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

FORM 8-K
CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of Earliest Event Reported): March 9, 2023

ANI PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-31812**	**58-2301143**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

210 Main Street West **Baudette, Minnesota**	**56623**
(Address of principal executive offices)	(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 March 9, 2023, ANI Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and fiscal year ended December 31, 2022. A copy of the press release is furnished herewith as Exhibit 99.1.*

Item 9.01 Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of the Company, dated March 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: March 9, 2023

ANI PHARMACEUTICALS, INC.

By: /s/ Stephen P. Carey
Name: Stephen P. Carey
Title: Senior Vice President Finance and Chief Financial Officer

Exhibit 99.1

FOR IMMEDIATE RELEASE

ANI Pharmaceuticals Reports Record Fourth Quarter Financial Results and Achieves Full Year 2022 Revenue Milestone; Initiates 2023 Guidance

Fourth Quarter and Full Year 2022 Financial Results

-- Q4 net revenues of $94.2 million, net loss available to common shareholders of $(4.7) million and diluted GAAP loss per share of $(0.28) –

-- Q4 Adjusted non-GAAP EBITDA of $23.3 million and adjusted non-GAAP diluted earnings per share of $0.76 --

-- Q4 net revenue growth of 54.7% and record quarterly net revenues --

-- Full year 2022 net revenues of $316.4 million, net loss available to common shareholders of $49.5 million, diluted GAAP loss per share of ($3.05) –

-- Full year 2022 adjusted non-GAAP EBITDA of $55.9 million and adjusted non-GAAP diluted earnings per share of $1.36 --

-- Lead Rare Disease asset, Purified Cortrophin® Gel (Repository Corticotrophin Injection USP) 80 U/ml (Cortrophin) full-year 2022 net sales of $41.7 million --

Full Year 2023 Guidance

-- Initiates total Company net revenue guidance of $360 million to $385 million; adjusted non-GAAP EBITDA guidance of $78 million to $88 million; adjusted non-GAAP earnings per share of $2.09 to $2.59 --

-- Initiates Purified Cortrophin Gel Revenue Guidance at $80 million to $90 million (representing 92% - 116% growth); Cortrophin SG&A increase estimated at ~10% including modest sales force expansion

Company Highlights

-- Continued strength of Cortrophin Gel launch, with more than 1,120 cases initiated by more than 510 unique prescribers; ACTH market showing year-on-year growth for eight consecutive months according to IQVIA --

-- Launched several limited-competition new generics; retained top 10 ranking for new ANDA approvals and second ranking for Competitive Generic Therapy approvals --

-- Consolidation of manufacturing network on track with manufacturing operations concluded at Oakville site in January 2023 --

BAUDETTE, Minn.--(BUSINESS WIRE) – March 9, 2023 – ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) (ANI or the Company) today announced business highlights and financial results for the three and 12 months ended December 31, 2022.

“2022 was a transformative year for ANI, taking us past critical inflection points for our two key growth drivers – the launch of Cortrophin Gel, our foundational Rare Disease asset, and investment in our generics business. Over the course of the past year, we built a strong Rare Disease platform to support Cortrophin Gel, which also creates the opportunity to acquire or partner on additional rare disease assets that can leverage this foundation. In addition, our continued focus on bringing limited-competition products to market, driving cost competitiveness and providing supply reliability has helped us absorb the generic product erosion and deliver results,” stated Nikhil Lalwani, President and CEO of ANI.

“ANI’s full-year 2022 revenues of $316.4 million marked a milestone achievement for the Company and reflects the dedication and commitment of our colleagues. As we look ahead to 2023, we will continue to focus on providing high-quality medicines to patients in need and to deliver value to all stakeholders,” concluded Lalwani.

Fourth Quarter 2022 Financial Highlights:

- Net revenues were $94.2 million compared to $60.9 million in Q4 2021.
- GAAP net loss available to common shareholders was ($4.7) million, and diluted GAAP loss per share was ($0.28).
- Adjusted non-GAAP EBITDA was $23.3 million compared to $7.2 million in Q4 2021.
- Adjusted non-GAAP diluted earnings per share was $0.76, compared to diluted earnings per share of $0.06 in Q4 2021.
- Cash and cash equivalents were $48.2 million, net accounts receivable was $165.4 million, and face value of debt was $297.0 million as of December 31, 2022.

