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): January 13, 2025

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 January 13, 2025, ANI Pharmaceuticals, Inc. (the "Company") issued a press release announcing select preliminary unaudited financial results for the fourth quarter and fiscal year ended December 31, 2024, as well as preliminary 2025 financial guidance. A copy of the press release is furnished herewith as Exhibit 99.1.*

In addition, on January 14 2025, Nikhil Lalwani, President & CEO of ANI Pharmaceuticals, Inc., will present at the 2025 J.P. Morgan Healthcare Conference in San Francisco, California. A copy of the investor presentation is attached as Exhibit 99.2 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	Press Release of the Company, dated January 13, 2025
99.2	Investor Presentation, dated January 14, 2025
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: January 13, 2025

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 Provides Preliminary Fourth Quarter and 2024 Financial Results and Preliminary 2025 Outlook

- *For full year 2024, the Company expects total net revenues, adjusted non-GAAP EBITDA, and adjusted non-GAAP diluted EPS to be at or above the guidance ranges provided on November 8, 2024*
- *Rare Disease Segment performed in line with expectations, with Purified Cortrophin Gel net revenues of $197.8 million to $198.4 million for the full year 2024 and ILUVIEN and YUTIQ net revenues of $30.4 million to $31.0 million for the post-acquisition period from September 16, 2024 to December 31, 2024, based on preliminary, unaudited results*
- *Established preliminary financial outlook for 2025, including total net revenues of $739 million to $759 million and adjusted non-GAAP EBITDA of $182 million to $192 million*

BAUDETTE, Minn., January 13, 2025 (GLOBE NEWSWIRE) -- ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) (ANI or the Company) today affirmed its prior net revenues, adjusted non-GAAP EBITDA, and adjusted non-GAAP diluted EPS guidance for 2024 and provided its preliminary financial outlook for 2025. Nikhil Lalwani, ANI's President and Chief Executive Officer, will discuss these updates as part of a presentation at the 43rd Annual J.P. Morgan Healthcare Conference on Tuesday, January 14, 2025, at 2:15 PST/5:15 EST.

"We are delighted to share that we had a strong close to 2024, which was a year of significant momentum for our business as we continued to execute on our strategic priorities while adding two important assets to our Rare Disease portfolio through the acquisition of Alimera," said Mr. Lalwani. "We're pleased to report that the integration is on track and that our overall Rare Disease business performed in line with our expectations during the fourth quarter. Looking ahead to 2025, we expect another year of robust growth led by our Rare Disease franchise, which is reflected by our preliminary financial targets. We remain dedicated to our purpose of 'Serving Patients, Improving Lives.'"

Preliminary Fourth Quarter and Full Year 2024 Financial Results

Based on preliminary, unaudited results, ANI expects Purified Cortrophin Gel net revenues of $59.2 million to $59.8 million for the fourth quarter of 2024 and $197.8 million to $198.4 million for the full year 2024. In addition, the company expects combined ILUVIEN and YUTIQ net revenues of $26.6 million to $27.2 million for the fourth quarter of 2024 and $30.4 million to $31.0 million for the post-acquisition period from September 16, 2024 to December 31, 2024.

Additionally, the Company expects full year 2024 total net revenues, adjusted non-GAAP EBITDA, and adjusted non-GAAP diluted EPS to be at or above the guidance ranges provided on November 8, 2024.

The information presented above is unaudited and reflects preliminary estimates subject to the completion of financial closing procedures and any adjustments that may result from the finalization of the quarterly and annual review of the Company's consolidated financial statements. ANI will report its full year 2024 results during its fourth quarter 2024 earnings conference call in late February.

Preliminary Full Year 2025 Outlook

For full year 2025, ANI expects total net revenues of between $739 million and $759 million, representing growth of 24% to 27% as compared to the midpoint of 2024 guidance, and adjusted non-GAAP EBITDA of between $182 million and $192 million.

ANI will provide its full 2025 financial guidance during its fourth quarter 2024 earnings conference call in late February.

Presentation

This financial information was announced in advance of the Company's presentation at the 43rd Annual J.P. Morgan Healthcare Conference on Tuesday, January 14, 2025, at 2:15pm PST/5:15pm EST, in San Francisco. The live and archived webcast will be accessible from the Company's website at www.anipharmaceuticals.com, under the Investors section under Events and Presentations. The replay of the webcast will be accessible for 90 days.

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.

Adjusted non-GAAP EBITDA is defined as net (loss) income, excluding tax provision or benefit, interest expense, net, other expense, net, loss on extinguishment of debt, depreciation and amortization expense, non-cash stock-based compensation expense, M&A transaction and integration expenses, contingent consideration fair value adjustments, unrealized gain on our investment in equity securities, gain on sale of the former Oakville, Ontario manufacturing site, litigation expenses related to certain matters, amortization of certain purchase price adjustments, severance expense, 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.

