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): November 8, 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 November 8, 2023, ANI Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2023. 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 November 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: November 8, 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 Third Quarter 2023 Financial Results and Raises Full-Year 2023 Guidance

Third Quarter 2023 Financial Results

-- Record quarterly net revenues of $131.8 million, representing year-over-year growth of 57.3%; net income available to common shareholders of $9.5 million and diluted GAAP income per share of $0.45 --

-- Record quarterly adjusted non-GAAP EBITDA of $36.5 million representing year-over-year growth of 98.3%; adjusted non-GAAP diluted earnings per share of $1.27 --

-- Lead Rare Disease asset, Purified Cortrophin® Gel (Repository Corticotrophin Injection USP) 80 U/ml (Cortrophin Gel) reported net sales of $29.7 million, a year-over-year increase of 135.9% --

-- Generics, Established Brands and Other reported net sales of $102.1 million, representing year-over-year growth of 43.4% --

Full Year 2023 Guidance

-- Company raises guidance: net revenue to $468 million to $478 million from $425 million to $445 million; adjusted non-GAAP EBITDA to $128 million to $133 million from $115 million to $125 million; adjusted non-GAAP earnings per share to $4.29 to $4.57 from $3.62 to $4.11--

-- Company is raising Cortrophin Gel specific revenue guidance to $100 million to $107 million from $90 million to $100 million, representing 139.9% to 156.7% 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 49.5%, adjusted non-GAAP EBITDA of 133.6%, and adjusted non-GAAP earnings per diluted share of 225.7% --

Company Highlights

-- Continued strong momentum for Cortrophin Gel; record number of new patient starts and new cases initiated in the third quarter of 2023; ACTH market posted six consecutive quarters of year-over-year growth according to IQVIA --

-- Continued increase in new unique prescribers, including growth with prescribers who are naive to ACTH therapy; ongoing strength in targeted specialties of neurology, nephrology, rheumatology and continued gains in pulmonology --

-- Announced FDA approval and commercial availability of new 1-mL vial size of Cortrophin Gel, the only approved purified corticotropin indicated for the treatment of acute gouty arthritis flares; received specific J-Code to support physician administration of 1 ml vial --

-- Company's Generics and Established Brands businesses continued to respond to pharmaceutical shortages arising from supply-chain disruptions by leveraging the Company's operational excellence and U.S.-based manufacturing footprint; softening seen with specific market opportunities that persisted in prior quarters --

-- Company's strong R&D organization delivered five new product launches and filed three new ANDAs and two new 505(b)(2) applications in the quarter; retained number two ranking in Competitive Generic Therapy (CGT) approvals --

-- Generated $74.2 million in cash from operating activities (year-to-date), ending Q3 with $193.1 million in cash --

BAUDETTE, Minn.--(BUSINESS WIRE) – November 8, 2023 – ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) (ANI or the Company) today announced business highlights and financial results for the three months ended September 30, 2023.

Nikhil Lalwani, President and CEO of ANI stated, "Strong execution has resulted in another record quarter for revenue and adjusted non-GAAP EBITDA, positioning us to raise full year 2023 guidance for the third consecutive quarter. Launch momentum of our lead Rare Disease asset, Purified Cortrophin Gel, continues to accelerate, with record quarterly new cases initiated and new patient starts, and increasing momentum with new unique prescribers, including many prescribers who were naive to ACTH therapy. In addition, the Company has received positive initial physician response in our new areas of pulmonology and acute gouty arthritis. We remain committed to increasing the scope and scale of our Rare Disease portfolio and believe that the strength of our financial results and cash flow position us well for targeted M&A and in-licensing."