Full Year 2022 Financial Highlights:

- Net revenues for 2022 were $316.4 million compared to $216.1 million in 2021.
- GAAP net loss available to common shareholders was ($49.5) million, and diluted GAAP loss per share was ($3.05).
- Adjusted non-GAAP EBITDA was $55.9 million.
- Adjusted non-GAAP diluted earnings per share was $1.36.

Fourth Quarter and Recent Business Highlights:

Rare Disease Business Update

Revenues for Cortrophin Gel totaled $17.6 million in the fourth quarter and reached $41.7 million for the full year. Importantly, according to IQVIA, the ACTH category, which has been declining since 2019, has experienced eight consecutive months of year-on-year growth from June 2022 – January 2023. As of March 8th, cumulative new patient cases increased to more than 1,120 with more than 510 unique prescribers. The Company continues to see growth in both the number of new unique and repeat prescribers.

The Company persists in its efforts with the PBMs and payers across commercial, Medicaid and Medicare to expand market access for Cortrophin Gel for patients in need. The Company is initiating 2023 revenue guidance for Purified Cortrophin Gel of $80 million to $90 million, representing 92% - 116% year over year growth. ANI has planned a modest expansion of its sales force and will continue to increase awareness of Cortrophin Gel through peer-to-peer education while maintaining direct SG&A expense within 10% of 2022 actual.

Rare Disease is a critical focus area for achieving future growth , and the Company is actively exploring assets to acquire or partner on to leverage its Rare Disease platform.

Generics Business Update

Sales of generic pharmaceuticals products grew 39.4% year-over-year in the fourth quarter. The continued focus on bringing limited-competition products to market and driving cost competitiveness enabled the Company to absorb some of the generic product line erosion. Today, ANI retains a top ten ranking for new ANDA approvals and a number two ranking for Competitive Generic Therapy Approvals. In 2022, ANI filed 12 ANDAs, and in the fourth quarter, launched multiple products, including Trimethoprim Tablets USP, 100 mg, Fluoxetine Oral Solution, USP 20 mg/5 mL, and Levocarnitine Tablets USP, 330 mg.

The Company is also taking important steps in the area of cost excellence. Consolidation of the Company's manufacturing network is on track. Manufacturing operations ceased at the Oakville, Ontario, site in January 2023, and the relocation of Oakville products to U.S. facilities has been completed. The Company is in active discussions with potential buyers for the Oakville site. Once fully executed, this operational efficiency is currently expected to improve GAAP profitability and cash flow by $7 million to $8 million on an annualized basis.

ANI is committed to delivering high-quality medicines to customers and patients in the United States. The U.S. Food and Drug Administration (FDA) conducted a routine Good Manufacturing Practices (cGMP) audit at ANI's manufacturing facility in Baudette, Minnesota. ANI implemented all corrective and preventive actions and has already received a favorable Establishment Inspection Report (EIR) classifying that its Baudette, Minnesota, facility is Voluntary Action Indicated (VAI). This outcome further exemplifies the strong compliance history of the Baudette facility.

Fourth Quarter 2022 Financial Results

(in thousands)	Three Months Ended December 31, 2022	2021	Change	% Change
Generics, Established Brands, and Other Segment				
Generic pharmaceutical products	$ 58,014	$ 41,619	$ 16,395	39.4%
Established brand pharmaceutical products	12,732	14,693	(1,961)	(13.3)%
Contract manufacturing	4,034	2,765	1,269	45.9%
Royalty and other	1,862	1,852	10	0.5%
Generics, established brands, and other segment total net revenues	$ 76,642	$ 60,929	$ 15,713	25.8%
Rare Disease Segment				
Rare disease pharmaceutical products	$ 17,590	$ —	$ 17,590	NM[(1)]
Total net revenues	$ 94,232	$ 60,929	$ 33,303	54.7%

[(1)] Not Meaningful

Net revenues for generic pharmaceutical products were $58.0 million during the three months ended December 31, 2022, an increase of 39.4% compared to $41.6 million for the same period in 2021. The net increase was primarily driven by revenues from multiple 2022 new product launches, including the launch of several limited competition products, partially tempered by a decrease in revenues from sales of several legacy ANI generic products.

