ANI Pharmaceuticals Reports Full Year and Fourth Quarter 2019 Results, Provides 2020 Guidance and Remains on Track to Submit Cortrophin® Gel sNDA to FDA in March 2020

For the full year ended December 31, 2019:

- **Record net revenues of $206.5 million, an increase of 2.5% versus 2018**
- **GAAP net income of $6.1 million and diluted GAAP earnings per share of $0.50**
- **Adjusted non-GAAP EBITDA of $83.2 million**
- **Adjusted non-GAAP diluted earnings per share of $5.06**

For the fourth quarter 2019:

- **Net revenues of $48.0 million versus $57.1 million in 2018**
- **GAAP net loss of $4.8 million and diluted GAAP loss per share of $0.41**
- **Adjusted non-GAAP EBITDA of $17.4 million**
- **Adjusted non-GAAP diluted earnings per share of $1.08**

Guidance for 2020:

- **Net revenues of $213 million to $223 million**
- **Adjusted non-GAAP EBITDA of $80 million to $86 million**
- **Adjusted non-GAAP diluted earnings per share of $4.46 to $4.86**

Baudette, Minnesota (February 27, 2020) – ANI Pharmaceuticals, Inc. ("ANI") (NASDAQ: ANIP) today reported its financial results for the three and twelve months ended December 31, 2019 and provided its 2020 financial guidance. The Company will host its earnings conference call this morning, February 27, 2020, at 10:30 AM ET. Investors and other interested parties can join the call by dialing (866) 776-8875. The conference ID is 4783883.

Financial Summary

(in thousands, except per share data)	Q4 2019	Q4 2018	2019[a]	2018[a]
Net revenues	$ 47,966	$ 57,122	$ 206,547	$ 201,576
Net (loss)/income	$ (4,835)	$ 5,430	$ 6,094	$ 15,494
GAAP (loss)/earnings per diluted share	$ (0.41)	$ 0.46	$ 0.50	$ 1.30
Adjusted non-GAAP EBITDA[b]	$ 17,383	$ 22,184	$ 83,158	$ 84,401
Adjusted non-GAAP diluted earnings per share[c]	$ 1.08	$ 1.32	$ 5.06	$ 5.07

[a] See ANI's Form 10-K filed February 27, 2020 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 generated record net revenues and non-GAAP gross profit in 2019 while continuing to diversify its commercial product offering and pipeline opportunities. While revenues and non-GAAP gross profit for three of our important generic products were negatively impacted in recent periods, overall our business remains resilient, and we look forward to leveraging important

recent launches such as Vancomycin Oral Solution and Bretylium Tosylate Injection as well as the recently acquired Amerigen portfolio in 2020. During 2019, we launched several new products, entered into collaborative arrangements with strategic partners and acquired both previously approved and development stage products we plan to launch in the future. We have utilized strong operating cash flows for asset acquisitions and investment into our portfolio of pipeline products and expect to continue to do so in the future.

During the fourth quarter, we successfully completed our fourth commercial scale batch of both Corticotropin API and the Cortrophin® Gel drug product, and importantly, remain on track to submit our supplemental NDA filing in March 2020."

2020 Financial Guidance

For the twelve months ending December 31, 2020, ANI is providing guidance on net revenue, adjusted non-GAAP EBITDA, and adjusted non-GAAP diluted earnings per share. The following table summarizes 2020 guidance as compared to 2019 actual results:

($ in millions except per share data)	2019	2020 Guidance Range			% Change from Prior Year		
	Actual	Low	Mid	High	Low	Mid	High
Net Revenues	$ 206.5	$ 213.0	$ 218.0	$ 223.0	3%	6%	8%
Adjusted non-GAAP EBITDA	$ 83.2	$ 80.0	$ 83.0	$ 86.0	-4%	0%	3%
Adjusted non-GAAP diluted earnings per share	$ 5.06	$ 4.46	$ 4.66	$ 4.86	-12%	-8%	-4%

In addition, we expect that adjusted non-GAAP gross margin, defined as the result of Net Revenues less Cost of Sales (excluding depreciation and amortization) as a percentage of Net Revenues, will decline from approximately 71% in 2019 to the mid 60% range in 2020, driven by the impact of negative price and product mix. Year over year changes of our Adjusted non-GAAP diluted earnings per share metric differ from our Adjusted non-GAAP EBITDA metric due to a projected increase in cash interest expense resulting from the refinancing of our convertible debt to bank debt.

ANI's full year 2020 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.

Cortrophin® Gel Re-commercialization Update

Product	Required Filing	Expected Filing Date	Total Annual Market[(d)]
Cortrophin® Gel	sNDA	March 2020	$1.0 billion

[(d)] Based on data from IQVIA

We continue to successfully progress our Cortrophin® Gel re-commercialization program. Significant accomplishments since the third quarter 2019 press release (dated November 6, 2019) include:

- ANI successfully completed API process validation by completing the fourth commercial scale batch of Corticotropin API. ANI also completed manufacturing for a fifth commercial scale batch of Corticotropin API. All five commercial scale batches were analytically consistent with each other and met all API release specifications. ANI expects to have 6 months stability on all API registration batches prior to the sNDA filing and by the end of first quarter 2020.

