



## ANI Pharmaceuticals Reports Second Quarter 2020 Results

August 6, 2020

- Second quarter 2020 net revenues of \$48.5 million -

- Nikhil Lalwani named President and CEO, effective September 8, 2020 –

- Pharmaceutical industry executives, Jeanne Thoma and Tony Pera, join Board of Directors -

BAUDETTE, Minn.--(BUSINESS WIRE)-- **ANI Pharmaceuticals, Inc. (“ANI” or the “Company”)** (NASDAQ: ANIP) today announced business highlights and financial results for the three and six months ended June 30, 2020.

### **Business and Recent Highlights :**

- Completed comprehensive gap assessment on lead product, Cortrophin® Gel, and expect to resubmit supplemental New Drug Application (“sNDA”) to the U.S. Food and Drug Administration (“FDA”) no later than the first quarter of 2021;
- Named Nikhil Lalwani as the Company’s new President and CEO, and Board member, effective September 8, 2020;
- Appointed pharmaceutical industry leaders, Jeanne Thoma and Tony Pera, to Board of Directors;
- Launched Omega-3 Acid Ethyl Esters Capsules USP (1g), Polyethylene Glycol 3350 (17g/Package) and Mexiletine Hydrochloride Capsules USP, 150mg, 200mg and 250mg, the first new product launch from the Company’s Oakville, Canada manufacturing site;
- Acquired Fluconazole Tablets USP, 50mg, 100mg, 150mg, and 200mg for \$3.0 million; and
- Retained a healthcare-focused investor relations firm and launched an updated Company website.

### **Second Quarter 2020 Financial Highlights :**

- Net revenues for Q2 2020 were \$48.5 million compared to \$54.4 million in Q2 2019.
- GAAP net loss for Q2 2020 was \$12.3 million, and diluted GAAP loss per share was \$1.03.
- Adjusted non-GAAP EBITDA for Q2 2020 was \$15.4 million.
- Adjusted non-GAAP diluted earnings per share for Q2 2020 was \$0.69.
- Cash and cash equivalents were \$27.7 million, net accounts receivable was \$73.2 million, and debt was \$190.2 million as of June 30, 2020.

“Despite the negative impact of the COVID-19 pandemic, we had a productive quarter by adding to our stable of generic products, successfully launching our first product from our manufacturing site in Oakville, Canada, a plant that we expect will play an important role in future launches, and making progress to advance our lead product candidate, Cortrophin Gel. I am proud of how our company has navigated these challenges, ensuring the continued manufacturing and availability of our products while keeping our employees safe,” stated Patrick Walsh, Interim President and CEO.

“In addition, we are delighted to welcome Nikhil, Jeanne and Tony, all exceptionally talented executives with deep industry knowledge who will collectively enable us to drive our future growth initiatives, execute on our corporate vision and achieve our strategic goals,” concluded Walsh.

### **Second Quarter 2020 Financial Results**

#### **Net Revenues**

(in thousands)

	Three Months Ended June 30	
	2020	2019
Generic pharmaceutical products	\$ 33,400	\$ 36,255
Branded pharmaceutical products	10,633	13,996
Contract manufacturing	2,900	3,687
Royalty and other income	1,537	419
Total net revenues	<u>\$ 48,470</u>	<u>\$ 54,357</u>

Net revenues were \$48.5 million in the second quarter of 2020 compared with \$54.5 million in the second quarter of 2019. Net revenues for generic pharmaceutical products were \$33.4 million during the three months ended June 30, 2020, a decrease of 8% compared to \$36.3 million for the same period in 2019. Net revenues for branded pharmaceutical products were \$10.6 million during the three months ended June 30, 2020, a decrease of 24% compared to \$14.0 million for the same period in 2019. During the three months ended June 30, 2020, the Company’s generic and branded product revenue results were negatively impacted by the COVID-19 pandemic.

Contract manufacturing revenues were \$2.9 million during the three months ended June 30, 2020, a decrease of 21% compared to \$3.7 million for the same period in 2019, due to a decreased volume of orders from contract manufacturing customers in the period.

Royalty and other revenues were \$1.5 million during the three months ended June 30, 2020, an increase of \$1.1 million from \$0.4 million for the same period in 2019, primarily due to increases in product development revenues earned by ANI Canada and an increase in royalty and laboratory service revenues.

Operating expenses increased to \$59.8 million for the three months ended June 30, 2020, from \$45.1 million in the prior year period.