Net revenues for established brand pharmaceutical products were $12.7 million during the three months ended December 31, 2022, a decrease of 13.3% compared to $14.7 million for the same period in 2021 driven by lower volumes of many of the Company's brand products.

Contract manufacturing revenues were $4.0 million during the three months ended December 31, 2022, an increase of 45.9% compared to $2.8 million for the same period in 2021, due to an increase in the volume of orders, primarily related to the addition of Novitium contract manufacturing revenues.

Net revenues of rare disease pharmaceutical products, which consist entirely of sales of Cortrophin, were $17.6 million during the three months ended December 31, 2022. The product was launched in late January 2022.

Operating expenses increased by 9.2% to $92.4 million for the three months ended December 31, 2022, from $84.7 million in the prior year period as a result of the following factors:

Cost of sales, excluding depreciation and amortization, increased by $2.4 million to $36.3 million in the fourth quarter of 2022 compared to $33.9 million in the prior year period, driven primarily by higher sales volumes.

Research and development expenses were $5.2 million in the fourth quarter of 2022, an increase of $2.1 million from the prior year period, primarily due to expenses related to generic products.

Selling, general and administrative expenses increased by 8.1% to $33.2 million in the fourth quarter of 2022, compared to $30.7 million in the prior year quarter, reflecting a $3.9 million increase in sales and marketing expenses related to our launch of Cortrophin, a full quarter's worth of Novitium headcount and activities (as compared to a partial quarter in prior year), and increased infrastructure to support the growth in our business, partially offset by a $4.4 million decrease in transaction expenses related to the Novitium acquisition.

Depreciation and amortization increased by 5.8% in the fourth quarter of 2022 to $14.5 million from $13.7 million in the comparable quarter in 2021, primarily due to amortization of intangible assets acquired in the Novitium acquisition.

Net loss available to common shareholders for the fourth quarter of 2022 was $(4.7) million as compared to net loss of $(24.3) million in the prior year period. Diluted loss per share for the three months ended December 31, 2022 was $(0.28) compared to diluted GAAP loss per share of $(1.72) in the prior year period.

Adjusted non-GAAP diluted earnings per share was $0.76 in the fourth quarter of 2022 compared to $0.06 in the fourth quarter of 2021.

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

Liquidity

As of December 31, 2022, the Company had $48.2 million in unrestricted cash and cash equivalents plus $165.4 million in net accounts receivable. The Company had $297.0 million (face value) in outstanding debt as of December 31, 2022.

2023 Financial Guidance

- Total Company expected Net Revenues between $360.0 million and $385.0 million, representing approximately 14% to 22% growth as compared to $316.4 million recognized in 2022;

- Cortrophin specific revenue guidance 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 between 59.5% and 61.0%;

- Total Company Adjusted non-GAAP EBITDA between $78.0 million and $88.0 million; and

- Adjusted non-GAAP Diluted Earnings per Share between $2.09 and $2.59.

In addition, we currently anticipate between 16.8 million and 17.1 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 fourth quarter 2022 conference call as follows:

Date	March 9, 2023
Time	8:30 a.m. ET
Toll free (U.S.)	800-343-5172
Global	203-518-9851

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 800-934-8367 and entering access code 2895031.

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 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 (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, 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 (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, 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 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 (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, 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.

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.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 anticipated closure of our Oakville, Ontario manufacturing plant, including the transition of certain products manufactured there to our other facilities which remains ongoing, or have difficulties finding a buyer for the plant and property; general business and economic conditions, such as inflationary pressures, 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.