“Our Generics and Established Brands businesses also performed well, delivering record quarterly revenues, and we continued to leverage our operational excellence and U.S.-based manufacturing footprint to serve patients facing pharmaceutical shortages due to supply chain disruptions. While we see softening of specific market opportunities that persisted in prior quarters, we believe we are poised to capitalize on current and future opportunities as a partner of choice for our customers. Our strong R&D capabilities were further demonstrated through the launch of five new products as well as the filing of three ANDAs and two 505(b)2 applications during the quarter. As we approach the end of 2023, I believe that our efforts during the year have created a strong foundation for continued success and fulfilling our purpose of Serving Patients, Improving Lives,” concluded Lalwani.

Third Quarter 2023 Financial Highlights:

- Net revenues were $131.8 million compared to $83.8 million in Q3 2022.
- GAAP net income available to common shareholders was $9.5 million, and diluted GAAP income per share was $0.45.
- Adjusted non-GAAP EBITDA was $36.5 million compared to $18.4 million in Q3 2022.
- Adjusted non-GAAP diluted earnings per share was $1.27, compared to diluted earnings per share of $0.58 in Q3 2022.
- Cash and cash equivalents were $193.1 million with year-to-date (nine month) cash flow from operations of $74.2 million.

Third Quarter and Recent Business Highlights:

Rare Disease Business Update

Revenues for our lead asset, Cortrophin Gel, totaled $29.7 million for the third quarter of 2023, an increase of 135.9% over the same period in 2022, driven by increased volume in this second year of launch. During the quarter, the Company achieved a record number of new cases initiated and new patient starts, and a continued increase in the number of new unique and repeat prescribers. Many of the new unique prescribers were naive to ACTH therapy. We believe the Company’s efforts to increase effectiveness of the field sales force and improve awareness of ACTH therapy for appropriate patients have yielded results. Since the launch of Cortrophin Gel, the overall ACTH category has experienced six consecutive quarters of year-over-year growth from second quarter 2022 to third quarter 2023.

Growth continued across both the initially targeted specialties of neurology, rheumatology, and nephrology, and two new areas. The Company saw positive physician response and momentum in pulmonology, a focus area that was initiated in the second quarter of 2023. The Company also announced the FDA approval and commercial availability of a 1-mL vial size of Purified Cortrophin® Gel for adjunctive treatment of certain patients with acute gouty arthritis flares. Recently, the Company received a specific J-Code for Cortrophin to support physician administration of the 1 ml vial. The commercial launch of the 1 ml vial is supported by ANI’s existing field sales force.

The Company is raising its 2023 revenue guidance for Cortrophin Gel to $100 million to $107 million, representing 139.9% - 156.7% year-over-year growth.

We continue to believe that Rare Disease remains ANI's largest future growth driver, and the Company is actively exploring opportunities to acquire assets and/or establish partnerships to increase the scope and scale of its Rare Disease platform.

Generics Business, Established Brands and Other Update

Sales of generic pharmaceuticals products, established brands and other grew 43.4% year-over-year in the third quarter of 2023. We believe that the Company's generics business is well positioned for delivering sustainable growth, driven by a strong R&D organization launching new products, cost competitiveness and supply reliability. During the quarter, ANI launched five products, including Colestipol Hydrochloride Tablets, Estradiol Gel, 0.1% and Thyroid Tablets, USP, filed five new ANDAs and two 505(b)2 applications, while maintaining its number two ranking in Competitive Generic Therapy approvals.

ANI continued to leverage its operational excellence and U.S.-based manufacturing during the quarter to take advantage of certain opportunities arising from supply disruptions in both generics and established brands. Recently, certain of these market conditions changed, and as a result, we expect fourth quarter 2023 demand and resultant revenues for certain generic and established brand products to be significantly lower as compared to the rate achieved during the first nine months of 2023. We remain well positioned to take advantage of current and future opportunities when they arise. In fact, to support the ongoing growth of the Generics, Established Brands and Other business segment, the Company has invested in expanding the manufacturing footprint and capacities at its New Jersey facility and expects these to be operational by early 2024.

