

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

**Current Report
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **March 9, 2021**

ANI PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-31812
(Commission File Number)

58-2301143
(I.R.S. Employer
Identification Number)

**210 Main Street West
Baudette, Minnesota**
(Address of principal executive offices)

56623
(Zip Code)

Registrant's telephone number, including area code: **(218) 634-3500**

(Former name or former address, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:

Common Stock

Trading Symbol(s)

ANIP

Name of each exchange on which registered:

Nasdaq Stock Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On March 9, 2021, ANI Pharmaceuticals, Inc. (“ANI”) issued a press release announcing its financial and operating results for the three months and year ended December 31, 2020. A copy of the press release is furnished as Exhibit 99.1 to this report.

In accordance with General Instruction B.2. of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

No.	Description
99.1	Press release, dated March 9, 2021, issued by ANI
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded in the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ANI PHARMACEUTICALS, INC.

By: /s/ Stephen P. Carey

Stephen P. Carey

Vice President, Finance and Chief Financial Officer

Dated: March 9, 2021



FOR IMMEDIATE RELEASE

ANI Pharmaceuticals Reports Fourth Quarter and Full Year 2020 Results; Company Positioned for Sustainable Future Growth

-- Fourth quarter 2020 net revenues of \$57.3 million; net loss of \$3.6 million and diluted loss per share of \$0.30 --

-- Fourth quarter adjusted non-GAAP EBITDA of \$17.2 million and adjusted non-GAAP diluted eps of \$0.80 --

-- ANI defines strategy for sustainable future growth and strengthens capital structure --

-- Definitive agreement to acquire Novitium Pharma strengthens R&D engine, and expands generics and CDMO business --

-- Cortrophin[®] Gel sNDA re-filing planned for Q2 2021; aligned with FDA on path forward --

-- Key additions to leadership team deepen commercial and manufacturing expertise --

Baudette, Minnesota (March 9, 2021) – ANI Pharmaceuticals, Inc. (“ANI” or the “Company”) (NASDAQ: ANIP) today announced business highlights and financial results for the three and 12 months ended December 31, 2020.

Corporate Strategy

The Company’s strategy for sustainable future growth is based on four key pillars:

- Build a successful Cortrophin franchise;
- Strengthen the Generics business by enhancing development capabilities and increased focus on niche opportunities. The acquisition of Novitium Pharma announced earlier today is an important step toward this goal;
- Maximize the value from established brands through programmatic business development, and innovative access and go-to-market strategies; and
- Expand CDMO business leveraging unique North American-based manufacturing capabilities.

ANI’s collaborative, purposeful and empowered team with their high-performance orientation is prepared to execute this strategy.

Fourth Quarter and Recent Business Highlights:

- Signed a definitive agreement to acquire Novitium Pharma, a privately held, New Jersey-based pharmaceutical company with development, manufacturing, and commercialization capabilities for \$163.5 million, including \$89.5 million in cash and \$74 million in equity, plus two potential future earnouts of up to \$46.5 million. The transaction is expected to be accretive to Adjusted non-GAAP earnings per share within the first 12 months and close in the second half of 2021 following the requisite approvals needed to close the transaction, which include obtaining the approval of ANI shareholders as required by Nasdaq.
-

- Engaged with the U.S. Food and Drug Administration (“FDA”) to refine regulatory path forward for Cortrophin[®] Gel. The Company believes it will refile a robust package with the FDA in the second quarter of 2021, which will provide the best opportunity for acceptance, and ultimately, approval.
- Announced the addition of three key pharmaceutical executives: Christopher K. Mutz as Chief Commercial Officer and Head of Rare Diseases; Ori Gutwerg as Senior Vice President of Generics; and Davinder Singh as General Manager, Canadian Operations.

Fourth Quarter 2020 Financial Highlights:

- Net revenues for Q4 2020 were \$57.3 million compared to \$48.0 million in Q4 2019 and \$53.0 million in Q3 2020.
- GAAP net loss for Q4 2020 was \$3.6 million, and diluted GAAP loss per share was \$0.30.
- Adjusted non-GAAP EBITDA for Q4 2020 was \$17.2 million.
- Adjusted non-GAAP diluted earnings per share for Q4 2020 was \$0.80.

