

**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): August 9, 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 August 9, 2023, ANI Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 2023. A copy of the press release is furnished herewith as Exhibit 99.1.*

Item 9.01 Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of the Company, dated August 9, 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: August 9, 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 Second Quarter 2023 Financial Results and Raises Full-Year 2023 Guidance

Second Quarter 2023 Financial Results

- Record quarterly net revenues of \$116.5 million, representing year-over-year growth of 57.8%; net income available to common shareholders of \$5.8 million and diluted GAAP income per share of \$0.29 --*
- Record quarterly adjusted non-GAAP EBITDA of \$34.1 million representing year-over-year growth of 246%; adjusted non-GAAP diluted earnings per share of \$1.28 --*
- Lead Rare Disease asset, Purified Cortrophin® Gel (Repository Corticotrophin Injection USP) 80 U/ml (Cortrophin Gel) reported net sales of \$24.3 million, a year-over-year increase of 138.2% --*
- Generics, Established Brands and Others reported net sales of \$92.2 million, representing year-over-year growth of 44.9% --*

Full Year 2023 Guidance

- Company is raising net revenue guidance to \$425 million to \$445 million from \$385 million to \$410 million; adjusted non-GAAP EBITDA guidance is raised to \$115 million to \$125 million from \$97 million to \$107 million; adjusted non-GAAP earnings per share guidance is raised to \$3.62 to \$4.11 from \$2.99 to \$3.45 --*
- Company is raising Cortrophin Gel specific revenue guidance to \$90 million to \$100 million from \$80 million to \$90 million, representing 116% to 140% growth as compared to \$41.7 million recognized in 2022 --*
- Mid-point of revised total Company guidance represents year-over-year growth in net revenues of 37%, adjusted non-GAAP EBITDA of 115%, and adjusted non-GAAP earnings per diluted share of 184% --*

Company Highlights

- Strong performance for Cortrophin Gel; record number of new patient starts and new cases initiated in the second quarter of 2023; ACTH market continues to show year-over-year growth for twelve consecutive months according to IQVIA --*
- Continued increase in new unique prescribers and number of repeat prescribers; growth across all targeted specialties of neurology, nephrology and rheumatology; pulmonology sales team gaining momentum --*
- Company's strong R&D capabilities, operational excellence and U.S.-based manufacturing footprint helped capture new business opportunities and drive growth in Generics and Established Brands --*
- Successfully completed public equity offering resulting in net proceeds of \$80.6 million; \$42.0 million in cash generated from operating activities (year-to-date), ending Q2 with \$161.7 million in cash --*

BAUDETTE, Minn.--(BUSINESS WIRE) – August 9, 2023 – ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) (ANI or the Company) today announced business highlights and financial results for the three months ended June 30, 2023.

“The second quarter of 2023 was another strong quarter for ANI, across all areas of the business. The Company is proud to report record net revenues and adjusted non-GAAP EBITDA and raise full-year 2023 guidance for the second quarter in a row. With record quarterly new patient starts, new cases initiated, new unique prescribers, and ongoing growth in repeat prescribers, the launch momentum for Purified Cortrophin Gel remains strong. In addition, the overall ACTH category is robust, with year-on-year growth in volumes every month during the first half of 2023. Following our recent successful equity raise and based on strong cash flow generation from operating activities, we believe ANI is well-positioned to seek opportunities to increase the scope and scale of our Rare Disease portfolio through M&A and in-licensing,” stated Nikhil Lalwani, President and CEO of ANI.

“Our Generics, Established Brands and Others segment also delivered strong results in the quarter. We received four generic ANDA approvals and expanded commercialization efforts into several new sales channels. We continued to serve patients in need and customers while capturing new business opportunities by leveraging our operational excellence and U.S.-based manufacturing footprint. With an impressive first half of 2023, we’re excited to build on the momentum, and grow our business while continuing to help patients in need,” concluded Lalwani.

Second Quarter 2023 Financial Highlights:

- Net revenues were \$116.5 million compared to \$73.9 million in Q2 2022.
- GAAP net income available to common shareholders was \$5.8 million, and diluted GAAP income per share was \$0.29.
- Adjusted non-GAAP EBITDA was \$34.1 million compared to \$9.9 million in Q2 2022.
- Adjusted non-GAAP diluted earnings per share was \$1.28, compared to diluted earnings per share of \$0.13 in Q2 2022.
- Cash and cash equivalents were \$161.7 million with year-to-date (six month) cash flow from operations of \$42.0 million.