ANI is not providing a reconciliation for the forward-looking full year 2024 and 2025 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 Diluted Earnings per Share

ANI’s management considers adjusted non-GAAP diluted 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 non-cash stock-based compensation, non-cash interest expense, depreciation and amortization, M&A transaction and integration 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, loss on extinguishment of debt, amortization of certain purchase price adjustments, severance expense, and certain other items that vary in frequency and impact on ANI’s results of operations. Management uses adjusted non-GAAP diluted earnings per share when analyzing Company performance.

Adjusted non-GAAP diluted earnings per share is defined as adjusted non-GAAP net 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 earnings per share should be considered in addition to, but not in lieu of, diluted earnings (loss) per share reported under GAAP.

ANI is not providing a reconciliation for the forward-looking full year 2024 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 committed to its mission of “Serving Patients, Improving Lives" by developing, manufacturing, and commercializing innovative and high-quality therapeutics. The Company is focused on delivering sustainable growth through its Rare Disease business, which markets novel products in the areas of ophthalmology, rheumatology, nephrology, neurology, and pulmonology; its Generics business, which leverages R&D expertise, operational excellence, and U.S.-based manufacturing; and its Established Brands business. For more information, visit 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, 2024 guidance, 2025 guidance, 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: our ability to continue to achieve commercial success with Cortrophin Gel, our first rare disease pharmaceutical product, including expanding the market and gaining market share, our business, financial condition, and results of operations will be negatively impacted; the ability of our approved products, including Cortrophin Gel, and products acquired in the acquisition of Alimera, to achieve commercialization at levels of market acceptance that will continue to allow us to achieve profitability; our ability to complete or achieve any, or all of the intended benefits of acquisitions and investments, including the acquisition of Alimera, in a timely manner or at all; the risks that our acquisitions and investments, including the recent acquisition of Alimera, could disrupt our business and harm our financial position and operating results; delays in production, increased costs and potential loss of revenues if we need to change suppliers due to the limited number of suppliers for our raw materials, active pharmaceutical ingredients, expedients, and other materials; our reliance on single source third party contract manufacturing supply for certain of our key products, including Cortrophin Gel and products acquired in the acquisition of Alimera; 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, United States Drug Enforcement Administration and other regulatory agencies, including among other things, drug recalls, regulatory approvals, facility inspections and potential enforcement actions; 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; the impact of changes or fluctuations in exchange rates; 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 in the Middle East, conflicts related to the 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 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.

Disclaimers

Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of Section 27A of the Act, and Section 21E of the Securities Exchange Act of 1934, as amended. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but are not always, made through the use of words or phrases such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would," or the negative of these words or other comparable terminology. Accordingly, these statements involve estimates, assumptions and uncertainties which could cause actual results to differ materially from those expressed in them. These statements may include, but are not limited to, statements concerning the following: our ability to continue to achieve commercial success with Cortrophin Gel, our first rare disease pharmaceutical product, including expanding the market and gaining market share, our business, financial condition, and results of operations will be negatively impacted; the ability of our approved products, including Cortrophin Gel, and the products acquired in the acquisition of Alimera Sciences, Inc. ("Alimera"), to achieve commercialization at levels of market acceptance that will continue to allow us to achieve profitability; our ability to complete or achieve any, or all of the intended benefits of acquisitions and investments, including the recent acquisition of Alimera, in a timely manner or at all; the risks that our acquisitions and investments, including the recent acquisition of Alimera, could disrupt our business and harm our financial position and operating results; delays in production, increased costs and potential loss of revenues if we need to change suppliers due to the limited number of suppliers for our raw materials, active pharmaceutical ingredients, excipients and other materials; our reliance on single source third party contract manufacturing supply for certain of our key products, including Cortrophin Gel and products acquired in the acquisition of Alimera; delays or failure in obtaining and maintaining approvals by the Food and Drug Administration (the "FDA") of the products we sell; changes in policy or actions that may be taken by the FDA, United States Drug Enforcement Administration, and other regulatory agencies, including among other things, drug recalls, regulatory approvals, facility inspections and potential enforcement actions; 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; the impact of changes or fluctuations in exchange rates; 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; 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 in the Middle East, conflicts related to the 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. You should not rely upon forward-looking statements as predictions of future events. Such statements are based on management's expectations as of the date of this presentation and involve many risks and uncertainties that could cause our actual results, events or circumstances to differ materially from those expressed or implied in our forward-looking statements. We undertake no obligation to update any forward-looking statements made in this presentation to reflect events or circumstances after the date of this presentation or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

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.

Presentation of Financial Information

Non-GAAP Financial Measures

Adjusted non-GAAP EBITDA

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Adjusted non-GAAP Diluted Earnings per Share

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ANI Pharmaceuticals: Rare Disease and Generics drive robust, profitable growth as we fulfill our purpose of Serving Patients, Improving Lives

ani Pharmaceuticals, Inc.

