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 20, 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 November 20, 2024, Nikhil Lalwani, President & CEO of ANI Pharmaceuticals, Inc., will present at the 2024 Jefferies London Healthcare Conference in London, UK. 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 November 20, 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.

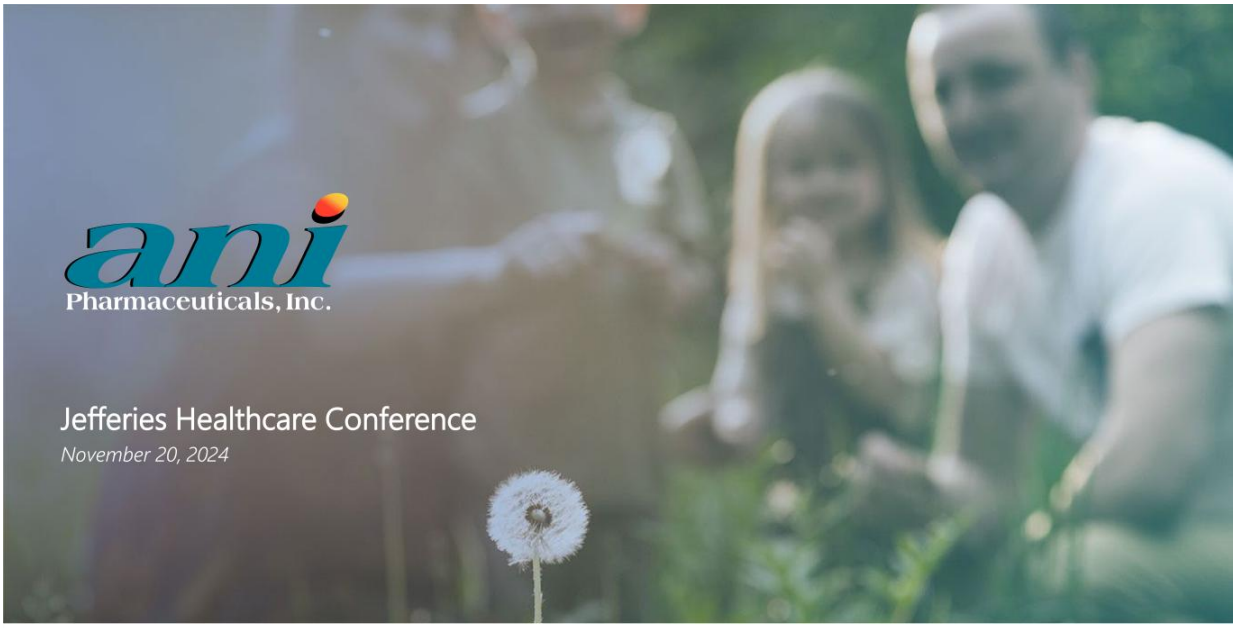
SIGNATURES

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: November 20, 2024

ANI PHARMACEUTICALS, INC.

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



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

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. 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 2024 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

ANI's management considers adjusted non-GAAP net income to be an important financial indicator of ANI's operating performance, providing investors and analysts with a useful measure of operating results unaffected by the 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 net income when analyzing Company performance. Adjusted non-GAAP net income is defined as net (loss) income, plus 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, 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 should be considered in addition to, but not in lieu of, net income reported under GAAP. A reconciliation of adjusted non-GAAP net income to the most directly comparable GAAP financial measure is provided below.

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. A reconciliation of adjusted non-GAAP diluted 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 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.

Other non-GAAP metrics

ANI's management considers non-GAAP research and development expenses and non-GAAP selling, general, and administrative expenses to be financial indicators of ANI's operating performance, providing investors and analysts with useful measures of operating results unaffected by 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. Management uses adjusted non-GAAP research and development expenses and non-GAAP selling, general, and administrative expenses when analyzing Company performance. Non-GAAP research and development expenses is defined as research and development expenses, excluding non-cash stock-based compensation expense, M&A transaction and integration expenses, and certain other items that vary in frequency and impact on ANI's results of operations. Non-GAAP selling, general, and administrative expenses is defined as selling, general, and administrative expenses, excluding impact of Canada operations, non-cash stock-based compensation expense, M&A transaction and integration expenses, litigation expenses related to certain matters, severance expense, and certain other items that vary in frequency and impact on ANI's results of operations. Each of adjusted non-GAAP research and development expenses and non-GAAP selling, general, and administrative expenses should be considered in addition to, but not in lieu of, research and development expenses, and selling, general, and administrative expenses reported under GAAP, respectively.