Second Quarter and Recent Business Highlights:

Rare Disease Business Update

Revenues for our lead asset, Cortrophin Gel, totaled \$24.3 million for the second quarter of 2023. During the quarter, the Company saw a record number of new cases initiated, new patient starts and new unique prescribers. Growth continued across targeted specialties of neurology, rheumatology and nephrology and the Company gained early traction from the newly launched Pulmonology sales force. Since the launch of Cortrophin Gel, the overall ACTH category has experienced twelve consecutive months of year-over-year growth from June 2022 to May 2023.

The Company is raising its 2023 revenue guidance for Cortrophin Gel to \$90 million to \$100 million, representing 116% - 140% 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 assets or establish partnerships to increase the scope and scale of its Rare Disease platform.

Generics Business, Established Brands and Others Update

Sales of generic pharmaceuticals products, established brands and others grew 44.9% year-over-year in the second quarter of 2023. The Company's generics business is well positioned for delivering sustainable growth, driven by a strong R&D organization launching new products. During the quarter, ANI received four Abbreviated New Drug Applications (ANDAs) approvals, including Colestipol Hydrochloride Tablets USP, 1 g and Nitrofurantoin Oral Suspension USP, 25 mg/5 ml. The Company also expanded commercialization efforts into several new sales channels.

During the second quarter, ANI continued to leverage its operational excellence and focus on U.S.-based manufacturing to take advantage of the numerous opportunities arising from supply disruptions in both generics and established brands. 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 remain ongoing.

Second Quarter 2023 Financial Results

(in thousands)	Three Months Ended June 30,		Change	% Change
	2023	2022		
Generics, Established Brands, and Other Segment				
Generic pharmaceutical products	\$ 63,317	\$ 49,863	\$ 13,454	27.0 %
Established brand pharmaceutical products, royalties, and other pharmaceutical services	28,926	13,790	15,136	109.8 %
Generics, established brands, and other segment total net revenues	\$ 92,243	\$ 63,653	\$ 28,590	44.9 %
Rare Disease Segment				
Rare disease pharmaceutical products	24,304	10,202	\$ 14,102	138.2 %
Total net revenues	\$ 116,547	\$ 73,855	\$ 42,692	57.8 %

Net revenues for generic pharmaceutical products were \$63.3 million during the three months ended June 30, 2023, an increase of 27.0% compared to \$49.9 million for the same period in 2022, driven by increased volumes on the base business, the annualization of 2022 launches and new product launches in 2023.

Net revenues for established brand pharmaceutical products, royalties, and other pharmaceutical services were \$28.9 million during the three months ended June 30, 2023, an increase of 109.8% compared to \$13.8 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 \$24.3 million during the three months ended June 30, 2023, an increase of \$14.1 million from \$10.2 million for the same period in 2022. This growth was driven by increased volume as the product was launched in late January 2022.

Operating expenses increased by 20.0% to \$104.1 million for the three months ended June 30, 2023, from \$86.8 million in the prior year period as a result of the following factors:

For the three months ended June 30, 2023, cost of sales increased to \$42.3 million from \$35.3 million for the same period in 2022, an increase of \$7.0 million, or 19.8%, primarily due to a significant growth in sales volumes of generic and Rare Disease pharmaceutical products.

Research and development expenses increased from \$4.2 million to \$7.4 million for the three months ended June 30, 2023, an increase of \$3.2 million or 77.0%, primarily due to a higher level of activity associated with generic projects coupled with an increase associated with projects related to Cortrophin Gel in the current year period.

Selling, general, and administrative expenses increased from \$32.0 million to \$38.8 million for the three months ended June 30, 2023, an increase of \$6.8 million, or 21.3%, primarily due to higher employment related costs and increased legal expenses.

Depreciation and amortization expense was \$14.7 million for the three months ended June 30, 2023, compared to \$13.8 million for the same period in 2022, an increase of \$0.9 million.