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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 December 31,		Twelve Months Ended December 31,	
	2022	**2021**	**2022**	**2021**
Net Revenues	$ 94,232	$ 60,929	$ 316,385	$ 216,136
Operating Expenses:				
Cost of sales (excl. depreciation and amortization)	36,326	33,898	138,785	100,610
Research and development	5,222	3,140	22,318	11,369
Selling, general, and administrative	33,188	30,706	124,044	84,294
Depreciation and amortization	14,484	13,684	56,972	47,252
Contingent consideration fair value adjustment	1,624	500	3,758	500
Legal settlement expense	-	350	-	8,750
Purified Cortrophin Gel pre-launch charges	-	-	-	780
Restructuring activities	1,568	-	5,679	-
Intangible asset impairment charge	-	2,374	112	2,374
Total Operating Expenses	92,412	84,652	351,668	255,929
Operating Income/(Loss)	1,820	(23,723)	(35,283)	(39,793)
Other Expense, net				
Interest expense, net	(7,506)	(4,440)	(28,052)	(11,922)
Other (expense)/income, net	(42)	(2,690)	670	(4,343)
Loss Before Benefit for Income Taxes	(5,728)	(30,853)	(62,665)	(56,058)
Benefit for income taxes	1,485	6,717	14,769	13,455
Net Loss	$ (4,243)	$ (24,136)	$ (47,896)	$ (42,603)
Dividends on Series A Convertible Preferred Stock	(407)	(190)	(1,625)	(190)
Net Loss Available to Common Shareholders	$ (4,650)	$ (24,326)	$ (49,521)	$ (42,793)
Basic and Diluted Loss Per Share:				
Basic Loss Per Share	$ (0.28)	$ (1.72)	$ (3.05)	$ (3.40)
Diluted Loss Per Share	$ (0.28)	$ (1.72)	$ (3.05)	$ (3.40)
Basic Weighted-Average Shares Outstanding	16,325	14,169	16,260	12,596
Diluted Weighted-Average Shares Outstanding	16,325	14,169	16,260	12,596

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

	December 31, 2022	December 31, 2021
Current Assets		
Cash and cash equivalents	$ 48,228	$ 100,300
Current restricted cash	5,006	-
Accounts receivable, net	165,438	128,526
Inventories, net	105,355	81,693
Prepaid income taxes	3,827	3,667
Assets held for sale	8,020	-
Prepaid expenses and other current assets	8,387	7,589
Total Current Assets	344,261	321,775
Non-current Assets		
Property and equipment	75,958	75,627
Accumulated depreciation	(32,712)	(22,956)
Property and equipment, net	43,246	52,671
Non-current restricted cash	-	5,001
Deferred tax assets, net of deferred tax liabilities and valuation allowance	81,363	67,936
Intangible assets, net	251,635	294,122
Goodwill	28,221	27,888
Derivatives and other non-current assets	11,361	2,205
Total Assets	$ 760,087	$ 771,598
Current Liabilities		
Current debt, net of deferred financing costs	$ 850	$ 850
Accounts payable	29,305	22,967
Accrued royalties	9,307	6,225
Accrued compensation and related expenses	10,312	8,522
Accrued government rebates	10,872	5,492
Returned goods reserve	33,399	35,831
Accrued expenses and other	5,394	7,650
Total Current Liabilities	99,439	87,537
Non-current Liabilities		
Non-current debt, net of deferred financing costs and current component	285,669	286,520
Non-current contingent consideration	35,058	31,000
Derivatives and other non-current liabilities	1,381	7,801
Total Liabilities	$ 421,547	$ 412,858
Mezzanine Equity		
Convertible preferred stock, Series A	24,850	24,850
Stockholders' Equity		
Common stock	1	1
Treasury stock	(5,094)	(3,135)
Additional paid-in capital	403,901	387,844
Accumulated deficit	(97,286)	(47,765)
Accumulated other comprehensive income/(loss), net of tax	12,168	(3,055)
Total Stockholders' Equity	313,690	333,890
Total Liabilities, Mezzanine Equity, and Stockholders' Equity	$ 760,087	$ 771,598

ANI Pharmaceuticals, Inc. and Subsidiaries
Table 3: Adjusted non-GAAP EBITDA Calculation and US GAAP to Non-GAAP Reconciliation
(unaudited, in thousands)

