Adial Pharmaceuticals Reports 2023 Fiscal Year Financial Results and Provides Business Update

Received Favorable Feedback from US and EU Regulatory Agencies

Advancing Discussions with Potential Strategic Partners

Received $4.3 Million in Gross Proceeds from Warrant Exercises Subsequent to Year-End 2023

GLEN ALLEN, Va., April 02, 2024 — **Adial Pharmaceuticals, Inc. (NASDAQ: ADIL; ADILW)** ("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 2023 fiscal year ended December 31, 2023.

Cary Claiborne, President and Chief Executive Officer of Adial, stated, "Throughout 2023 we made important progress that provided us with a clearer path forward to the potential approval and commercial launch of our lead investigational new drug product, AD04, to treat Alcohol Use Disorder, along with our companion diagnostic. Specifically, we conducted meetings and received favorable feedback from both US and European regulators, allowing us to refine our clinical development plan. We have engaged expert advisors and are currently finalizing our plan, which we anticipate will include conducting two Phase 3 clinical trials of AD04 in parallel to support potential approval in the shortest timeframe possible while minimizing risk. Our current plan includes focusing on approval in the US, as the US standards may translate to acceptance with other non-US regulators."

"In addition, we are advancing discussions with potential strategic partners who have expressed interest in supporting the development and commercial launch of AD04 in both the US and other countries. We believe quality partnerships would provide us with additional resources to swiftly advance the studies and the ability to rapidly penetrate the market following approval. Moreover, we have maintained a strong balance sheet, which enables us to reach important upcoming milestones. Overall, we are encouraged by our progress and look forward to providing meaningful updates in the near term."

Other Developments

Management

On January 18, 2024, Adial announced the appointment of Tony Goodman as Chief Operating Officer. Mr. Goodman is a highly accomplished pharmaceutical industry executive and member of Adial's Board of Directors since 2017. He will oversee the Company's strategic growth initiatives, including clinical development and commercial planning for Adial's lead investigational new drug product, AD04, as well as business development initiatives focused on partnership opportunities in the area of addiction treatment, and continue to serve on Adial's Board.

Intellectual Property

In October 2023, Adial was awarded a key patent from the United States Patent and Trademark Office (USPTO) combining the use of the Company's proprietary genetic diagnostic to detect select genotypes for genetically targeted treatment of Alcohol Use Disorder and opioid use disorder (OUD) with the Company's lead investigational new drug product AD04.

In February 2024, Adial was awarded an important patent from the USPTO which expands the estate covering the combination of the Company's proprietary genetic diagnostic to identify patients with specific genotypes for genetically targeted treatment of Alcohol Use Disorder and drug dependencies, such as opioid use disorder (OUD), with the Company's lead investigational new drug product AD04.

In addition, Adial announced patent number 11,905,562 was issued on February 20, 2024 by the USPTO. The patent covers the Company's lead investigational new drug product, AD04, and its ability to target the serotonin transporter gene for the potential treatment of opioid use disorder (OUD).

Awards

On October 18, 2023, Adial was awarded the 2023 Best Practices Technology Innovation Leadership Award in the North American precision medicine for addiction disorders industry by Frost & Sullivan, an American business consulting firm that offers market research and analysis, growth strategy consulting, and corporate training. The complete Frost & Sullivan award report is available at www.frost.com/Adial-Pharmaceuticals.

Purnovate

On December 16, 2023, Adial received the final development cost reimbursement payment of $350,000 from Adovate, LLC under the terms of the final asset purchase agreement (the "FAA") executed with Adovate for the purchase of the assets and business of the Company's wholly owned subsidiary, Purnovate, Inc.

Under the agreement, the Company is also eligible to receive up to approximately $11 million in development and approval milestones for each compound (up to $33 million in total development and approval milestones for the first three compounds alone), as well as a total of $50 million in additional commercial milestones, for a total consideration of up to $83 million with potential milestone payments on additional compounds. Additionally, the Company will receive a low, single-digit royalty and acquired a 15% equity stake in Adovate.

Fiscal Year 2023 Financial Results

- Cash and cash equivalents were $2.8 million as of December 31, 2023, compared to $4.0 million as of December 31, 2022. Subsequent to the end of the year, the Company received total gross proceeds of approximately $4.3 million from recent warrant exercises. Including the proceeds from warrant exercises, the company believes that its existing cash and cash equivalents will allow it to accelerate the development of AD04 and fund its operating expenses into the first quarter of 2025.
- Research and development expenses decreased by approximately $683 thousand (35%) in the year ended December 31, 2023 compared to the year ended December 31, 2022. This decrease was led by a significant decrease in the use of clinical and statistical consultants of approximately $303 thousand and clinical materials manufacturing expenses of $231 thousand with the completion of the AD04 trial.
- General and administrative expenses decreased by approximately $3.3 million (37%) in the year ended December 31, 2023 compared to the year ended December 31, 2022. The single largest component of this decrease was the reduction in equity-based compensation of G&A directed employees and consultants of approximately $1.6 million, resulting from reduced issuances of options and share grants and the completion of the vesting periods of grants made in prior years. The cost of salaries and other cash compensation of G&A directed employees decreased by approximately $905 thousand, primarily due to the redirection of executives to activities now classified as discontinued.
- Net Loss was $5.1 million for the year ended December 31, 2023, compared to a net loss of $12.7 million for the year ended December 31, 2022.

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 the approval and commercial launch of the Company's lead investigational new drug product, AD04, to treat Alcohol Use Disorder, along with its companion diagnostic, conducting two Phase 3 clinical trials of AD04 in parallel to support potential approval in the shortest timeframe possible while minimizing risk, US standards translating to acceptance with other non-US regulators, advancing discussions with potential strategic partners who have expressed interest in supporting the development and commercial launch of AD04 in both the US and other countries, quality partnerships providing the Company with additional resources to swiftly advance the studies and the ability to rapidly penetrate the market following approval, the Company's strong balance sheet enabling it to reach important upcoming milestones, providing meaningful updates in the near term, the expected contribution of Tony Goodman, receiving up to approximately $11 million in development and approval milestones for each compound (up to $33 million in total development and approval milestones for the first three compounds alone), as well as a total of $50 million in additional commercial milestones, for a total consideration of up to $83 million with potential milestone payments on additional compounds under the Purnovate FAA, existing cash and cash equivalents allowing the Company to accelerate the development of AD04 and fund its operating expenses into the first quarter of 2025and 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 retain our key employees or maintain our Nasdaq listing, 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, 2022, 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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