Serving Patients, Improving Lives.

Key Growth Drivers

Rare Disease business with **three** growing and durable commercial assets: **Purified Cortrophin Gel, ILUVIEN** and **YUTIQ.** Portfolio expansion through M&A and in-licensing.

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

Financial Strength

$594-602M
2024 Estimated net revenue[1]

22-24%
Year-over-year net revenue growth[1]

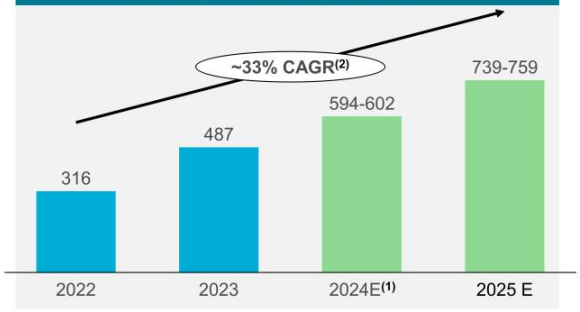
$149-153M
2024 Adjusted Non-GAAP EBITDA[1],[3]

$145M
Cash[2]

1. Based upon 2024 guidance issued on November 8, 2024.
2. As of September 30, 2024.
3. Adj. Non-GAAP EBITDA is a Non-GAAP financial measure.

Delivered superior 2024 performance and well-positioned to continue driving strong growth

Total Company Net Revenues ($ millions)[1]



Adjusted Non-GAAP EBITDA ($ millions)[1],[3]

2024 Highlights & Achievements

- Expect total 2024 Net Revenue, Adjusted non-GAAP EBITDA and adjusted non-GAAP diluted EPS at or above previously announced 2024 guidance
- Lead Rare Disease asset Cortrophin Gel achieved almost $200M of sales in the third year of launch
- Expanded Rare Disease franchise with the acquisition of Alimera
- Launched 17 new generic products and retained #2 ranking in Competitive Generic Therapy (CGT) approvals

1. Based on 2024 financial guidance as issued on November 8, 2024.
2. CAGR calculated using 2022-2025E utilizing mid-point of full year 2025 guidance.
3. Adjusted Non-GAAP EBITDA is a Non-GAAP financial measure.

Momentum continued in 2024 with ANI delivering record results in Q4

Highlights

- Business delivered record results in Q4 2024, with preliminary results in line or higher vs. guidance
- Drove steady gains throughout 2024 for lead Rare Disease asset Cortrophin Gel across core therapeutic areas (rheumatology, neurology, nephrology), with strong traction in newer therapeutic areas (ophthalmology and pulmonology)
- New Rare Disease assets ILUVIEN and YUTIQ performed in-line with guidance for the first full quarter of ownership
- Continued to leverage superior new product launch execution (17 new products launched in 2024), operational excellence, and U.S.-based manufacturing footprint to reliably serve patients in Generics and Established Brands

4Q Total Revenues[1]
$170-178M
↑ 32% YoY

4Q Rare Disease Revenues[2]
$86-87M
↑ 107% YoY

4Q Cortrophin Gel Revenues[2]
$59-60M
↑ 42% YoY

4Q ILUVIEN & YUTIQ Revenues[2]
~$27M

4Q Adj. Non-GAAP EBITDA[1,3]
$43-47M
↑ 49% YoY

1. Based on 2024 financial guidance as issued on November 8, 2024.
2. Based upon preliminary, unaudited Q4 2024 results.
3. Adjusted non-GAAP EBITDA and Adjusted Diluted non-GAAP EPS are non-GAAP financial measures.

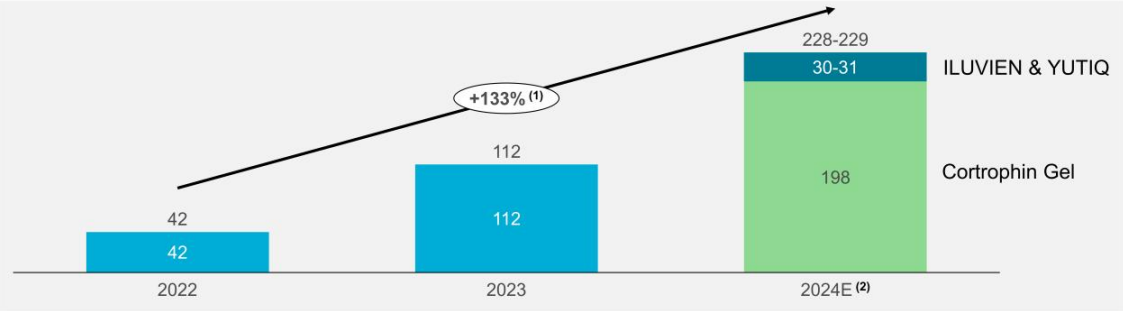
Preliminary 2025 Outlook

Metric ($ millions)	Full Year 2025 Guidance	Mid-Point 2024 Guidance[1]	2025 Growth vs 2024 Guidance Midpoint
Net Revenue (Total Company)	$739 - $759	$598	24 - 27%
Adjusted Non-GAAP EBITDA [2]	$182 - $192	$151	21 - 27%

1. Based upon 2024 financial guidance as issued on November 8, 2024.
2. Adjusted Non-GAAP EBITDA is a Non-GAAP financial measure.

