

**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 8, 2023

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 No.)

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

56623
(Zip Code)

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

Not Applicable
(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 (see General Instruction A.2. below):

- 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 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 May 8, 2023, ANI Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 31, 2023. A copy of the press release is furnished herewith as Exhibit 99.1.*

Item 9.01 Exhibits

(d) Exhibits

<u>Exhibit</u>	<u>Description</u>
<u>No.</u>	
99.1	Press Release of the Company, dated May 8, 2023
104	Cover Page Interactive Data File (embedded with the Inline XBRL document)

* The information in Item 2.02 of this Form 8-K shall not be deemed “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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

SIGNATURES

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.

Dated: May 8, 2023

ANI PHARMACEUTICALS, INC.

By: /s/ Stephen P. Carey

Name: Stephen P. Carey

Title: Senior Vice President Finance and Chief Financial Officer



FOR IMMEDIATE RELEASE

ANI Pharmaceuticals Reports Record First Quarter 2023 Financial Results and Raises Full-Year 2023 Guidance

First Quarter 2023 Financial Results

-- Record quarterly net revenues of \$106.8 million, representing year-over-year growth of 65.6%; 2023 first-quarter net income available to common shareholders of \$1.0 million and diluted GAAP income per share of \$0.06 --

-- Record quarterly adjusted non-GAAP EBITDA of \$33.0 million; 2023 first quarter adjusted non-GAAP diluted earnings per share of \$1.17 --

-- Company's financial results represent strength across all core business segments --

-- Lead Rare Disease asset, Purified Cortrophin[®] Gel (Repository Corticotrophin Injection USP) 80 U/ml (Cortrophin Gel), first quarter 2023 net sales of \$16.3 million --

Full Year 2023 Guidance

-- Raises Company net revenue guidance to \$385 million to \$410 million from \$360 million to \$385 million; adjusted non-GAAP EBITDA guidance to \$97 million to \$107 million from \$78 million to \$88 million; adjusted non-GAAP earnings per share to \$2.99 to \$3.45 from \$2.09 to \$2.59 --

-- Mid-point of revised guidance represents year-over-year growth in net revenues of approximately 26%, adjusted non-GAAP EBITDA of approximately 83% and adjusted non-GAAP earnings per diluted share of approximately 137% --

-- Maintains Cortrophin Gel net revenue guidance at \$80 million to \$90 million (representing 92% - 116% growth versus 2022); maintains Cortrophin Gel SG&A estimate at ~10% increase versus 2022, including modest sales force expansion --

Company Highlights

-- Accelerating momentum of Cortrophin Gel launch; Record number of cases initiated in the first quarter of 2023 and record number of new patient starts and cases initiated in the month of April 2023; ACTH market continues to show year-over-year growth for ten consecutive months according to IQVIA --

-- Strengthened efforts to increase market awareness of Cortrophin Gel through peer-to-peer education and completed modest sales force expansion into Pulmonology; Continued increase in the number of unique and repeat prescribers --

-- Operational excellence in generics and branded pharmaceuticals results in significant year-over-year and sequential revenue growth and capture of market opportunities --

-- FDA inspection of East Windsor, NJ facility completed in March 2023 with zero 483s and No Action Indicated status --

-- Retained top ten ranking for new ANDA approvals and second ranking for Competitive Generic Therapy approvals --

BAUDETTE, Minn.--(BUSINESS WIRE) – May 8, 2023 – ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) (ANI or the Company) today announced business highlights and financial results for the three months ended March 31, 2023.

“Our outstanding performance in the first quarter of 2023 further demonstrates ANI’s ability to compete and win across our core business segments. We are pleased to announce record quarterly net revenues and adjusted non-GAAP EBITDA and a significant increase to full-year 2023 guidance. Importantly, we continue to invest behind the launch of our foundational Rare Disease asset, Purified Cortrophin Gel. We continually strive to strengthen the team, improve our approach to servicing patient, physician and payor needs, and increase access to ACTH therapy for patients in need. These efforts have resulted in the further acceleration of our launch momentum with record quarterly new cases initiated in the first quarter of 2023, record monthly new patient starts and cases initiated in April 2023 and first quarter net revenues of Cortrophin Gel of \$16.3 million in-line with our expectations,” stated Nikhil Lalwani, President and CEO of ANI.

