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): May 10, 2022

ANI PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

001-31812

(State or other jurisdiction of incorporation)

(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 \Box

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. \Box

Item 2.02 Results of Operations and Financial Condition.

On May 10, 2022, ANI Pharmaceuticals, Inc. ("ANI") issued a press release announcing its financial and operating results for the three months ended March 31, 2022. 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 | |
|-------------|--|--|
| <u>99.1</u> | Press release, dated May 10, 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: May 10, 2022



FOR IMMEDIATE RELEASE

ANI Pharmaceuticals Reports First Quarter 2022 Results; Provides Purified Cortrophin[®] Gel Net Revenue Guidance and Full-Year 2022 Total Company Net Revenue Guidance of \$295 Million to \$315 Million

-- First quarter net revenues of \$64.5 million, net loss of \$(20.1) million and diluted GAAP loss per share of \$(1.27) --

-- First quarter adjusted non-GAAP EBITDA of \$4.3 million and adjusted non-GAAP diluted loss per share of \$(0.12) --

-- Provides Purified Cortrophin[®] Gel (Cortrophin Gel) 2022 Net Revenue guidance of \$35 million to \$40 million, Total Company Net Revenue guidance of \$295 million to \$315 million and adjusted non-GAAP EBITDA guidance to \$54 million to \$60 million --

-- Strong physician demand for Cortrophin Gel resulting in over 250 new cases initiated from more than 125 unique prescribers coupled with expanded market access leading to over 100 million lives covered on formulary --

-- With robust R&D engine in place, launched several new products, including Misoprostol Tablets, Rifabutin Capsules, and Bisoprolol Tablets; filed six new ANDA applications; retained position as market leader in Competitive Generic Therapies --

-- Appointed Renee P. Tannenbaum, Pharm.D., MBA, an experienced commercial leader, to the Board of Directors --

BAUDETTE, Minn.--(BUSINESS WIRE) – May 10, 2022 – ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) (ANI or the Company) today announced business highlights and financial results for the three months ended March 31, 2022.

"During the first quarter, we launched Cortrophin Gel, the lead asset in our Rare Disease business, and can now offer patients suffering from certain chronic autoimmune conditions a choice in ACTH therapy. We are pleased with the increasing trajectory of patients enrolled and the strong execution of our commercial team. Driven by the Cortrophin Gel launch, we are increasing our full-year net revenue guidance and continuing to invest to bring this therapy to patients in need," said Nikhil Lalwani, President and CEO of ANI.

"In this quarter, we also saw the benefits of having Novitium, a world-class R&D engine, after the acquisition was fully closed in November last year. We successfully launched several products totaling approximately \$240 million in annualized sales, according to IQVIA, and a majority of these launches had fewer than three competitors. In addition, we filed six new ANDAs to further strengthen our product pipeline. Our teams also continue to make progress on synergy capture efforts across Procurement, Distribution and Operations," concluded Lalwani.

First Quarter 2022 Financial Highlights:

- Net revenues were \$64.5 million compared to \$54.5 million in Q1 2021.
- GAAP net loss was \$(20.1) million, and diluted GAAP loss per share was \$(1.27).
- Adjusted non-GAAP EBITDA was \$4.3 million compared to \$18.9 million in Q1 2021.
- · Adjusted non-GAAP diluted loss per share was \$(0.12), compared to diluted earnings per share of \$1.04 in Q1 2021.
- Cash and cash equivalents were \$76.9 million, net accounts receivable was \$131.6 million, and face value of debt was \$299.3 million as of March 31, 2022.

Cortrophin Gel Launch Progress:

On January 24, 2022, the Company announced the U.S. commercial availability and launch of Cortrophin Gel (Repository Corticotropin Injection USP) 80 U/mL, an adrenocorticotropic hormone (ACTH) indicated for the treatment of certain chronic autoimmune disorders. Today, the Company is issuing 2022 revenue guidance for Cortrophin Gel in the range of \$35 million to \$40 million.

Key highlights of the launch progress include:

- Launch Trajectory: Over 250 new patient cases have been initiated since the launch on January 24, with steady growth in the number of new patient cases per week. Since launch, the average time from new case initiation to patient dispense has significantly improved, leading to a steady increase of patients on Cortrophin Gel. The Company's market access efforts to date have led to formulary coverage for Cortrophin Gel for over 100 million lives.
- Physician Interest: The ANI Rare Disease team has generated significant awareness of and interest in Cortrophin Gel among physicians. Over 125 unique prescribers have initiated new cases for Cortrophin Gel therapy, and of these, approximately 25% have enrolled more than one patient. Initial enrollments are distributed relatively evenly across targeted specialties of rheumatology, neurology and nephrology.
- Strong Execution: The Company's dedicated and experienced Rare Disease sales team has already reached approximately 50% of targeted prescribers. In addition, the Company continues to invest significantly in marketing and market access with cross-functional teams engaging key stakeholders. Our patient services organization remains focused on establishing expanded access to Cortrophin Gel for patients and their caregivers throughout the treatment journey.