	Three Months Ended December 31,			Reconciliation of certain adjusted non-GAAP accounts:							
				Net Revenues		Cost of sales (excl. depreciation and amortization)		Selling, general, and administrative expenses		Research and development expenses	
				Three Months Ended December 31,		Three Months Ended December 31,		Three Months Ended December 31,		Three Months Ended December 31,	
	2022	2021		2022	2021	2022	2021	2022	2021	2022	2021
Net Loss	$ (4,243)	$ (24,136)	As reported:	$ 94,232	$ 60,929	$ 36,326	$ 33,898	$ 33,188	$ 30,706	$ 5,222	$ 3,140
Add/(Subtract):											
Interest expense, net	7,506	4,440									
Other expense, net	42	3,390									
Benefit for income taxes	(1,485)	(6,717)									
Depreciation and amortization	14,484	13,684									
Legal settlement expense	-	350									
Contingent consideration fair value adjustment	1,624	500									
Restructuring activities	1,568	-									
Impact of Canada operations[2]	79	-	Impact of Canada operations[2]	(1,227)	-	(474)	-	(776)	-	(56)	-
Stock-based compensation	3,737	2,968	Stock-based compensation	-	-	(104)	(5)	(3,444)	(2,822)	(189)	(141)
Asset impairments[3]	-	2,737	Asset impairments[3]	-	-	-	(363)	-	-	-	-
Excess of fair value over cost of acquired inventory	48	3,743	Excess of fair value over cost of acquired inventory	-	-	(48)	(3,743)	-	-	-	-
Novitium transaction expenses	(31)	4,319	Novitium transaction expenses	-	-	-	-	31	(4,319)	-	-
Royalty settlement	-	1,934	Royalty settlement	-	-	-	(1,934)	-	-	-	-
Adjusted non-GAAP EBITDA [4]	$ 23,329	$ 7,212	As adjusted:	$ 93,005	$ 60,929	$ 35,700	$ 27,853	$ 28,999	$ 23,565	$ 4,977	$ 2,999

	Twelve Months Ended December 31,			Reconciliation of certain adjusted non-GAAP accounts:							
				Net Revenues		Cost of sales (excl. depreciation and amortization)		Selling, general, and administrative expenses		Research and development expenses	
				Twelve Months Ended December 31,		Twelve Months Ended December 31,		Twelve Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021		2022	2021	2022	2021	2022	2021	2022	2021
Net Loss	$ (47,896)	$ (42,603)	As reported:	$ 316,385	$ 216,136	$ 138,785	$ 100,610	$ 124,044	$ 84,294	$ 22,318	$ 11,369
Add/(Subtract):											
Interest expense, net	28,052	11,922									
Other expense, net[1]	80	6,243									
Benefit for income taxes	(14,769)	(13,455)									
Depreciation and amortization	56,972	47,252									
Contingent consideration fair value adjustment	3,758	500									
Legal settlement expense	-	8,750									
Intangible asset impairment charge	112	-									
Restructuring activities	5,679	-									
Impact of Canada operations[2]	2,740	-	Impact of Canada operations[2]	(3,241)	-	(2,404)	-	(3,374)	-	(203)	-
Stock-based compensation	14,599	10,489	Stock-based compensation	-	-	(546)	(20)	(13,302)	(9,905)	(751)	(564)
Asset impairments[3]	-	2,737	Asset impairments[3]	-	-	-	(363)	-	-	-	-
Excess of fair value over cost of acquired inventory	5,294	7,460	Excess of fair value over cost of acquired inventory	-	-	(5,294)	(7,460)	-	-	-	-
Novitium transaction expenses	1,244	9,382	Novitium transaction expenses	-	-	-	-	(1,244)	(9,382)	-	-
Royalty settlement	-	1,934	Royalty settlement	-	-	-	(1,934)	-	-	-	-
Adjusted non-GAAP EBITDA [4]	$ 55,865	$ 50,611	As adjusted:	$ 313,144	$ 216,136	$ 130,541	$ 90,833	$ 106,124	$ 65,007	$ 21,364	$ 10,805

[1] Adjustment to other expense, net excludes $750 thousand of income related to the sale of an ANDA during the three months ended December 31, 2021, and excludes $750 thousand and $1.9 million of income related to the sale of an ANDA during the twelve months ended December 31, 2022 and 2021, respectively.