Cost of sales, excluding depreciation and amortization, increased by \$5.1 million to \$20.7 million in the second quarter of 2020, primarily due to increased volumes related to a shift in product mix toward generic products, \$1.4 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, inventory reserve charges related to excess inventory on hand and discontinued projects, and increased sales of products subject to profit-sharing arrangements. Excluding the \$1.4 million impact, cost of sales as a percentage of net revenues increased to 40% during the three months ended June 30, 2020, from 29% during same period in 2019 for the reasons mentioned above.

Research and development expense decreased by \$2.7 million in the second quarter of 2020 to \$3.0 million compared with \$5.8 million in the second quarter of 2019, primarily due to the non-recurrence of \$2.3 million of expense related to in-process research and development acquired from Coeptis Pharmaceuticals, Inc. in the second quarter of 2019 and a decrease in expense related to the Cortrophin re-commercialization project. These decreases were tempered by \$0.4 million of severance expense associated with the restructuring of the Company's internal Cortrophin development team. The Company currently anticipates that Cortrophin-related expenses in the second half of 2020 will approximate the first half of 2020, as we continue to focus on our supplemental New Drug Application ("sNDA") resubmission efforts.

Selling, general and administrative costs rose by \$7.0 million in the second quarter of 2020 to \$21.2 million compared to \$14.2 million in the comparable quarter in 2019. The increase primarily reflects \$6.5 million of one-time termination expenses related to the departure of the Company's former President and CEO and costs incurred for the CEO recruitment process.

Depreciation and amortization increased by \$1.7 million in the second quarter of 2020 to \$11.2 million compared to \$9.5 million in the comparable quarter in 2019 due to amortization of the Abbreviated New Drug Applications ("ANDAs"), and marketing and distribution rights acquired in January 2020 from Amerigen.

The Company also had \$3.6 million in the build of Cortrophin pre-launch commercial inventories, which are expensed for U.S. GAAP; there were no such comparable activities in the second quarter 2019.

Net loss for the second quarter of 2020 was \$12.3 million as compared to net income of \$6.6 million in the prior year period. The effective consolidated tax benefit rate for the three months ended June 30, 2020 was 10.5%. Diluted loss per share for the three months ended June 30, 2020 was \$1.03, compared to diluted earnings per share of \$0.53 in the prior year period.

Adjusted non-GAAP diluted earnings per share was \$0.69 in the second quarter of 2020 compared to adjusted non-GAAP diluted earnings per share of \$1.44 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.

#### **Guidance for the Full Year 2020**

Due to inherent uncertainties regarding the duration and impact of the COVID-19 pandemic, ANI has suspended its previously announced 2020 financial guidance.

#### **Liquidity**

As of June 30, 2020, the Company had \$27.7 million in unrestricted cash and cash equivalents plus \$73.2 million in net accounts receivable. The Company had \$190.2 million in outstanding debt as of June 30, 2020.

#### **Cortrophin Gel Re-commercialization Update**

The Company has made progress in advancing its lead product, Cortrophin Gel. In collaboration with a prominent consulting firm, the Company completed a comprehensive gap assessment and made significant changes to the project's leadership team. The majority of the identified deficiencies have already been remediated, and timelines for completing the remaining tasks, including additional data to bolster analytical comparability to the legacy drug product, have been established. The Company expects to resubmit the sNDA no later than the first quarter of 2021.

#### **Conference Call**

As previously announced, ANI Pharmaceuticals management will host its second quarter 2020 conference call as follows:

Date	Thursday, August 6, 2020
Time	10:30 a.m. ET
Toll free (U.S.)	(866) 776-8875
Webcast (live and replay)	<a href="http://www.anipharmaceuticals.com">www.anipharmaceuticals.com</a> , under the "Investors" section

A replay of the conference call will be available within two hours of the call's completion and will remain accessible for one-week by dialing (800) 585-8367 and entering access code 9589496.

#### **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, CEO transition expenses, 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 below.

#### **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, CEO transition expenses, non-cash interest expense, depreciation and amortization, inventory reserve recoveries, Cortrophin pre-launch charges, acquired in-process research and development ("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, CEO transition expenses, 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 below.

#### **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, CEO transition expenses, 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 below.

#### **About ANI**

ANI Pharmaceuticals, Inc. is an integrated specialty pharmaceutical company developing, manufacturing, and marketing branded and generic prescription pharmaceuticals. The Company's targeted areas of product development currently include narcotics, oncology (anti-cancers), hormones and steroids, and complex formulations involving extended release and combination products. For more information, please visit our website [www.anipharmaceuticals.com](http://www.anipharmaceuticals.com).

