
**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 15, 2022**

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:	Trading Symbol(s)	Name of each exchange on which registered:
Common Stock	ANIP	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 15, 2022, ANI Pharmaceuticals, Inc. (“ANI”) issued a press release announcing its financial and operating results for the three months and year ended December 31, 2021. 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 15, 2022, 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

Senior Vice President, Finance and Chief Financial Officer

Dated: March 15, 2022



ANI Pharmaceuticals Reports Fourth Quarter and Full Year 2021 Results; Strong Foundation in Place to Drive Sustainable Growth

-- Fourth quarter net revenues of \$60.9 million; net loss of \$24.1 million and diluted loss per share of \$1.72 --

-- Fourth quarter adjusted non-GAAP EBITDA of \$16.2 million and adjusted non-GAAP diluted earnings per share of \$0.54 --

-- Full year 2021 revenues of \$216.1 million; net loss of \$42.6 million and adjusted non-GAAP EBITDA of \$64.8 million --

-- Launched Purified Cortrophin™ Gel for the treatment of certain chronic autoimmune disorders --

-- Experienced Rare Disease leadership and team in place to drive successful commercial launch of Purified Cortrophin™ Gel --

-- Closed acquisition and seamlessly integrating Novitium Pharma to strengthen generics business with technical capabilities to bring increased limited competition products to market --

-- Strong balance sheet with new capital structure can propel the next phase of ANI's growth --

BAUDETTE, Minn.--(BUSINESS WIRE) -- ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) (ANI or the Company) today announced business highlights and financial results for the three and twelve months ended December 31, 2021.

Fourth Quarter and Recent Business Highlights:

- Received U.S. Food and Drug Administration approval for Purified Cortrophin™ Gel (Repository Corticotropin Injection USP) 80 U/mL, an adrenocorticotrophic hormone (ACTH) indicated for the treatment of certain chronic autoimmune disorders, and subsequently launched it on January 24th, 2022.
 - Completed build of experienced Rare Disease team, including addition of Mary Pao, M.D., Ph.D., as Chief Medical Officer, and Elizabeth Powell, J.D., as Chief Compliance Officer and Head of Legal.
 - Closed acquisition of Novitium Pharma LLC in November 2021. Integration in progress with multiple new product launches since deal closure; initiated capturing of synergies.
 - Closed \$75 million public offering of common stock in November 2021.
-

Fourth Quarter 2021 Financial Highlights:

- Net revenues were \$60.9 million compared to \$57.3 million in Q4 2020.
- GAAP net loss was \$24.1 million, and diluted GAAP loss per share was \$1.72.
- Adjusted non-GAAP EBITDA was \$16.2 million compared to \$17.2 million in Q4 2020.
- Adjusted non-GAAP diluted earnings per share was \$0.54, compared to \$0.80 in Q4 2020.
- Cash and cash equivalents were \$100.3 million, net accounts receivable was \$128.5 million, and face value of debt was \$300.0 million as of December 31, 2021.

Full Year 2021 Financial Highlights:

- Net revenues for 2021 were \$216.1 million compared to \$208.5 million in 2020.
- GAAP net loss was \$42.6 million, and diluted GAAP loss per share was \$3.40.
- Adjusted non-GAAP EBITDA was \$64.8 million.
- Adjusted non-GAAP diluted earnings per share was \$3.21.

“The past few months have been an exciting time for ANI as we completed the build out of our Rare Disease business team. Our senior leadership has experience across over 20 Rare Disease launches and 75% of our high-performing sales colleagues have won President’s Club or equivalent in the past few years. In parallel, we invested significantly in the infrastructure needed to drive a successful launch, including a secure supply chain, specialty pharmacy distribution network, a hub and patient support programs. Our efforts culminated in the commercial launch of Cortrophin Gel in January, and we are pleased with the early physician response for Cortrophin. After decades with only one treatment option, patients suffering from certain chronic autoimmune conditions now have another choice in ACTH therapy,” said Nikhil Lalwani, President and CEO of ANI.