[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, 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.

[3] For the three and twelve months ended December 31, 2021, Asset impairments is comprised of an ANDA intangible asset impairment and related inventory reserve charge.

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

- For the twelve month period ended December 31, 2022, non-GAAP financial measures have been recast to include $1.2 million of incremental R&D expense and a corresponding reduction in full year Adjusted non-GAAP EBITDA as compared to the amount reported in our third quarter 2022 earnings release and associated Form 8-K.

- For the three month period ended December 31, 2021, non-GAAP results have been recast to include $9.0 million of Cortrophin related SG&A expense and a corresponding reduction in full year Adjusted non-GAAP EBITDA of $9.0 million.

- For the twelve month period ended December 31, 2021, non-GAAP results have been recast to include $780K of additional Purified Cortrophin Gel pre-launch charges and $13.4 million of Cortrophin related SG&A expense, and a corresponding reduction in full year Adjusted non-GAAP EBITDA of $14.2

million.

ANI Pharmaceuticals, Inc. and Subsidiaries
Table 4: Adjusted non-GAAP Net Income and Adjusted non-GAAP Diluted Earnings per Share Reconciliation
(unaudited, in thousands, except per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
Net Loss Available to Common Shareholders	$ (4,650)	$ (24,136)	$ (49,521)	$ (42,603)
Add/(Subtract):				
Non-cash interest expense	982	771	3,865	2,415
Depreciation and amortization expense	14,484	13,684	56,972	47,252
Contingent consideration fair value adjustment	1,624	500	3,758	500
Restructuring activities	1,568	-	5,679	-
Legal settlement expense	-	350	-	8,750
Intangible asset impairment charge	-	-	112	-
Impact of Canada operations[(1)]	79	-	2,740	-
Asset impairments[(2)]	-	2,737	-	2,737
Stock-based compensation	3,737	2,968	14,599	10,489
Excess of fair value over cost of acquired inventory	48	3,743	5,294	7,460
Credit facility ticking fee expense	-	1,781	-	4,216
Novitium transaction expenses	(31)	4,319	1,244	9,382
Royalty settlement	-	1,934	-	1,934
Less:				
Estimated tax impact of adjustments (calc. at 24%)	(5,398)	(7,869)	(22,623)	(22,832)
Adjusted non-GAAP Net Income Available to Common Shareholders [(3)]	$ 12,443	$ 782	$ 22,119	$ 29,700
Diluted Weighted-Average Shares Outstanding	16,325	14,169	16,260	12,596
Adjusted Diluted Weighted-Average Shares Outstanding	16,357	14,215	16,282	12,618
Adjusted non-GAAP Diluted Earnings per Share	$ 0.76	$ 0.06	$ 1.36	$ 2.35

[(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)] For the three and twelve months ended December 31, 2021, Asset impairments is comprised of an ANDA intangible asset impairment and related inventory reserve charge.

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

- For the period ended December 31, 2022, non-GAAP financial measures have been recast to include $1.2 million of incremental R&D expense and a related reduction in full year Adjusted non-GAAP Diluted Earnings per Share of $0.06 as compared to amount reported in our third quarter 2022 earnings release and associated Form 8-K.

- For the three month period ended December 31, 2021, non-GAAP results have been recast to include $9.0 million of Cortrophin related SG&A expense and a corresponding reduction in full year Adjusted non-GAAP Diluted Earnings per Share of $0.48, resulting in a revised three months ended December 31, 2021 Adjusted non-GAAP Diluted Earnings per share of $0.06.

- For the period ended December 31, 2021, non-GAAP results have been recast to include $780K of additional Purified Cortrophin Gel pre-launch charges and $13.4 million of Cortrophin related SG&A expense, and a related reduction in full year Adjusted non-GAAP Diluted Earnings per Share of $0.86, resulting in a revised 2021 Adjusted non-GAAP Diluted Earnings per Share of $2.35.