ANI Pharmaceuticals Reports First Quarter 2020 Results and Appoints Interim CEO

For the first quarter 2020, ANI reports:

- **Net revenues of $49.8 million versus $52.9 million in 2019**
- **GAAP net loss of $7.0 million and diluted GAAP loss per share of $0.59**
- **Adjusted non-GAAP EBITDA of $17.6 million**
- **Adjusted non-GAAP diluted earnings per share of $1.04**

Integrates Amerigen Pharmaceuticals, Ltd. portfolio

Launches five generic products increasing total commercialized product line to 60 product families

Appoints Patrick D. Walsh interim President and CEO

Suspends guidance for 2020

Baudette, Minnesota (May 7, 2020) – ANI Pharmaceuticals, Inc. ("ANI") (NASDAQ: ANIP) today reported its financial results for the three months ended March 31, 2020. The Company will host its earnings conference call this morning, May 7, 2020, at 10:30 AM ET. Investors and other interested parties can join the call by dialing (866) 776-8875. The conference ID is 5243607.

Financial Summary

(in thousands, except per share data)	**Q1 2020**	**Q1 2019**
Net revenues	$ 49,774	$ 52,887
Net (loss)/income	$ (7,011)	$ 449
GAAP (loss)/earnings per diluted share	$ (0.59)	$ 0.04
Adjusted non-GAAP EBITDA[(a)]	$ 17,554	$ 22,299
Adjusted non-GAAP diluted earnings per share[(b)]	$ 1.04	$ 1.30

[(a)] See Table 3 for US GAAP reconciliation.
[(b)] See Table 4 for US GAAP reconciliation.

Arthur S. Przybyl, President and CEO, stated,

> "ANI generated net revenues and non-GAAP earnings that met management's expectations during a period that was marked by significant uncertainties due to the COVID-19 pandemic. Our performance during this period is a testament to the commitment of our employees and to the strength of the business that we have built. I am proud of the accomplishments that were made during my eleven-year tenure as CEO of ANI. During this time, we have built ANI from a small private company to a thriving public specialty pharmaceutical business with an increasing diverse commercial product offering and an incredibly valuable pipeline opportunity in Cortrophin® Gel. As I depart ANI, I am confident that I leave the business in good health, in the hands of a very strong management team, and with its best days ahead of it. I welcome Patrick Walsh from the Board of Directors to the role of interim CEO and trust in his ability to lead the Company until such time as my replacement is identified."

Appoints Interim CEO

As previously announced, Mr. Przybyl will depart as President and CEO on May 10, 2020. The Board of Directors of ANI (BOD) has appointed Patrick D. Walsh interim President and CEO, effective May 11, 2020, until such time that Mr. Przybyl's permanent replacement is hired. Mr. Walsh has served on the ANI BOD since 2018 and has extensive pharmaceutical industry experience. For Mr. Walsh's complete bio, please refer to ANI's proxy statement filed on April 23, 2020. The BOD has retained nationally recognized executive search firm Heidrick & Struggles and is currently conducting the search for a President and CEO.

Continues Expansion of Commercialized Product Portfolio

During the first quarter of 2020, we successfully integrated the Amerigen Pharmaceuticals, Ltd. U.S. product portfolio, which was purchased in January for $52.5 million. This transaction increased our commercialized generic product portfolio by nine products from 35 to 44 and increased our pipeline portfolio by an additional thirteen opportunities. In addition, we launched five generic products during the quarter, further expanding our generic offerings to 49, and our total commercialized offerings including brands to 60.

First Quarter Results

Net Revenues (in thousands)	**Three Months Ended March 31,**			
	2020	**2019**	**Change**	**% Change**
Generic pharmaceutical products	$ 37,495	$ 31,599	$ 5,896	19%
Branded pharmaceutical products	9,157	17,543	(8,386)	(48)%
Contract manufacturing	1,974	2,437	(463)	(19)%
Royalty and other income	1,148	1,308	(160)	(12)%
Total net revenues	$ 49,774	$ 52,887	$ (3,113)	(6)%

Generic Pharmaceutical Products

Net revenues for generic pharmaceutical products were $37.5 million during the three months ended March 31, 2020, an increase of 19% compared to $31.6 million for the same period in 2019. The primary drivers of the increase are the September 2019 launch of Vancomycin Oral Solution and the January 2020 launch of Miglustat, Mixed Amphetamine Salts, Penicillamine and Paliperidone, all products acquired in January from Amerigen Pharmaceuticals, Ltd. ("Amerigen"). These increases were tempered by decreases in sales of Vancomycin capsules, Esterified Estrogen with Methyltestosterone ("EEMT"), Erythromycin Ethylsuccinate ("EES"), and Ezetimibe Simvastatin.

Branded Pharmaceutical Products

Net revenues for branded pharmaceutical products were $9.2 million during the three months ended March 31, 2020, a decrease of 48% compared to $17.5 million for the same period in 2019. The primary reasons for the decrease were lower unit sales of Inderal XL, Inderal LA and Atacand as well as decreased sales of Arimidex.

Contract Manufacturing

Contract manufacturing revenues were $2.0 million during the three months ended March 31, 2020, a decrease of 19% compared to $2.4 million for the same period in 2019, due to the timing and volume of orders from contract manufacturing customers in the period.