“We are also pleased to have closed our acquisition of Novitium Pharma, which brings a world-class R&D engine to ANI. Since deal closure, our integrated team has launched eight new products, filed five new ANDAs, and initiated enhancement of R&D productivity and capture of procurement, distribution, and operational efficiencies. These achievements, together with the strengthening of our balance sheet through our debt refinancing and recent \$75 million equity raise, position us well to deliver long-term sustainable growth,” concluded Lalwani.

2022 Financial Guidance

For the twelve months ending December 31, 2022, ANI is providing guidance on ex-Cortrophin Net Revenue and adjusted non-GAAP EBITDA, total Company Research and Development expense, and Cortrophin specific SG&A. The following summarizes 2022 guidance:

Total Company Ex-Purified Cortrophin Gel measures:

- Net Revenues of between \$260.0 million and \$275.0 million, representing approximately 20% to 27% growth as compared to 2021
- Adjusted non-GAAP EBITDA of between \$70.0 million and \$75.0 million, representing 8% to 16% growth as compared to 2021

Total Company measures:

- Research and Development expense of between \$16.0 and \$18.0 million

Purified Cortrophin Gel specific measures:

- Direct Selling, General and Administrative expenses of between \$42.0 million and \$46.0 million

In addition, we currently anticipate between 16.9 and 17.3 million shares outstanding and an effective tax rate of approximately 24% prior to any federal tax reform.

Fourth Quarter 2021 Financial Results

Net Revenues (in thousands)	Three Months Ended December 31,	
	2021	2020
Generic pharmaceutical products	\$ 41,619	\$ 38,650
Branded pharmaceutical products	14,693	15,759
Contract manufacturing	2,765	2,195
Royalty and other income	1,852	648
Total net revenues	<u>\$ 60,929</u>	<u>\$ 57,252</u>

Net revenues for generic pharmaceutical products were \$41.6 million during the three months ended December 31, 2021, an increase of 8% compared to \$38.7 million for the same period in 2020. The net increase was primarily due to the November 19th closure of the Novitium acquisition and the third quarter 2021 launch of Nebivolol, tempered by sales declines for Tolterodine and Vancomycin and a decrease in average selling prices of generic products.

Net revenues for branded pharmaceutical products were \$14.7 million during the three months ended December 31, 2021, a decrease of 7% compared to \$15.8 million for the same period in 2020. The change was a result of fewer units sold of Arimidex and Inderal XL, partially offset by the second quarter 2021 launch of brand products acquired from Sandoz.

Contract manufacturing revenues were \$2.8 million during the three months ended December 31, 2021, an increase of 26% compared to \$2.2 million for the same period in 2020, principally due to the November 19th closure of the Novitium acquisition.

Operating expenses increased by 49% to \$84.7 million for the three months ended December 31, 2021, up from \$56.9 million in the prior year period.

Cost of sales, excluding depreciation and amortization, increased by \$9.4 million to \$33.9 million in the fourth quarter of 2021 compared to \$24.5 million in the prior year period, primarily as a result of increased volumes. The increase also included a charge of \$3.7 million to recognize the excess of fair value over cost for inventory acquired in asset acquisitions and a business combination, and \$1.9 million of legal settlement expense charged to royalties, which were tempered by a \$1.6 million decrease related to sales of products subject to profit sharing arrangements.

Research and development expenses declined from \$3.7 million to \$3.1 million, a decrease of 15%, primarily due to the timing of research and development activities, including the completion of the R&D phase of the Cortrophin re-commercialization project, tempered by the addition of Novitium research and development expenses incurred subsequent to the acquisition.

Selling, general and administrative expenses increased by \$16.3 million in the fourth quarter of 2021 to \$30.7 million compared to \$14.4 million in the comparable quarter in 2020. The increase primarily reflects \$4.3 million of transaction expenses related to the Novitium acquisition, \$9.2 million in sales and marketing expenses related to Cortrophin pre-launch activities, and increased headcount costs, including those associated with Novitium occurring subsequent to the acquisition.