Third Quarter 2023 Financial Results

	Three Months Ended September 30,			
(in thousands)	2023	2022	Change	% Change
Generics, Established Brands, and Other Segment				
Generic pharmaceutical products	$ 70,593	$ 53,136	$ 17,457	32.9 %
Established brand pharmaceutical products, royalties, and other pharmaceutical services	31,502	18,083	13,419	74.2 %
Generics, established brands, and other segment total net revenues	$ 102,095	$ 71,219	$ 30,876	43.4 %
Rare Disease Segment				
Rare disease pharmaceutical products	29,734	12,602	17,132	135.9 %
Total net revenues	$ 131,829	$ 83,821	$ 48,008	57.3 %

Net revenues for generic pharmaceutical products were $70.6 million during the three months ended September 30, 2023, an increase of 32.9% compared to $53.1 million for the same period in 2022, driven by increased volumes on the base business and the inclusion of 2022 launches and new product launches in 2023. From a product perspective, the increase was principally driven by revenues from year over year increases in products such as Colestipol, Famotidine, Mixed Amphetamine Salts Extended Release, Nitrofurantoin, Thyroid and various other products tempered by a decrease in revenues of Fenofibrate, Nebivolol, and Prazosin, among others.

Net revenues for established brand pharmaceutical products, royalties, and other pharmaceutical services were $31.5 million during the three months ended September 30, 2023, an increase of 74.2% compared to $18.1 million for the same period in 2022, driven by a net increase in volume.

Net revenues of Rare Disease pharmaceutical products, which consist entirely of sales of Cortrophin Gel, were $29.7 million during the three months ended September 30, 2023, an increase of $17.1 million from $12.6 million for the same period in 2022. This increase was driven by increased volume in this second year of launch (product was launched in late January 2022).

Operating expenses increased by 28.2% to $113.9 million for the three months ended September 30, 2023, from $88.8 million in the prior year period as a result of the following factors:

For the three months ended September 30, 2023, cost of sales increased to $48.1 million from $32.9 million for the same period in 2022, an increase of $15.2 million, or 46.2%, primarily due to a significant growth in sales volumes of generic and Rare Disease pharmaceutical products.

Research and development expenses increased from $7.7 million to $11.1 million for the three months ended September 30, 2023, an increase of $3.5 million or 45.2%, primarily due to expenses related to a 505(b)(2) filing for one product of approximately $1.6 million, and a higher level of activity associated with ongoing and new projects in the three months ended September 30, 2023.

Selling, general, and administrative expenses increased from $30.1 million to $42.0 million for the three months ended September 30, 2023, an increase of $11.9 million, or 39.6%, primarily due to increased employment related costs, legal expenses, as well as an overall increase in activities required to support the growth in our business.

Depreciation and amortization expense was $15.2 million for the three months ended September 30, 2023, compared to $14.2 million for the same period in 2022, an increase of $1.0 million, primarily due to the amortization of intangible assets acquired in the Slayback and Akorn asset acquisitions, and amortization of acquired in-process research, and development ("IPR&D") which commenced during the quarter.

We recognized a gain of $(2.6) million and loss of $2.5 million in the three months ended September 30, 2023 and 2022, respectively, for the contingent consideration fair value adjustment. The change in the fair value adjustment is primarily related to a change in the anticipated cash flows, specifically extending the timeframe over which cash flows will be generated by the products, and the passage of time (i.e., moving closer to the anticipated payment date of the consideration), and an increase to the probability of payment for the product development-based milestone payments.

The Company recognized restructuring activities of $1.5 million of expense in the three months ended September 30, 2022, in relation to the closure of its Oakville, Ontario, Canada facility. Costs included $0.3 million in termination benefits, $1.2 million in fixed asset impairments and accelerated depreciation. There were no restructuring expenses in the three

months ended September 30, 2023. Manufacturing operations ceased at the Oakville, Ontario, site in January 2023, with the successful relocation of the Oakville products to U.S. facilities. On November 6, 2023, the Company entered into an agreement for the purchase and sale of the Oakville, Ontario site, at a total purchase price of $17.85 million Canadian dollars, or approximately $13.0 million US dollars based on the current exchange rate, subject to certain market adjustments. Closing of the sale is expected to occur in the first quarter of 2024.

