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 12, 2026

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.)

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))

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

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 12, 2026, 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, 2025, as well as preliminary 2026 financial guidance. A copy of the press release is furnished herewith as Exhibit 99.1.*

The selected financial results are based on preliminary unaudited information and management estimates, are not a comprehensive statement of the Company's financial results for either the fourth quarter or fiscal year ended December 31, 2025 and are subject to change. Such changes may be material. Our independent registered public accounting firm has not conducted an audit or review of, and does not express an opinion or provide any other form of assurance with respect to, these preliminary results.

In addition, on January 13, 2026, Nikhil Lalwani, President & CEO of the Company, will present at the 44th Annual 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 12, 2026
99.2	Investor Presentation, dated January 2026
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, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

SIGNATURE

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 12, 2026

ANI PHARMACEUTICALS, INC.

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

ANI Pharmaceuticals Highlights Significant Growth in 2025, Provides 2026 Financial Guidance, and Outlines Strategic Priorities

- For full year 2025, total net revenues, adjusted non-GAAP EBITDA, and adjusted non-GAAP diluted EPS expected to be within or above guidance ranges of $854 million to $873 million, $221 million to $228 million and $7.37 to $7.64, respectively
- Rare Disease business delivered exceptional growth with full year 2025 Purified Cortrophin® Gel net revenues of $347.8 million, up 76% year-over-year, and ILUVIEN and YUTIQ net revenues of $74.9 million, based on preliminary, unaudited results
- Provides full year 2026 financial guidance, which includes:
  - Total net revenues of $1,055 million to $1,115 million
  - Cortrophin Gel net revenues of $540 million to $575 million
  - Adjusted non-GAAP EBITDA of $275 million to $290 million
  - Rare Disease business to represent approximately 60% of total net revenues
- Announces ~90-person expansion of Rare Disease organization to capture unique opportunity for Cortrophin Gel in acute gouty arthritis flares; expected to deploy in mid-2026

PRINCETON, N.J., Jan. 12, 2026 -- ANI Pharmaceuticals, Inc. (“ANI” or the “Company”) (Nasdaq: ANIP) today announced preliminary select financial results for full year 2025, provided full year 2026 financial guidance, and outlined its strategic priorities for continued growth. Nikhil Lalwani, ANI’s President and Chief Executive Officer, will discuss these updates as part of a presentation at the 44th Annual J.P. Morgan Healthcare Conference on Tuesday, January 13, 2026, at 3:00 p.m. PT/6:00 p.m. ET.

“2025 was a pivotal year for ANI, as we drove significant growth for Cortrophin Gel and outperformed in our Generics business, enabling us to achieve at least 39% growth in total net revenues and at least 42% growth in adjusted non-GAAP EBITDA,” said Nikhil Lalwani, President and CEO of ANI. “We are entering 2026 in a position of strength and expect to generate over $1 billion in total net revenues this year, approximately 60% of which will be represented by our high-growth Rare Disease business.”

Mr. Lalwani added, “To accelerate our transformation into a leading Rare Disease company, we are focused on maximizing the substantial, multi-year growth opportunity for Cortrophin Gel by addressing the significant unmet medical need across indications. In 2026, we will continue momentum in our current priority therapeutic areas and also plan to expand our Rare Disease organization by mid-year, enabling us to capture the opportunity in acute gouty arthritis flares, an indication unique to ANI. Importantly, the ongoing execution across our Generics and Brands business will provide healthy cash generation to support our Rare Disease business. We look forward to driving long-term growth in 2026 and beyond to fulfill our purpose of Serving Patients, Improving Lives, while also creating durable value across the company.”

Preliminary Fourth Quarter and Full Year 2025 Financial Results

Based on preliminary, unaudited results, ANI expects Cortrophin Gel net revenues of approximately $111.4 million for the fourth quarter of 2025, up 88% year-over-year, and approximately $347.8 million for the full year 2025, up 76% year-over-year. In addition, the Company expects ILUVIEN net revenues of approximately $19.8 million for the fourth quarter of 2025 and combined ILUVIEN and YUTIQ net revenues of approximately $74.9 million for the full year 2025.

Additionally, the Company expects full year 2025 total net revenues, adjusted non-GAAP EBITDA, and adjusted non-GAAP diluted EPS to be within or above the guidance ranges provided on November 7, 2025, of $854 million to $873 million, $221 million to $228 million and $7.37 to $7.64, respectively.

As of December 31, 2025, the Company had approximately $285 million in unrestricted cash and cash equivalents.

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 audit of the Company's consolidated financial statements. ANI will report its full year 2025 results during its fourth quarter 2025 earnings conference call in late February.