Rare Disease well positioned to continue driving strong growth

Rare Disease Net Revenues ($ millions)[1]



1. 2022-24 CAGR is based on the midpoint of full-year 2024 preliminary, unaudited results
2. Based on full-year 2024 preliminary, unaudited results

ANI Rare Disease markets three therapeutics with growth and durability

	Purified Cortrophin Gel repository corticotropin injection USP 80 U/mL 	ILUVIEN fluocinolone acetonide intravitreal implant 0.19mg 	YUTIQ 0.18 mg fluocinolone acetonide intravitreal implant 0.18 mg
U.S. Indications	FDA-approved ACTH treatment option with 22 indications for patients suffering with specific chronic autoimmune and inflammatory conditions, including multiple sclerosis, rheumatoid arthritis, excess urinary protein due to nephrotic syndrome, acute gouty arthritis flares, and acute and chronic allergic and inflammatory processes involving the eye and its adnexa	Indicated for the treatment of diabetic macular edema (DME) in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure.	Indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.
Ex-US Indications	N/A	For DME and NIU-PS in the Middle East, and 17 European countries	N/A
US Approval Date	**November 2021** *sNDA*	**September 2014**	**October 2018**
		Added via acquisition of Alimera in September 2024	

Rare Disease portfolio focuses on patients not well-served by other therapies

Select Indications

- Idiopathic Nephrotic Syndrome
- Lupus Nephritis
- Systemic Dermatomyositis
- Sarcoidosis
- Keratitis
- Chronic Non-Infectious Uveitis Posterior Segment

Purified Cortrophin Gel repository corticotropin injection USP 80 U/mL

YUTIQ fluocinolone acetonide intravitreal implant 0.18 mg

- Rheumatoid Arthritis
- Multiple Sclerosis
- Systemic Lupus Erythematosus
- Psoriatic Arthritis
- Ankylosing Spondylitis
- Acute Gouty Arthritis
- Diabetic Macular Edema
- Non-Infectious Uveitis

ILUVIEN fluocinolone acetonide intravitreal implant 0.19 mg

Purified Cortrophin Gel repository corticotropin injection USP 80 U/mL

* Based on US FDA considered definition of rare disease - disorders affecting <200 000 persons, translating to a prevalence of 58.5 per 100 000 at current time

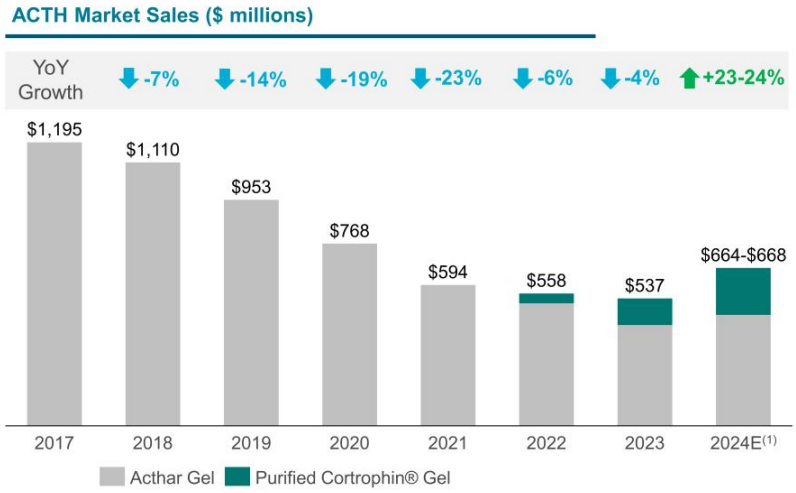
Cortrophin Gel: Primary growth engine for ANI Rare Disease

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 disorders
- 1 Limited competition (only one other ACTH product on the market); long-term sustainability driven by high barriers to entry
- Estimated $600M ACTH market at launch in 2022 and ~$670M in 2024; potential for significant future growth driven by both new and returning prescribers serving appropriate patients
- Approved for multiple indications; initially launched into therapeutic areas of neurology, nephrology and rheumatology; subsequently expanded into ophthalmology and pulmonology
- 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)

ACTH market has returned to growth following the launch of Cortrophin Gel



- Following launch of Cortrophin Gel in 2022, the ACTH class stabilized after years of volume decline and returned to double-digit growth in 2024
- ACTH market is expected to grow >20% in 2024 on a dollar basis
- Number of patients on ACTH therapy today is substantially lower than several years ago, with potential for significant growth

1. Full year 2024 Cortrophin Gel net revenues based on preliminary unaudited results. MNK expects ~10% growth for Acthar Gel in 2024 per its third quarter 2024 earnings release (Nov 5, 2024). ACTH market sales of $664-668 million for 2024E is based on Cortrophin Gel preliminary unaudited revenues + Acthar Gel guidance by MNK.

