ANI Pharmaceuticals Reports Third Quarter Results

For the third quarter 2019:

- **Net revenues of $51.3 million, an increase of 1% versus prior year**
- **GAAP net income of $3.9 million and diluted GAAP earnings per share of $0.32**
- **Adjusted non-GAAP EBITDA of $19.8 million and adjusted non-GAAP diluted earnings per share of $1.23**
- **ANI updates guidance for the full year 2019**

Baudette, Minnesota (November 6, 2019) – ANI Pharmaceuticals, Inc. ("ANI") (NASDAQ: ANIP) today reported its financial results for the three and nine months ended September 30, 2019 and updated its 2019 financial guidance for net revenues, adjusted non-GAAP EBITDA and adjusted non-GAAP earnings per share. The Company will host its earnings conference call this morning, November 6, 2019, at 10:30 AM ET. Investors and other interested parties can join the call by dialing (866) 776-8875. The conference ID is 2599456.

Financial Summary

(in thousands, except per share data)	**Q3 2019**	**Q3 2018**	**YTD 2019[a]**	**YTD 2018[a]**
Net revenues	$ 51,337	$ 50,703	$ 158,581	$ 144,454
Net income	$ 3,895	$ 5,037	$ 10,929	$ 10,064
GAAP earnings per diluted share	$ 0.32	$ 0.42	$ 0.89	$ 0.85
Adjusted non-GAAP EBITDA[b]	$ 19,795	$ 21,429	$ 65,775	$ 62,217
Adjusted non-GAAP diluted earnings per share[c]	$ 1.23	$ 1.29	$ 3.98	$ 3.74

[a] See ANI's Form 10-Q filed November 6, 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,

> "In the third quarter, we reached a significant milestone in our Cortrophin® Gel re-commercialization program when we announced positive clinical data from our cortisol dose response study. It was also the first time we dosed human volunteers with our finished dosage form Cortrophin® Gel drug. We continue to meet our Cortrophin® development milestones and remain on track to file our supplemental NDA in March of 2020.
>
> Recently, we launched our fourth and fifth generic products of 2019. In September, we launched Vancomycin HCl for Oral Solution, and in October, we launched Aspirin and Extended Release Dipyridamole Capsules. Vancomycin HCl for Oral Solution represents a meaningful revenue opportunity and provides an FDA approved and easy to administer alternative to a market that is largely serviced by compounding pharmacies. Lastly, we recently announced plans to launch Bretylium Tosylate Injection, USP 500mg / 10ml in December. This product is an important life-saving cardiac drug that provides physicians a valuable tool to treat patients with ventricular arrhythmias in an emergency setting."

ANI Updates Guidance for the Full Year 2019

ANI has updated its full year guidance for net revenues, adjusted non-GAAP EBITDA and adjusted non-GAAP earnings per share in order to reflect additional competition against two of its important generic franchises.

ANI's estimates are based upon actual results for the nine months ending September 30, 2019 and projected results for the remaining three 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.

The following table summarizes 2019 guidance:

($ in millions except per share data)

	2019 Guidance
Net Revenues	$209.0 to $212.0
Adjusted non-GAAP EBITDA	$84.7 to $86.8
Adjusted non-GAAP diluted earnings per share	$5.06 to $5.23

Third Quarter Results

Net Revenues (in thousands)	**Three Months Ended September 30,**			
	2019	**2018**	**Change**	**% Change**
Generic pharmaceutical products	$ 31,753	$ 30,287	$ 1,466	5%
Branded pharmaceutical products	16,605	14,589	2,016	14%
Contract manufacturing	2,376	2,826	(450)	(16)%
Royalty and other	603	3,001	(2,398)	(80)%
Total net revenues	$ 51,337	$ 50,703	$ 634	1%

Generic Pharmaceutical Products

Third Quarter Net Revenues - Results and Update

Net revenues from sales of generic pharmaceuticals increased 5% to $31.8 million from $30.3 million in the prior period, primarily due to the launch of Vancomycin HCl for Oral Solution, Candesartan, and other products launched in 2018 and 2019, as well as increased unit sales of Vancomycin tablets. These increases were tempered by decreases in sales of Esterified Estrogen with Methlytestosterone ("EEMT"), Diphenoxylate Hydrochloride and Atropine Sulfate, and Fenofibrate.