Full Year 2026 Financial Guidance

Metric	Full Year 2026 Guidance	Year-over-Year Growth[3]
Net Revenue (Total Company)	$1,055 million - $1,115 million	24% - 28%
Cortrophin Gel Net Revenue	$540 million - $575 million	55% - 65%
ILUVIEN Net Revenue	$78 million - $83 million	4% - 11%
Adjusted Non-GAAP EBITDA[1]	$275 million - $290 million	24% - 27%
Adjusted Non-GAAP Diluted EPS[1][2]	$8.83 - $9.34	20% - 22%

1. Adjusted Non-GAAP EBITDA and Adjusted Non-GAAP Diluted EPS are Non-GAAP financial measures.
2. For full year 2026 guidance, Non-GAAP Adjusted Diluted Weighted-Average Shares Outstanding exclude certain dilutive shares related to the 2029 senior convertible notes as they are intended to be covered by ANI's capped call transactions.
3. Year-over-year growth is calculated based on 2026 guidance ranges compared to 2025 guidance ranges provided by ANI on November 7, 2025, for all metrics except Cortrophin Gel net revenue and ILUVIEN net revenue for which the comparison is to 2025 preliminary, unaudited results.

ANI expects full year total company adjusted non-GAAP gross margin between 59.3% and 60.3%. The Company will continue to tax effect non-GAAP adjustments for computation of adjusted non-GAAP diluted earnings per share at a tax rate of 26%, unless the item being adjusted is not tax deductible in whole or in part.

The Company anticipates approximately 21.5 million and 21.8 million shares outstanding for the purpose of calculating full year adjusted non-GAAP diluted EPS and expects its annual U.S. GAAP effective tax rate to be between 26% and 28%.

2026 Strategic Priorities

In 2026, the Company plans to focus on the following initiatives:

- Accelerate ANI's transformation into a leading Rare Disease company:
  - Cortrophin Gel: Maximize the substantial, multi-year growth opportunity for the Company's lead asset by addressing the significant unmet medical need across indications
    - Focus efforts to continue momentum established in Nephrology, Neurology, Rheumatology and Pulmonology as the ACTH market expands
    - Build a ~90-person organization dedicated to acute gouty arthritis flares, an indication unique to Cortrophin Gel in the ACTH category. Deploy organization by mid-year, targeting appropriate patients in Podiatry and Primary Care
    - Advance a Phase 4 clinical trial to support further scientific evidence and clinical data generation of Cortrophin Gel in patients with acute gouty arthritis flares
    - Continue to evaluate opportunities to enhance patient convenience
  - ILUVIEN: Return to growth by leveraging the commercial and patient access initiatives established in 2025

- Drive strong execution in Generics business
  - Leverage superior R&D capabilities, strong operational execution, U.S. manufacturing footprint, and business development expertise to continue cash generation and growth
  - Maintain current cadence of 10 to 15 new product launches annually

- Execute disciplined capital allocation strategy
  - Explore opportunities to expand the scope and scale of the Rare Disease business
  - Invest in the dedicated organization focused on acute gouty arthritis flares for Cortrophin Gel
  - Invest high single-digit percentage of Generics revenue into R&D to support the business

J.P. Morgan Presentation and Webcast

ANI will present at the 44th Annual J.P. Morgan Healthcare Conference on Tuesday, January 13, 2026, at 3:00 p.m. PT/6:00 p.m. ET 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 30 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 income (loss), excluding tax expense (benefit), interest expense, net, other (income) expense, net, depreciation and amortization expense, non-cash stock-based compensation expense, M&A transaction and integration expenses, contingent consideration fair value adjustments, unrealized (gain) loss on our investment in equity securities, loss (gain) on disposal of assets, intangible asset impairment charges, litigation expenses related to certain matters, 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 2026 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) loss on our investment in equity securities, loss (gain) on disposal of assets, intangible asset impairment charges, litigation expenses related to certain matters, 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.

Non-GAAP Adjusted Diluted Weighted-Average Shares Outstanding excludes certain dilutive shares related to the 2029 senior convertible notes as they are intended to be covered by our capped call transactions. Our outstanding capped call transactions are intended to offset the dilutive effect of the 2029 convertible senior notes recognized in the calculation of GAAP diluted EPS and have been excluded from the calculation of the Non-GAAP Adjusted Diluted Weighted-Average Shares outstanding.

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 2026 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 Pharmaceuticals, Inc.

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 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, 2026 financial guidance, expansion plans for the Rare Disease business and transformation of ANI into a leading rare disease company, growth opportunities for Cortrophin Gel and ILUVIEN, anticipated R&D developments and clinical trial advances, and other statements that are not historical in nature, particularly those that utilize terminology such as “anticipates,” “will,” “expects,” “plans,” “potential,” “future,” “believes,” “intends,” “continue,” the negatives thereof, or 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: the ability of our approved products, including Cortrophin Gel and ILUVIEN, to achieve commercialization at levels of market acceptance that will continue to allow us to achieve continued profitability; our ability to complete or achieve any, or all of the intended benefits of acquisitions and investments, in a timely manner or at all; the limitation of our cash flow as a result of the indebtedness and liabilities incurred from the acquisition of Alimera; the risks that our acquisitions and investments, could disrupt our business and harm our financial position and operating results; delays and disruptions in production of our approved products, 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; delays and disruptions in production of our approved products as a result of our reliance on single source third party contract manufacturing supply for certain of our key products, including Cortrophin Gel and ILUVIEN; 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, and the focus of the current U.S. presidential administration, 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, including increased costs due to tariffs; 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; our obligations in agreements under which we license, develop or commercialize rights to products or technology from third parties and our ability to maintain such licenses; 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; the potential impact of new U.S. tax legislation on our business; and general business and economic conditions, such as inflationary pressures, geopolitical conditions.