Cortrophin Gel: Successful launch and strong underlying demand; further strengthening the franchise to support a strong multi-year growth journey

Growth in core specialties targeted from launch[1]

- Continued strong growth across initially targeted specialties; **neurology**, **rheumatology, and nephrology**
- Prescribing momentum across existing and new prescribers
- Momentum continued in Q4 with record-initiated cases and new patient starts

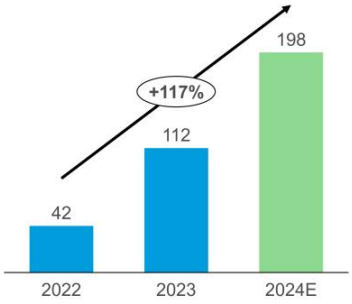
Gaining traction in newer therapeutic areas

- Expanded **Ophthalmology** sales team to 46 with Alimera acquisition; ophthalmology new patient starts increased ~2x Q/Q increase in Q4
- **Acute gouty arthritis** flares indication has grown to ~15% of Cortrophin use; only approved ACTH therapy for this indication
- Focused smaller **pulmonology sales team** yielding positive results

Further strengthening the franchise

- **Investing in research** to provide additional support for the use of Cortrophin
- Recently presented two abstracts at American Society of Nephrology
- Completed the **development of a Pre-Filled Syringe** for Cortrophin Gel and submitted a supplemental NDA; launch planned for the first half of 2025.
- Exploring other ideas to enhance the convenience for patients and providers
- Investing in **high ROI** commercial efforts such as expanding sales team to **drive growth** in core specialties targeted at launch and newer therapeutic areas

Cortrophin Gel Net Revenues ($ millions)[2]



1. Purified Cortrophin Gel was launched in January 2022.
2. 2024 based upon preliminary, unaudited results. 2022-24 CAGR is based on the midpoint of 2024 preliminary, unaudited results.

Acute gouty arthritis Indication could be a significant growth driver for Cortrophin Gel

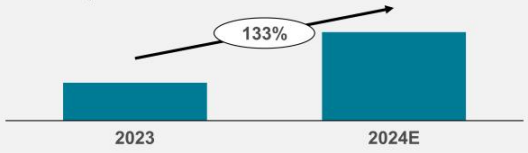
Tremendous Growth Potential

- Gout affects **>9M patients** in the US[1] with ~3.6M receiving treatment for it annually[2]
- Patients experience an average of **~1.5 - 2 flares/year** that are reported to their physician[3]
- Commonly treated with NSAIDs, steroids or colchicine as equivalent first-line options
- Many patients require treatment beyond first-line treatments for several reasons, including co-morbidities, intolerance or flares refractory to first-line options, severe pain, and high flare frequency
  - These patients generate significant healthcare expenditures, with the cost of treating a single flare exceeding $15,000 in the top 5% of events[4]
- **Addressable patient population of ~300,000 patients**
  - ~8% of patients currently receive some form of injectable therapy to treat an acute flare[4]
- Only one other product has been approved for acute gout flares since 2009

Early Indicators & Next Steps

- Cortrophin Gel is the only ACTH therapy approved for acute gouty arthritis flares
- Launched a new 1mL vial of Cortrophin Gel focused on the acute gouty arthritis flares indication in Q4'23
- Treatment of acute gouty arthritis flares has grown to ~15% of Cortrophin use
- Gout represented the first patient on therapy for almost 15% of HCPs using Cortrophin for the first time in 2024

Cortrophin volume for Gout more than doubled[5]



1- Singh G, Lingala B, Mithal A. Gout and hyperuricaemia in the USA: prevalence and trends. Rheumatology (Oxford). 2019 Dec 1;58(12):2177-2180. doi: 10.1093/rheumatology/kez196. PMID: 31168609.,
2 Thorpe K. Partnership to fight chronic disease. May 21, 2018
3 https://acrjournals.onlinelibrary.wiley.com/doi/full/10.1002/acr2.11759#:; ANI claims data analysis (data on file), Proudman C, et al. *Arthritis Res Ther*. 2019;21:132.
4 ANI analysis to be presented at AMCP 2025 conference
5 Based on ANI claims analysis

Highly synergistic acquisition of Alimera Sciences on track to deliver financial targets in 2025

Alimera

- **2** Two differentiated commercial assets with high barriers to genericization and significant growth potential, which we expect to further unlock through commercial synergies and execution
- Projected to meet or exceed prior guidance of **$35-38M** in adjusted non-GAAP EBITDA and **high single-digit to low double-digit** accretion in adjusted diluted non-GAAP EPS in 2025
- 46-person combined Ophthalmology sales force, who have been cross-trained and promoting ILUVIEN, YUTIQ and Cortrophin since mid-October
- Successfully retained key Alimera employees and implemented actions to ensure we are on track to capture **$10 million of synergies in 2025**.