The Company recognized a contingent consideration fair value adjustment relating to its 2021 acquisition of Novitium of \$1.0 million and \$(1.1) million in the three months ended June 30, 2023 and 2022, respectively.

The Company recognized restructuring activities of \$2.6 million of expense in the three months ended June 30, 2022, in relation to the closure of its Oakville, Ontario, Canada facility. Costs included \$1.4 million in termination benefits, \$0.9 million in fixed asset impairments and accelerated depreciation, and \$0.3 million of other costs. The restructuring activities recognized in the three months ended June 30, 2023, were immaterial.

Net income available to common shareholders for the second quarter of 2023 was \$5.8 million as compared to net loss of \$(15.3) million in the prior year period. Diluted earnings per share for the three months ended June 30, 2023, was \$0.29 compared to diluted GAAP loss per share of \$(0.94) in the prior year period.

Adjusted non-GAAP diluted earnings per share was \$1.28 in the second quarter of 2023 compared to diluted earnings per share of \$0.13 in the second 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 June 30, 2023, the Company had \$161.7 million in unrestricted cash and cash equivalents, \$172.9 million in net accounts receivable and \$295.5 million (face value) in outstanding debt. The Company generated year-to-date cash flow from operations of \$42.0 million.

2023 Financial Guidance Upward Revisions

	Revised Full Year 2023 Guidance	Prior Full Year 2023 Guidance	Prior Year Actual	Growth
Net Revenue (total Company)	\$425 million - \$445 million	\$385 million - \$410 million	\$316.4 million	34% - 41%
Cortrophin Gel Net Revenue	\$90 million - \$100 million	\$80 million - \$90 million	\$41.7 million	116% - 140%
Adj. Non-GAAP Gross Margin	63% to 64.8%	60% to 62.5%	58.3%	4.7 pts to 6.5 pts
Adjusted Non-GAAP EBITDA	\$115 million - \$125 million	\$97 million - \$107 million	\$55.9 million	106% - 124%
Adjusted Non-GAAP Diluted EPS	\$3.62 - \$4.11	\$2.99 - \$3.45	\$1.36	166% - 202%

In addition, ANI currently anticipates between 19.1 million and 19.3 million shares outstanding and a U.S. GAAP effective tax rate of between approximately 6.0% to 10.0%. The Company will continue to tax affect adjustments for computation of adjusted non-GAAP diluted earnings per share at a tax rate of 24%.

Conference Call

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

Date Wednesday, August 9, 2023
Time 8:30 a.m. ET
Toll free (U.S.) 800-267-6316

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 two weeks by dialing 800-839-2461 and entering access code 119757.

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 biopharmaceutical 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 scaling up our Rare Disease business through the successful launch of our lead asset, Purified Cortrophin® Gel, 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.anipharmaceuticals.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 but not limited to 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net Revenues	\$ 116,547	\$ 73,855	\$ 223,333	\$ 138,332
Operating Expenses				
Cost of sales (excluding depreciation and amortization)	42,284	35,294	79,992	69,565
Research and development	7,374	4,165	13,298	9,439
Selling, general, and administrative	38,760	31,958	75,228	60,775
Depreciation and amortization	14,690	13,764	29,390	28,321
Contingent consideration fair value adjustment	1,035	(1,095)	1,996	(342)
Restructuring activities	2	2,570	1,132	2,570
Intangible asset impairment charge	—	112	—	112
Total Operating Expenses	104,145	86,768	201,036	170,440
Operating Income (Loss)	12,402	(12,913)	22,297	(32,108)
Other Expense, net				
Interest expense, net	(7,100)	(6,669)	(14,796)	(13,282)
Other (expense) income, net	(53)	764	(87)	675
Income (Loss) Before Income Tax Benefit	5,249	(18,818)	7,414	(44,715)
Income tax benefit	996	3,895	270	9,662
Net Income (Loss)	\$ 6,245	\$ (14,923)	\$ 7,684	\$ (35,053)
Dividends on Series A Convertible Preferred Stock	(407)	(407)	(813)	(812)
Net Income (Loss) Available to Common Shareholders	\$ 5,838	\$ (15,330)	\$ 6,871	\$ (35,865)
Basic and Diluted Income (Loss) Per Share:				
Basic Income (Loss) Per Share	\$ 0.30	\$ (0.94)	\$ 0.36	\$ (2.21)
Diluted Income (Loss) Per Share	\$ 0.29	\$ (0.94)	\$ 0.36	\$ (2.21)
Basic Weighted-Average Shares Outstanding	17,688	16,272	17,044	16,205
Diluted Weighted-Average Shares Outstanding	17,855	16,272	17,177	16,205