A reconciliation of each of non-GAAP research and development expenses and non-GAAP selling, general and administrative expenses to the most directly comparable GAAP financial measure is provided below in the Appendices.

ANI's management also considers non-GAAP gross margin to be a financial indicator of ANI's operating performance, providing investors and analysts with a useful measure of operating results unaffected by unaffected by 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. Management uses non-GAAP gross margin when analyzing Company performance. Non-GAAP gross margin is defined as adjusted non-GAAP net revenues less non-GAAP cost of sales (excluding depreciation and amortization) divided by non-GAAP net revenues. Non-GAAP gross margin should be considered in addition to, but not in lieu of, gross margin reported under GAAP.

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

Serving Patients, Improving Lives.

Key Growth Drivers

Purified Cortrophin Gel | ILUVIEN | YUTIQ

- **Rare Disease** business with **three** growing and durable commercial assets: **Purified Cortrophin Gel, ILUVIEN** and **YUTIQ.** 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)

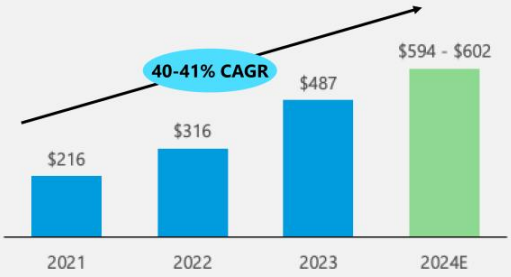
$149-153M
2024 Adjusted Non-GAAP EBITDA(1),(3)

$145M
Cash(2)

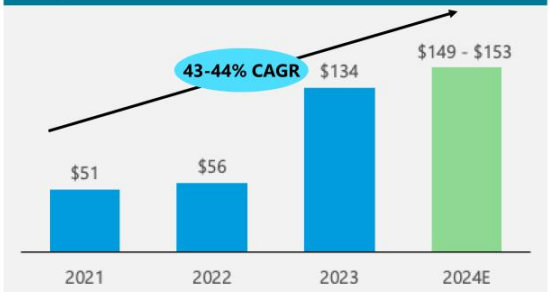
1. Full year 2024 guidance.
2. Cash and cash equivalents as of September 30, 2024.
3. Adj. Non-GAAP EBITDA is a Non-GAAP financial measure. See appendix for reconciliation to most directly comparable GAAP measure.

Well positioned to continue driving strong growth

Total Company Net Revenues ($ millions)[1]



Adjusted Non-GAAP EBITDA ($ millions)[1],[2]



Rare Disease operating leverage driving strong EBITDA growth following investment in Rare Disease infrastructure for Cortrophin launch in 2022

1. CAGR calculated using 2021-2024E utilizing full year 2024 guidance.
2. Adj Non-GAAP EBITDA is a Non-GAAP financial measure. See appendix for reconciliation to most directly comparable GAAP measure.

Momentum has continued in 2024 with ANI delivering record results in Q3

Highlights

- Steady gains through the first three quarters of 2024 for lead Rare Disease asset Cortrophin Gel across core therapeutic areas (rheumatology, neurology, nephrology) with strong traction into new areas of opportunity (pulmonology and ophthalmology)
- Acquisition of ILUVIEN and YUTIQ in September 2024 expected to add an estimated $30 - $32 million[2] of revenue in FY2024
- Continued to leverage exceptional new product launch execution (sixteen new products launched YTD[3]), operational excellence, and U.S.-based manufacturing footprint to reliably serve patients in Generics and Established Brands

3Q Total Revenues
$148M
↑ 13% YoY

3Q Rare Disease Revenues
$56M
↑ 90% YoY

3Q Diluted Non-GAAP EPS[1]
$1.34
↑ 6% YoY

3Q Adj. Non-GAAP EBITDA[1]
$35M
↓ 4% YoY

1. Adjusted non-GAAP EBITDA and Adjusted Diluted non-GAAP EPS are non-GAAP financial measures. See appendix for reconciliation to most directly comparable GAAP measure.
2. Full year 2024 guidance
3. As of November 8, 2024.