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, and other periodic reports, as well as other filings with the SEC. All forward-looking statements in this news release speak only as of the date of this news release and are based on the Company's current beliefs, assumptions, and expectations. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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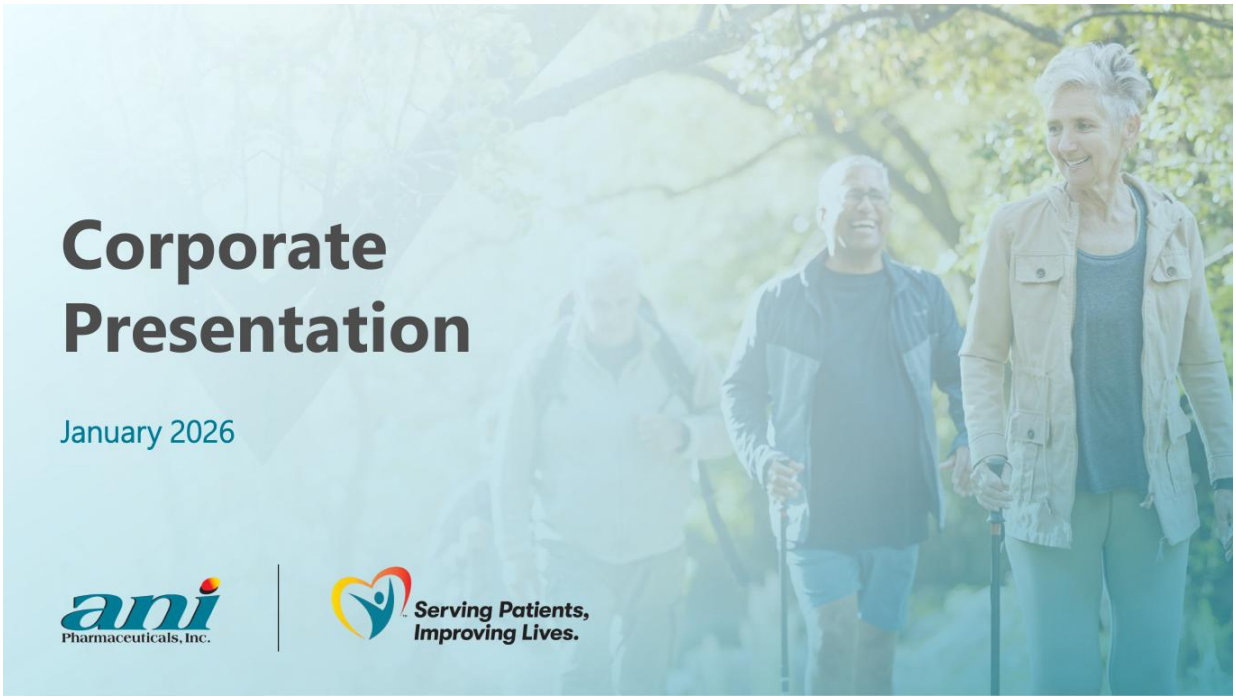
E: ani@argotpartners.com

Media Relations:
Deborah Elson, Argot Partners
E: ani@argotpartners.com

Corporate Presentation

January 2026



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. The guidance included herein is from or supplemental to the Company's press release on January 12, 2026. The Company is neither reconfirming this guidance as of the date of this investor presentation nor assuming any obligation to update or revise such guidance.

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. These statements may 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, 2026 financial guidance, expansion plans for the Rare Disease business and transformation of ANI into a leading rare disease company, growth opportunities for Cortrophin Gel and ILUVIEN and anticipated R&D developments and clinical trial advances, and other statements that are not historical in nature. These statements involve estimates, assumptions and uncertainties which could cause actual results to differ materially from those expressed in them Uncertainties and risks include, but are not limited to: the ability of our approved products, including Cortrophin Gel and ILUVIEN, to achieve commercialization at levels of market acceptance that will continue to allow us to achieve continued profitability; our ability to complete or achieve any, or all of the intended benefits of acquisitions and investments, in a timely manner or at all; the limitation of our cash flow as a result of the indebtedness and liabilities incurred from the acquisition of Alimera; the risks that our acquisitions and investments, could disrupt our business and harm our financial position and operating results; delays and disruptions in production of our approved products, 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; delays and disruptions in production of our approved products as a result of our reliance on single source third party contract manufacturing supply for certain of our key products, including Cortrophin Gel and ILUVIEN; 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, and the focus of the current U.S. presidential administration, 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, including increased costs due to tariffs; 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; our obligations in agreements under which we license, develop or commercialize rights to products or technology from third parties and our ability to maintain such licenses; 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; the potential impact of new U.S. tax legislation on our business; and general business and economic conditions, such as inflationary pressures, geopolitical conflicts and conditions, and other risks and uncertainties that are described in the Company's most recent Annual Report on Form 10-K, any subsequent quarterly reports filed by the Company 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.