Net income available to common shareholders for the third quarter of 2023 was $9.5 million as compared to net loss of $(9.0) million in the prior year period. Diluted earnings per share for the three months ended September 30, 2023, was $0.45 compared to diluted GAAP loss per share of $(0.55) in the prior year period.

Adjusted non-GAAP diluted earnings per share was $1.27 in the third quarter of 2023 compared to diluted earnings per share of $0.58 in the third 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 September 30, 2023, the Company had $193.1 million in unrestricted cash and cash equivalents, $178.8 million in net accounts receivable and $294.8 million (face value) in outstanding debt. The Company generated year-to-date cash flow from operations of $74.2 million.

2023 Financial Guidance Upward Revisions

	Revised Full Year 2023 Guidance	Prior Full Year 2023 Guidance	Prior Year Actual	Growth
Net Revenue (total Company)	$468 million - $478 million	$425 million - $445 million	$316.4 million	47.9% - 51.1%
Cortrophin Gel Net Revenue	$100 million - $107 million	$90 million - $100 million	$41.7 million	139.9% - 156.7%
Adj. Non-GAAP Gross Margin	63.0% to 63.8%	63% to 64.8%	58.3%	4.7 pts to 5.5 pts
Adjusted Non-GAAP EBITDA	$128 million - $133 million	$115 million - $125 million	$55.9 million	129.1% - 138.1%
Adjusted Non-GAAP Diluted EPS	$4.29 - $4.57	$3.62 - $4.11	$1.36	215.4% - 236.0%

In addition, ANI currently anticipates between 19.2 million and 19.3 million shares outstanding for purpose of calculating EPS and a U.S. GAAP effective tax rate of between approximately 9.0% to 13.0%. The Company will continue to tax affect adjustments for computation of adjusted non-GAAP diluted earnings per share at a tax rate of 24.0%.

Conference Call

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

Date Wednesday, November 8, 2023
Time 8:30 a.m. ET
Toll free (U.S.) 800-445-7795

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 800-839-6737 and entering access code 4379958.

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 difficulties finding a buyer for the plant and property resulting from the closure of our Oakville, Ontario manufacturing plant; and general business and economic conditions, such as inflationary pressures, geopolitical conditions including but not limited to the conflict between Russia and the Ukraine, the conflict between Israel and Gaza, 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 September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Net Revenues	$ 131,829	$ 83,821	$ 355,162	$ 222,153
Operating Expenses				
Cost of sales (excluding depreciation and amortization)	48,101	32,894	128,093	102,459
Research and development	11,121	7,657	24,419	17,096
Selling, general, and administrative	42,007	30,081	117,235	90,856
Depreciation and amortization	15,207	14,167	44,597	42,488
Contingent consideration fair value adjustment	(2,555)	2,476	(559)	2,134
Restructuring activities	—	1,541	1,132	4,111
Intangible asset impairment charge	—	—	—	112
Total Operating Expenses	113,881	88,816	314,917	259,256
Operating Income (Loss)	17,948	(4,995)	40,245	(37,103)
Other Expense, net				
Interest expense, net	(6,398)	(7,264)	(21,194)	(20,546)
Other (expense) income, net	(39)	37	(126)	712
Income (Loss) Before Income Tax (Expense) Benefit	11,511	(12,222)	18,925	(56,937)
Income tax (expense) benefit	(1,571)	3,622	(1,301)	13,284
Net Income (Loss)	$ 9,940	$ (8,600)	$ 17,624	$ (43,653)
Dividends on Series A Convertible Preferred Stock	(406)	(406)	(1,219)	(1,218)
Net Income (Loss) Available to Common Shareholders	$ 9,534	$ (9,006)	$ 16,405	$ (44,871)
Basic and Diluted Income (Loss) Per Share:				
Basic Income (Loss) Per Share	$ 0.46	$ (0.55)	$ 0.84	$ (2.76)
Diluted Income (Loss) Per Share	$ 0.45	$ (0.55)	$ 0.83	$ (2.76)
Basic Weighted-Average Shares Outstanding	18,883	16,303	17,663	16,238
Diluted Weighted-Average Shares Outstanding	19,125	16,303	17,823	16,238

