

Adial Pharmaceuticals Reports Third Quarter 2024 Financial Results and Provides Business Update

GLEN ALLEN, Va., Nov. 13, 2024 (GLOBE NEWSWIRE) -- **Adial Pharmaceuticals, Inc. (NASDAQ: ADIL)** ("Adial" or the "Company"), a clinical-stage biopharmaceutical company focused on developing therapies for the treatment and prevention of addiction and related disorders, today provided a business update and reported its financial results for the third quarter of 2024.

Cary Claiborne, President and Chief Executive Officer of Adial, stated, "We reached an important milestone this quarter with the successful database lock of the pharmacokinetics study for AD04, our lead investigational, genetically targeted therapeutic for the treatment of Alcohol Use Disorder (AUD). The pharmacokinetics study is essential for validating AD04's dosing and safety profile, and we expect to report topline results soon. This accomplishment would position us to begin regulatory preparations, reinforcing our mission to bring a safe, effective AUD treatment to market."

"Building on our commitment to personalized addiction care, we have entered into a strategic partnership with Boudicca Dx to support the development plan for our companion diagnostic genetic test and help ensure compliance with FDA guidelines. This innovative tool is designed to identify genetic markers that indicate a patient's responsiveness to AD04, paving the way for more targeted and effective treatment options."

"Furthermore, the National Institute on Alcohol Abuse and Alcoholism recently introduced a new, broader definition of recovery, which expands the concept beyond abstinence alone. This inclusive perspective acknowledges the various paths individuals may take in their recovery journeys. By aligning with this comprehensive definition, we are optimistic that it will stimulate additional support for programs like AD04. Overall, we are proud of the meaningful progress made during the quarter and believe we are making progress in advancing AD04 toward commercialization," concluded Mr. Claiborne.

Other Developments

Management

On November 5, 2024, [Adial announced the appointment of Vinay Shah as Chief Financial Officer](#), effective November 16, 2024.

Patents

On October 17, 2024, [Adial announced that the United States Patent and Trademark Office has issued a Notice of Allowance for a new patent](#). The patent, once issued, will cover additional genotype combinations identified through the Company's proprietary genetic diagnostic tool.

On July 31, 2024, Adial announced that, after an extensive review of data and information from the Onward Study, it [had filed a new patent application](#) to protect core assets and extend IP exclusivity on its core technology. This patent, assuming granted, is expected to protect Adial's core assets through at least 2044.

Financing

During the third quarter the Company received total gross proceeds of approximately \$3.8 million from utilization of its at-the-market facility.

Third Quarter 2024 Financial Results

- Cash and cash equivalents were \$5.2 million as of September 30, 2024, compared to \$2.8 million as of December 31, 2023. The Company believes that its existing cash and cash equivalents will fund its operating expenses into the second half of 2025 based on currently committed development plans.

- Research and development expenses increased by approximately \$825 thousand (399%) in the three months ended September 30, 2024, compared to the three months ended September 30, 2023. This change was due to an increase of approximately \$771 thousand in clinical trial expenses related to the pharmacokinetics (PK) study during the quarter and chemistry, manufacturing, and controls (CMC) expenses which increased by approximately \$204 thousand, as stability testing took place to support the PK study. These increases were partially offset by modest decreases in license royalty expense and decreases in the salaries and equity-based compensation of R&D personnel.
- General and administrative expenses increased by approximately \$29 thousand (3%) in the three months ended September 30, 2024, compared to the three months ended September 30, 2023.
- Net Loss was \$2.2 million for the three months ended September 30, 2024, compared to a net loss of \$1.4 million for the three months ended September 30, 2023. The increase in Net Loss was primarily driven by the increases in R&D and G&A expenses described above.

About Adial Pharmaceuticals, Inc.

Adial Pharmaceuticals is a clinical-stage biopharmaceutical company focused on the development of therapies for the treatment and prevention of addiction and related disorders. The Company's lead investigational new drug product, AD04, is a genetically targeted, serotonin-3 receptor antagonist, therapeutic agent for the treatment of Alcohol Use Disorder (AUD) in heavy drinking patients and was recently investigated in the Company's ONWARD™ pivotal Phase 3 clinical trial for the potential treatment of AUD in subjects with certain target genotypes identified using the Company's proprietary companion diagnostic genetic test. ONWARD showed promising results in reducing heavy drinking in heavy drinking patients, and no overt safety or tolerability concerns. AD04 is also believed to have the potential to treat other addictive disorders such as Opioid Use Disorder, gambling, and obesity. Additional information is available at www.adial.com.

Forward-Looking Statements

This communication contains certain "forward-looking statements" within the meaning of the U.S. federal securities laws. Such statements are based upon various facts and derived utilizing numerous important assumptions and are subject to known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Statements preceded by, followed by or that otherwise include the words "believes," "expects," "anticipates," "intends," "projects," "estimates," "plans" and similar expressions or future or conditional verbs such as "will," "should," "would," "may" and "could" are generally forward-looking in nature and not historical facts, although not all forward-looking statements include the foregoing. The forward-looking statements include statements regarding reporting topline results from the pharmacokinetics study of AD04 soon, beginning regulatory preparations, bringing a safe, effective AUD treatment to market, ensuring compliance with FDA guidelines, identify genetic markers that indicate a patient's responsiveness to AD04, paving the way for more targeted and effective treatment options, the broader definition of recovery stimulating additional support for programs like AD04, making progress in advancing AD04 toward commercialization, the new patent application protecting core assets through at least 2044, existing cash and cash equivalents funding operating expenses into the second half of 2025 based on currently committed development plans and the potential of AD04 to treat other addictive disorders such as opioid use disorder, gambling, and obesity. Any forward-looking statements included herein reflect our current views, and they involve certain risks and uncertainties, including, among others, our ability to pursue our regulatory strategy, our ability to advance ongoing partnering discussions, our ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, our ability to develop

strategic partnership opportunities and maintain collaborations, our ability to obtain or maintain the capital or grants necessary to fund our research and development activities, our ability to complete clinical trials on time and achieve desired results and benefits as expected, regulatory limitations relating to our ability to promote or commercialize our product candidates for specific indications, acceptance of our product candidates in the marketplace and the successful development, marketing or sale of our products, our ability to maintain our license agreements, the continued maintenance and growth of our patent estate and our ability to retain our key employees or maintain our Nasdaq listing. These risks should not be construed as exhaustive and should be read together with the other cautionary statement included in our Annual Report on Form 10-K for the year ended December 31, 2023, subsequent Quarterly Reports on Form 10-Q and current reports on Form 8-K filed with the Securities and Exchange Commission. Any forward-looking statement speaks only as of the date on which it was initially made. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, changed circumstances or otherwise, unless required by law.

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