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

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- 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 (GLOBE NEWSWIRE) -- 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 44 th 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.

Investor Relations:
Courtney Mogerley, Argot Partners
E: ani@argotpartners.com

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