Full Year 2020 Financial Highlights:

- Net revenues were \$208.5 million compared to \$206.5 million in 2019.
- GAAP net loss was \$22.5 million, and diluted GAAP loss per share was \$1.88.
- Adjusted non-GAAP EBITDA was \$67.1 million.
- Adjusted non-GAAP diluted earnings per share was \$3.50.

Cash and cash equivalents were \$7.9 million, net accounts receivable was \$95.8 million, and debt was \$185.7 million as of December 31, 2020.

“Over the past six months, I have understood ANI’s core strengths and the landscape of potential opportunities to develop the four-pronged strategy for delivering sustainable future growth,” stated Nikhil Lalwani, President and CEO.

“The acquisition of Novitium creates a sustainable generics growth engine and enhances scale of our CDMO business. Although the additional work we are doing on Cortrophin impacts our timeline by one quarter, we believe it will result in a more comprehensive and robust refiling to support its approval. This is an important and exciting time for ANI, and we look forward to providing updates as we move forward on our growth journey,” concluded Lalwani.

Fourth Quarter 2020 Financial Results

Net Revenues (in thousands)	Three Months Ended December 31	
	2020	2019
Generic pharmaceutical products	\$ 38,650	\$ 29,121
Branded pharmaceutical products	15,759	15,624
Contract manufacturing	2,195	2,640
Royalty and other income	648	581
Total net revenues	<u>\$ 57,252</u>	<u>\$ 47,966</u>

Net revenues for generic pharmaceutical products were \$38.7 million during the three months ended December 31, 2020, an increase of 32.7% compared to \$29.1 million for the same period in 2019. This increase primarily reflects the January 2020 launches of Paliperidone, Miglustat, Mixed Amphetamine Salts, Tolterodine, Bexarotene and other products acquired from Amerigen, the January 2020 launch of Potassium Citrate ER, and increased revenues of Candesartan. These increases were tempered by decreases in revenues of Ezetimibe Simvastatin, Esterified Estrogen with Methyltestosterone (“EEMT”), and Methazolamide.

Net revenues for branded pharmaceutical products were \$15.8 million during the three months ended December 31, 2020, an increase of 0.9% compared to \$15.6 million for the same period in 2019, primarily due to increased revenues of Inderal LA, which were tempered by a decrease in unit sales of Innopran XL.

Contract manufacturing revenues were \$2.2 million during the three months ended December 31, 2020, a decrease of 16.8% compared to \$2.6 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 \$0.6 million during the three months ended December 31, 2020, and December 31, 2019.

Operating expenses increased to \$56.9 million for the three months ended December 31, 2020, from \$52.6 million in the prior year period.

Cost of sales, excluding depreciation and amortization, increased by \$6.7 million to \$24.5 million in the fourth quarter of 2020, primarily as a result of increased volumes during the quarter, including a shift in product mix toward generic products, an increase related to sales of products subject to profit-sharing arrangements, increased freight charges, and fourth quarter 2020 inventory reserve charges. The increases were tempered by the non-recurrence of the fourth quarter 2019 inventory reserve charge primarily related to the exit from the market of Methylphenidate Extended Release.

Research and development expense decreased by \$1.0 million in the fourth quarter of 2020 to \$3.7 million compared with \$4.7 million in the fourth quarter of 2019, primarily due to a decrease in expense related to the Cortrophin re-commercialization project and the non-recurrence of 2019 milestone expenses related to the Bretylium Tosylate project.

The Company recognized Cortrophin pre-launch charges of \$3.0 million in the three months ended December 31, 2020, compared to Cortrophin pre-launch charges of \$6.5 million in the three months ended December 31, 2019.

Selling, general, and administrative expenses rose by \$0.4 million in the fourth quarter of 2020 to \$14.4 million compared to \$14.0 million in the comparable quarter in 2019.

Depreciation and amortization increased by \$1.3 million in the fourth quarter of 2020 to \$10.9 million compared to \$9.6 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 and the ANDA acquired in July 2020.

Net loss for the fourth quarter of 2020 was \$3.6 million as compared to net loss of \$4.8 million in the prior year period. Diluted loss per share for the three months ended December 31, 2020 was (\$0.30), compared to diluted loss per share of (\$0.41) in the prior year period.

Adjusted non-GAAP diluted earnings per share was \$0.80 in the fourth quarter of 2020 compared to adjusted non-GAAP diluted earnings per share of \$1.08 in the prior year period.