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 income (loss), excluding tax expense (benefit), interest expense, net, other (income) expense, net, depreciation and amortization expense, non-cash stock-based compensation expense, M&A transaction and integration expenses, contingent consideration fair value adjustments, unrealized (gain) loss on our investment in equity securities, loss (gain) on disposal of assets, intangible asset impairment charges, litigation expenses related to certain matters, 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 2026 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) loss on our investment in equity securities, loss (gain) on disposal of assets, intangible asset impairment charges, litigation expenses related to certain matters, 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.

Non-GAAP Adjusted Diluted Weighted-Average Shares Outstanding excludes certain dilutive shares related to the 2029 senior convertible notes as they are intended to be covered by our capped call transactions. Our outstanding capped call transactions are intended to offset the dilutive effect of the 2029 convertible senior notes recognized in the calculation of GAAP diluted EPS and have been excluded from the calculation of the Non-GAAP Adjusted Diluted Weighted-Average Shares outstanding.

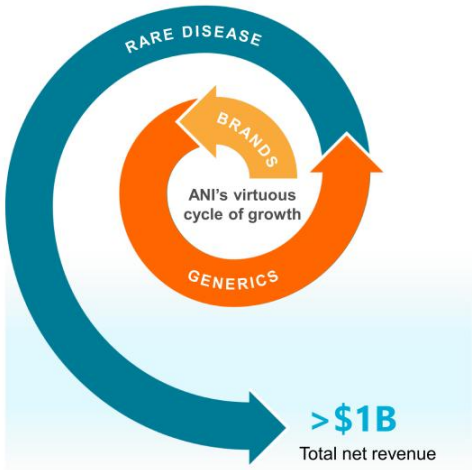
Adjusted non-GAAP diluted earnings per share is defined as adjusted non-GAAP net income, as defined above, divided by the diluted weighted average shares outstanding during the period. Management will continually analyze this metric and may include additional adjustments in the calculation in order to 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 2026 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.

Please refer to the Company's quarterly earnings releases filed with the SEC and that are linked on our website at https://investor.anipharmaceuticals.com/ for the reconciliations of Adjusted Non-GAAP EBITDA and Adjusted Non-GAAP Diluted Earnings per Share.

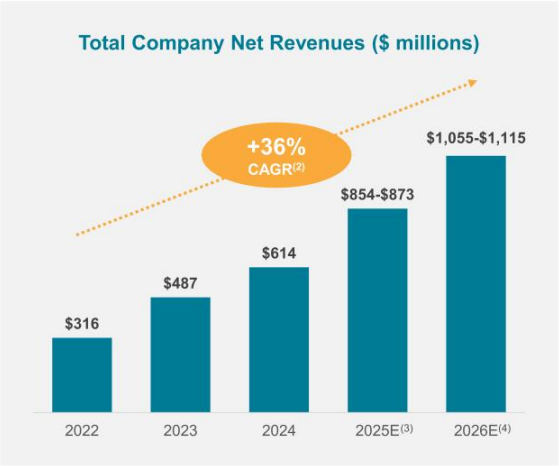
A profitable, high-growth biopharmaceutical organization transforming into a leading Rare Disease company

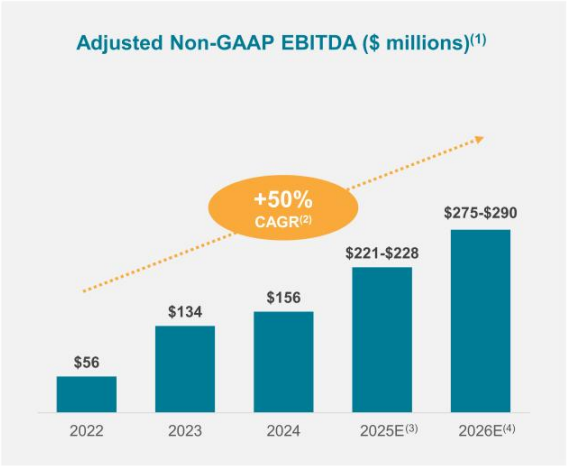
- **Projecting >$1B in revenue in 2026**
  - >39% YoY increase in 2025
  - >26% YoY increase in 2026[1]
- **Rare Disease business** is primary focus
  - Targeting to represent **~60% of total revenues in 2026**
  - Lead asset, **Cortrophin Gel,** provides substantial, durable **multi-year growth opportunity**
- **Generics business delivering strong cash flows** enabled by superior R&D capabilities, operational execution, and U.S. manufacturing



1. YoY growth rates calculated using the midpoint of full year 2025 and 2026 guidance provided by the Company on November 7, 2025, and January 12, 2026, respectively.