Transaction closed September 2024

Alimera acquisition aligned with M&A strategy

Expanded Scope and Scale of Rare Disease Business

- Added two commercial assets
- We expect Rare Disease to account for over 50% of ANI revenues in 2025
- Increased geographic footprint to ex-US markets

Priority Therapeutic Area

- Ophthalmology as a percentage of total ACTH prescribers has almost doubled to more than 10% over four years[1]

Assets with Growth & Durability

- Double-digit growth assets
- Patent protection
- High barriers to genericization

1. Per Veeva Compass claims dataset for Acthar + Cortrophin internal prescribing data.

ILUVIEN and YUTIQ: Novel, long-acting implants for serious eye diseases

Diabetic Macular Edema

ILUVIEN® (fluocinolone acetonide intravitreal implant) 0.19mg

- **Disease state:** DME, a chronic disease that is the leading cause of vision loss in diabetic patients
  - ~4% of diabetic patients develop clinically significant macular edema
- Causes blurred vision in the early stage and may cause cumulative damage over the long term

Chronic Non-Infectious Uveitis

YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg

US

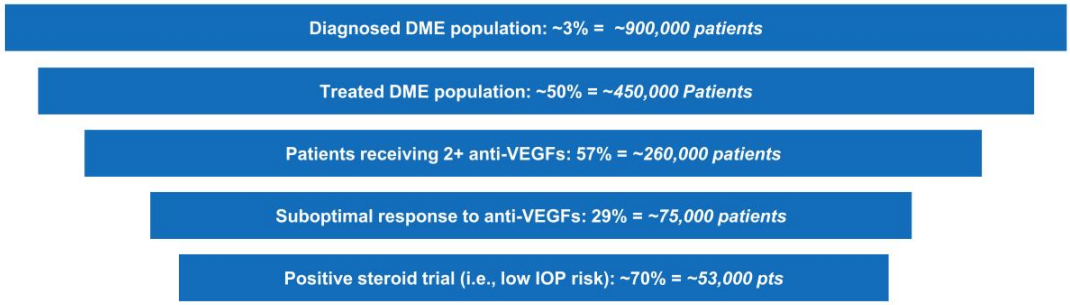
ILUVIEN® (fluocinolone acetonide intravitreal implant) 0.19mg

Ex-US

- **Disease state:** Chronic non-infectious uveitis affecting the posterior segment (NIU-PS) is inflammation of the eye that can lead to pain, visual impairment and vision loss
- Over 500,000 patients in U.S., many of working age, with non-infectious uveitis

The most underserved patient group within DME represents more than 50,000 patients in the US alone

DME epidemiology model flow – inputs informed by ANI's market research



>50,000 patients in the US are not well served by anti-VEGF therapy

Significant room for ILUVIEN growth - <5,000 patient starts annually for DME in the US

Source: Ophthalmologists survey, n = 64

Larger ophthalmology sales team expected to accelerate growth of Cortrophin Gel, ILUVIEN, and YUTIQ

Purified Cortrophin Gel repository corticotropin injection USP 80 U/mL

ANI deployed a targeted ophthalmology-focused sales team in Q1 2024

+

ILUVIEN® (fluocinolone acetonide intravitreal implant) 0.19mg

0.18 mg YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg

Alimera had a US commercial team of 35 field reps

ANI now has a combined team of 46 ophthalmology specialists

Combined efforts expected to expand the ability to drive **appropriate utilization of all three products** for patients in need

Significant overlap between ILUVIEN/YUTIQ and Cortrophin targeted ophthalmologists

>50% overlap among those with the highest prescribing potential

Expanded team increases reach to ~3,600 ophthalmologists

Identifying patients with unmet needs

Complementary patient support capabilities focused on **ensuring patients have access** to therapy

Long-term clinical studies, real-world use, and ongoing trials provide a strong foundation for ILUVIEN and YUTIQ

NEW DAY STUDY

ILUVIEN® (fluocinolone acetonide intravitreal implant) 0.19mg

- **NEW DAY** investigates the **earlier utilization of ILUVIEN** in patients with DME in **combination with anti-VEGF** treatment
- Multicenter, single masked, randomized, controlled trial comparing ILUVIEN + supplemental anti-VEGF therapy to the current standard of care, anti-VEGF therapy alone
- The study has enrolled 306 treatment-naïve, or almost naïve, DME patients
- LPLV for New Day has been completed
- Topline data expected in the **second quarter of 2025**.