For reconciliations of adjusted non-GAAP EBITDA and adjusted non-GAAP diluted earnings per share to the most directly comparable GAAP financial measure, please see Table 3 and Table 4, respectively.

Liquidity

As of December 31, 2020, the Company had \$7.9 million in unrestricted cash and cash equivalents plus \$95.8 million in net accounts receivable. The Company had \$185.7 million in outstanding debt as of December 31, 2020.

Conference Call

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

Date	Tuesday, March 9, 2021
Time	8:30 a.m. ET
Toll free (U.S.)	(866) 776-8875

Webcast (live and replay) www.anipharmaceuticals.com, 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 (855) 859-2056 and entering access code 2681582.

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, (net), other expense, (net), depreciation, amortization, the excess of fair value over cost of acquired inventory, non-cash stock-based compensation expense, CEO transition expenses, expense from acquired in-process research and development, transaction and integration expenses, Cortrophin pre-launch charges, asset impairments, 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, Cortrophin pre-launch charges, acquired in-process research and development ("IPR&D") expense, transaction and integration expenses, asset impairments, 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, non-cash 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, asset impairments, 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, and tax benefit related to the ANI Canada transfer pricing agreement. 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, Cortrophin pre-launch charges, acquired IPR&D expense, transaction and integration expenses, asset impairments, 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, oncolytics (anti-cancers), hormones and steroids, and complex formulations involving extended release and combination products. For more information, please visit our website 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 corporate strategy, the pending acquisition of Novitium and anticipated results of such acquisition, future operations, products, financial position, operating results and prospects, including plans for growth, the Company's pipeline or potential markets therefor, plans for existing ANDAs, timing for resubmission of a sNDA for Cortrophin Gel and commercialization plans, 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 not be able to obtain the requisite approvals to complete the Novitium acquisition, the Company may face with respect to importing raw materials; the use of single source suppliers and the time it may take to validate and qualify another supplier, if necessary; increased competition and strategies employed by competitors; the ability to realize benefits anticipated from acquisitions; costs and regulatory requirements relating to 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 for our products; regulatory environment and changes; and regulatory and other approvals relating to product development and manufacturing.

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. 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. Except as required by law, the Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Additional Information about the Proposed Novitium Transaction And Where To Find It

In connection with the proposed acquisition of Novitium and the issuances of equity contemplated thereby and in the accompanying PIPE transaction (collectively, the "Proposed Transactions") described in the separate press release issued today and the related SEC filing, the Company will file a proxy statement on Schedule 14A with the SEC to obtain the approval of ANI shareholders for both issuances as required by the Nasdaq listing standards. Additionally, the Company plans to file other relevant materials with the SEC in connection with the Proposed Transactions. This release is not a substitute for the proxy statement or any other document relating to the Proposed Transactions which the Company may file with the SEC. The definitive proxy statement will be sent or given to the stockholders of the Company and will contain important information about the Proposed Transactions. INVESTORS IN AND SECURITY HOLDERS OF THE COMPANY ARE URGED TO READ THE PROXY STATEMENT AND ANY OTHER RELEVANT DOCUMENTS THAT ARE FILED OR FURNISHED OR WILL BE FILED OR WILL BE FURNISHED WITH THE SEC, AS WELL AS ANY AMENDMENTS OR SUPPLEMENTS TO THESE DOCUMENTS, CAREFULLY AND IN THEIR ENTIRETY BEFORE MAKING ANY VOTING OR INVESTMENT DECISION WITH RESPECT TO THE PROPOSED TRANSACTIONS BECAUSE THEY CONTAIN OR WILL CONTAIN IMPORTANT INFORMATION ABOUT THE MERGER, RELATED MATTERS AND THE PARTIES TO THE MERGER. The materials to be filed by the Company with the SEC may be obtained free of charge at the SEC's website at www.sec.gov or by contacting the investor relations department of the Company.

Participants in the Solicitation

This report does not constitute a solicitation of a proxy from any stockholder with respect to the Proposed Transactions. However, the Company and its directors and executive officers may be deemed to be participants in the solicitation of proxies from Company stockholders in connection with the Proposed Transactions. Investors and security holders may obtain more detailed information regarding the names, affiliations and interests of the Company's executive officers and directors in the solicitation by reading the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020, the Company's definitive proxy statement on Schedule 14A for the 2021 Annual Meeting of Stockholders and the other relevant materials filed with the SEC in connection with the Proposed Transactions if and when they become available. Additional information concerning the interests of the Company's participants in the solicitation, which may, in some cases, be different than those of the Company's stockholders generally, will be set forth in the proxy statement relating to the Proposed Transactions when it becomes available. You may obtain free copies of these documents as described in the preceding paragraph filed, with or furnished to the SEC. All such documents, when filed or furnished, are available free of charge at the SEC's website at www.sec.gov or by contacting the investor relations department of the Company.