Depreciation and amortization expense was \$13.7 million for the three months ended December 31, 2021, an increase of \$2.8 million compared to \$10.9 million for the same period in 2020. This increase is primarily a result of amortization of intangible assets acquired in the Novitium transaction.

Net loss for the fourth quarter of 2021 was \$24.1 million as compared to a net loss of \$3.6 million in the prior year period. Diluted loss per share for the three months ended December 31, 2021 was \$1.72, compared to diluted loss per share of \$0.30 in the prior year period.

Adjusted non-GAAP diluted earnings per share was \$0.54 in the fourth quarter of 2021 compared to \$0.80 in the fourth quarter of 2020.

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, 2021, the Company had \$100.3 million in unrestricted cash and cash equivalents plus \$128.5 million in net accounts receivable. The Company had \$300.0 million (face value) in outstanding debt as of December 31, 2021.

Conference Call

As previously announced, ANI Pharmaceuticals management will host its fourth quarter 2021 conference call as follows:

Date	Tuesday, March 15, 2022
Time	8:30 a.m. ET
Toll free (U.S.)	866-518-6930
Global	(203) 518-9797
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 888-269-5332 and entering access code 8402712.

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, expense from acquired in-process research and development, Novitium transaction expenses, Cortrophin pre-launch charges, asset impairments, legal and royalty settlement expense, credit facility ticking fee expense, contingent consideration fair value adjustment, 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.

ANI is not providing a reconciliation for the forward-looking full year 2022 ex-Purified Cortrophin Gel adjusted EBITDA guidance because it does not currently have sufficient information to accurately estimate all of the variables and individual adjustments for such reconciliation, including “with” and “without” tax provision information. As such, ANI’s management cannot estimate on a forward-looking basis without unreasonable effort the impact these variables and individual adjustments will have on its reported results.

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, Cortrophin pre-launch charges, acquired in-process research and development ("IPR&D") expense, Novitium transaction expenses, asset impairments, legal and royalty settlement expense, credit facility ticking fee expense, contingent consideration fair value adjustment, 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, Novitium transaction expenses, non-cash interest expense, depreciation and amortization expense, expense from acquired in-process research and development, Cortrophin pre-launch charges, asset impairments, legal and royalty settlement expense, credit facility ticking fee expense, contingent consideration fair value adjustment, 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, non-cash interest expense, depreciation and amortization, Cortrophin pre-launch charges, acquired IPR&D expense, Novitium transaction expenses, asset impairments, legal and royalty settlement expense, credit facility ticking fee expense, contingent consideration fair value adjustment, 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. 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 is a diversified bio-pharmaceutical company serving patients in need by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceutical products, including for diseases with high unmet medical need. Our team is focused on delivering sustainable growth by building a successful Purified Cortrophin™ Gel franchise, strengthening our generics business with enhanced development capability, innovation in established brands and leveraging our North American manufacturing capabilities. For more information, please visit 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 under the heading “2022 Financial Guidance,” statements about the Company’s corporate strategy, the commercial launch of Cortrophin Gel and the potential benefit of Cortrophin Gel to patients as a new treatment option, expectations regarding sales of Cortrophin Gel, future operations, products, financial performance, financial position, operating results and prospects, including plans for sustainable growth, 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 costs involved in commercializing Cortrophin Gel, the ability to maintain regulatory approval of the product and maintain sufficiency of the product, the ability to obtain reimbursement from third-party payors for this product, evolving government legislation, the opinions and views of key opinion leaders and physicians who treat patients with chronic diseases and who may prescribe Cortrophin Gel, ANI’s ability to generate projected net product revenue and gain market share on the timeline expected, actions taken by competitors in response to a new market entrant; the ability of the Company to successfully maintain manufacturing capabilities and adequate commercial quantities of Cortrophin Gel at acceptable costs and quality levels; broad acceptance of Cortrophin Gel by physicians, patients and the healthcare community; the acceptance of pricing and placement of Cortrophin Gel on payers’ formularies; risks 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; manufacturing difficulties or delays, ANI’s reliance on third parties over which it may not always have full control, 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 and uncertainties regarding the COVID-19 pandemic; market trends for our products; regulatory environment and changes; and regulatory and other approvals relating to product development and manufacturing, and other risks and uncertainties that are described in ANI’s Annual Report on Form 10-K, quarterly reports on Form 10-Q, and other periodic reports filed with the Securities and Exchange Commission.

