ANI Pharmaceuticals Completes Acquisition of Novitium Pharma, Significantly Enhancing R&D Capabilities and Scale of Generics and CDMO Businesses

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-- Combined company creates generics growth engine with technical capabilities to bring complex, high-value products to market in efficient and cost effect manner --

-- Proven track record with largest number of Competitive Generic Therapy (CGT) approvals --

-- Deep pipeline with a focus on niche opportunities, including 505(b)(2) candidates in Oncology and Hypertension --

-- Pro-forma September 30, 2021 YTD revenues are $202.5 million and non-GAAP EBITDA $66.6 million --

-- Founders Samy Shanmugam and Chad Gassert to join Executive Team and Mr. Shanmugam to join Board of Directors --

-- Immediately accretive to Adjusted non-GAAP earnings per share --

-- New capital structure in place --

BAUDETTE, Minn.--(BUSINESS WIRE)-- ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) (ANI or the Company) today announced that it has completed the previously announced acquisition of Novitium Pharma, a privately held, New Jersey-based pharmaceutical company with development, manufacturing, and commercialization capabilities.

“Today marks a major milestone for ANI and the many patients who rely on our high-quality, cost-effective medications. With the completion of this acquisition, we bring on board a world-class R&D engine in the generic and 505 (b)(2) sectors, and a highly-compliant U.S. based manufacturing facility, positioning us well for sustainable long-term growth. Novitium has continued to perform in-line or above our investment thesis since deal signing on March 9th with thirteen new product approvals, strong quarter-on-quarter EBITDA growth and a successful FDA GMP inspection completed in July 2021,” stated Nikhil Lalwani, President and Chief Executive Officer of ANI.

“ANI is thrilled to welcome the expertise and leadership of Novitium’s founders, Samy Shanmugam, Chad Gassert and Vijay Thorappadi, along with over 100 talented and dedicated employees, who have joined the ANI team. Our robust product pipeline includes several more CGT and 505 (b)(2) candidates and will be further expanded to maximize the value of our bolstered R&D engine,” concluded Lalwani.

Samy Shanmugam, co-founder of Novitium and ANI’s new Head of Research & Development and Chief Operating Officer of New Jersey Operations added, “Today is an exciting day for all of our employees, as we combine the complementary strengths of our two platforms. We are energized by today’s events and look forward to strong contributions in driving the future success of an united ANI.”

“ANI’s new capital structure, comprised of the recently completed $75 million equity raise and the closure of a new $300 million Term Loan-B, $40 million revolver and $25 million PIPE, gives the Company significant flexibility in supporting the integration of Novitium into ANI, ensuring a strong Purified Cortrophin™ Gel commercial launch and will propel the next phase of growth for ANI,” stated Stephen Carey, Senior Vice President and Chief Financial Officer of ANI.

Compelling Investment Thesis

- **Proven R&D Engine Fuels Sustainable Growth**

Novitium has a strong pipeline with 20+ new product launches planned in the next 18 months, including products with U.S. Food and Drug Administration (FDA) Competitive Generic Therapy designation. Novitium received thirteen approvals since March 2021, several of which were limited competition launches. Novitium’s proven R&D leadership team of Samy Shanmugam, Chad Gassert and Vijay Thorapaddi will drive the combined company’s R&D engine.

- **Expands ANI’s R&D Pipeline Focused on Niche Opportunities**

Novitium has expanded the 505 (b)(2) portfolio beyond the three initial 505(b)(2) candidates in Oncology and Hypertension. The combined company has also expanded dosage forms to include injectables and gels.

- **Enhances scale of CDMO Business & U.S. Based Manufacturing Capacity.**

Novitium adds nine new customers to ANI’s growing CDMO business. Additionally, Novitium brings a U.S. based, state-of-the-art manufacturing facility enhancing manufacturing capabilities and CDMO opportunities.

- **Compelling Financial Profile**

Immediately accretive to Adjusted non-GAAP earnings per share. The acquisition diversifies ANI’s revenue base by contributing to each of its reporting segments: Generics, Contract Manufacturing, Royalties/Other and, following the launch of Novitium’s 505(b)(2) pipeline products, the Brand segment.

The Transaction has satisfied customary closing conditions, and received approval from shareholders and relevant regulatory agencies, including clearance under the Hart-Scott Rodino Antitrust Improvements Act. As previously announced, the U.S. Federal Trade Commission (the FTC) has accepted the proposed consent order in connection with ANI's definitive agreement to acquire Novitium Pharma. The divestitures required by the FTC of development rights to one generic drug and assets with respect to another generic drug are immaterial to the Company's business and have been completed. The acceptance by the FTC satisfies all required antitrust clearances needed to be obtained for the acquisition.

Terms of the Transaction and Debt Re-Financing

Under the terms of the transaction, the Purchase Price is comprised of (i) a cash payment of $89.5 million and (ii) the issuance of 2,466,654 common shares of ANI equity. Novitium is also eligible to receive (i) $25 million in contingent payments upon the achievement of financial targets related to Generics products and filing of certain ANDAs and (ii) $21.5 million in contingent payments upon the achievement of financial targets from the 505(b)(2) products.

Commensurate with the completion of the transaction, ANI retired its existing Term Loan-A credit facility (including the repayment of $200.1 million of face value outstanding) and closed a new $300 million Term Loan-B and a $25 million PIPE investment with Ampersand Capital Partners. The new credit facility also includes a $40 million revolver that is un-drawn at this time. The new debt financing is secured by substantially all the assets of ANI and its subsidiaries.

Advisors

Bourne Partners, Truist Securities and Houlihan Lokey acted as financial advisors to ANI Pharmaceuticals. SVB Leerink acted as financial advisor to Novitium Pharma and its shareholders. Hughes Hubbard & Reed LLP were ANI’s legal advisors and Orrick, Herrington & Sutcliffe LLP acted as legal advisors to Novitium and its shareholders.

About ANI Pharmaceuticals, Inc.

ANI Pharmaceuticals is a diversified bio-pharmaceutical company serving patients in need by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceutical products, including for diseases with high unmet medical need. For more information, please 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 development, manufacturing and commercialization of future product candidates and any additional product launches from the Company’s generic pipeline, those relating to expansion of the R&D engine, expected growth and similar 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, the risk that the Company may face with respect to importing raw materials; the use of single source suppliers and the time it may take to validate and qualify another supplier, if necessary; increased competition and strategies employed by competitors; the ability to realize benefits anticipated from acquisitions; costs and regulatory requirements relating to contract manufacturing arrangements; the ability of the Company to successfully maintain manufacturing capabilities and adequate commercial quantities of Cortrophin Gel at acceptable costs and quality levels; broad acceptance of Cortrophin Gel by physicians, patients and the healthcare community; the acceptance of pricing and placement of Cortrophin Gel on payers’ formularies; delays or failure in obtaining future product approvals from the U.S. Food and Drug Administration; general business and economic conditions, including the ongoing impact of the COVID-19 pandemic; market trends for our products; regulatory environment and changes; and regulatory and other approvals relating to product development and manufacturing.

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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