Contact

Investor Relations:

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

T: 212-452-2793

E: lwilson@insitecony.com

SOURCE: ANI Pharmaceuticals, Inc.

Financial Tables Follow

ANI Pharmaceuticals, Inc. and Subsidiaries
Table 1: US GAAP Statement of Operations
(unaudited, in thousands, except per share amounts)

	<u>Three Months Ended December 31,</u>		<u>Year Ended December 31,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Net Revenues	\$ 57,252	\$ 47,966	\$ 208,475	\$ 206,547
Operating Expenses				
Cost of sales (excl. depreciation and amortization)	24,540	17,795	87,157	63,154
Research and development	3,683	4,678	16,001	19,806
Selling, general, and administrative	14,365	14,014	64,986	55,843
Depreciation and amortization	10,899	9,564	44,638	44,612
Cortrophin pre-launch charges	2,988	6,511	11,263	6,706
Intangible asset impairment charge	446	75	446	75
Total Operating Expenses	<u>56,921</u>	<u>52,637</u>	<u>224,491</u>	<u>190,196</u>
Operating Income/(Loss)	331	(4,671)	(16,016)	16,351
Other Expense, Net				
Interest expense, net	(2,554)	(2,870)	(9,452)	(12,966)
Other expense, net	(159)	(111)	(494)	(228)
(Loss)/Income Before (Provision)/Benefit for Income Taxes	(2,382)	(7,652)	(25,962)	3,157
(Provision)/Benefit for income taxes	(1,253)	2,817	3,414	2,937
Net (Loss)/Income	<u>\$ (3,635)</u>	<u>\$ (4,835)</u>	<u>\$ (22,548)</u>	<u>\$ 6,094</u>
Basic and Diluted (Loss)/Earnings Per Share:				
Basic (Loss)/Earnings Per Share	\$ (0.30)	\$ (0.41)	\$ (1.88)	\$ 0.51
Diluted (Loss)/Earnings Per Share	\$ (0.30)	\$ (0.41)	\$ (1.88)	\$ 0.50
Basic Weighted-Average Shares Outstanding	11,996	11,886	11,964	11,841
Diluted Weighted-Average Shares Outstanding	<u>11,996</u>	<u>11,886</u>	<u>11,964</u>	<u>12,040</u>

ANI Pharmaceuticals, Inc. and Subsidiaries
Table 2: US GAAP Balance Sheets
(unaudited, in thousands)

	December 31, 2020	December 31, 2019
Current Assets		
Cash and cash equivalents	\$ 7,864	\$ 62,332
Accounts receivable, net	95,793	72,129
Inventories, net	60,803	48,163
Prepaid income taxes	-	1,076
Prepaid expenses and other current assets	5,861	3,995
Total Current Assets	170,321	187,695
Property and equipment, net	41,269	40,551
Restricted cash	5,003	5,029
Deferred tax assets, net of deferred tax liabilities and valuation allowance	51,704	38,326
Intangible assets, net	188,511	180,388
Goodwill	3,580	3,580
Other non-current assets	802	1,220
Total Assets	\$ 461,190	\$ 456,789
Current Liabilities		
Current debt, net of deferred financing costs	\$ 13,243	\$ 9,941
Accounts payable	11,261	14,606
Accrued expenses and other	2,456	2,362
Accrued royalties	6,407	5,084
Accrued compensation and related expenses	6,231	3,736
Current income taxes payable, net	3,906	-
Accrued government rebates	7,826	8,901
Returned goods reserve	27,155	16,595
Deferred revenue	80	451
Total Current Liabilities	78,565	61,676
Non-current debt, net of deferred financing costs and current component	172,443	175,808
Derivatives and other non-current liabilities	14,482	6,514
Total Liabilities	265,490	243,998
Stockholders' Equity		
Common stock	1	1
Treasury stock	(2,246)	(723)
Additional paid-in capital	214,354	200,800
(Accumulated deficit)/retained earnings	(4,972)	17,584
Accumulated other comprehensive loss, net of tax	(11,437)	(4,871)
Total Stockholders' Equity	195,700	212,791
Total Liabilities and Stockholders' Equity	\$ 461,190	\$ 456,789