Proven track record of delivering top- and bottom-line growth





1. Adjusted Non-GAAP EBITDA is a Non-GAAP financial measure.
2. 2022-2026 CAGR calculated using the midpoint of full year 2026 guidance provided by the Company on January 12, 2026.
3. Based on 2025 financial guidance issued by the Company on November 7, 2025.
4. Based on 2026 financial guidance issued by the Company on January 12, 2026.

2025 accomplishments drove robust expansion across the business

Rare Disease generated
84%
YoY topline growth

- Lead Rare Disease asset Cortrophin Gel delivered **exceptional YoY growth of 76%**
  - **Accelerated momentum** across neurology, rheumatology, nephrology, and pulmonology through sales force expansion
  - Acute gouty arthritis flares grown to over **15% of Cortrophin use**
  - Realized synergies from **combined ophthalmology salesforce**
- Established **ILUVIEN commercial and access initiatives** to support growth in 2026

Generics outperformed with
>20%
YoY topline growth

- Outperformance driven by **superior R&D capabilities**, **operational execution**, and **U.S. based manufacturing footprint**
- **Delivered strong cadence of new product launches**, including first-to-market launch of prucalopride and partnered generic launch

Metric[1] ($ millions, except EPS)	2025	YoY Growth[4]
Net Revenue (Total Company)	$854 - $873	>39%
Cortrophin Gel Net Revenue	$348	76%
ILUVIEN Net Revenue	$75	N/M
Adjusted Non-GAAP EBITDA[2]	$221 - $228	>42%
Adjusted Non-GAAP Diluted EPS[2][3]	$7.37 - $7.64	>42%

1. Represents 2025 financial guidance provided by the Company on November 7, 2025, except for Cortrophin Gel and ILUVIEN net revenue which represent preliminary, unaudited results provided by the Company on January 12, 2026.
2. Adjusted non-GAAP EBITDA and Adjusted Diluted non-GAAP EPS are non-GAAP financial measures.
3. Non-GAAP Adjusted Diluted Weighted-Average Shares Outstanding exclude certain dilutive shares related to the 2029 senior convertible notes as they are intended to be covered by our capped call transactions.
4. Year-over-year growth is based on the low end of 2025 guidance ranges except for Cortrophin Gel net revenue for which the comparison is to preliminary, unaudited 2025 results.

2026 priorities to drive long-term growth and value creation

ACCELERATE ANI'S TRANSFORMATION INTO A LEADING RARE DISEASE COMPANY

Cortrophin Gel

- **Maximize multi-year growth opportunity** by addressing significant unmet need across indications
- **Build on momentum** in underpenetrated specialty indications: nephrology, neurology, rheumatology, and pulmonology
- **Build and deploy** ~90-person organization dedicated to acute gouty arthritis flares by mid-year
- **Advance Phase 4 trial** to establish further evidence supporting Cortrophin Gel in acute gouty arthritis flares
- Continue to evaluate opportunities to **enhance patient convenience**

ILUVIEN

- **Return to growth** by leveraging the commercial and patient access initiatives established in 2025

CONTINUED EXECUTION IN GENERICS BUSINESS

- **Leverage** superior R&D capabilities, operational execution, U.S. manufacturing footprint, and business development expertise to continue expanding cash generation
- **Maintain** current cadence of 10-15 launches annually

EXECUTE DISCIPLINED CAPITAL ALLOCATION STRATEGY

- **Explore opportunities to expand** scope and scale of Rare Disease business
- **Invest in dedicated organization** for Cortrophin Gel in gout
- **Invest** high single-digit percentage of Generics revenue into R&D

2026 guidance reflects strong top- and bottom-line growth driven by Rare Disease business

