Quarter Revenue Results and Update

Revenues from sales of generic pharmaceuticals increased 36% to $31.6 million from $23.2 million in the prior period, primarily due to the launch of Ezetimibe-Simvastatin, Candesartan, and other products launched in 2018, as well as increased unit sales of Vancomycin.

Key Generic Pipeline Products

Product	**Reference Drug**	**Required Filing**	**Timing**	**Total Annual Market[(c)]**
Methylphenidate ER Tablets	Concerta®	None (approved)	36 mg and 54 mg launch Q2-Q3 2019	$ 563M
Aspirin/Dipyridamole ER Capsules	Aggrenox®	None (approved)	Launch no later than October 1, 2019	$ 117M
Undisclosed	Undisclosed	ANDA approved April 2019	Launch in Q2 2019	$ 45M

(c) Based on data from IQVIA

Branded Pharmaceutical Products

First Quarter Revenue Results and Update

Revenues from sales of branded pharmaceuticals increased 6%, to $17.5 million from $16.6 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 of Inderal® LA and InnoPran XL®.

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	$1,110M

[(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. 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 first quarter of 2019, ANI completed its second commercial scale batch of Corticotropin API, which was analytically consistent with previously-manufactured development batches as well as the first commercial scale API batch. ANI has also initiated API manufacturing process validation and has started to manufacture the first of three registration stability batches to support the sNDA filing. Qualification will be completed for all raw materials and manufacturing equipment prior to manufacturing process validation batches. ANI has completed method validation for all of the analytical methods to be used for API batch release and stability testing, which will be used to support analysis of all three registration batches. In the second quarter of 2019, ANI plans to complete the first and initiate the second API registration batch, and also initiate viral clearance studies. ANI also plans to manufacture Cortrophin Gel batches in the second quarter of 2019 using commercial scale API.

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

First Quarter Revenue Results and Update

Contract manufacturing revenue increased 158% to $2.4 million from $0.9 million in the prior year period, primarily due to the impact of contract manufacturing revenue from ANI's Canadian subsidiary, ANI Pharmaceuticals Canada Inc. ("ANI Canada"), which was acquired in August 2018. ANI has continued the integration of the ANI Canada operations in the first quarter.

Royalty and Other Income

First Quarter Revenue Result and Update

Royalty and other income decreased 77% to $1.3 million from $5.7 million, primarily due to the launches of Atacand®, Atacand HCT®, Arimidex®, and Casodex® under the ANI label in the second half of 2018. The revenue from those products are now included in the net sales of branded pharmaceutical products. This decline was tempered by product development and lab services net revenue from our ANI Canada subsidiary, as well as royalties related to a true-up from our former partner for the authorized generic for Vancocin® and royalties on sales of Yescarta®.

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").

Operating Expenses

Operating expenses increased to $48.5 million for the three months ended March 31, 2019, from $39.9 million in the prior year period. The increase was due to a $4.3 million increase in selling, general, and administrative expense as compared with the prior period, as a result of costs related to the new ANI Canada subsidiary, increased U.S.-based headcount and pharmacovigilance compliance costs in continued support of the expansion of our commercial portfolio, higher GDUFA and PDUFA user fees paid to the U.S. FDA, higher legal fees, and increased sales and marketing-related costs. In addition, depreciation and amortization increased by $7.9 million, primarily due to the $6.8 million cumulative amortization expense recorded in relation to a royalty buy out. These increases were partially offset by a $6.0 million decrease in cost of sales.

Cost of sales as a percentage of net revenues decreased to 28% during the three months ended March 31, 2019, from 32% during same period in 2018, excluding $5.6 million of net inventory step-up costs related to sales of Inderal® XL and InnoPran XL® in the first quarter of 2018. The decrease was primarily due to lower royalty expense resulting from a royalty buy out.

Net Income and Diluted Earnings per Share

Net income was $0.4 million for the three months ended March 31, 2019, as compared to net income of $2.3 million in the prior year period. The effective consolidated tax rate (US GAAP) for the three months ended March 31, 2019 was 51%.

Diluted earnings per share for the three months ended March 31, 2019 was $0.04, based on 11,823 thousand diluted shares outstanding, as compared to diluted earnings per share of $0.19 in the prior year period. Adjusted non-GAAP diluted earnings per share was $1.30, as compared to adjusted non-GAAP diluted earnings per share of $1.32 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.

ANI Product Development Pipeline

ANI's pipeline consists of 103 products, addressing a total annual market size of $4.3 billion, based on data from IQVIA. Of these 103 products, 99 were acquired and of these acquired products, ANI expects that at least 55 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