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

	September 30, 2023	December 31, 2022
Current Assets		
Cash and cash equivalents	$ 193,078	$ 48,228
Current restricted cash	—	5,006
Accounts receivable, net	178,842	165,438
Inventories	106,590	105,355
Prepaid income taxes	—	3,827
Assets held for sale	8,020	8,020
Prepaid expenses and other current assets	10,690	8,387
Total Current Assets	497,220	344,261
Non-current Assets		
Property and equipment, net	44,189	43,246
Deferred tax assets, net of deferred tax liabilities and valuation allowance	84,389	81,363
Intangible assets, net	219,828	251,635
Goodwill	28,221	28,221
Derivatives and other non-current assets	16,067	11,361
Total Assets	$ 889,914	$ 760,087
Current Liabilities		
Income taxes payable	$ 594	$ —
Current debt, net of deferred financing costs	850	850
Accounts payable	34,077	29,305
Accrued royalties	11,975	9,307
Accrued compensation and related expenses	15,328	10,312
Accrued government rebates	10,923	10,872
Returned goods reserve	31,438	33,399
Current contingent consideration	23,939	—
Accrued expenses and other	5,228	5,394
Total Current Liabilities	134,352	99,439
Non-current Liabilities		
Non-current debt, net of deferred financing costs and current component	285,032	285,669
Non-current contingent consideration	10,560	35,058
Other non-current liabilities	5,259	1,381
Total Liabilities	$ 435,203	$ 421,547
Mezzanine Equity		
Convertible Preferred Stock, Series A	24,850	24,850
Stockholders' Equity		
Common Stock	2	1
Treasury stock	(9,850)	(5,094)
Additional paid-in capital	506,513	403,901
Accumulated deficit	(80,880)	(97,286)
Accumulated other comprehensive income, net of tax	14,076	12,168
Total Stockholders' Equity	429,861	313,690
Total Liabilities, Mezzanine Equity, and Stockholders' Equity	$ 889,914	$ 760,087

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 September 30,			Reconciliation of certain adjusted non-GAAP accounts:							
				Net Revenues		Cost of sales (excluding depreciation and amortization)		Selling, general, and administrative expenses		Research and development expenses	
				Three Months Ended September 30,		Three Months Ended September 30,		Three Months Ended September 30,		Three Months Ended September 30,	
	2023	2022		2023	2022	2023	2022	2023	2022	2023	2022
Net Income (Loss)	$ 9,940	$ (8,600)	As reported:	$ 131,829	$ 83,821	$ 48,101	$ 32,894	$ 42,007	$ 30,081	$ 11,121	$ 7,657
Add/(Subtract):											
Interest expense, net	6,398	7,264									
Other expense (income), net	39	(37)									
Income tax expense (benefit)	1,571	(3,622)									
Depreciation and amortization	15,207	14,167									
Contingent consideration fair value adjustment	(2,555)	2,476									
Restructuring activities	—	1,541									
Impact of Canada operations (1)	275	840	Impact of Canada operations (1)	—	(969)	(128)	(681)	(147)	(1,052)	—	(76)
Stock-based compensation	5,444	3,869	Stock-based compensation	—	—	(182)	(149)	(5,023)	(3,524)	(239)	(196)
Excess of fair value over cost of acquired inventory	—	443	Excess of fair value over cost of acquired inventory	—	—	—	(443)	—	—	—	—
Novitium transaction expenses	165	59	Novitium transaction expenses	—	—	—	—	(165)	(59)	—	—
Adjusted non-GAAP EBITDA	$ 36,484	$ 18,400	As adjusted:	$ 131,829	$ 82,852	$ 47,791	$ 31,621	$ 36,672	$ 25,446	$ 10,882	$ 7,385

(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 (complete as of March 31, 2023) and the sale of the facility (on-going as of September 30, 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.

