Adial Pharmaceuticals Reports 2022 Fiscal Year Financial Results and Provides Business Update

Secured meetings with U.S. and European regulatory agencies

Advancing partnership activities in both the U.S. and Europe

Ended 2022 fiscal year with cash and cash equivalents of $4.0 million

CHARLOTTESVILLE, Va., March 30, 2023 — **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 2022 fiscal year ended December 31, 2022.

Cary Claiborne, President and Chief Executive Officer of Adial, stated, "We made significant advancements throughout 2022. Specifically, we announced topline data from our pivotal ONWARD™ phase 3 clinical trial evaluating the efficacy, safety, and tolerability of AD04 in patients with Alcohol Use Disorder (AUD) and selected polymorphisms in the serotonin transporter and receptor genes. ONWARD results showed that AD04 achieved a statistically significant reduction of heavy drinking days in the "heavy drinkers" subgroup of patients. We recently conducted a detailed analysis of our prior Phase 2 and our ONWARD results and identified two specific genotypes that outperformed the others, which provides us a high level of confidence in our ability to pursue and obtain regulatory approval in the United States and Europe. As a result, we requested meetings with the appropriate regulatory agencies. We held a meeting with the Swedish Medical Product Agency in March and have secured meeting dates in the second quarter of 2023 with the Federal Institute for Drugs and Medical Devices (BfArM) in Germany and the U.S. Food and Drug Administration (FDA). Meeting dates for France, Finland, and the United Kingdom are still pending. These meetings are intended to provide us with a clearer understanding of a path forward to approval. As we effectively cut down on costs associated with Purnovate and reduce expenses related to research and administration, we have positioned ourselves in a much stronger financial position, while focusing on strategic partnership opportunities to further the clinical development and commercialization of AD04. Overall, we are encouraged by our progress, and look forward to providing further updates."

Other Recent Developments

Partnering

The Company recently engaged The Keswick Group, LLC, a biotech strategic commercial and business development advisory firm, to support advancement of the Company's partnering activities. The Keswick Group is led by Tony Goodman, a current member of Adial's Board of Directors. Mr. Goodman's career spans over 23 years in the pharmaceutical and biotech industries. Having held senior leadership and business development positions at a variety of pharmaceutical companies, Mr. Goodman brings significant expertise and experience in strategically important partnering transactions and extensive relationships in the healthcare market.

Financing

The Company closed an at-the-market registered direct offering of 1,829,269 shares of common stock at a purchase price of $0.41 per share of common stock with a single institutional investor for gross proceeds of $0.75 million before deducting the placement agent's fees and other estimated offering expenses payable by the Company.

Purnovate

The Company entered into an option agreement for the sale of the assets of Purnovate, Inc. ("Purnovate"), a wholly owned subsidiary of Adial, to Adovate, LLC (formerly known as Adenomed, LLC) ("Adovate"), a new company formed by

Purnovate Chief Executive Officer William Stilley, founder and former Chief Executive Officer of Adial. Under the terms of the agreement, Adovate has 120 days to exercise the option with the right to purchase two 30-day extensions. Adial would receive $450,000 upon exercise of the option, and then be reimbursed for any Purnovate expenditures incurred and paid after December 1, 2022. Under the acquisition agreement, the Company would also be 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 would receive a low, single-digit royalty and acquire a 19.9% equity stake in Adovate. Through this transaction, Adovate would assume all current Adial obligations related to Purnovate.

The proposed transaction was independently evaluated and unanimously approved, first by the Adial Audit Committee of the Board of Directors, and then by Adial's Board of Directors, with Mr. Stilley, a current board member, abstaining from the vote.

Fiscal Year 2022 Financial Results

- Cash Position: As of December 31, 2022, cash and cash equivalents were $4.0 million as compared to $6.1 million as of December 31, 2021. The Company believes that its existing cash and cash equivalents will fund its operating expenses into the third quarter of 2023 if the option to sell Purnovate is not exercised by Adovate. If Adovate exercises the option as expected, the Company would receive non-dilutive funding and the sale would significantly reduce its current cash burn rate, which would extend the Company's cash into the first quarter of 2024.
- Research and Development expenses decreased by $4.2 million (50%) to $4.2 million for the year ended December 31, 2022, compared to $8.4 million for the year ended December 31, 2021. The decrease was driven by lower costs related to the ONWARD Phase 3 trial as clinical activities were substantially complete in midyear 2022.
- General and Administration expenses decreased by $0.2 million (2%) to $9.3 million for the year ended December 31, 2022, compared to $9.5 million for the year ended December 31, 2021.
- Net Loss was $12.7 million for the year ended December 31, 2022, compared to a net loss of $19.4 million for the year ended December 31, 2021.

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 (estimated to be approximately one-third of the AUD population) 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. The Company is also developing adenosine analogs for the treatment of pain and other disorders. 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 pursuing and obtaining regulatory approval for AD04 in the United States and Europe, focusing on strategic partnership opportunities to further the clinical development and commercialization of AD04, providing further updates regarding the clinical development and commercialization of AD04, entering into a definitive agreement for the sale of the assets of Purnovate, Inc. to Adovate, LLC pursuant to which the Company will receive $450,000, be reimbursed for Purnovate expenditures incurred and paid after December 1, 2022 and be 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, together with a single-digit royalty and a 19.9% equity stake in Adovate, 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 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, our ability to retain our key employees or maintain our Nasdaq listing, our ability to consummate the Company's proposed sale of Purnovate to Adovate, maximizing the value of the early-stage assets in Purnovate, significantly reducing the Company's current burn rate and extending its cash runway, providing an update with regards the Company's detailed strategic plan for AD04, continuing discussions with potential pharmaceutical partners both in the U.S. and in Europe, our ability to reduce our current burn rate and extend our cash runway, and our ability to implement our strategic plan for AD04 and continue discussions with potential pharmaceutical partners. 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, 2021, 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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