#### **Forward-Looking Statements**

To the extent any statements made in this release relate to 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 the Company's future operations, products, financial position, operating results and prospects, the Company's pipeline or potential markets therefor, timing for submission of a sNDA for Cortrophin Gel 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, including the ongoing impact of the COVID-19 pandemic; market trends; regulatory environment and changes; 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.

Financial Tables Follow

#### **ANI Pharmaceuticals, Inc. and Subsidiaries**

#### **Table 1: US GAAP Statement of Operations**

*(unaudited, in thousands, except per share amounts)*

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net Revenues	\$ 48,470	\$ 54,357	\$ 98,244	\$ 107,244
Operating Expenses				
Cost of sales (excl. depreciation and amortization)	20,695	15,632	42,499	30,357
Research and development	3,035	5,773	9,379	10,146
Selling, general, and administrative	21,213	14,188	34,896	27,472
Depreciation and amortization	11,198	9,472	22,381	25,575
Cortrophin pre-launch charges	3,636	-	8,238	-
Total Operating Expenses	59,777	45,065	117,393	93,550
Operating (Loss)/Income	(11,307)	9,292	(19,149)	13,694
Other Expense, Net				
Interest expense, net	(2,356)	(3,406)	(4,388)	(6,760)
Other (expense)/income, net	(116)	46	(106)	(84)
(Loss)/Income Before Benefit for Income Taxes	(13,779)	5,932	(23,643)	6,850
Benefit for Income Taxes	1,443	653	4,296	184
Net (Loss)/Income	\$ (12,336)	\$ 6,585	\$ (19,347)	\$ 7,034
<b>(Loss)/Earnings Per Share</b>				
Basic (Loss)/Earnings Per Share	\$ (1.03)	\$ 0.55	\$ (1.62)	\$ 0.59
Diluted (Loss)/Earnings Per Share	\$ (1.03)	\$ 0.53	\$ (1.62)	\$ 0.57
Basic Weighted-Average Shares Outstanding	11,967	11,851	11,935	11,799
Diluted Weighted-Average Shares Outstanding	11,967	12,269	11,935	12,046

**ANI Pharmaceuticals, Inc. and Subsidiaries**

**Table 2: US GAAP Balance Sheets**

*(unaudited, in thousands)*

	<u>June 30, 2020</u>	<u>December 31, 2019</u>
Current Assets		
Cash and cash equivalents	\$ 27,702	\$ 62,332
Accounts receivable, net	73,162	72,129
Inventories, net	52,563	48,163
Prepaid income taxes	-	1,076
Prepaid expenses and other current assets	3,117	3,995
Total Current Assets	156,544	187,695
Property and equipment, net	39,937	40,551
Restricted cash	5,002	5,029
Deferred tax assets, net of deferred tax liabilities and valuation allowance	53,488	38,326
Intangible assets, net	205,745	180,388
Goodwill	3,580	3,580
Other non-current assets	1,095	1,220
Total Assets	\$ 465,391	\$ 456,789
Current Liabilities		
Current debt, net of deferred financing costs	\$ 12,329	\$ 9,941
Accounts payable	14,209	14,606
Accrued expenses and other	3,066	2,362
Accrued royalties	6,004	5,084

Accrued compensation and related expenses	5,349	3,736
Current income taxes payable, net	8,286	-
Accrued government rebates	9,717	8,901
Returned goods reserve	20,003	16,595
Deferred revenue	125	451
<b>Total Current Liabilities</b>	<b>79,088</b>	<b>61,676</b>
Non-current debt, net of deferred financing costs and current component	177,879	175,808
Other non-current liabilities	17,080	6,514
<b>Total Liabilities</b>	<b>274,047</b>	<b>243,998</b>
Stockholders' Equity		
Common stock	1	1
Treasury stock	(2,246)	(723)
Additional paid-in capital	209,409	200,800
(Accumulated deficit)/retained earnings	(1,771)	17,584
Accumulated other comprehensive loss, net of tax	(14,049)	(4,871)
<b>Total Stockholders' Equity</b>	<b>191,344</b>	<b>212,791</b>
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$ 465,391</b>	<b>\$ 456,789</b>