	Nine Months Ended September 30,			Reconciliation of certain adjusted non-GAAP accounts:							
				Net Revenues		Cost of sales (excluding depreciation and amortization)		Selling, general, and administrative		Research and development	
				Nine Months Ended September 30,		Nine Months Ended September 30,		Nine Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022		2023	2022	2023	2022	2023	2022	2023	2022
Net Income (Loss)	$ 17,624	$ (43,653)	As reported:	$ 355,162	$ 222,153	$ 128,093	$ 102,459	$ 117,235	$ 90,856	$ 24,419	$ 17,096
Add/(Subtract):											
Interest expense, net	21,194	20,546									
Other expense (income), net (1)	126	38									
Income tax expense (benefit)	1,301	(13,284)									
Depreciation and amortization	44,597	42,488									
Contingent consideration fair value adjustment	(559)	2,134									
Intangible asset impairment charge	—	112									
Restructuring activities	1,132	4,111									
Impact of Canada operations(2)	2,414	2,661	Impact of Canada operations(2)	(565)	(2,014)	(1,833)	(1,930)	(1,073)	(2,598)	(73)	(147)
Stock-based compensation	15,031	10,862	Stock-based compensation	—	—	(521)	(442)	(13,839)	(9,858)	(671)	(562)
Excess of fair value over cost of acquired inventory	—	5,246	Excess of fair value over cost of acquired inventory	—	—	—	(5,246)	—	—	—	—
Novitium transaction expenses	757	1,276	Novitium transaction expenses	—	—	—	—	(757)	(1,276)	—	—
Adjusted non-GAAP EBITDA	$103,617	$ 32,537	As adjusted:	$ 354,597	$ 220,139	$ 125,739	$ 94,841	$ 101,566	$ 77,124	$ 23,675	$ 16,387

(1) Adjustment to other expense (income), net excludes $750 thousand related to the sale of an ANDA during the nine months ended September 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 (complete as of March 31, 2023) and the sale of the facility (on-going as of September 30, 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net Income (Loss) Available to Common Shareholders	$ 9,534	$ (9,006)	$ 16,405	$ (44,871)
Add/(Subtract):				
Non-cash interest expense	856	963	2,530	2,883
Depreciation and amortization	15,207	14,167	44,597	42,488
Contingent consideration fair value adjustment	(2,555)	2,476	(559)	2,134
Restructuring activities	—	1,541	1,132	4,111
Intangible asset impairment charge	—	—	—	112
Impact of Canada operations(1)	275	840	2,414	2,661
Stock-based compensation	5,444	3,869	15,031	10,862
Excess of fair value over cost of acquired inventory	—	443	—	5,246
Novitium transaction expenses	165	59	757	1,276
Less:				
Estimated tax impact of adjustments (calc. at 24%)	(4,654)	(5,846)	(15,816)	(17,226)
Adjusted non-GAAP Net Income Available to Common Shareholders (2)	$ 24,272	$ 9,506	$ 66,491	$ 9,676
Diluted Weighted-Average				
Shares Outstanding	19,125	16,303	17,823	16,238
Adjusted Diluted Weighted-Average				
Shares Outstanding	19,125	16,317	17,823	16,252
Adjusted non-GAAP				
Diluted Earnings per Share	$ 1.27	$ 0.58	$ 3.73	$ 0.60

(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 (complete as of March 31, 2023) and the sale of the facility (on-going as of September 30, 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.