Novitium Integration Update:

On November 19, 2022, the Company completed the acquisition of Novitium Pharma, creating a generics growth engine with technical capabilities to bring complex, limited competition products to market in an efficient and cost-effective manner. The combined team has continued to execute well on ensuring continuity of business operations and capturing synergies from the combination.

Key updates of the integration include:

- Focus on R&D Excellence: The R&D engine continues to deliver with six new ANDA filings and several limited competition new product launches in the first quarter. In addition, the Company retained its leadership in Competitive Generic Therapy (CGT) approvals. Most recently, ANI received CGT approval and associated 180 days of exclusivity for betaine anyhydrous solution. The Company remains focused on strengthening the product pipeline to increase sustainability of the generics business.
- **Commercial Integration:** The commercial team has fully integrated and executed several new product launches successfully, strengthened relationships with key customers, and captured organizational synergies.
- **Operational Synergies:** The Company has captured synergies in key areas such as Procurement, Distribution, and Manufacturing Operations. The Company will increase efforts in this area to drive cost-competitiveness.

First Quarter 2022 Financial Results

| | Three Months Ended | | | | | |
|--|--------------------|-----------|--------|--|--|--|
| Products and Services | March 31, | March 31, | | | | |
| (in thousands) | 2022 | | 2021 | | | |
| Sales of generic pharmaceutical products | \$ 49,107 | \$ | 32,988 | | | |
| Sales of established brand pharmaceutical products | 8,452 | | 7,517 | | | |
| Sales of rare disease pharmaceutical products | 1,292 | | _ | | | |
| Sales of contract manufactured products | 2,904 | | 2,573 | | | |
| Royalties from licensing agreements | 1,903 | | 11,210 | | | |
| Product development services | 566 | | 158 | | | |
| Other | 253 | | 75 | | | |
| Total net revenues | \$ 64,477 | \$ | 54,521 | | | |

Net revenues for generic pharmaceutical products were \$49.1 million during the three months ended March 31, 2022, an increase of 49% compared to \$33.0 million for the same period in 2021. The net increase was primarily driven by revenues of \$15.7 million from products acquired in our acquisition of Novitium, the addition of revenues from Nebivolol, which ANI launched in September 2021, and the return of volumes to essentially pre-pandemic levels.

Net revenues for branded pharmaceutical products were \$8.5 million during the three months ended March 31, 2022, an increase of 12% compared to \$7.5 million for the same period in 2021. The net increase was driven by modest increases in sales over a number of the portfolio products, including those acquired from Sandoz and launched in April 2021, partially offset by a decrease in sales of Casodex[®]. As with generic pharmaceutical products, volumes of branded products are returning to essentially pre-pandemic levels.

Contract manufacturing revenues were \$2.9 million during the quarter, an increase of 13% compared to \$2.6 million for the same period in 2021, due to an increase in the volume of orders, including \$1.1 million from Novitium contract manufacturing revenues.

Royalty and other revenues were \$2.7 million during the quarter, a decrease of \$8.7 million from the same period in 2021, due to a final royalty payment received from Kite Pharma, Inc. during the quarter ended March 31, 2021. Royalty and other revenues in the first quarter of 2022 consisted primarily of \$1.9 million in royalty revenues related to Novitium arrangements and \$0.6 million in product development service revenues.

Net revenues of rare disease pharmaceutical products were \$1.3 million for the quarter, consisting entirely of sales of Cortrophin Gel. There were no sales of rare disease pharmaceutical products during the comparable prior year period.

Operating expenses increased by 63% to \$83.7 million for the three months ended March 31, 2022, from \$51.5 million in the prior year period.

Cost of sales, excluding depreciation and amortization, increased by \$14.3 million to \$34.3 million in the first quarter of 2022 compared to \$20.0 million in the prior year period, primarily as a result of increased volumes, including \$9.5 million of costs related to Novitium, and \$3.8 million of costs representing the excess of fair value over cost for inventory acquired from Novitium and in a previous asset acquisition, partially offset by a decline in sales tied to profit-sharing arrangements.

Research and development expenses were \$5.3 million in the first quarter of 2022, an increase of \$2.3 million from the prior year period due primarily to Novitium-related activities, partially offset by a decrease in expense associated with the completion of our Cortrophin Gel development efforts.

