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

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of Earliest Event Reported): May 14, 2024

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 May 14, 2024, Nikhil Lalwani, President & CEO of ANI Pharmaceuticals, Inc., participated in a panel discussion at the Capital One Securities 1st Annual Biotech/Biopharma Disruptors Event in New York City. A copy of the investor presentation is attached as Exhibit 99.1 hereto and incorporated herein by reference.*

Item 7.01 **Regulation FD Disclosure**

The information included under Item 2.02 of this Current Report on Form 8-K is incorporated into this Item 7.01 by reference.*

Item 9.01 **Exhibits**

(d) Exhibits

Exhibit No.	**Description**
99.1	Investor Presentation, dated May 14, 2024
104	Cover Page Interactive Data File (embedded with the Inline XBRL document)

* The information in Item 2.02 of this Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

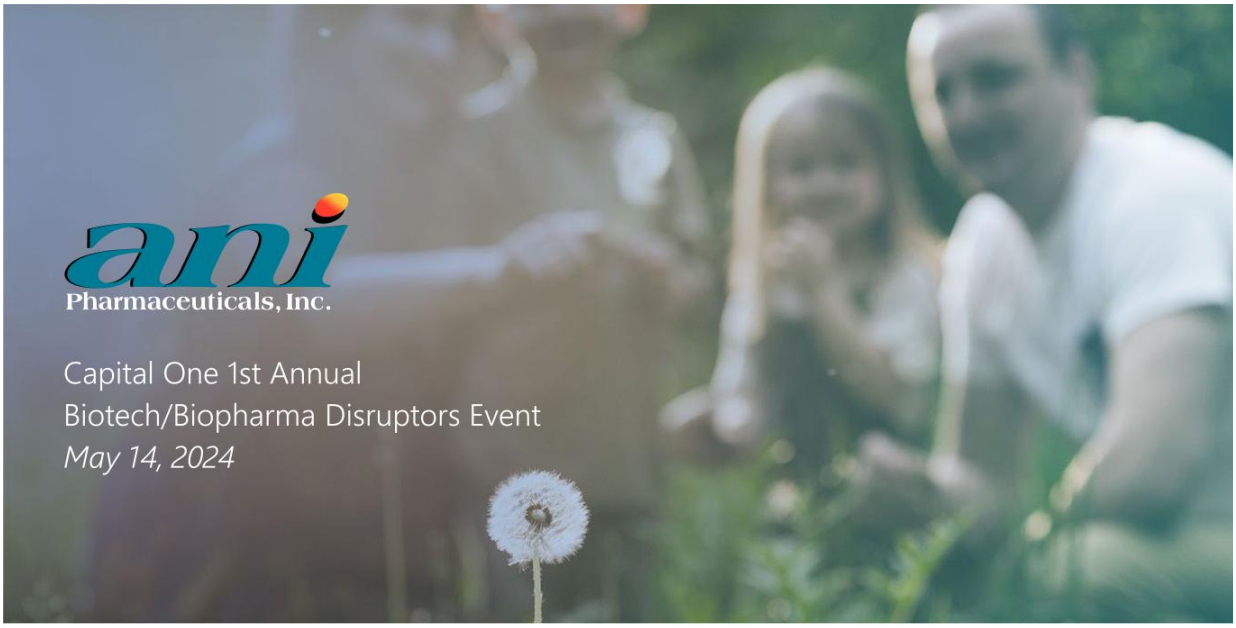
SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: May 14, 2024

ANI PHARMACEUTICALS, INC.

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



Disclaimer

To the extent any statements made in this presentation 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: Cortrophin Gel is our first rare disease pharmaceutical product; to the extent we are not able to continue to achieve commercial success with this product, including expanding the market and gaining market share, our business, financial condition, and results of operations will be negatively impacted; our approved products, including Cortrophin Gel, may not achieve commercialization at levels of market acceptance that will continue to allow us to achieve profitability; acquisitions and other investments could disrupt our business and harm our financial position and operating results; the limited number of suppliers for our active pharmaceutical ingredients could result in lengthy delays in production if we need to change suppliers; delays or failure in obtaining or 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; acceptance of our products at levels that will allow us to achieve profitability; 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; 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; 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; 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, or conflicts relating to attacks on cargo ships in the Red Sea, and the effects and duration of outbreaks of public health emergencies, 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.

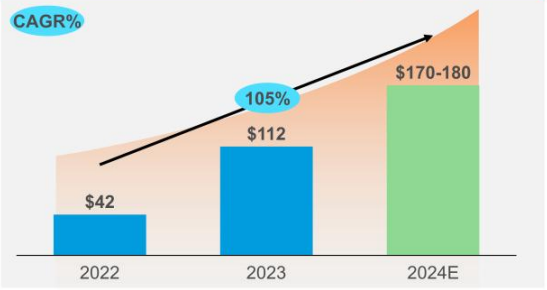
More detailed information on these and additional factors that could affect the Company's actual results are described in the Company's filings with the Securities and Exchange Commission (SEC), including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as other filings with the SEC. All forward-looking statements in this presentation speak only as of the date of this presentation 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.