“Robust results in our Generics, Established Brands and Others segment showcases ANI’s ability to leverage our U.S. manufacturing footprint and our agility in operations to deliver timely solutions to our customers. During the past two years, we have enhanced ANI’s operational excellence by combining long-standing strengths in manufacturing and our strong GMP track record with best-in-class research and development capabilities, all with a ‘patient-first’ orientation. This has enabled us to capture market demand arising from the numerous supply disruptions impacting patient access to much-needed medicines. We are pleased with the strong start to 2023 and look forward to continuing to serve patients in need and working hard to build on the growth momentum throughout the year,” concluded Lalwani.

First Quarter 2023 Financial Highlights:

- Net revenues were \$106.8 million compared to \$64.5 million in Q1 2022.
 - GAAP net income available to common shareholders was \$1.0 million, and diluted GAAP income per share was \$0.06.
 - Adjusted non-GAAP EBITDA was \$33.0 million compared to \$4.3 million in Q1 2022.
 - Adjusted non-GAAP diluted earnings per share was \$1.17, compared to diluted loss per share of \$(0.12) in Q1 2022.
 - Cash and cash equivalents were \$67.8 million, net accounts receivable was \$174.7 million, and face value of debt was \$296.3 million as of March 31, 2023.
-

First Quarter and Recent Business Highlights:

Rare Disease Business Update

Revenues for Cortrophin Gel totaled \$16.3 million in the first quarter, in line with internal expectations. The Company continues to see significant growth momentum as evidenced by a record number of new cases initiated in the first quarter of 2023 and new monthly records for new patient starts and new cases in April 2023. Importantly, the ACTH category, which had been declining since 2019, has experienced ten consecutive months of year-on-year growth from June 2022 – March 2023. In fact, the ACTH market has continued to see double-digit growth in volumes in each month of the first quarter of 2023.

The Company has ramped-up promotional efforts to continue to build awareness of Cortrophin Gel through peer-to-peer education programs across target indications of Rheumatology, Neurology and Nephrology. In addition, the Company has executed upon its previously discussed plans to modestly expand its sales force, and its Pulmonology sales force is now fully staffed and operational.

This strong first-quarter performance is in line with expectations, and thus the Company is maintaining its 2023 revenue guidance for Cortrophin Gel of \$80 million to \$90 million, representing 92% - 116% year-over-year growth.

Rare Disease remains a critical focus area for achieving future growth, and the Company continues to actively explore opportunities to acquire or establish partnerships to leverage its Rare Disease platform.

Generics Business, Established Brands and Others Update

Sales of generic pharmaceuticals products grew 29.7% year-over-year in the first quarter of 2023 and increased 10% sequentially from a strong fourth quarter in 2022. The Company's generics business is well positioned for delivering sustainable growth driven by a strong R&D engine launching new products. Today, ANI retains a top ten ranking for new ANDA approvals and a number two ranking for Competitive Generic Therapy Approvals. In addition, ANI received multiple Abbreviated New Drug Applications (ANDAs) approvals, including Nitrofurantoin Oral Suspension USP, 25 mg/5 ml and Colestipol Hydrochloride Tablets USP, 1 g.

ANI's enhanced focus on operational excellence and U.S. based manufacturing sites have enabled the Company to capture numerous opportunities arising from supply disruptions in both generics and established brands. In addition, the Company augmented its strong GMP (Good Manufacturing Practices) track record with the successful conclusion of a U.S Food and Drug Administration (FDA) audit at its New Jersey site with zero 483s and No Actions Indicated (NAI) status.

As previously announced, manufacturing operations ceased at the Oakville, Ontario, site in January 2023, with the successful relocation of the Oakville products to U.S. facilities. Discussions with potential buyers for the Oakville site are ongoing.