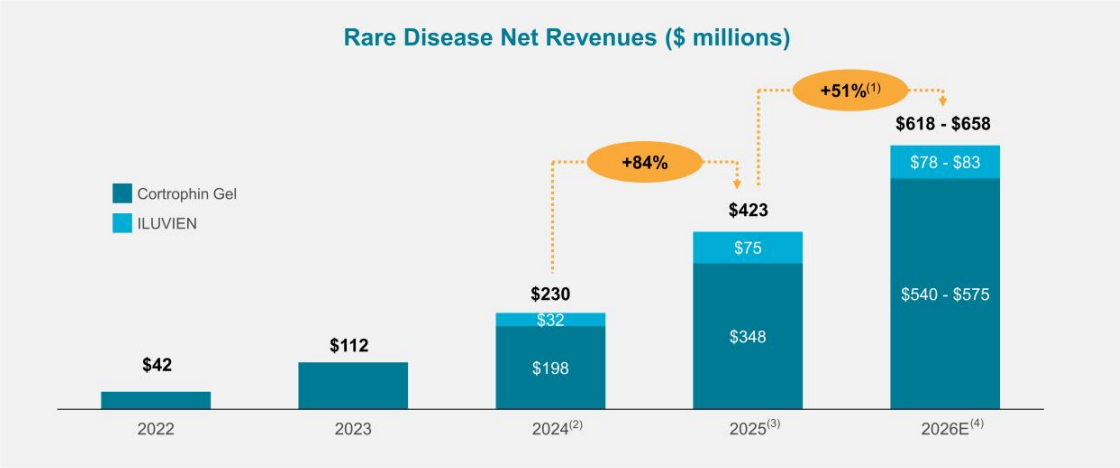
Metric ($ millions, except EPS)	Full Year 2026 Guidance	YoY Growth[3]
Net Revenue (Total Company)	$1,055 - $1,115	24 - 28%
Cortrophin Gel Net Revenue	$540 - $575	55 - 65%
ILUVIEN Net Revenue	$78 - $83	4 - 11%
Adjusted Non-GAAP EBITDA[1]	$275 - $290	24 - 27%
Adjusted Non-GAAP Diluted EPS[1][2]	$8.83 - $9.34	20 - 22%

2026 adjusted non-GAAP gross margin expected to be 59.3% - 60.3%[4]

1. Adjusted Non-GAAP EBITDA and Adjusted Non-GAAP Diluted EPS are Non-GAAP financial measures.
2. For full year 2026 guidance, Non-GAAP Adjusted Diluted Weighted-Average Shares Outstanding exclude certain dilutive shares related to the 2029 senior convertible notes as they are intended to be covered by our capped call transactions.
3. Year-over-year growth is calculated based on 2026 guidance ranges compared to 2025 guidance ranges provided by ANI on November 7, 2025, for all metrics except Cortrophin Gel net revenue and ILUVIEN net revenue for which the comparison is to 2025 preliminary, unaudited results.
4. Blended royalty rate due to Merck for Cortrophin Gel net sales expected to be in high-20 percent range in 2026.

Rare Disease Business

Rare Disease business represents primary driver of growth; expected to account for ~60% of revenues in 2026



1. Percent change calculated based on the midpoint of 2026 financial guidance range.
2. Alimera acquisition occurred in September 2024; ILUVIEN revenue only represents partial year of ownership.
3. Represents preliminary, unaudited results provided by the Company on January 12, 2026.
4. Represents 2026 financial guidance ranges provided by the Company on January 12, 2026.

Cortrophin Gel: Lead Rare Disease Asset

Cortrophin Gel is purified corticotropin (ACTH), a **late-line treatment option** for patients struggling with certain chronic autoimmune disorders

Fast growing two-player ACTH market estimated to reach ~$992M[1] in 2025, up 45% YoY

Approved for multiple indications in neurology, nephrology, rheumatology, ophthalmology and pulmonology

Long-term sustainability driven by high barriers (regulatory, IP) to generic entry

Potential for strong multi-year growth as key indications have significant unmet medical need

Multiple presentations such as Pre-Filled Syringe and vials available to **enhance patient convenience**

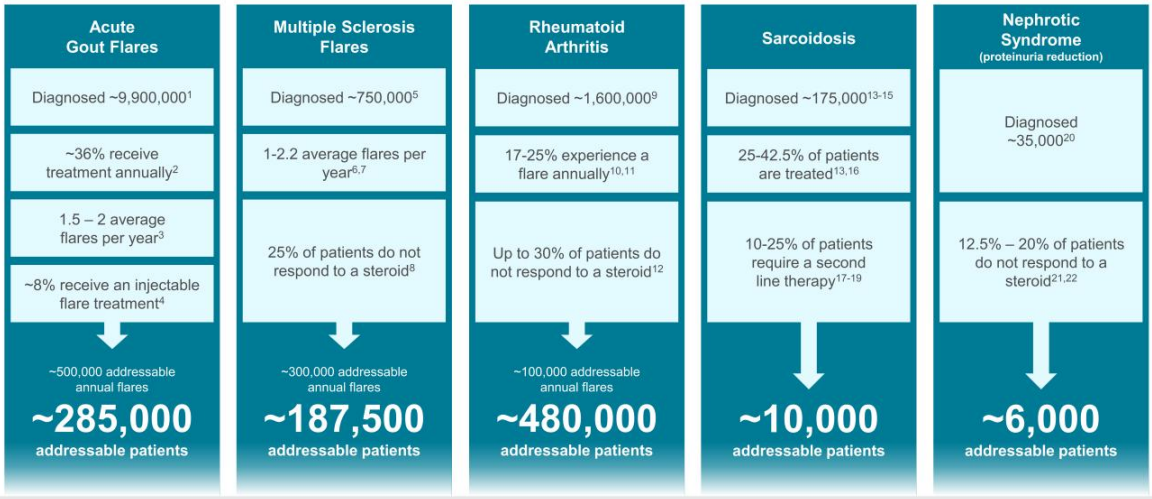
1. Based on the sum of preliminary unaudited results for 2025 Cortrophin Gel net revenue and Keenova Therapeutics' 2025 guidance for Acthar Gel per its third quarter 2025 earnings release (November 10, 2025).

