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

January 13, 2025

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

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

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

Preliminary Fourth Quarter and Full Year 2024 Financial Results

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

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

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

Preliminary Full Year 2025 Outlook

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

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

Presentation

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

Non-GAAP Financial Measures

Adjusted non-GAAP EBITDA

ANI's management considers adjusted non-GAAP EBITDA to be an important financial indicator of ANI's operating performance, providing investors and analysts with a useful measure of operating results unaffected by non-cash stock-based compensation and differences in capital structures, tax structures, capital investment cycles, ages of related assets, and compensation structures among otherwise comparable companies. Management uses adjusted non-GAAP EBITDA when analyzing Company performance.

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

but not in lieu of, net income or loss reported under GAAP.

ANI is not providing a reconciliation for the forward-looking full year 2024 and 2025 adjusted EBITDA guidance because it does not currently have sufficient information to accurately estimate all of the variables and individual adjustments for such reconciliation, including “with” and “without” tax provision information. As such, ANI’s management cannot estimate on a forward-looking basis without unreasonable effort the impact these variables and individual adjustments will have on its reported results.

Adjusted non-GAAP Diluted Earnings per Share

ANI’s management considers adjusted non-GAAP diluted earnings per share to be an important financial indicator of ANI’s operating performance, providing investors and analysts with a useful measure of operating results unaffected by the non-cash stock-based compensation, non-cash interest expense, depreciation and amortization, M&A transaction and integration expenses, contingent consideration fair value adjustment, unrealized gain on our investment in equity securities, gain on sale of the former Oakville, Ontario manufacturing site, litigation expenses related to certain matters, loss on extinguishment of debt, amortization of certain purchase price adjustments, severance expense, and certain other items that vary in frequency and impact on ANI’s results of operations. Management uses adjusted non-GAAP diluted earnings per share when analyzing Company performance.

Adjusted non-GAAP diluted earnings per share is defined as adjusted non-GAAP net income, as defined above, divided by the diluted weighted average shares outstanding during the period. Management will continually analyze this metric and may include additional adjustments in the calculation in order to provide further understanding of ANI’s results. Adjusted non-GAAP diluted earnings per share should be considered in addition to, but not in lieu of, diluted earnings (loss) per share reported under GAAP.

ANI is not providing a reconciliation for the forward-looking full year 2024 adjusted diluted earnings per share guidance because it does not currently have sufficient information to accurately estimate all of the variables and individual adjustments for such reconciliation, including “with” and “without” tax provision information. As such, ANI’s management cannot estimate on a forward-looking basis without unreasonable effort the impact these variables and individual adjustments will have on its reported results.

About ANI

ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) is a diversified biopharmaceutical company committed to its mission of “Serving Patients, Improving Lives" by developing, manufacturing, and commercializing innovative and high-quality therapeutics. The Company is focused on delivering sustainable growth through its Rare Disease business, which markets novel products in the areas of ophthalmology, rheumatology, nephrology, neurology, and pulmonology; its Generics business, which leverages R&D expertise, operational excellence, and U.S.-based manufacturing; and its Established Brands business. For more information, visit www.anipharmaceuticals.com.

Forward-Looking Statements

To the extent any statements made in this release deal with information that is not historical, these are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, those relating to the commercialization and potential sales of the product and any additional product launches from the Company’s generic pipeline, 2024 guidance, 2025 guidance, other statements that are not historical in nature, particularly those that utilize terminology such as “anticipates,” “will,” “expects,” “plans,” “potential,” “future,” “believes,” “intends,” “continue,” other words of similar meaning, derivations of such words and the use of future dates.

Uncertainties and risks may cause the Company’s actual results to be materially different than those expressed in or implied by such forward-looking statements. Uncertainties and risks include, but are not limited to: our ability to continue to achieve commercial success with Cortrophin Gel, our first rare disease pharmaceutical product, including expanding the market and gaining market share, our business, financial condition, and results of operations will be negatively impacted; the ability of our approved products, including Cortrophin Gel, and products acquired in the acquisition of Alimera, to achieve commercialization at levels of market acceptance that will continue to allow us to achieve profitability; our ability to complete or achieve any, or all of the intended benefits of acquisitions and investments, including the acquisition of Alimera, in a timely manner or at all; the risks that our acquisitions and investments, including the recent acquisition of Alimera, could disrupt our business and harm our financial position and operating results; delays in production, increased costs and potential loss of revenues if we need to change suppliers due to the limited number of suppliers for our raw materials, active pharmaceutical ingredients, expedients, and other materials; our reliance on single source third party contract manufacturing supply for certain of our key products, including Cortrophin Gel and products acquired in the acquisition of Alimera; delays or failure in obtaining and maintaining approvals by the FDA of the products we sell; changes in policy or actions that may be taken by the FDA, United States Drug Enforcement Administration and other regulatory agencies, including among other things, drug recalls, regulatory approvals, facility inspections and potential enforcement actions; risks that we may face with respect to importing raw materials and delays in delivery of raw materials and other ingredients and supplies necessary for the manufacture of our products from both domestic and overseas sources due to supply chain disruptions or for any other reason; the ability of our manufacturing partners to meet our product demands and timelines; the impact of changes or fluctuations in exchange rates; our ability to develop, license or acquire, and commercialize new products; the level of competition we face and the legal, regulatory and/or legislative strategies employed by our competitors to prevent or delay competition from generic alternatives to branded products; our ability to protect our intellectual property rights; the impact of legislative or regulatory reform on the pricing for pharmaceutical products; the impact of any litigation to which we are, or may become, a party; our ability, and that of our suppliers, development partners, and manufacturing partners, to comply with laws, regulations and standards that govern or affect the pharmaceutical and biotechnology industries; our ability to maintain the services of our key executives and other personnel; and general business and economic conditions, such as inflationary pressures, geopolitical conditions including but not limited to the conflict between Russia and the Ukraine, the conflict in the Middle East, conflicts related to the attacks on cargo ships in the Red Sea, and the effects and duration of outbreaks of public health emergencies, and other risks and uncertainties that are described in ANI’s Annual Report on Form 10-K, quarterly reports on Form 10-Q, and other periodic reports filed with the Securities and Exchange Commission.

More detailed information on these and additional factors that could affect the Company’s actual results are described in the Company’s filings with the Securities and Exchange Commission (SEC), including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as other filings with the SEC. All forward-looking statements in this news release speak only as of the date of this news release and are based on the Company’s current beliefs, assumptions, and expectations. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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