First Quarter 2023 Financial Results

(in thousands)	Three Months Ended March 31,		Change	% Change
	2023	2022		
Generics, Established Brands, and Other Segment				
Generic pharmaceutical products	\$ 63,713	\$ 49,107	\$ 14,606	29.7%
Established brand pharmaceutical products, royalties, and other pharmaceutical services	26,743	14,078	12,665	90.0%
Generics, established brands, and other segment total net revenues	90,456	63,185	27,271	43.2%
Rare Disease Segment				
Rare disease pharmaceutical products	16,330	1,292	15,038	NM ⁽¹⁾
Total net revenues	\$ 106,786	\$ 64,477	\$ 42,309	65.6%

(1) Not Meaningful

Net revenues for generic pharmaceutical products were \$63.7 million during the three months ended March 31, 2023, an increase of 29.7% compared to \$49.1 million for the same period in 2022, driven by increased volume from the annualization of 2022 launches and a favorable product mix.

Net revenues for established brand pharmaceutical products, royalties, and other pharmaceutical services were \$26.7 million during the three months ended March 31, 2023, an increase of 90.0% compared to \$14.1 million for the same period in 2022, driven by an increase in volume.

Net revenues of rare disease pharmaceutical products, which consist entirely of sales of Cortrophin Gel, were \$16.3 million during the three months ended March 31, 2023, an increase of \$15.0 million from \$1.3 million for the same period in 2022. This increase was driven by increased volume as the product was launched in late January 2022.

Operating expenses increased by 15.8% to \$96.9 million for the three months ended March 31, 2023, from \$83.7 million in the prior year period as a result of the following factors:

For the three months ended March 31, 2023, cost of sales increased to \$37.7 million from \$34.3 million for the same period in 2022, an increase of \$3.4 million, or 10.0%. The increase is primarily due to a shift in product mix and increased volumes of sales of generic and rare disease pharmaceutical products. During the three months ended March 31, 2022, we recognized \$3.8 million in cost of sales representing the excess of fair value over cost for inventory acquired in acquisitions and subsequently sold during the three months ended March 31, 2022. There are no comparable expenses in the three months ended March 31, 2023.

Research and development expenses increased from \$5.3 million to \$5.9 million, an increase of \$0.7 million or 12.3%, primarily due to year over year timing of work associated with generic projects coupled with an increase associated with projects related to Cortrophin Gel in the three months ended March 31, 2023.

Selling, general, and administrative expenses increased from \$28.8 million to \$36.5 million, an increase of \$7.7 million, or 26.6%, primarily due to a \$3.4 million increase in sales and marketing expenses related to Cortrophin Gel and increased headcount related costs tempered by a \$0.7 million decrease in transaction expenses related to the Novitium acquisition.

Depreciation and amortization increased slightly in the first quarter of 2023 to \$14.7 million from \$14.6 million in the comparable quarter in 2022, an increase of \$0.1 million.

The Company recognized a contingent consideration fair value adjustment of \$1.0 million and \$0.8 million expense in the three months ended March 31, 2023, and 2022, respectively, related to the 2021 acquisition of Novitium Pharma LLC.

The Company recognized restructuring activities of \$1.1 million of expense in the three months ended March 31, 2023, in relation to the closure of our Oakville, Ontario, Canada facility. Costs included severance and other employee benefits costs of \$0.2 million, \$0.7 million of accelerated depreciation costs, and \$0.2 million for other miscellaneous costs accrued in 2022.

Net income available to common shareholders for the first quarter of 2023 was \$1.0 million as compared to net loss of \$(20.5) million in the prior year period. Diluted income per share for the three months ended March 31, 2023, was \$0.06 compared to diluted GAAP loss per share of \$(1.27) in the prior year period.

Adjusted non-GAAP diluted earnings per share was \$1.17 in the first quarter of 2023 compared to a diluted loss per share of \$(0.12) in the first quarter of 2022.

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 March 31, 2023, the Company had \$67.8 million in unrestricted cash and cash equivalents plus \$174.7 million in net accounts receivable. The Company had \$296.3 million (face value) in outstanding debt as of March 31, 2023.