ACTH market returned to growth following the launch of Cortrophin Gel

- Following launch of Cortrophin Gel, **ACTH class returned to double-digit growth in 2024**
- **Strong future multi-year growth potential** driven by large market opportunity as key indications remain significantly underpenetrated
- Proven ability to **reach new HCPs and patients** with approximately half of Cortrophin Gel prescribers naive to the ACTH category before prescribing Cortrophin Gel

1. Based on the sum of preliminary unaudited results for 2025 Cortrophin Gel net revenue and Keenova Therapeutics' 2025 guidance for Acthar Gel per its third quarter 2025 earnings release (November 10, 2025).

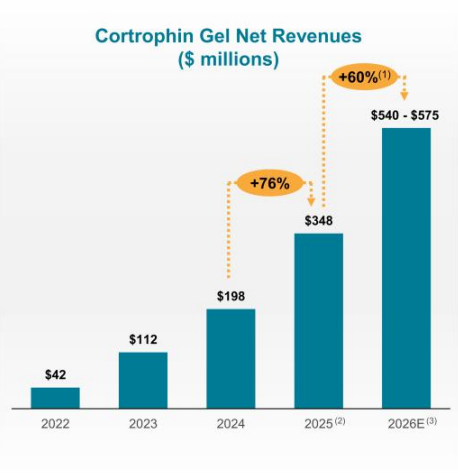
Cortrophin Gel has strong multi-year growth potential with addressable patient populations across indications significantly under-penetrated



* All references provided in appendix. Addressable patient populations shared for select indications.

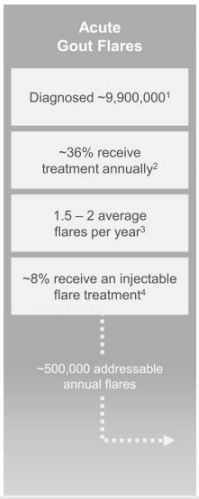
Cortrophin to deliver significant growth in fifth year of launch with multi-year growth opportunity ahead

Investing in High ROI commercial initiatives	• Focus efforts to **continue momentum** established in Nephrology, Neurology, Rheumatology and Pulmonology as the ACTH market expands • Building a **new ~90-person** organization dedicated to gout that targets primary care and podiatrist offices, expected to deploy mid-2026 • Realizing synergies with integrated ophthalmology team
Generation of scientific and clinical evidence	• **Advancing Phase 4 clinical trial** of Cortrophin Gel in acute gouty arthritis flares • **Robust pipeline** of investigator-initiated trials across disease states • Continued investment in **preclinical data and publications**
Enhancing convenience	• Launched Pre-Filled Syringe in 2025 • **Continuing to evaluate** opportunities to enhance patient convenience



1. Year-over-year growth calculated based on the midpoint of 2026 financial guidance rage issued by the Company on January 12, 2026.
2. Represents preliminary, unaudited results issued by the Company on January 12, 2026.
3. Represents 2026 financial guidance issued by the Company on January 12, 2026.

Capturing sizable additional opportunity in gout through commercial organization expansion



Large underpenetrated market opportunity

- **Focus on most severe patients: ~285,000** who are currently treated with injectables for their flares
- Need for new treatments for those patients not well served by first line options
- Co-morbidities may limit certain treatment options

Successful track record in Gout

- **Only approved ACTH therapy** to treat acute gouty arthritis flares
- **Gout indication generated ~15%** of Cortrophin Gel volume in 2025, largely from nephrologists and rheumatologists
- **Prefilled syringe and subcutaneous option for Cortrophin self-administration** enables flare readiness, unlike most injectable options

Our approach to serving more patients

- In 2025, ran **successful pilots** across 10 territories in primary care and podiatry
- By mid-2026, **deploying new ~90-person commercial organization** to target high priority PCPs and podiatrists who see most severe acute gouty arthritis patients
- **Investing in evidence generation** through Phase 4 trial to expand use over time

~285,000 patients

* All references provided in appendix. Addressable patient populations shared for select indications.

ILUVIEN is a long-acting ocular therapy approved for DME and chronic NIU-PS

ILUVIEN®
(fluocinolone acetonide intravitreal implant) 0.19mg

36-months of continuous therapy via CONTINUOUS MICRODOSING™ of fluocinolone acetonide (FAc) in patients with retinal disease

Diabetic Macular Edema (DME):

- Chronic disease that is the leading cause of vision loss in diabetic patients; ~4% of diabetic patients develop clinically significant macular edema
- >50,000 patients in the U.S. are not well served by anti-VEGF therapy; <5,000 patient starts annually for DME in the U.S.
- Strong global clinical evidence in DME supported by NEW DAY study results

Chronic non-infectious uveitis affecting the posterior segment (NIU-PS):

- Inflammation of the eye that can lead to pain, visual impairment, and vision loss
- >75,000 patients in the U.S. are candidates for treatment, and steroids are the standard of care; <5,000 patient starts annually for NIU-PS in the U.S.