Selling, general and administrative expenses increased to \$28.8 million in the first quarter of 2022, or 64%, compared to \$17.6 million in the prior year quarter, reflecting a \$11.0 million increase in sales and marketing expenses related to our launch of Cortrophin Gel and \$2.7 million of expenses related to the addition of Novitium headcount and activities, offset by a \$1.9 million decrease in transaction expenses related to the Novitium acquisition.

Depreciation and amortization expense was \$14.6 million for the three months ended March 31, 2022, an increase of \$3.7 million compared to \$10.9 million for the same period in 2021. This increase is primarily a result of amortization of intangible assets acquired in the Novitium transaction.

Net loss for the first quarter of 2022 was (20.1) million as compared to a net income of 0.1 million in the prior year period. Diluted loss per share for the three months ended March 31, 2022 was (1.27), compared to diluted earnings per share of 0.01 in the prior year period.

Adjusted non-GAAP diluted loss per share was \$(0.12) in the first quarter of 2022 compared to \$1.04 in the first quarter of 2021.

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

Liquidity

As of March 31, 2022, the Company had \$76.9 million in unrestricted cash and cash equivalents plus \$131.6 million in net accounts receivable. The Company had \$299.3 million (face value) in outstanding debt as of March 31, 2022.

2022 GUIDANCE

ANI is initiating guidance on Cortrophin Gel specific Net Revenue, total Company Net Revenue, total Company adjusted non-GAAP EBITDA, and total Company adjusted non-GAAP Diluted Earnings per Share, and is reiterating its previous guidance on total Company research and development expense and Cortrophin Gel Selling, General and Administrative expense. The following summarizes 2022 guidance:

Total Company measures:

- Net Revenue between \$295.0 million and \$315.0 million, representing approximately 36% to 46% growth as compared to \$216.1 million recognized in 2021
- Research and Development expense between \$16.0 and \$18.0 million
- Adjusted non-GAAP EBITDA between \$54.0 million and \$60.0 million
- Adjusted non-GAAP Diluted Earnings per Share between \$1.34 and \$1.62

Purified Cortrophin Gel specific measures:

- Net Revenue between \$35.0 million and \$40.0 million
- Direct Selling, General and Administrative expenses between \$42.0 and \$46.0 million

In addition, we currently anticipate between 16.9 and 17.0 million shares outstanding and an effective tax rate of approximately 24% prior to any federal tax reform.

Conference Call

As previously announced, ANI management will host its first quarter 2022 conference call as follows:

| Date | Tuesday, May 10, 2022 |
|------------------|-----------------------|
| Time | 8:30 a.m. ET |
| Toll free (U.S.) | 866-342-8591 |
| Global | 203-518-9822 |

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 800-753-4606 and entering access code 5146584.

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 (loss)/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, Novitium transaction expenses, Cortrophin Gel pre-launch charges, 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 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 (Loss)/Income

ANI's management considers adjusted non-GAAP net (loss)/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 Gel pre-launch charges, Novitium transaction expenses, 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 (loss)/income when analyzing Company performance.

Adjusted non-GAAP net (loss)/income is defined as net (loss)/income, plus the excess of fair value over cost of acquired inventory sold, non-cash stockbased compensation expense, Novitium transaction expenses, non-cash interest expense, depreciation and amortization expense, Cortrophin Gel pre-launch charges, 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 (loss)/income should be considered in addition to, but not in lieu of, net (loss)/income reported under GAAP. A reconciliation of adjusted non-GAAP net (loss)/income to the most directly comparable GAAP financial measure is provided below.

Adjusted non-GAAP Diluted (Loss)/Earnings per Share

ANI's management considers adjusted non-GAAP diluted (loss)/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 Gel pre-launch charges, Novitium transaction expenses, 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 (loss)/earnings per share when analyzing Company performance.

Adjusted non-GAAP diluted (loss)/earnings per share is defined as adjusted non-GAAP net (loss)/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 (loss)/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 (loss)/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 regarding 2022 Financial Guidance, statements about the Company's corporate strategy, 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 uncertai

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

Lisa M. Wilson In-Site Communications, Inc. 212-452-2793 <u>lwilson@insitecony.com</u>

SOURCE: ANI Pharmaceuticals, Inc.

