ANI Pharmaceuticals Reports Second Quarter Results

For the second quarter 2019:

- **Net revenues of $54.4 million, an increase of 15% versus prior year**
- **GAAP net income of $6.6 million and diluted GAAP earnings per share of $0.53, increases of 137% and 130% versus prior year, respectively**
- **Record adjusted non-GAAP EBITDA of $23.7 million and adjusted non-GAAP diluted earnings per share of $1.44, increases of 24% and 27% versus prior year, respectively**
- **Reaffirms 2019 adjusted non-GAAP EBITDA and adjusted non-GAAP diluted earnings per share guidance and updates guidance for 2019 net revenues**

Baudette, Minnesota (August 7, 2019) – ANI Pharmaceuticals, Inc. ("ANI") (NASDAQ: ANIP) today reported its financial results for the three and six months ended June 30, 2019 and reaffirmed its previously issued guidance for adjusted non-GAAP EBITDA and adjusted non-GAAP earnings per share, while updating its 2019 financial guidance for net revenues. The Company will host its earnings conference call this morning, August 7, 2019, at 10:30 AM ET. Investors and other interested parties can join the call by dialing (866) 776-8875. The conference ID is 3823848.

Financial Summary

(in thousands, except per share data)	**Q2 2019**	**Q2 2018**	**YTD 2019[a]**	**YTD 2018[a]**
Net revenues	$ 54,357	$ 47,268	$ 107,244	$ 93,751
Net income	$ 6,585	$ 2,777	$ 7,034	$ 5,027
GAAP earnings per diluted share	$ 0.53	$ 0.23	$ 0.57	$ 0.42
Adjusted non-GAAP EBITDA[b]	$ 23,681	$ 19,034	$ 45,980	$ 40,788
Adjusted non-GAAP diluted earnings per share[c]	$ 1.44	$ 1.13	$ 2.75	$ 2.45

[a] See ANI's Form 10-Q filed August 7, 2019 for discussion of year-to-date results.
[b] See Table 3 for US GAAP reconciliation.
[c] See Table 4 for US GAAP reconciliation.

Arthur S. Przybyl, President and CEO, stated,

> "ANI had a strong second quarter, generating net revenues of $54.4 million, an increase of 15% over the prior year period, and record adjusted non-GAAP EBITDA of $23.7 million, an increase of 24% over the prior year period. More importantly, we remain on track to file our supplemental NDA for Cortrophin® Gel in the first quarter of 2020.
>
> Generic product revenues increased 20% over the prior year period and we launched one new generic product in late June, Ranitidine capsules. We also received FDA approval for 250 mg/5 ml Vancomycin Oral Solution, which we intend to launch in the third quarter.
>
> During the second quarter, we continued to add to our generic portfolio, through an April distribution agreement with a specialty injectable manufacturer and the June acquisition of seven development stage generic products, which expanded our pipeline of injectable drugs to six."

ANI Updates Guidance for Net Revenues for the Full Year 2019

ANI has updated its full year guidance for net revenues due to the competitive landscape of the Methylphenidate ER market. ANI's guidance for adjusted non-GAAP EBITDA and adjusted non-GAAP earnings per diluted share remains unchanged from previously issued guidance.

Revised guidance for 2019 net revenues of $220 million to $226 million reflects sales growth of between 9% and 12% over 2018 full year actual results. Previous guidance for net revenues was $231 million to $245 million.

The following table summarizes 2019 guidance:

($ in millions except per share data)

	2019 Guidance
Net Revenues	$220 to $226
Adjusted non-GAAP EBITDA	$95 to $105
Adjusted non-GAAP diluted earnings per share	$5.57 to $6.21

ANI's estimates are based upon actual results for the six months ending June 30, 2019 and projected results for the remaining six 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 revenues, adjusted non-GAAP EBITDA, and adjusted non-GAAP diluted earnings per share.

Second Quarter Results

Net Revenues (in thousands)	**Three Months Ended June 30,**			
	2019	**2018**	**Change**	**% Change**
Generic pharmaceutical products	$ 36,255	$ 30,202	$ 6,053	20%
Branded pharmaceutical products	13,996	10,530	3,466	33%
Contract manufacturing	3,687	1,679	2,008	120%
Royalty and other	419	4,857	(4,438)	(91%)
Total net revenues	$ 54,357	$ 47,268	$ 7,089	15%

Generic Pharmaceutical Products

Second Quarter Net Revenues - Results and Update

Net revenues from sales of generic pharmaceuticals increased 20% to $36.3 million from $30.2 million in the prior period, primarily due to the launch of Ezetimibe-Simvastatin, Candesartan, and other products launched in 2018 and 2019, as well as increased unit sales of Vancomycin.