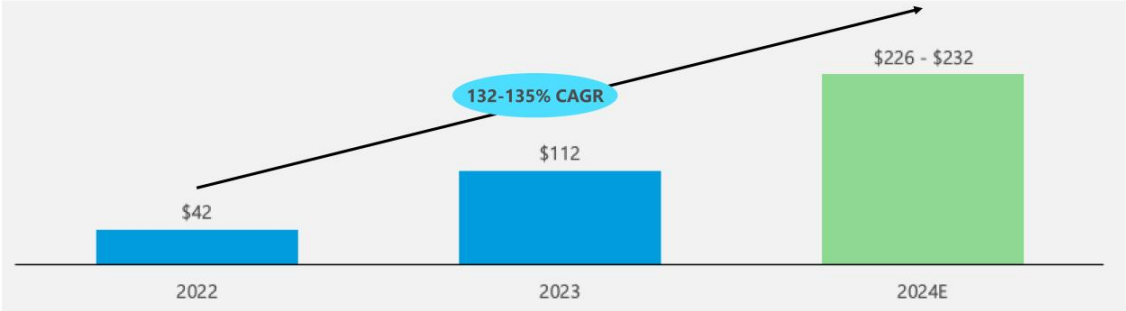
2024 Guidance

Metric ($ millions except per share amounts)	Full Year 2024 Guidance	2023 Actuals	Growth vs Prior Year Actuals
Net Revenue (Total Company)	$594 - $602	$486.8	22 - 24%
Cortrophin Gel Net Revenue	$196 - $200	$112.1	75 - 78%
ILUVIEN and YUTIQ Net Revenue	$30 - $32	NA	NA
Adjusted Non-GAAP EBITDA (1)	$149 - $153	$133.8	11 - 14%
Adjusted Non-GAAP Diluted EPS (1)	$4.90 - $5.05	$4.71	4 - 7%

1. Adjusted Non-GAAP EBITDA and Adjusted Non-GAAP Diluted EPS are Non-GAAP financial measures. See appendix for reconciliation to most directly comparable GAAP measure.

Rare Disease franchise expected to drive strong growth in 2024 and beyond

Rare Disease Net Revenues ($ millions)[1]



1. CAGR calculated using 2022-2024E (2024E based on full year 2024 guidance). Cortrophin Gel was launched in 2022.

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 (fluocinolone acetonide intravitreal implant) 0.18 mg 
US Ophthalmology Indications	**Severe acute and chronic allergic and inflammatory conditions affecting the eye and its adnexa**	**Diabetic macular edema (DME)**	**Non-infectious uveitis affecting the posterior segment (NIU-PS)**
Ex-US Indications	--	**DME and NIU-PS** *Middle East and 17 European countries*	--
US Approval Date	**November 2021** *sNDA*	**September 2014**	**October 2018** *Alimera acquired license from Eyepoint in May 2023*
		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

* 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; ~$1.2B category at peak in 2017; potential for 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; recently 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)

Cortrophin Gel: Successful launch and strong demand

Growth in specialties targeted at launch[1]

- Continued strong growth across initially targeted specialties; **neurology**, **rheumatology, and nephrology**
- Prescribing momentum across existing and new prescribers
- Momentum continues with highest number unique prescribers and new patient starts in Q3'24 and record number of new cases initiated in October 2024

Gaining traction in new therapeutic areas

- **Ophthalmology** sales team pilot in early 2024 successful
- Expanded Ophthalmology sales team to ~46 with Alimera acquisition

- Launched **1-mL vial size** of Cortrophin Gel during Q4 2023, the only approved ACTH therapy indicated for the treatment of **acute gouty arthritis flares**

- Expansion of **pulmonology sales team** yielding positive results

Strengthening the franchise

- **Investing in research** to provide additional support for the use of Cortrophin
- Recently presented two abstracts at American Society of Nephrology

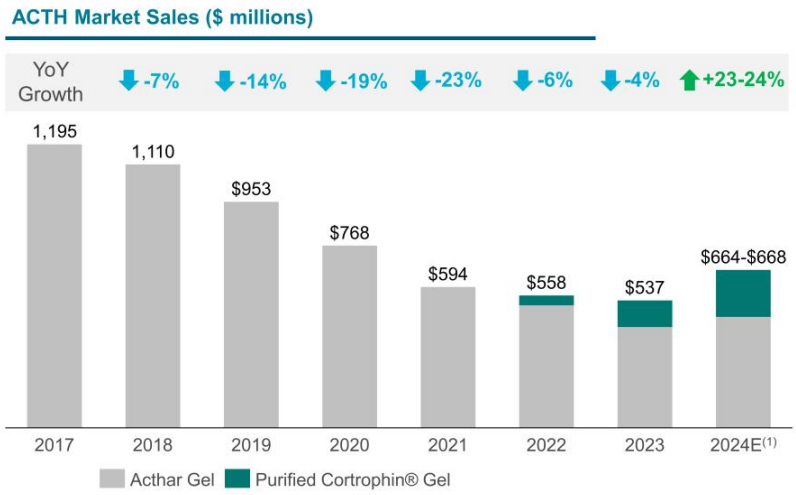
- Completed the **development of a Pre-Filled Syringe** for Cortrophin Gel and submitted a supplemental NDA; launch planned for the first half of 2025.
- Exploring other ideas to enhance the convenience for patients and providers