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

| | Three Months | Three Months Ended March 31, | | |
|---|------------------|------------------------------|---------|--|
| | 2022 | | 2021 | |
| Net Revenues | \$ 64,47 | 7 \$ | 54,521 | |
| Operating Expenses: | | | | |
| Cost of sales (excl. depreciation and amortization) | 34,27 | l | 19,985 | |
| Research and development | 5,27 | ŧ | 2,968 | |
| Selling, general, and administrative | 28,81 | 7 | 17,587 | |
| Depreciation and amortization | 14,55 | 7 | 10,898 | |
| Contingent consideration fair value adjustment | 75 | 3 | - | |
| Purified Cortrophin Gel pre-launch charges | | | 38 | |
| Total Operating Expenses | 83,67 | 2 | 51,476 | |
| Operating (Loss)/Income | (19,19 | 5) | 3,045 | |
| Other Expense, Net | | | | |
| Interest expense, net | (6,61) | 3) | (2,454) | |
| Other expense, net | (8) | <i>)</i>) | (515) | |
| (Loss)/Income Before Benefit for Income Taxes | (25,89 | 7) | 76 | |
| Benefit for income taxes | 5,76 | 7 | 10 | |
| Net (Loss)/Income | \$ (20,13) |)) \$ | 86 | |
| | | | | |
| Dividends on Series A Convertible Preferred Stock | (40. | <u>;)</u> | - | |
| Net (Loss)/Income Allocated to Common Shares | <u>\$ (20,53</u> | 5) <u>\$</u> | 86 | |
| Basic and Diluted (Loss)/Earnings Per Share: | | | | |
| Basic (Loss)/Earnings Per Share | \$ (1.2 | 7) \$ | 0.01 | |
| Diluted (Loss)/Earnings Per Share | | 7) \$ | 0.01 | |
| Basic Weighted-Average Shares Outstanding | 16,13 | 7 | 12,004 | |
| Diluted Weighted-Average Shares Outstanding | 16,13 | / | 12,017 | |

ANI Pharmaceuticals, Inc. and Subsidiaries Table 2: US GAAP Balance Sheets

(unaudited, in thousands)

| | March 31, 2022 | December 31, 2021 | |
|--|-------------------|----------------------|--|
| Current Assets | | | |
| Cash and cash equivalents | \$ 76,911 | \$ 100,300 | |
| Accounts receivable, net | 131,625 | 128,526 | |
| Inventories, net | 83,155 | 81,693 | |
| Prepaid income taxes | 1,982 | 3,667 | |
| Prepaid expenses and other current assets | 7,726 | 7,589 | |
| Total Current Assets | 301,399 | 321,775 | |
| Non-current Assets | | | |
| Property and equipment | 77,677 | 75,627 | |
| Accumulated depreciation | (24,964) | (22,956) | |
| Property and equipment, net | 52,713 | 52,671 | |
| Restricted cash | 5,000 | 5,001 | |
| Deferred tax assets, net of deferred tax liabilities and valuation allowance | 73,539 | 67,936 | |
| Intangible assets, net | 281,573 | 294,122 | |
| Goodwill | 28,188 | 27,888 | |
| Derivatives and other non-current assets | 2,434 | 2,205 | |
| Total Assets | \$ 744,846 | \$ 771,598 | |
| Current Liabilities | | | |
| Current debt, net of deferred financing costs | \$ 850 | \$ 850 | |
| Accounts payable | 22,059 | 22,967 | |
| Accrued royalties | 4,998 | 6,225 | |
| Accrued compensation and related expenses | 3,265 | 8,522 | |
| Accrued government rebates | 4,557 | 5,492 | |
| Returned goods reserve | 35,554 | 35,831 | |
| Deferred revenue | 116 | 87 | |
| Accrued expenses and other | 8,133 | 7,563 | |
| Total Current Liabilities | 79,532 | 87,537 | |
| Non-current Liabilities | | | |
| Non-current debt, net of deferred financing costs and current component | 286,307 | 286,520 | |
| Non-current contingent consideration | 32,053 | 31,000 | |
| Derivatives and other non-current liabilities | 860 | 7,801 | |
| Total Liabilities | 398,752 | 412,858 | |
| Mezzanine Equity | | | |
| Convertible preferred stock, Series A | 24,850 | 24,850 | |
| Stockholders' Equity | | | |
| Common stock | 1 | 1 | |
| Treasury stock | (4,253) | | |
| Additional paid-in capital | 391,084 | 387,844 | |
| Accumulated deficit | (68,300) | | |
| Accumulated other comprehensive income/(loss), net of tax | 2,712 | (3,055) | |
| Total Stockholders' Equity | 321,244 | 333,890 | |
| Total Liabilities, Mezzanine Equity, and Stockholders' Equity | \$ 744,846 | \$ 771,598 | |
| | +,010 | | |

ANI Pharmaceuticals, Inc. and Subsidiaries

Table 3: Adjusted non-GAAP EBITDA Calculation and US GAAP to Non-GAAP Reconciliation