Royalty and Other

Royalty and other were $1.1 million during the three months ended March 31, 2020, a decrease of $0.2 million from $1.3 million for the same period in 2019, primarily due to a decrease in royalty and laboratory service revenues, tempered by increases in product development revenues earned by ANI Canada during the three months ended March 31, 2020.

Operating Expenses

Operating expenses increased to $57.6 million for the three months ended March 31, 2020, from $48.5 million in the prior year period. The increase was primarily due to the following:

- $7.1 million increase in cost of sales, primarily as a result of $2.7 million in cost of sales representing the excess of fair value over cost for inventory acquired in the Amerigen acquisition and subsequently sold during the period, increased volumes related to a shift in product mix towards generic products, current period inventory reserve charges and increased sales of products subject to profit-sharing arrangements,
- $4.6 million in the build of Cortrophin® pre-launch commercial inventories (which are expensed for US GAAP); there were no such comparable activities in the first quarter 2019, and
- $2.0 million increase in research and development expense, primarily due to $3.8 million in-process research and development expense from the Amerigen acquisition, partially offset by a decrease in expense related to the Cortrophin® re-commercialization project as we begin to complete our development efforts.

These increases were tempered by a $4.9 million decrease in depreciation and amortization expense, primarily due to the non-reoccurrence of amortization expense recorded in relation to the January 2019 royalty buy out, partially offset by the amortization of the Abbreviated New Drug Applications and marketing and distribution rights acquired in January 2020 from Amerigen.

Cost of sales exclusive of the $2.7 million net impact related to the excess of fair value over the cost of inventory sold during the period as a percentage of net revenues increased to 38% during the three months ended March 31, 2020, from 28% during same period in 2019, primarily as a result of a shift in product mix to an increased volume of generic products, which have lower average selling prices, inventory reserve charges in the current quarter as well as increased sales of products subject to profit-sharing arrangements during the current quarter.

Net Loss and Diluted Loss per Share

Net loss was $7.0 million for the three months ended March 31, 2020, as compared to net income of $0.4 million in the prior year period. The effective consolidated tax benefit rate for the three months ended March 31, 2020 was 29.7%.

Diluted loss per share for the three months ended March 31, 2020 was $0.59, based on 11,902 thousand diluted shares outstanding, as compared to diluted earnings per share of $0.04 in the prior year period. Adjusted non-GAAP diluted earnings per share was $1.04, as compared to adjusted non-GAAP diluted

earnings per share of $1.30 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.

Cortrophin® Gel Re-commercialization Update

Product	Required Filing	Total Annual Market[(c)]
Cortrophin® Gel	sNDA	$950 million

[(c)] Based on data from IQVIA

ANI filed the sNDA for Cortrophin® Gel re-commercialization on March 23, 2020, on track with our long-standing publicly projected Q1 2020 target filing date. The FDA initially set a PDUFA goal date of July 23, 2020, however as announced on April 29, 2020, subsequently issued a Refusal to File (RTF) letter. ANI will request a Type-A meeting with the FDA in order to discuss the deficiencies identified in the RTF letter and our plan to address each of them. In addition, significant accomplishments since the fourth quarter 2020 press release (dated February 27, 2020) include:

- ANI successfully completed manufacturing for a sixth commercial scale batch of Corticotropin API. All six commercial scale batches have been analytically consistent with each other and have met all API release specifications.
- ANI obtained 6 months accelerated and real-time stability on all API registration batches which facilitated sNDA filing by the end of first quarter 2020.
- ANI successfully completed three media fill simulations demonstrating sterility assurance for our Cortrophin® Gel manufacturing process.
- ANI obtained 6 months accelerated and real-time stability on all drug product registration batches which also facilitated sNDA filing by the end of first quarter 2020.
- ANI successfully completed full shipping validation which confirmed that the integrity of Cortrophin® Gel is fully maintained to support our commercial launch and distribution plan.
- In preparation for a future launch, ANI has continued to stockpile porcine pituitaries and corticotropin API to ensure that it can satisfy market demand.

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

ANI Guidance for the Full Year 2020

Due to inherent uncertainties regarding the duration and impact of the coronavirus (COVID-19) pandemic, ANI is suspending its previously announced 2020 financial guidance.

ANI Product Development Pipeline

ANI's pipeline consists of 116 products, addressing a total annual market size of $5.8 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

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, excluding tax expense or benefit, 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 on inventory reserve recoveries, 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 the excess of fair value over cost of acquired inventory sold, non-cash stock-based compensation, non-cash interest expense, depreciation and amortization, inventory reserve recoveries, Cortrophin pre-launch charges, acquired IPR&D expense, transaction and integration expenses and certain other items 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, plus the excess of fair value over cost of acquired inventory sold, stock-based compensation expense, transaction and integration expenses, non-cash interest expense, depreciation and amortization expense, expense from acquired in-process research and development, 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 the excess of fair value over cost of acquired inventory sold, non-cash stock-based compensation, non-cash interest expense, depreciation and amortization, inventory reserve recoveries, Cortrophin pre-launch charges, acquired IPR&D expense, transaction and integration expenses and certain other items 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, the appointment of an Interim President and CEO and our ongoing CEO search 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; the ability to identify and attract qualified candidates for the President and Chief Executive Officer position, the length of time before a successor is appointed and potential disruption in the management team during the transition period; 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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