2023 Financial Guidance Updates

- Raised total Company net revenue guidance to between \$385.0 million and \$410.0 million as compared to previously issued guidance of \$360.0 million to \$385.0 million. Revised guidance represents approximately 22% to 30% growth as compared to \$316.4 million recognized in 2022;
 - Maintained Cortrophin Gel specific revenue guidance of between \$80.0 million to \$90.0 million, representing 92% to 116% growth as compared to \$41.7 million recognized in 2022;
 - Total Company non-GAAP gross margin to between 60.0% and 62.5% as compared to previously issued guidance of 59.5% and 61.0%;
-

- Raised total Company adjusted non-GAAP EBITDA to between \$97.0 million and \$107.0 million as compared to previously issued guidance of \$78.0 million and \$88.0 million. Revised guidance represents approximately 74% to 91% growth as compared to \$55.9 million recognized in 2022; and
- Raised adjusted non-GAAP diluted earnings per share to between \$2.99 and \$3.45 as compared to previously issued guidance of \$2.09 and \$2.59.

In addition, ANI currently anticipates between 16.8 million and 17.1 million shares outstanding and an effective tax rate of approximately 24.0% prior to any federal tax reform.

Conference Call

As previously announced, ANI management will host its first quarter 2023 conference call as follows:

Date	May 8, 2023
Time	8:30 a.m. ET
Toll free (U.S.)	800-245-3047
Global	203-518-9765

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 888-274-8330 and entering access code 534116.

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. Beginning in the fourth quarter of 2022, ANI no longer excludes expense for In-Process Research & Development or Cortrophin Gel pre-launch charges and sales and marketing expenses from its non-GAAP results. Historically, the Company excluded these charges. These changes have been made to align with views expressed by the U.S. Securities and Exchange Commission. Prior periods have been recast to reflect these changes.

Adjusted non-GAAP EBITDA is defined as net income (loss), 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, 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 2023 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 (Loss)

ANI’s management considers adjusted non-GAAP net income (loss) 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, 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 income (loss) when analyzing Company performance. Beginning in the fourth quarter of 2022, ANI no longer excludes expense for In-Process Research & Development or Cortrophin Gel pre-launch charges and sales and marketing expenses from its non-GAAP results. Historically, the Company excluded these charges. These changes have been made to align with views expressed by the U.S. Securities and Exchange Commission. Prior periods have been recast to reflect these changes.

Adjusted non-GAAP net income (loss) is defined as net income (loss), 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, 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 (loss) should be considered in addition to, but not in lieu of, net income (loss) reported under GAAP. A reconciliation of adjusted non-GAAP net income (loss) 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, 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 income (loss), 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.

ANI is not providing a reconciliation for the forward-looking full year 2023 adjusted diluted earnings per share 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.

About ANI

ANI Pharmaceuticals, Inc. (NASDAQ: ANIP) 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 our website www.anipharma.com.

Forward-Looking Statements

To the extent any statements made in this release deal with information that is not historical, these are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, those relating to the commercialization and potential sales of the product and any additional product launches from the Company's generic pipeline, 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: risks that we may face with respect to importing raw materials and delays in delivery of raw materials and other ingredients and supplies necessary for the manufacture of our products from both domestic and overseas sources due to supply chain disruptions or for any other reason; delays or failure in obtaining and maintaining approvals by the FDA of the products we sell; changes in policy or actions that may be taken by the FDA and other regulatory agencies, including drug recalls; the ability of our manufacturing partners to meet our product demands and timelines; our dependence on single source suppliers of ingredients due to the time and cost to validate a second source of supply; acceptance of our products at levels that will allow us to achieve profitability; our ability to develop, license or acquire, and commercialize new products; the level of competition we face and the legal, regulatory and/or legislative strategies employed by our competitors to prevent or delay competition from generic alternatives to branded products; our ability to protect our intellectual property rights; the impact of legislative or regulatory reform on the pricing for pharmaceutical products; the impact of any litigation to which we are, or may become, a party; our ability, and that of our suppliers, development partners, and manufacturing partners, to comply with laws, regulations and standards that govern or affect the pharmaceutical and biotechnology industries; our ability to maintain the services of our key executives and other personnel; whether we experience disruptions to our operations resulting from the closure of our Oakville, Ontario manufacturing plant, including the transition of certain products manufactured there to our other facilities which has been completed, or have difficulties finding a buyer for the plant and property; and general business and economic conditions, such as inflationary pressures, geopolitical conditions including the conflict between Russia and the Ukraine, and the effects and duration of outbreaks of public health emergencies, such as COVID-19, 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 (SEC), including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as other filings with the SEC. All forward-looking statements in this news release speak only as of the date of this news release and are based on the Company's current beliefs, assumptions, and expectations. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Investor Contact