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

	June 30, 2023	December 31, 2022
Current Assets		
Cash and cash equivalents	\$ 161,707	\$ 48,228
Current restricted cash	—	5,006
Accounts receivable, net	172,925	165,438
Inventories	104,323	105,355
Prepaid income taxes	4,088	3,827
Assets held for sale	8,020	8,020
Prepaid expenses and other current assets	8,248	8,387
Total Current Assets	<u>459,311</u>	<u>344,261</u>
Non-current Assets		
Property and equipment, net	44,371	43,246
Deferred tax assets, net of deferred tax liabilities and valuation allowance	81,500	81,363
Intangible assets, net	230,299	251,635
Goodwill	28,221	28,221
Derivatives and other non-current assets	15,639	11,361
Total Assets	<u>\$ 859,341</u>	<u>\$ 760,087</u>
Current Liabilities		
Current debt, net of deferred financing costs	\$ 850	\$ 850
Accounts payable	28,505	29,305
Accrued royalties	9,885	9,307
Accrued compensation and related expenses	11,493	10,312
Accrued government rebates	11,971	10,872
Returned goods reserve	29,798	33,399
Current contingent consideration	25,025	—
Accrued expenses and other	5,338	5,394
Total Current Liabilities	<u>122,865</u>	<u>99,439</u>
Non-current Liabilities		
Non-current debt, net of deferred financing costs and current component	285,244	285,669
Non-current contingent consideration	12,029	35,058
Other non-current liabilities	4,731	1,381
Total Liabilities	<u>424,869</u>	<u>421,547</u>
Mezzanine Equity		
Convertible Preferred Stock, Series A	24,850	24,850
Stockholders' Equity		
Common Stock	2	1
Treasury stock	(9,180)	(5,094)
Additional paid-in capital	495,488	403,901
Accumulated deficit	(90,414)	(97,286)
Accumulated other comprehensive income, net of tax	13,726	12,168
Total Stockholders' Equity	<u>409,622</u>	<u>313,690</u>
Total Liabilities, Mezzanine Equity, and Stockholders' Equity	<u>\$ 859,341</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 June 30,		As reported:	Net Revenues		Cost of sales (excluding depreciation and amortization)		Selling, general, and administrative expenses		Research and development expenses	
	2023	2022		Three Months Ended June 30,	Three Months Ended June 30,	Three Months Ended June 30,	Three Months Ended June 30,	Three Months Ended June 30,	Three Months Ended June 30,	Three Months Ended June 30,	Three Months Ended June 30,
	2023	2022	2023	2022	2023	2022	2023	2022	2023	2022	
Net Income (Loss)	\$ 6,245	\$ (14,923)	As reported:	\$ 116,547	\$ 73,855	\$ 42,284	\$ 35,294	\$ 38,760	\$ 31,958	\$ 7,374	\$ 4,165
Add/(Subtract):											
Interest expense, net	7,100	6,669									
Other expense (income), net (1)	53	(14)									
Income tax benefit	(996)	(3,895)									
Depreciation and amortization	14,690	13,764									
Contingent consideration fair value adjustment	1,035	(1,095)									
Intangible asset impairment charge	—	112									
Restructuring activities	2	2,570									
Impact of Canada operations (2)	492	1,820	Impact of Canada operations(2)	—	(1,045)	(289)	(1,249)	(194)	(1,545)	(9)	(71)
Stock-based compensation	5,249	3,756	Stock-based compensation	—	—	(188)	(144)	(4,836)	(3,417)	(225)	(195)
Excess of fair value over cost of acquired inventory	—	973	Excess of fair value over cost of acquired inventory	—	—	—	(973)	—	—	—	—
Novitium transaction expenses	249	124	Novitium transaction expenses	—	—	—	—	(249)	(124)	—	—
Adjusted non-GAAP EBITDA	<u>\$ 34,119</u>	<u>\$ 9,861</u>	As adjusted:	<u>\$ 116,547</u>	<u>\$ 72,810</u>	<u>\$ 41,807</u>	<u>\$ 32,928</u>	<u>\$ 33,481</u>	<u>\$ 26,872</u>	<u>\$ 7,140</u>	<u>\$ 3,899</u>

⁽¹⁾ Adjustment to Other (income)/expense, net excludes \$750 thousand of income related to the sale of an ANDA during the three months ended June 30, 2022.