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.

For more details, visit www.cortrophin.com.

Investor Contact

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SOURCE: ANI Pharmaceuticals, Inc.

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>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Net Revenues	\$ 60,929	\$ 57,252	\$ 216,136	\$ 208,475
Operating Expenses:				
Cost of sales (excl. depreciation and amortization)	33,898	24,540	100,610	87,157
Research and development	3,140	3,683	11,369	16,001
Selling, general, and administrative	30,706	14,365	84,294	64,986
Depreciation and amortization	13,684	10,899	47,252	44,638
Contingent consideration fair value adjustment	500	-	500	-
Legal settlement expense	350	-	8,750	-
Purified Cortrophin Gel pre-launch charges	-	2,988	780	11,263
Intangible asset impairment charge	2,374	446	2,374	446
	<u>84,652</u>	<u>56,921</u>	<u>255,929</u>	<u>224,491</u>
Total Operating Expenses				
Operating (Loss)/Income	(23,723)	331	(39,793)	(16,016)
Other Expense, Net				
Interest expense, net	(4,440)	(2,554)	(11,922)	(9,452)
Other expense, net	(2,690)	(159)	(4,343)	(494)
	<u>(30,853)</u>	<u>(2,382)</u>	<u>(56,058)</u>	<u>(25,962)</u>
Loss Before Benefit/(Provision) for Income Taxes				
Benefit/(Provision) for income taxes	6,717	(1,253)	13,455	3,414
	<u>(24,136)</u>	<u>(3,635)</u>	<u>(42,603)</u>	<u>(22,548)</u>
Net Loss				
Dividends on Series A Convertible Preferred Stock	(190)	-	(190)	-
	<u>(24,326)</u>	<u>(3,635)</u>	<u>(42,793)</u>	<u>(22,548)</u>
Net Loss Allocated to Common Shares				
Loss Per Share				
Basic Loss Per Share	\$ (1.72)	\$ (0.30)	\$ (3.40)	\$ (1.88)
Diluted Loss Per Share	\$ (1.72)	\$ (0.30)	\$ (3.40)	\$ (1.88)
Basic Weighted-Average Shares Outstanding	14,169	11,996	12,596	11,964
Diluted Weighted-Average Shares Outstanding	<u>14,169</u>	<u>11,996</u>	<u>12,596</u>	<u>11,964</u>