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

212-452-2793

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)

	Three Months Ended March 31,	
	2023	2022
Net Revenues	\$ 106,786	\$ 64,477
Operating Expenses:		
Cost of sales (excluding depreciation and amortization)	37,708	34,271
Research and development	5,924	5,274
Selling, general, and administrative	36,468	28,817
Depreciation and amortization	14,700	14,557
Contingent consideration fair value adjustment	961	753
Restructuring activities	1,130	-
Total Operating Expenses	96,891	83,672
Operating Income (Loss)	9,895	(19,195)
Other Expense, net		
Interest expense, net	(7,696)	(6,613)
Other expense, net	(34)	(89)
Income (Loss) Before Income Tax (Provision) Benefit	2,165	(25,897)
Income tax (provision) benefit	(726)	5,767
Net Income (Loss)	\$ 1,439	\$ (20,130)
Dividends on Series A Convertible Preferred Stock	(406)	(405)
Net Income (Loss) Available to Common Shareholders	\$ 1,033	\$ (20,535)
Basic and Diluted Income (Loss) Per Share:		
Basic Income (Loss) Per Share	\$ 0.06	\$ (1.27)
Diluted Income (Loss) Per Share	\$ 0.06	\$ (1.27)
Basic Weighted-Average Shares Outstanding	16,392	16,137
Diluted Weighted-Average Shares Outstanding	16,531	16,137

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

	March 31, 2023	December 31, 2022
Current Assets		
Cash and cash equivalents	\$ 67,757	\$ 48,228
Current restricted cash	-	5,006
Accounts receivable, net	174,713	165,438
Inventories	103,654	105,355
Prepaid income taxes	3,735	3,827
Assets held for sale	8,020	8,020
Prepaid expenses and other current assets	6,874	8,387
Total Current Assets	<u>364,753</u>	<u>344,261</u>
Non-current Assets		
Property and equipment	70,553	75,958
Accumulated depreciation	(27,278)	(32,712)
Property and equipment, net	43,275	43,246
Deferred tax assets, net of deferred tax liabilities and valuation allowance	80,956	81,363
Intangible assets, net	238,791	251,635
Goodwill	28,221	28,221
Derivatives and other non-current assets	9,228	11,361
Total Assets	<u>\$ 765,224</u>	<u>\$ 760,087</u>
Current Liabilities		
Current debt, net of deferred financing costs	\$ 850	\$ 850
Accounts payable	32,687	29,305
Accrued royalties	8,957	9,307
Accrued compensation and related expenses	13,051	10,312
Accrued government rebates	8,607	10,872
Returned goods reserve	34,108	33,399
Current contingent consideration	22,761	-
Accrued expenses and other	4,804	5,394
Total Current Liabilities	<u>125,825</u>	<u>99,439</u>
Non-current Liabilities		
Non-current debt, net of deferred financing costs and current component	285,457	285,669
Non-current contingent consideration	13,258	35,058
Other non-current liabilities	1,202	1,381
Total Liabilities	<u>425,742</u>	<u>421,547</u>
Mezzanine Equity		
Convertible Preferred Stock, Series A	24,850	24,850
Stockholders' Equity		
Common stock	1	1
Treasury stock	(8,643)	(5,094)
Additional paid-in capital	408,395	403,901
Accumulated deficit	(96,252)	(97,286)
Accumulated other comprehensive income, net of tax	11,131	12,168
Total Stockholders' Equity	<u>314,632</u>	<u>313,690</u>
Total Liabilities, Mezzanine Equity, and Stockholders' Equity	<u>\$ 765,224</u>	<u>\$ 760,087</u>

ANI Pharmaceuticals, Inc. and Subsidiaries

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

(unaudited, in thousands)