>50,000 patients in the US are not well served by anti-VEGF therapy

SYNCHRONICITY

0.18 mg YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg

- Multicenter, open label study investigates YUTIQ across patients with **chronic NIU-PS**
- The study has enrolled 110 patients in approximately 25 sites around the U.S.
- LPLV expected in November 2025
- Topline data readout expected in Q1 2026

~100,000 patients in U.S., many of working age, with non-infectious uveitis in posterior segment

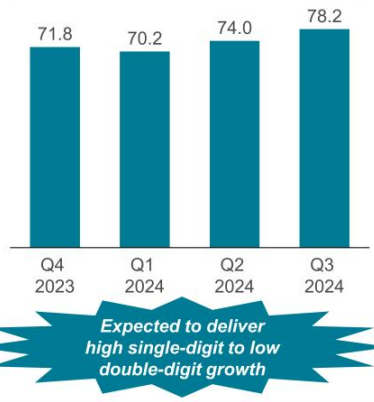
Strong R&D capabilities and operational excellence driving growth in Generics

Robust pipeline and new product launch execution
- Launched seventeen new products in 2024, including two Competitive Generic Therapy (CGT) products with 180-day exclusivity
- Number two ranking in CGT approvals and top 15 manufacturer in number of product approvals
- Increased 2024 R&D spend to deliver new launches fueling high single-digit/low double-digit growth

Strong operational backbone and U.S.-based manufacturing footprint
- During 2023, supplied over 1.8 billion doses of therapeutics to patients in need
- Substantial progress in 2024 in significant capacity expansion at New Jersey site
- Strong GMP track record with all sites currently in VAI or NAI status

Focus on cost excellence
- Systematic and relentless approach to reducing raw materials and finished goods costs
- Lean and entrepreneurial mentality towards all corporate spend

Generics Net Revenues ($ millions)



Expected to deliver high single-digit to low double-digit growth

U.S.-based manufacturing footprint with strong GMP track record

Baudette, MN
130k sf

Baudette, MN
Containment Facility - 47k sf

East Windsor, NJ
120k sf

Facility Overview and Capabilities	• Manufacturing, packaging, warehouse • Schedule CII vault & CIII cage space • Lab space - R&D/analytical testing • Solutions, suspensions, topicals, tablets, capsules, and powder for suspension • DEA-licensed for Schedule II controlled substances	• Manufacturing, packaging, warehouse • Low-humidity suite for moisture-sensitive compounds • Fully-contained high potency facility for hormone, steroid, and oncolytic products • DEA Schedule III capability	• 100K ft^2 of manufacturing, packaging, lab, warehouse, and administrative space • 20K ft^2 expansion added 15 new manufacturing suites and new QC lab • Solid oral tablets and capsules, liquid suspensions and solutions, powder for oral suspension, controlled substances as well as containment & nano-milling • API development & low volume production
Annual Capacity	• Solid Dose ~2.5BN doses • Liquid Unit ~23MM doses • Liquids ~20MM bottles • Powder ~4MM bottles	• Tablets ~2.5BN doses • Capsules ~150MM doses • Blisters ~ 45MM doses	• Tablets & Capsules ~3.0BN doses • Packaged Units ~20MM units • Liquids ~10MM bottles • Powder ~ 2MM bottles ; Semi Solids
GMP	*Five FDA inspections since 2013* **Latest FDA inspection – December 2024** **Current site status: VAI**	*Seven DEA inspections since 2013* **Latest DEA inspection – August 2023** **Current site status: VAI**	*Seven FDA inspections since 2017, Four DEA inspections since 2016* **Latest FDA inspection – January 2024** **Current site status: NAI status (zero 483s)**

Investment summary

Strategic focus on strong and growing Rare Disease business

- Expected to represent ~50% of 2025 revenues and be largest driver of future growth
- Cortrophin Gel reached ~$198M [2] revenue in 2024 and is on a strong multi-year growth trajectory
- 2024 acquisition of ILUVIEN and YUTIQ added growing and durable assets to platform

Robust foundational Generics business delivering high single-digit to low double-digit growth

- Highly-seasoned R&D, manufacturing and commercial infrastructure delivering value to customers
- Well-diversified product portfolio with over 110 product families
- Reliable US-based manufacturing with strong GMP track record; over 1.8[4] billion doses filled annually

Financial Strength

- $145M cash and cash equivalents with disciplined approach toward debt levels; post- acquisition 3.0x net leverage[1]
- Projected 2024[3] :
  - Revenues of $594-602M representing 22-24% year-over-year growth
  - Adjusted non-GAAP EBITDA of $149-153M
  - Adjusted non-GAAP diluted EPS of $4.90-$5.05