- ANI successfully completed drug product process validation in the fourth quarter of 2019. ANI also completed manufacturing of a fourth commercial scale batch of Cortrophin® Gel. This batch was analytically consistent with previously manufactured batches and met all drug product release specifications. ANI had already completed manufacturing for three commercial scale registration stability batches of Cortrophin® Gel and expects to have 6 months stability on each prior to the sNDA filing and by the end of first quarter 2020.

ANI is on track to file the sNDA as planned by March 2020.

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

Fourth Quarter Results

Net Revenues (in thousands)	**Three Months Ended December 31,**			
	2019	**2018**	**Change**	**% Change**
Generic pharmaceutical products	$ 29,121	$ 33,735	$ (4,614)	(14)%
Branded pharmaceutical products	15,624	18,840	(3,216)	(17)%
Contract manufacturing	2,640	3,669	(1,029)	(28)%
Royalty and other income	581	878	(297)	(34)%
Total net revenues	$ 47,966	$ 57,122	$ (9,156)	(16)%

Generic Pharmaceutical Products

Fourth Quarter Net Revenues - Results and Update

Net revenues from sales of generic pharmaceuticals decreased 14% to $29.1 million from $33.7 million in the prior period, primarily due to decreases in sales of Esterified Estrogen with Methlytestosterone ("EEMT"), Erythromycin Ethylsuccinate ("EES"), Propafenone, and Fenofibrate. These decreases were tempered by the September 2019 launch of Vancomycin HCl for Oral Solution as well as increased unit sales of Vancomycin tablets.

Branded Pharmaceutical Products

Fourth Quarter Net Revenues - Results and Update

Net revenues from sales of branded pharmaceuticals decreased 17% to $15.6 million from $18.8 million in the prior period, primarily due to decrease in sales of Inderal® LA, Atacand® and Atacand HCT®. These decreases were tempered by increased sales of InnoPran XL®.

Contract Manufacturing

Fourth Quarter Net Revenues - Results and Update

Contract manufacturing revenues decreased 28% to $2.6 million from $3.7 million in the prior year period, due to the timing and volume of orders from contract manufacturing customers in the period.

Royalty and Other

Fourth Quarter Net Revenues - Result and Update

Royalty and Other decreased 34% to $0.6 million from $0.9 million, primarily due to the timing and volume of product development and laboratory services revenue earned by ANI Canada.

Operating Expenses

Operating expenses increased to $52.6 million for the three months ended December 31, 2019, from $45.7 million in the prior year period. The increase was primarily due to the following:

- $6.5 million in the build of Cortrophin pre-launch commercial inventories (which are expensed for US GAAP); there were no such activities in 2018,
- $1.2 million increase in research and development expense, primarily due to Q4 2019 development-based milestone payments earned by collaborative partners, and
- $0.9 million increase in depreciation and amortization expense, 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 $2.3 million decrease in cost of sales as a result of the previously mentioned royalty buyout in January 2019 and a decrease in sales over the comparable periods, tempered by Q4 2019 inventory reserve charges of $4.6 million primarily related to the Company's exit from the Methylphenidate Extended Release market.

Cost of sales as a percentage of net revenues increased to 37% during the three months ended December 31, 2019, from 35% during same period in 2018. The increase was primarily due to the inventory reserve charges recognized in the fourth quarter 2019 and negative price, which were tempered by reductions related to the 2019 royalty buyout.

Net Loss and Diluted Loss per Share

Net loss was $4.8 million for the three months ended December 31, 2019, as compared to net income of $5.4 million in the prior year period. The net loss was driven by the previously mentioned $6.5 million build of Cortrophin pre-launch commercial inventories and $4.6 million of inventory reserve charges. The effective consolidated tax benefit rate for the three months ended December 31, 2019 was 37%.

Diluted loss per share for the three months ended December 31, 2019 was $0.41, based on 11,886 thousand diluted shares outstanding, as compared to diluted earnings per share of $0.46 in the prior year period. Adjusted non-GAAP diluted earnings per share was $1.08, 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 118 products, addressing a total annual market size of $7.0 billion, based on data from IQVIA. Of these, ANI expects that at least 52 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, non-cash impairment charges, Cortrophin pre-launch charges, other income / expense and certain other items, including expensed milestone payments and inventory reserve charges, 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, non-cash impairment charges, Cortrophin pre-launch charges and certain other items, including expensed milestone payments and inventory reserve charges, that vary in frequency and impact on ANI's results of operations. 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, including expensed milestone payments and inventory reserve charges, 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, non-cash impairment charges, Cortrophin pre-launch charges and certain other items, including expensed milestone payments and inventory reserve charges, that vary in frequency and impact on ANI's results of operations.

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 (in 2019), 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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