Returning ILUVIEN to growth by leveraging established commercial and patient access initiatives

Generics Business

Generics business driving strong cash flow generation with superior R&D capabilities, U.S. manufacturing footprint, and operational excellence

Robust, diversified pipeline and new product launch execution

- Robust pipeline in place to deliver 10-15 new product launches annually
- Invest high single-digit percentage of Generics revenue into Generics R&D to support business
- Diversified portfolio of ~125 product families and largest product expected to account for less than 5% of Generics revenues in 2026

Strong operational backbone with a focus on cost efficiency

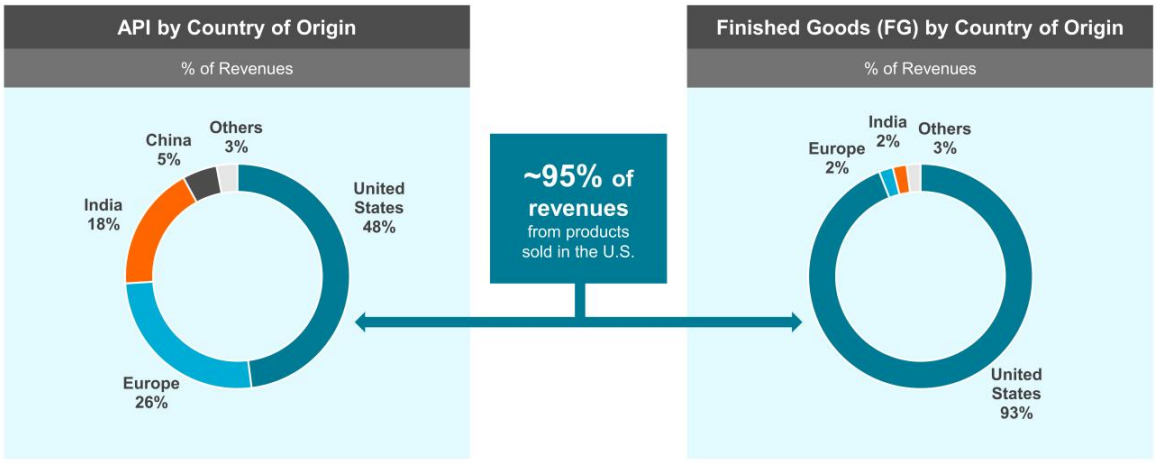
- Three U.S. based manufacturing sites with strong GMP track record; all sites currently in VAI or NAI status
- Manufactured and supplied over 2.5 billion doses of therapeutics in last 12 months(1)
- Systematic approach to reducing raw materials and finished goods costs and lean corporate spend

Generics Net Revenues ($ millions)

1. Per IQVIA NSP Sales data - MAT November 2025 data.

U.S. Manufacturing Footprint

Over 90% of ANI's revenues come from finished goods manufactured in the U.S.; only ~5% revenues have a direct reliance on China



NOTE: Statistics on this slide based upon internal analysis utilizing estimated / projected full year 2025 Revenue, procurement, manufacturing and other data as prepared June 2025

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)**

Summary

ANI well positioned to deliver long-term growth and value creation

2026 STRATEGIC PRIORITIES

Accelerate transformation into leading Rare Disease company

Continued excellence in Generics R&D and operations

Execute disciplined capital allocation strategy

FINANCIAL STRENGTH

2026 total revenues[1]	2026 adjusted EBITDA[1][2]	2025 year-end cash[3]	2025 year-end net leverage[3]
>$1B	~$283M	~$285M	<1.7x
⬆26% YoY	⬆ 26% YoY		

VIRTUOUS CYCLE OF GROWTH DRIVES TRANSFORMATION INTO A LEADING RARE DISEASE COMPANY

- **Rare Disease** expected to represent **~60%** of total revenue in 2026
- Lead asset, **Cortrophin Gel**, expected to deliver **+60%** YoY growth in 2026 with substantial, multi-year growth opportunity[4]
- **Strong Generics cash flows** further enables investments in Rare Disease business

1. Based on the midpoint of 2026 financial guidance ranges issued by the Company on January 12, 2026.
2. Adjusted Non-GAAP EBITDA is a Non-GAAP financial measure.
3. Cash is preliminary unaudited balance as of December 31, 2026. Net leverage as of September 30, 2026 was 1.7x and the Company expects or-going de-levering in the fourth quarter of 2025.
4. YoY growth rate calculated using the midpoint of 2026 financial guidance provided by the Company on January 12, 2026, compared to preliminary, unaudited results.

Appendix

References for Cortrophin Gel Addressable Patient Population

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