Key Generic Pipeline Product

In October 2019, ANI's collaborative partner Pharmaceutics International Inc. received FDA approval of a Prior Approval Supplement for Bretylium Tosylate Injection, USP 500mg/10ml. ANI plans to launch this currently unavailable drug in December 2019, introducing this critical drug for the treatment of ventricular fibrillation and life-threatening ventricular arrhythmias, such as ventricular tachycardia.

Branded Pharmaceutical Products

Third Quarter Net Revenues - Results and Update

Net revenues from sales of branded pharmaceuticals increased 14% to $16.6 million from $14.6 million in the prior period, primarily due to increased sales of Atacand® and Atacand HCT®, which were launched under ANI's label in October 2018 and previously included as Royalty and other, and increases in sales of Inderal® LA, and Vancocin®. These increases were tempered by a decrease in sales of Arimidex® and Innopran XL®.

Key Brand Pipeline Product

Product	Required Filing	Filing Date	Total Annual Market[(d)]
Cortrophin® Gel	sNDA	March 2020	$1.1 billion

[(d)] Based on data from IQVIA

Cortrophin® Gel Re-commercialization Update

ANI continues to successfully progress our Cortrophin® re-commercialization program. Significant accomplishments since the second quarter 2019 press release (dated August 7, 2019) include:

- The completion of a fourth commercial scale batch of Corticotropin API. This batch was analytically consistent with previously manufactured batches and met all specifications. ANI has completed manufacturing for three registration stability batches and expects to complete API process validation in early fourth quarter of 2019.
- The successful completion of viral clearance studies.
- The completion of a third commercial scale batch of Cortrophin® Gel. This batch was analytically consistent with previously manufactured batches and met all specifications. ANI has completed manufacturing for three registration stability batches and expects to complete drug product process validation in fourth quarter of 2019 using commercial scale API.
- Receipt of clinical data on Cortrophin® Gel (80 units/mL) from a study that evaluated the blood-level cortisol response in a 20-person healthy volunteer population. The results indicate that ANI's Cortrophin® Gel (80 units/mL) is effective for its intended use. The data demonstrates that ANI's modernized drug product has a cortisol response profile consistent with that observed in historical scientific literature that evaluated the drug product manufactured in the 1960s. No adverse safety events were reported and minor events were as expected.

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

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

Contract Manufacturing

Third Quarter Net Revenues - Results and Update

Contract manufacturing revenues decreased 16% to $2.4 million from $2.8 million in the prior year period, due to the timing and volume of orders from contract manufacturing customers in the period.

Royalty and Other

Third Quarter Net Revenues - Result and Update

Royalty and other decreased 80% to $0.6 million from $3.0 million, primarily due to the launch of Atacand® and Atacand HCT® under ANI's label in October 2018. The net sales from those products are now included in the net sales of branded pharmaceutical products.

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 $44.0 million for the three months ended September 30, 2019, from $40.6 million in the prior year period. The increase was primarily due to a $2.6 million increase in selling, general, and administrative expense as compared with the prior period, as a result of costs related to the ANI Canada subsidiary, increased U.S.-based headcount and pharmacovigilance compliance costs in continued support of the expansion of our commercial portfolio, increased stock compensation expense, higher legal fees, and increased sales and marketing-related costs. In addition, depreciation and amortization increased by $0.9 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 $0.6 million decrease in cost of sales.

Cost of sales as a percentage of net revenues decreased to 29% during the three months ended September 30, 2019, from 31% 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 $3.9 million for the three months ended September 30, 2019, as compared to net income of $5.0 million in the prior year period. The effective consolidated tax rate excluding impacts of discrete items for the three months ended September 30, 2019 was 8.4%.

Diluted earnings per share for the three months ended September 30, 2019 was $0.32, based on 12,085 thousand diluted shares outstanding, as compared to diluted earnings per share of $0.42 in the prior year period. Adjusted non-GAAP diluted earnings per share was $1.23, as compared to adjusted non-GAAP diluted earnings per share of $1.29 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 109 products, addressing a total annual market size of $5.4 billion, based on data from IQVIA. Of these 109 products, 104 were acquired and of these acquired products, ANI expects that at least 53 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, Cortrophin pre-launch charges, other income / expense and certain other items that vary in frequency and impact on ANI's results of operations. 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, non-cash impairment charges, Cortrophin pre-launch charges and certain other items that vary in frequency and impact on ANI's results of operations, 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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