Key Generic Pipeline Product

Product	Reference Drug	Required Filing	Timing	Total Annual Market[(d)]
Aspirin/Dipyridamole ER Capsules	Aggrenox®	None (approved)	Launch no later than October 1, 2019	$ 105M

[(d)] Based on data from IQVIA

Branded Pharmaceutical Products

Second Quarter Net Revenues - Results and Update

Net revenues from sales of branded pharmaceuticals increased 33% to $14.0 million from $10.5 million in the prior period, primarily due to sales of Arimidex® and Casodex®, which were launched under ANI's label in July 2018 and sales of Atacand® and Atacand HCT®, which were launched under ANI's label in October 2018. Prior to the launch under the ANI label, net revenues generated by these products was recorded via royalties received and was reported as Royalty and Other.

Key Brand Pipeline Products

Product	Required Filing	Filing Date	Total Annual Market[(e)]
Vancocin® for Oral Solution	PAS	Approved June 2019, launch Q3 2019	$ 450M
Cortrophin® Gel	sNDA	Q1 2020	$1,110M

[(e)] Based on data from IQVIA

Vancocin® for Oral Solution Update

ANI is currently advancing a commercialization effort for Vancocin® for oral solution. ANI filed a prior approval supplement ("PAS") in September 2018 and it was approved in June 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

ANI continues to successfully progress our Cortrophin® re-commercialization program. Significant accomplishments since the first quarter 2019 press release (dated May 9, 2019) include:

- The completion of a third commercial scale batch of Corticotropin API. This batch was analytically consistent with previously manufactured batches and met all specifications. ANI expects to complete API process validation and registration stability batch manufacturing in the third quarter of 2019.
- The initiation of viral clearance studies, which are expected to be completed in the third quarter of 2019.
- The manufacture of two commercial scale batches of Cortrophin® Gel using commercial scale API. ANI intends to complete the third and final registration batch of drug product in the third quarter of 2019.

ANI remains on track to file a supplemental NDA in the first quarter of 2020.

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

Contract Manufacturing

Second Quarter Net Revenues - Results and Update

Contract manufacturing revenues increased 120% to $3.7 million from $1.7 million in the prior year period, primarily due to the impact of contract manufacturing revenues from ANI's Canadian subsidiary, ANI Pharmaceuticals Canada Inc. ("ANI Canada"), which was acquired in August 2018.

Royalty and Other

Second Quarter Net Revenues - Result and Update

Royalty and other decreased 91% to $0.4 million from $4.9 million, primarily due to the launches of Atacand®, Atacand HCT®, Arimidex®, and Casodex® under the ANI label in the second half of 2018. The net revenues 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 revenues from ANI Canada.

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 $45.1 million for the three months ended June 30, 2019, from $40.0 million in the prior year period. The increase was primarily due to a $4.2 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 $1.2 million, primarily due to additional amortization expense associated with a March 2019 asset acquisition and a January 2019 royalty buyout payment related to a prior period asset acquisition. These increases were partially offset by a $1.0 million decrease in cost of sales.

Cost of sales as a percentage of net revenues decreased to 29% during the three months ended June 30, 2019, from 35% during same period in 2018. The decrease was primarily due to lower royalty expense resulting from a royalty buy out and lower sales of products under profit-sharing arrangements.

Net Income and Diluted Earnings per Share

Net income was $6.6 million for the three months ended June 30, 2019, as compared to net income of $2.8 million in the prior year period. The effective consolidated tax rate excluding impacts of discrete items for the three months ended June 30, 2019 was 16.8%.

Diluted earnings per share for the three months ended June 30, 2019 was $0.53, based on 12,269 thousand diluted shares outstanding, as compared to diluted earnings per share of $0.23 in the prior year period. Adjusted non-GAAP diluted earnings per share was $1.44, as compared to adjusted non-GAAP diluted earnings per share of $1.13 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 111 products, addressing a total annual market size of $5.2 billion, based on data from IQVIA. Of these 111 products, 106 were acquired and of these acquired products, ANI expects that at least 56 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, as adjusted for the dilutive effect of the convertible debt notes, when applicable. 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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