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

	December 31, 2021	December 31, 2020
Current Assets		
Cash and cash equivalents	\$ 100,300	\$ 7,864
Accounts receivable, net	128,526	95,793
Inventories, net	81,693	60,803
Prepaid income taxes	3,667	-
Prepaid expenses and other current assets	7,589	5,861
Total Current Assets	<u>321,775</u>	<u>170,321</u>
Non-current Assets		
Property and equipment	75,627	58,796
Accumulated depreciation	<u>(22,956)</u>	<u>(17,527)</u>
Property and equipment, net	52,671	41,269
Restricted cash	5,001	5,003
Deferred tax assets, net of deferred tax liabilities and valuation allowance	67,936	51,704
Intangible assets, net	294,122	188,511
Goodwill	27,888	3,580
Other non-current assets	2,205	802
Total Assets	<u>\$ 771,598</u>	<u>\$ 461,190</u>
Current Liabilities		
Current debt, net of deferred financing costs	\$ 850	\$ 13,243
Accounts payable	22,967	11,261
Accrued royalties	6,225	6,407
Accrued compensation and related expenses	8,522	6,231
Current income taxes payable, net	-	3,906
Accrued government rebates	5,492	7,826
Returned goods reserve	35,831	27,155
Deferred revenue	87	80
Accrued expenses and other	7,563	2,456
Total Current Liabilities	<u>87,537</u>	<u>78,565</u>
Non-current Liabilities		
Non-current debt, net of deferred financing costs and current component	286,520	172,443
Non-current contingent consideration	31,000	-
Derivatives and other non-current liabilities	7,801	14,482
Total Liabilities	<u>412,858</u>	<u>265,490</u>
Mezzanine Equity		
Convertible preferred stock, Series A	24,850	-
Stockholders' Equity		
Common stock	1	1
Treasury stock	(3,135)	(2,246)
Additional paid-in capital	387,844	214,354
Accumulated deficit	(47,765)	(4,972)
Accumulated other comprehensive loss, net of tax	(3,055)	(11,437)
Total Stockholders' Equity	<u>333,890</u>	<u>195,700</u>
Total Liabilities, Mezzanine Equity, and Stockholders' Equity	<u>\$ 771,598</u>	<u>\$ 461,190</u>

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,	
	2021	2020
Net Loss	\$ (24,136)	\$ (3,635)
Add/(Subtract):		
Interest expense, net	4,440	2,554
Other expense, net	3,390	159
(Benefit)/Provision for income taxes	(6,717)	1,253
Depreciation and amortization	13,684	10,899
Legal settlement expense	350	-
Contingent consideration fair value adjustment	500	-
Cortrophin pre-launch charges and sales & marketing expenses	8,992	2,988
Stock-based compensation	2,968	2,392
CEO transition items ⁽²⁾	-	37
Asset impairments ⁽³⁾	2,737	446
Excess of fair value over cost of acquired inventory	3,743	113
Novitium transaction expenses	4,319	-
Royalty settlement	1,934	-
Adjusted non-GAAP EBITDA	\$ 16,204	\$ 17,206

Reconciliation of certain adjusted non-GAAP accounts:

	Cost of sales (excl. depreciation and amortization)		Selling, general, and administrative expenses		Research and development expenses	
	Three Months Ended December 31,		Three Months Ended Decemebr 31,		Three Months Ended December 31,	
	2021	2020	2021	2020	2021	2020
As reported:	\$ 33,898	\$ 24,540	\$ 30,706	\$ 14,365	\$ 3,140	\$ 3,683
Cortrophin pre-launch charges and sales & marketing expenses			(8,992)			
Stock-based compensation	(5)	(30)	(2,822)	(2,241)	(141)	(121)
CEO transition items ⁽²⁾				(37)		
Asset impairments ⁽³⁾	(363)					
Excess of fair value over cost of acquired inventory	(3,743)	(113)				
Novitium transaction expenses			(4,319)			
Royalty settlement	(1,934)					
As adjusted:	<u>\$ 27,853</u>	<u>\$ 24,397</u>	<u>\$ 14,573</u>	<u>\$ 12,087</u>	<u>\$ 2,999</u>	<u>\$ 3,562</u>

	Year Ended December 31,	
	2021	2020
Net Loss	\$ (42,603)	\$ (22,548)
Add/(Subtract):		
Interest expense, net	11,922	9,452
Other expense, net	6,243	494
Benefit for income taxes	(13,455)	(3,414)
Depreciation and amortization	47,252	44,638
Legal settlement expense	8,750	-
Contingent consideration fair value adjustment	500	-
Cortrophin pre-launch charges and sales & marketing expenses	14,228	11,263
Stock-based compensation ⁽¹⁾	10,489	9,470
CEO transition items ⁽²⁾	-	7,386
Cortrophin team restructuring	-	401
Acquired IPR&D expense	-	3,784
Asset impairments ⁽³⁾	2,737	1,330
Excess of fair value over cost of acquired inventory	7,460	4,296
Charges related to market exits	-	567
Novitium transaction expenses	9,382	-
Royalty settlement	1,934	-
Adjusted non-GAAP EBITDA	\$ 64,839	\$ 67,119