Non-GAAP Financial Measures

This presentation includes certain non-GAAP financial measures, including Adjusted EBITDA and Adjusted Earnings Per Share (Adjusted EPS), that management reviews to evaluate its business, measure its performance and make strategic decisions. Management believes that such non-GAAP financial measures provide useful information to investors and others in understanding and evaluating its operating results in the same manner as management. Adjusted non-GAAP EBITDA is defined as net income (loss), excluding tax expense or benefit, interest expense, (net), other expense, (net), depreciation, amortization, non-cash stock-based compensation expense, Novitium transaction expenses, contingent consideration fair value adjustment, unrealized gain on our investment in equity securities, gain on sale of the former Oakville, Ontario manufacturing site, litigation expenses related to certain matters, and certain other items that vary in frequency and impact on ANI's results of operations. Adjusted non-GAAP net income (loss) is defined as net income (loss), non-cash stock-based compensation expense, Novitium transaction expenses, non-cash interest expense, depreciation and amortization expense, contingent consideration fair value adjustment, unrealized gain on our investment in equity securities, gain on sale of the former Oakville, Ontario manufacturing site, litigation expenses related to certain matters, 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. Adjusted non-GAAP diluted (loss)/earnings per share is defined as adjusted non-GAAP net income (loss) divided by the diluted weighted average shares outstanding during the period. Adjusted EBITDA, Adjusted EPS and any other ratio or metrics derived therefrom are financial measures not calculated in accordance with GAAP and should not be considered as substitutes for revenue, net income, operating profit, or any other operating performance measure calculated in accordance with GAAP. Using these non-GAAP financial measures to analyze the business would have material limitations because their calculations are based on the subjective determination of management regarding the nature and classification of events and circumstances that investors may find significant. In addition, although other companies in its industry may report measures titled Adjusted EBITDA or similar measures, such non-GAAP financial measures may be calculated differently from how management calculates its non-GAAP financial measures, which reduces their overall usefulness as comparative measures. Because of these limitations, you should consider Adjusted EBITDA and Adjusted EPS alongside other financial performance measures, including net income and other financial results presented in accordance with GAAP. Please refer to the Appendix in this presentation for a reconciliation of the non-GAAP financial measure to the most directly comparable GAAP measure. ANI is not providing a reconciliation for the forward-looking full year 2024 adjusted non-GAAP measures 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.

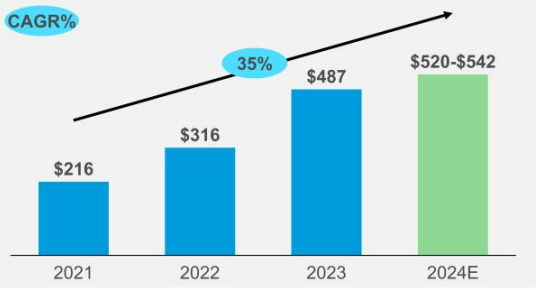
ANI Pharmaceuticals: Rare Disease Business expected to be the largest driver of growth

Rare Disease Revenues ($ millions)



Rare Disease business with lead asset **Purified Cortrophin® Gel** and expansion through M&A and in-licensing

Total Company Revenues ($ millions)



Ex-Rare Disease Business Units

Generics with enhanced R&D capabilities driving new product launches; operational excellence

Established brands with unique commercial capability, high margins and strong cash flow generation

*Based on midpoint of 2024 Guidance shared on Q1 2024 earnings call (May 10, 2024)

1. CAGR is calculated based on midpoint

Why Purified Cortrophin® Gel?

Purified Cortrophin® Gel
repository corticotropin injection USP 80 U/mL

Launched
January 2022

- Cortrophin Gel is purified corticotropin (ACTH), a treatment option for patients struggling with certain chronic autoimmune disorder
- Re-introduced a much-needed patient and physician choice into the U.S. ACTH market (only one ACTH product had been available for multiple decades)
- Estimated $600M ACTH market at launch; over $1B+ category at peak; potential for significant future growth among both new and returning prescribers
- Initially launched into the therapeutic areas of neurology, nephrology and rheumatology
- 1 Limited competition (only one other ACTH product on the market)

Investing in the Cortrophin Gel franchise to drive growth in 2024 and beyond

2023 Rare Disease Revenues
$112M

Est. 2024
$170-$180M

+52-61% YoY growth

- Recently launched a targeted **ophthalmology** sales force and added a **second** geographical region to **pulmonology** sales force
- Ophthalmology and pulmonology are expected to meaningfully drive Cortrophin **growth**

- Ongoing efforts to enhance **support** and **remove challenges** for patients starting on ACTH and their healthcare providers

- Plans to use strong balance sheet and well-proven platform to expand through **M&A** and **in-licensing** of commercial or near-commercial products

Rare Disease: Strong finish to 2023 with continued momentum in 2024

Growth in specialties targeted at launch[1]

- Continued prescription growth for original therapeutic areas of **neurology**, **nephrology** and **rheumatology**
- Prescribing momentum across existing and new prescribers

Gaining traction in new therapeutic areas

- Given strong traction in **pulmonology**, added a second geographical region to pulmonology sales force in Q1 2024
- Highest number of new patient starts in Pulmonology in Q1'24
- Deployed a targeted **ophthalmology** sales force in Q1 2024
- Launched 1-mL vial size of Cortrophin Gel during Q4'23, the only approved ACTH therapy indicated for the treatment of **acute gouty arthritis** flares

Expansion of market and Rare Disease platform

- Number of **patients on ACTH therapy** today is substantially lower than a few years ago, with room for significant growth
- Expanding the scope and scale of our Rare Disease business through **M&A and in-licensing** remains a high priority
- ANI has infrastructure and capabilities across medical affairs, patient support, specialty pharmacy distribution, and market access

Highest number of new patients starts in April 2024

2023 Rare Disease Revenues
$112M
169% YoY

Q1 2024 Rare Disease Revenues
$37M
126% YoY

Est. 2024 Rare Disease Revenues
$170-$180M
52%-61% YoY

1. Purified Cortrophin® Gel was launched in January 2022

Focused efforts ongoing to increase scope and scale of Rare Disease business through M&A and in-licensing