**ANI Pharmaceuticals, Inc. and Subsidiaries**

**Table 3: Adjusted non-GAAP EBITDA Calculation and US GAAP to Non-GAAP Reconciliation**  
(unaudited, in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net (Loss)/Income	\$ (12,336)	\$ 6,585	\$ (19,347)	\$ 7,034
Add/(Subtract):				
Interest expense, net	2,356	3,406	4,388	6,760
Other expense/(income), net	116	(46)	106	84
Benefit for income taxes	(1,443)	(653)	(4,296)	(184)
Depreciation and amortization	11,198	9,472	22,381	25,575
Cortrophin pre-launch charges	3,636	-	8,238	-
Stock-based compensation <sup>(1)</sup>	2,271	2,593	4,695	4,303
CEO transition items <sup>(2)</sup>	7,145	-	7,145	-
Cortrophin team restructuring	401	-	401	-
Acquired IPR&D expense	-	2,324	3,784	2,324
Excess of fair value over cost of acquired inventory	1,420	-	4,071	-
Asset impairments <sup>(3)</sup>	40	-	792	-
Charges related to market exits	567	-	567	-
Transaction and integration expenses	-	-	-	84
<b>Adjusted non-GAAP EBITDA</b>	<b>\$ 15,371</b>	<b>\$ 23,681</b>	<b>\$ 32,925</b>	<b>\$ 45,980</b>

(1) For the three and six months ended June 30, 2020, Stock-based compensation excludes \$3.4 million of stock-based compensation expense associated with the departure of our former President and CEO. This amount is included in this table as part of CEO transition items.

(2) CEO transition items is comprised of \$3.4 million of stock compensation expense and \$3.1 million of expense for salary continuation, bonus and other fringe benefits associated with the departure of our former President and CEO, as well as certain legal and recruiting costs related to the search for a permanent replacement.

(3) For the three months ended June 30, 2020, Asset impairments is comprised of a finished goods inventory reserve for Breylium. For the six months ended June 30, 2020, it is comprised of finished goods inventory reserves for Breylium and an accounts receivable reserve due to customer bankruptcy, tempered by a modest recovery of previously reserved inventory related to market exits.

**ANI Pharmaceuticals, Inc. and Subsidiaries**

**Table 4: Adjusted non-GAAP Net Income and Adjusted non-GAAP Diluted Earnings per Share Reconciliation**  
(unaudited, in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net (Loss)/Income	\$ (12,336)	\$ 6,585	\$ (19,347)	\$ 7,034
Add/(Subtract):				
Non-cash interest expense	500	1,856	657	3,655
Depreciation and amortization expense	11,198	9,472	22,381	25,575
Cortrophin pre-launch charges	3,636	-	8,238	-
Acquired IPR&D expense	-	2,324	3,784	2,324
Stock-based compensation <sup>(1)</sup>	2,271	2,593	4,695	4,303
CEO transition items <sup>(2)</sup>	7,145	-	7,145	-
Cortrophin team restructuring	401	-	401	-
Asset impairments <sup>(3)</sup>	40	-	792	-
Excess of fair value over cost of acquired inventory	1,420	-	4,071	-
Charges related to market exits	567	-	567	-
Transaction and integration expenses	-	-	-	84
Less:				
Tax impact of adjustments	(6,523)	(3,899)	(12,655)	(8,626)
Discrete tax benefit related to ANI Canada transfer pricing agreement	-	(1,653)	-	(1,653)
Adjusted Non-GAAP Net Income	\$ 8,319	\$ 17,278	\$ 20,729	\$ 32,696
Diluted Weighted-Average				
Shares Outstanding	11,967	12,269	11,935	12,046
Less: Dilutive Effect of Notes	-	(306)	-	(153)
Adjusted Diluted Weighted-Average				
Shares Outstanding	11,982	11,963	11,964	11,893
Adjusted Non-GAAP				
Diluted Earnings per Share	\$ 0.69	\$ 1.44	\$ 1.73	\$ 2.75

(1) For the three and six months ended June 30, 2020, Stock-based compensation excludes \$3.4 million of stock-based compensation expense associated with the departure of our former President and CEO. This amount is included in this table as part of CEO transition items.

(2) CEO transition items is comprised of \$3.4 million of stock compensation expense and \$3.1 million of expense for salary continuation, bonus and other fringe benefits associated with the departure of our former President and CEO, as well as certain legal and recruiting costs related to the search for a permanent replacement.

(3) For the three months ended June 30, 2020, Asset impairments is comprised of a finished goods inventory reserve for Breylium. For the six months ended June 30, 2020, it is comprised of finished goods inventory reserves for Breylium and an accounts receivable reserve due to customer bankruptcy, tempered by a modest recovery of previously reserved inventory related to market exits.



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Investor Relations:

Lisa M. Wilson, In-Site Communications, Inc.

T: 212-452-2793

E: [lwilson@insitecony.com](mailto:lwilson@insitecony.com)

Source: ANI Pharmaceuticals, Inc.