2025 Priorities

- Deliver strong revenue growth and profitability
- Expand adoption of Cortrophin in targeted specialties and grow the ACTH category
- Complete Alimera integration, drive synergies
- Explore further expansion in scope and scale of Rare Disease business

1. As of September 30, 2024; leverage ratio TTM period pro-forma for Alimera acquisition utilizing non-GAAP adjusted EBITDA of $167.7 million.
2. Based upon preliminary, unaudited full year 2024 results.
3. Based on 2024 financial guidance issued on November 8, 2024.
4. Per IQVIA EUTRx data - Rx (NPA) MAT Oct 2024 data

Adjusted non-GAAP EBITDA Calculation and US GAAP to Non-GAAP Reconciliation

($ in thousands, except per share amounts)	Three months ended September 30, 2024	Nine months ended September 30, 2024	Twelve months ended December 31, 2023	2022	2021
Net (Loss) Income	(24,166)	(8,246)	18,779	(47,896)	(42,603)
Add/(Subtract):					
Interest expense, net	2,331	11,587	26,940	28,052	11,922
Other expense, net [a]	2,535	2,655	159	80	6,243
Loss on extinguishment of debt	7,468	7,468	—	—	—
Provision (benefit) for income taxes	(7,332)	(204)	1,093	(14,769)	(13,455)
Depreciation and amortization	15,748	45,131	59,791	56,972	47,252
Contingent consideration fair value adjustment	825	1,274	1,426	3,758	500
Legal settlement expense	—	—	—	—	8,750
Intangible asset impairment charges	—	—	—	112	—
Restructuring activities	—	—	1,132	5,679	—
Gain on sale of building	—	(5,347)	—	—	—
Unrealized gain on investment in equity security	(1,355)	(8,298)	—	—	—
Impact of Canada operations [b]	—	—	2,697	2,740	—
Stock-based compensation	7,484	22,283	20,652	14,599	10,489
Asset impairments [c]	—	—	—	—	2,737
M&A transaction expenses	9,945	14,198	1,148	1,244	9,382
Royalty settlement	—	—	—	—	1,934
Litigation expenses	2,899	4,738	—	—	—
Inventory step-up amortization	3,224	3,224	—	5,294	7,460
Severance	5,308	5,308	—	—	—
Equity payout	10,190	10,190	—	—	—
Adjusted non-GAAP EBITDA	35,104	105,961	133,817	55,865	50,611

[a] Adjustment to other expense, net 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.

[b] 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 (complete as of March 31, 2024). 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.

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

Adjusted non-GAAP Diluted Earnings per Share Calculation and US GAAP to Non-GAAP Reconciliation

($ in thousands, except per share amounts)	Three months ended September 30, 2024	Twelve months ended December 31, 2023
Net (Loss) Available to Common Shareholders	(24,572)	17,154
Add/(Subtract):		
Non-cash interest (income)	(18)	3,335
Depreciation and amortization	15,748	59,791
Contingent consideration fair value adjustment	825	1,426
Loss on extinguishment of debt	7,468	—
Restructuring activities	—	1,132
Unrealized (gain) on investment in equity securities	(1,355)	—
Impact of Canada operations [a]	—	2,697
Stock-based compensation	7,484	20,652
M&A transaction expenses	9,945	1,148
Litigation expenses	2,899	—
Inventory step-up amortization	3,224	—
Severance	5,308	—
Equity payout	10,190	—
Other expense	2,493	—
Less:		
Estimated tax impact of adjustments	(13,147)	(21,643)
Adjusted non-GAAP Net Income Available to Common Shareholders [b]	26,492	85,692
Diluted Weighted-Average Shares Outstanding	19,404	18,194
Adjusted Diluted Weighted-Average Shares Outstanding	19,766	18,194
Adjusted Non-GAAP Diluted Earnings per Share	1.34	4.71

[a] 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 (complete as of March 31, 2024). 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.

[b] Adjusted non-GAAP Net Income Available to Common Shareholders excludes undistributed earnings to participating securities.

Strong balance sheet to support Rare Disease business development

	2022	2023	Q3 2024[2]
Cash & Cash Equivalents	$48M	$221M	$145M
Net Debt/EBITDA	4.4x	0.5x	3.0x
Gross Debt	$297M	$294M	$641M
Net Debt	$249M	$73M	$496M
Adjusted Non-GAAP EBITDA [1]	$56M	$134M	$168M

1. Adjusted Non-GAAP EBITDA is a Non-GAAP financial measure.
2. Balance sheet metrics as on September 30, 2024; Adjusted Non-GAAP EBTIDA represents trailing twelve-month period pro-forma for Alimera acquisition