⁽²⁾ 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.

Reconciliation of certain adjusted non-GAAP accounts:

	Six Months Ended June 30,		As reported:	Net Revenues		Cost of sales (excluding depreciation and amortization)		Selling, general, and administrative		Research and development	
				Six Months Ended June 30,		Six Months Ended June 30,		Six Months Ended June 30,		Six Months Ended June 30,	
	2023	2022		2023	2022	2023	2022	2023	2022	2023	2022
Net Income (Loss)	\$ 7,684	\$ (35,053)	As reported:	\$ 223,333	\$ 138,332	\$ 79,992	\$ 69,565	\$ 75,228	\$ 60,775	\$ 13,298	\$ 9,439
Add/(Subtract):											
Interest expense, net	14,796	13,282									
Other expense (income), net (1)	87	75									
Income tax benefit	(270)	(9,662)									
Depreciation and amortization	29,390	28,321									
Contingent consideration fair value adjustment	1,996	(342)									
Intangible asset impairment charge	—	112									
Restructuring activities	1,132	2,570									
Impact of Canada operations (2)	2,138	1,820	Impact of Canada operations(2)	(565)	(1,045)	(1,705)	(1,249)	(925)	(1,545)	(73)	(71)
Stock-based compensation	9,587	6,992	Stock-based compensation	—	—	(339)	(288)	(8,816)	(6,338)	(432)	(366)
Excess of fair value over cost of acquired inventory	—	4,802	Excess of fair value over cost of acquired inventory	—	—	—	(4,802)	—	—	—	—
Novitium transaction expenses	591	1,217	Novitium transaction expenses	—	—	—	—	(591)	(1,217)	—	—
Adjusted non-GAAP EBITDA	<u>\$ 67,131</u>	<u>\$ 14,134</u>	As adjusted:	<u>\$ 222,768</u>	<u>\$ 137,287</u>	<u>\$ 77,948</u>	<u>\$ 63,226</u>	<u>\$ 64,896</u>	<u>\$ 51,675</u>	<u>\$ 12,793</u>	<u>\$ 9,002</u>

⁽¹⁾ Adjustment to Other (income)/expense, net excludes \$750 thousand of income related to the sale of an ANDA during the three months ended June 30, 2022.

⁽²⁾ 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net Income (Loss) Available to Common Shareholders	\$ 5,838	\$ (15,330)	\$ 6,871	\$ (35,865)
Add/(Subtract):				
Non-cash interest expense	710	967	1,675	1,920
Depreciation and amortization	14,690	13,764	29,390	28,321
Contingent consideration fair value adjustment	1,035	(1,095)	1,996	(342)
Restructuring activities	2	2,570	1,132	2,570
Intangible asset impairment charge	—	112	—	112
Impact of Canada operations(1)	492	1,820	2,138	1,820
Stock-based compensation	5,249	3,756	9,587	6,992
Excess of fair value over cost of acquired inventory	—	973	—	4,802
Novitium transaction expenses	249	124	591	1,217
Less:				
Estimated tax impact of adjustments (calc. at 24%)	(5,382)	(5,518)	(11,162)	(11,379)
Adjusted non-GAAP Net Income Available to Common Shareholders (2)	\$ 22,883	\$ 2,143	\$ 42,218	\$ 168
Diluted Weighted-Average				
Shares Outstanding	17,855	16,272	17,177	16,205
Adjusted Diluted Weighted-Average				
Shares Outstanding	17,855	16,282	17,177	16,218
Adjusted non-GAAP				
Diluted Earnings per Share	\$ 1.28	\$ 0.13	\$ 2.46	\$ 0.01

(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.