Cortrophin Gel Net Revenues ($ millions)[2]

Full year 2024 guidance of $196 - $200 million

1. Purified Cortrophin Gel was launched in January 2022.
2. Q4 '24E is based on full year 2024 financial guidance.

Strong multi-year growth trajectory for Cortrophin Gel and the overall ACTH market



- 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
- Acute Gouty Arthritis flares not included in peak sales of $1.2 bn in 2017, provides further growth opportunity

1. Full year 2024 Cortrophin Gel net revenue guidance. 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 guidance + Acthar Gel guidance by MNK.

Highly synergistic acquisition of Alimera Sciences closed in September with integration progressing well

Alimera

- **2** Two differentiated commercial assets with high barriers to genericization and significant growth potential, which can be further unlocked through commercial synergies and execution
- Projected to add **$35-$38M** in adjusted non-GAAP EBITDA and deliver **high single-digit to low double-digit accretion** in adjusted diluted non-GAAP EPS
- 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 taken 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

Expands Scope and Scale of Rare Disease Business

- Added two commercial assets
- 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

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

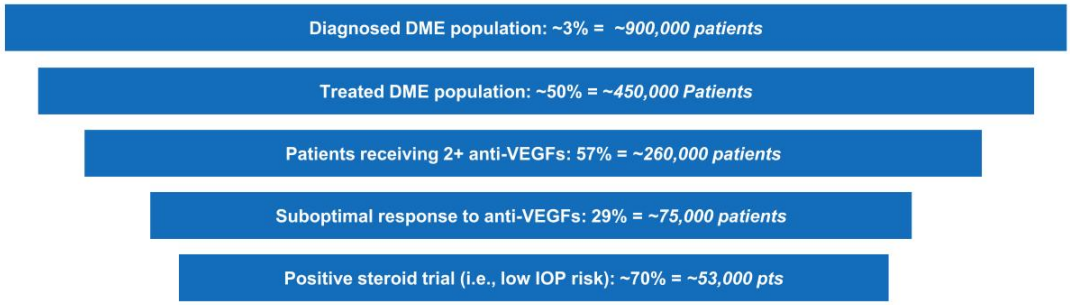
Expanded team increases reach to ~3,600 ophthalmologists

Identifying patients with unmet needs

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

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

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 expected in December 2024
- 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 sixteen new products 2024 YTD[1], including a Competitive Generic Therapy (CGT) product 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 1.5 billion doses of therapeutics to patients in need
- Excellent compliance track record with successful FDA audits across all sites
- Substantial progress in Q3'24 in bringing online the significant capacity expansion at New Jersey site
- New Jersey site successfully completed both a pre-approval and a pharmacovigilance inspection with the FDA with zero observations

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

1. As of November 8, 2024.

U.S.-based manufacturing footprint; strong GMP track record, including successful FDA audits at all three sites

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	*Four FDA inspections since 2013* **Latest FDA inspection – November 2022** **Results: VAI status**	*Seven DEA inspections since 2013* **Latest DEA inspection – August 2023** **Results: VAI status**	*Seven FDA inspections since 2017, Four DEA inspections since 2016* **Latest FDA inspection – January 2024** **Results: NAI status (zero 483s)**

Investment summary

Strategic focus on strong and growing Rare Disease business

- Expected to represent ~50% of 2025 revenues and largest driver of future growth
- Cortrophin Gel to reach ~$198M [2] revenue in 2024 with strong multi-year growth trajectory
- 2024 acquisition of ILUVIEN and YUTIQ adds 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 100 product families
- Reliable US-based manufacturing with strong GMP track record; over 1.7[3] billion prescriptions filled annually

Financial Strength

- $145M cash and cash equivalents with disciplined approach toward debt levels; post-acquisition 3.0x net leverage[1]
- Projected 2024[2] :
  - Revenues of $597M representing 23% year-over-year growth
  - Adjusted non-GAAP EBITDA of $151M
  - Adjusted non-GAAP diluted EPS of $4.98

Experienced purpose-driven team

- Over 1,000 purpose-driven organization: Serving Patients, Improving Lives
- Highly seasoned executive management team with best-in-class experience and expertise
- High-performance and ethical mindset with strong cross functional collaboration

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. Mid-point of 2024 annual guidance
3. 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