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 December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Net (Loss)/Income	\$ (3,635)	\$ (4,835)	\$ (22,548)	\$ 6,094
Add/(Subtract):				
Interest expense, net	2,554	2,870	9,452	12,966
Other expense, net	159	111	494	228
Provision/(Benefit) for income taxes	1,253	(2,817)	(3,414)	(2,937)
Depreciation and amortization	10,899	9,564	44,638	44,612
Cortrophin pre-launch charges	2,988	6,511	11,263	6,706
Expensed FDA approval milestone payment	-	-	-	329
Stock-based compensation ⁽¹⁾	2,392	2,444	9,470	9,217
CEO transition items ⁽²⁾	37	-	7,386	-
Cortrophin team restructuring	-	-	401	-
Acquired IPR&D expense	-	-	3,784	2,324
Excess of fair value over cost of acquired inventory	113	-	4,296	-
Asset impairments ⁽³⁾	446	75	1,330	75
Charges related to market exits	-	3,460	567	3,460
Transaction and integration expenses	-	-	-	84
Adjusted non-GAAP EBITDA	<u>\$ 17,206</u>	<u>\$ 17,383</u>	<u>\$ 67,119</u>	<u>\$ 83,158</u>

⁽¹⁾ For the year ended December 31, 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 for the year ended December 31, 2020 is comprised of \$3.4 million of stock-based 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 December 31, 2020, Asset impairments is comprised of the impairment of a marketing and distribution right intangible asset. For the year ended December 31, 2020, Asset impairments is comprised of finished goods inventory reserves for Bretylium, accounts receivable reserves due to customer bankruptcy, and the impairment of the marketing and distribution right intangible asset, tempered by a modest recovery of previously reserved inventory related to market exits. For the three and twelve month period ended December 2019, Asset impairments was comprised of the impairment of a product right intangible asset.

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 December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Net (Loss)/Income	\$ (3,635)	\$ (4,835)	\$ (22,548)	\$ 6,094
Add/(Subtract):				
Non-cash interest expense	566	1,308	1,788	6,833
Depreciation and amortization expense	10,899	9,564	44,638	44,612
Cortrophin pre-launch charges	2,988	6,511	11,263	6,706
Expensed FDA approval milestone payment	-	-	-	329
Acquired IPR&D expense	-	-	3,784	2,324
Stock-based compensation ⁽¹⁾	2,392	2,444	9,470	9,217
CEO transition items ⁽²⁾	37	-	7,386	-
Cortrophin team restructuring	-	-	401	-
Asset impairments ⁽³⁾	446	75	1,330	75
Excess of fair value over cost of acquired inventory	113	-	4,296	-
Charges related to market exits	-	3,460	567	3,460
Transaction and integration expenses	-	-	-	84
Less:				
Tax impact of adjustments	(4,186)	(5,607)	(20,382)	(17,674)
Discrete tax benefit related to ANI Canada transfer pricing agreement	-	-	-	(1,653)
Adjusted Non-GAAP Net Income	\$ 9,620	\$ 12,920	\$ 41,993	\$ 60,407
Diluted Weighted-Average Shares Outstanding	11,996	11,886	11,964	12,040
Less: Dilutive Effect of Notes	-	-	-	(96)
Adjusted Diluted Weighted-Average Shares Outstanding	12,009	11,980	11,986	11,944
Adjusted Non-GAAP Diluted Earnings per Share	\$ 0.80	\$ 1.08	\$ 3.50	\$ 5.06

⁽¹⁾ For the year ended December 31, 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 for the year ended December 31, 2020 is comprised of \$3.4 million of stock-based 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 December 31, 2020, Asset impairments is comprised of the impairment of a marketing and distribution right intangible asset. For the year ended December 31, 2020, Asset impairments is comprised of finished goods inventory reserves for Bretylium, accounts receivable reserves due to customer bankruptcy, and the impairment of the marketing and distribution right intangible asset, tempered by a modest recovery of previously reserved inventory related to market exits. For the three and twelve month period ended December 2019, Asset impairments was comprised of the impairment of a product right intangible asset.