Reconciliation of certain adjusted non-GAAP accounts:

	Cost of sales (excl. depreciation and amortization)		Selling, general, and administrative expenses		Research and development expenses	
	Year Ended December 31,		Year Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020	2021	2020
As reported:	\$ 100,610	\$ 87,157	\$ 84,294	\$ 64,986	\$ 11,369	\$ 16,001
Cortrophin pre-launch charges and sales & marketing expenses			(13,448)			
Stock-based compensation ⁽¹⁾	(20)	(137)	(9,905)	(8,737)	(564)	(596)
CEO transition items ⁽²⁾				(7,386)		
Cortrophin team restructuring				(47)		(354)
Acquired IPR&D expense						(3,784)
Asset impairments ⁽³⁾	(363)	(740)		(52)		(92)
Excess of fair value over cost of acquired inventory	(7,460)	(4,296)				
Charges related to market exits		(267)				(300)
Novitium transaction expenses			(9,382)			
Royalty settlement	(1,934)					
As adjusted:	\$ 90,833	\$ 81,717	\$ 51,559	\$ 48,764	\$ 10,805	\$ 10,875

⁽¹⁾ For the twelve months ended December 31, 2020, Stock-based compensation excludes \$3.4 million of stock-based compensation expense associated with the departure of a former President and CEO. This amount is included in this table as part of CEO transition items.

⁽²⁾ CEO transition items for the twelve months 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 months ended December 31, 2021, Asset impairments is comprised of an ANDA intangible asset impairment and related inventory reserve charge.

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,	
	2021	2020	2021	2020
Net Loss	\$ (24,136)	\$ (3,635)	\$ (42,603)	\$ (22,548)
Add/(Subtract):				
Non-cash interest expense	771	566	2,415	1,788
Depreciation and amortization expense	13,684	10,899	47,252	44,638
Cortrophin pre-launch charges and sales & marketing expenses	8,992	2,988	14,228	11,263
Legal settlement expense	350	-	8,750	-
Contingent consideration fair value adjustment	500	-	500	-
Acquired IPR&D expense	-	-	-	3,784
Stock-based compensation ⁽¹⁾	2,968	2,392	10,489	9,470
CEO transition items ⁽²⁾	-	37	-	7,386
Cortrophin team restructuring	-	-	-	401
Asset impairments ⁽³⁾	2,737	446	2,737	1,330
Excess of fair value over cost of acquired inventory	3,743	113	7,460	4,296
Charges related to market exits	-	-	-	567
Credit facility ticking fee expense	1,781	-	4,216	-
Novitium transaction expenses	4,319	-	9,382	-
Royalty settlement	1,934	-	1,934	-
Less:				
Estimated tax impact of adjustments (calc. at 24%)	(10,027)	(4,186)	(26,247)	(20,382)
Adjusted non-GAAP Net Income	\$ 7,616	\$ 9,620	\$ 40,513	\$ 41,993
Diluted Weighted-Average				
Shares Outstanding	14,169	11,996	12,596	11,964
Adjusted Diluted Weighted-Average				
Shares Outstanding	14,215	12,009	12,618	11,986
Adjusted non-GAAP				
Diluted Earnings per Share	\$ 0.54	\$ 0.80	\$ 3.21	\$ 3.50

⁽¹⁾ For the twelve months ended December 31, 2020, Stock-based compensation excludes \$3.4 million of stock-based compensation expense associated with the departure of a former President and CEO. This amount is included in this table as part of CEO transition items.

⁽²⁾ CEO transition items for the twelve months 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 months ended December 31, 2021, Asset impairments is comprised of an ANDA intangible asset impairment and related inventory reserve charge.