(unaudited, in thousands)

| | Three Months I | Three Months Ended March 31, | | |
|---|----------------|------------------------------|--|--|
| | 2022 | 2021 | | |
| Net (Loss)/Income | \$ (20,130) | \$ 86 | | |
| | | | | |
| Add/(Subtract): | | | | |
| Interest expense, net | 6,613 | 2,454 | | |
| Other expense/(income), net | 89 | 515 | | |
| Benefit for income taxes | (5,767) | (10) | | |
| Depreciation and amortization | 14,557 | 10,898 | | |
| Contingent consideration fair value adjustment | 753 | - | | |
| Cortrophin pre-launch charges and sales & marketing expenses $^{(1)}$ | - | 141 | | |
| Stock-based compensation | 3,237 | 1,869 | | |
| Excess of fair value over cost of acquired inventory | 3,829 | - | | |
| Novitium transaction expenses | 1,092 | 2,943 | | |
| Adjusted non-GAAP EBITDA | \$ 4,273 | \$ 18,896 | | |

Reconciliation of certain adjusted non-GAAP accounts:

| | Cost of sales (excl. depreciation and amortization) Three Months Ended March 31, | | | | Selling, general, and administrative expenses Three Months Ended March 31, | | | Research and development <u>expenses</u> Three Months Ended March 31, | | nt Ended | | |
|--|--|---------|----|--------|--|---------|----|---|----|-------------|----|-------|
| | | 2022 | | 2021 | | 2022 | | 2021 | | 2022 | | 2021 |
| As reported: | \$ | 34,271 | \$ | 19,985 | \$ | 28,817 | \$ | 17,587 | \$ | 5,274 | \$ | 2,968 |
| | | | | | | | | | | | | |
| Cortrophin pre-launch charges | | | | | | | | | | | | |
| and sales & marketing expenses ^{(1)} | | | | | | - | | (103) | | | | |
| Stock-based compensation | | (145) | | (4) | | (2,839) | | (1,746) | | (253) | | (119) |
| Excess of fair value over cost of | | | | | | | | | | | | |
| acquired inventory | | (3,829) | | | | | | | | | | |
| Novitium transaction expenses | | | | | | (1,092) | | (2,943) | | | | |
| As adjusted: | \$ | 30,297 | \$ | 19,981 | \$ | 24,886 | \$ | 12,795 | \$ | 5,021 | \$ | 2,849 |

⁽¹⁾ Beginning in 2022, we no longer adjust for "Cortrophin pre-launch charges and sales and marketing expenses" in arriving at Adjusted non-GAAP EBITDA and Adjusted non-GAAP Net (Loss)/Income.

ANI Pharmaceuticals, Inc. and Subsidiaries

 Table 4: Adjusted non-GAAP Net (Loss)/Income and Adjusted non-GAAP Diluted (Loss)/Earnings per Share Reconciliation

 (unaudited, in thousands, except per share amounts)

| | Three | Three Months Ended March 31, | | |
|---|-------|---------------------------------|--|--|
| | 2022 | 2021 | | |
| Net (Loss)/Income | \$ (2 | 0,535) \$ 86 | | |
| Add/(Subtract): | | | | |
| Non-cash interest expense | | 953 546 | | |
| Depreciation and amortization expense | 1 | 4,557 10,898 | | |
| Contingent consideration fair value adjustment | - | 753 | | |
| Cortrophin pre-launch charges and sales & marketing expenses ⁽¹⁾ | | - 141 | | |
| Stock-based compensation | | 3,237 1,869 | | |
| Excess of fair value over cost of acquired inventory | | 3,829 - | | |
| Novitium transaction expenses | | 1,092 2,943 | | |
| Less: | | | | |
| Estimated tax impact of adjustments (calc. at 24%) | (| 5,861) (3,935) | | |
| | | | | |
| Adjusted non-GAAP Net (Loss)/Income | \$ (| 1,975) \$ 12,548 | | |
| | | | | |
| Diluted Weighted-Average | | | | |
| Shares Outstanding | 1 | 6,137 12,017 | | |
| Adjusted Diluted Weighted-Average | | | | |
| Shares Outstanding | 1 | 6,137 12,017 | | |
| Adjusted non-GAAP | | | | |
| Diluted (Loss)/Earnings per Share | \$ | (0.12) \$ 1.04 | | |

⁽¹⁾ Beginning in 2022, we no longer adjust for "Cortrophin pre-launch charges and sales and marketing expenses" in arriving at Adjusted non-GAAP EBITDA and Adjusted non-GAAP Net (Loss)/Income.