	Reconciliation of certain adjusted non-GAAP accounts:										
	Three Months Ended March 31,		As reported:	Net Revenues Three Months Ended March 31,		Cost of sales (excluding depreciation and amortization) Three Months Ended March 31,		Selling, general, and administrative expenses Three Months Ended March 31,		Research and development expenses Three Months Ended March 31,	
				2023	2022	2023	2022	2023	2022	2023	2022
	2023	2022		2023	2022	2023	2022	2023	2022	2023	2022
Net Loss	\$ 1,439	\$ (20,130)	As reported:	\$ 106,786	\$ 64,477	\$ 37,708	\$ 34,271	\$ 36,468	\$ 28,817	\$ 5,924	\$ 5,274
Add/(Subtract):											
Interest expense, net	7,696	6,613									
Other expense, net	34	89									
Income tax provision (benefit)	726	(5,767)									
Depreciation and amortization	14,700	14,557									
Contingent consideration fair value adjustment	961	753									
Restructuring activities	1,130	-									
Impact of Canada operations ⁽¹⁾	1,647	-	Impact of Canada operations ⁽¹⁾	(565)	-	(1,416)	-	(1,861)	-	(64)	-
Stock-based compensation	4,338	3,237	Stock-based compensation	-	-	(151)	(145)	(3,980)	(2,839)	(207)	(253)
Excess of fair value over cost of acquired inventory	-	3,829	Excess of fair value over cost of acquired inventory	-	-	-	(3,829)	-	-	-	-
Novitium transaction expenses	342	1,092	Novitium transaction expenses	-	-	-	-	(342)	(1,092)	-	-
Adjusted non-GAAP EBITDA	<u>\$ 33,013</u>	<u>\$ 4,273</u>	As adjusted:	<u>\$ 106,221</u>	<u>\$ 64,477</u>	<u>\$ 36,141</u>	<u>\$ 30,297</u>	<u>\$ 30,285</u>	<u>\$ 24,886</u>	<u>\$ 5,653</u>	<u>\$ 5,021</u>

⁽¹⁾ Impact of Canada operations includes CDMO revenues, cost of sales relating to CDMO revenues, all selling, general, and administrative expenses, and all research and development expenses recorded in Canada in the period presented, exclusive of restructuring activities, stock-based compensation, and depreciation and amortization, which are included within their respective line items above. The adjustment of Canada operations represents revenues, cost of sales and expense that will not recur after the completion of the closure of our Canada operations, which is complete as of March 31, 2023. The adjustment of Canada operations does not adjust for revenues, cost of sales, and expense that will recur at our other manufacturing facilities after the transfer of certain manufacturing activities is complete.

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 March 31,	
	2023	2022
Net Income (Loss) Available to Common Shareholders	\$ 1,033	\$ (20,535)
Add/(Subtract):		
Non-cash interest expense	987	953
Depreciation and amortization expense	14,700	14,557
Contingent consideration fair value adjustment	961	753
Restructuring activities	1,130	-
Impact of Canada operations ⁽¹⁾	1,647	-
Stock-based compensation	4,338	3,237
Excess of fair value over cost of acquired inventory	-	3,829
Novitium transaction expenses	342	1,092
Less:		
Estimated tax impact of adjustments (calc. at 24%)	(5,785)	(5,861)
Adjusted non-GAAP Net Income (Loss) Available to Common Shareholders (2)	\$ 19,353	\$ (1,975)
Diluted Weighted-Average		
Shares Outstanding	16,531	16,137
Adjusted Diluted Weighted-Average		
Shares Outstanding	16,531	16,137
Adjusted non-GAAP		
Diluted Earnings (Loss) per Share	<u>\$ 1.17</u>	<u>\$ (0.12)</u>

⁽¹⁾ Impact of Canada operations includes CDMO revenues, cost of sales relating to CDMO revenues, all selling, general, and administrative expenses, and all research and development expenses recorded in Canada in the period presented, exclusive of restructuring activities, stock-based compensation, and depreciation and amortization, which are included within their respective line items above. The adjustment of Canada operations represents revenues, cost of sales and expense that will not recur after the completion of the closure of our Canada operations, expected to be complete by March 31, 2023. The adjustment of Canada operations does not adjust for revenues, cost of sales, and expense that will recur at our other manufacturing facilities after the transfer of certain manufacturing activities is complete.

⁽²⁾ Adjusted non-GAAP Net Income (Loss) Available to Common Shareholders excludes undistributed earnings to participating securities.