

Adial Pharmaceuticals Reports Second Quarter 2023 Financial Results and Provides Business Update

August 21, 2023

Reported Positive Feedback from US and EU Regulatory Meetings

Sale of Purnovate Significantly Reduces Cash Burn Rate

Charlottesville, Va., Aug. 21, 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 second quarter of 2023.

Cary Claiborne, President and Chief Executive Officer of Adial, stated, “We continue to advance AD04 to meaningful inflection points and recently received favorable feedback from our US and EU regulatory meetings. Following the feedback, we made a strategic decision to focus our efforts on obtaining FDA approval, as the US standard should translate to acceptance in other international markets. In addition, the FDA confirmed the primary endpoint based on Percentage of No Heavy Drinking Days (PNHDD)-patients who reduced their alcohol consumption to zero heavy drinking days in the last two months of a six-month study. Furthermore, the FDA acknowledged that our post hoc analysis showing a statistically and clinical meaningful effect in specific genetic subtypes was positive and promising but requested additional data to support an NDA submission. As a result, we are currently planning to conduct two Phase 3 trials with AD04 in parallel to support potential approval in the shortest timeframe possible. Toward this end, and now having received regulatory feedback, we are progressing our partnering discussions and intend to provide further updates as appropriate. Overall, we remain confident in AD04’s ability to address a significant unmet need for patients suffering from alcohol use disorder, representing an addressable market of approximately \$40 billion in the U.S. alone. Moreover, the sale of our Purnovate business during the quarter provided non-dilutive funding and significantly reduced our current cash burn rate. Overall, we believe we are well positioned to execute on our development strategy, as well as reach meaningful milestones that we believe will drive significant value for shareholders.”

Other Recent Developments

Purnovate

On May 16, 2023, Adovate, LLC, exercised its option for the purchase of the assets and business of the Company’s wholly owned subsidiary, Purnovate, Inc. The Option Agreement provides that the parties will enter into a final acquisition agreement for the sale of the Purnovate assets under previously agreed financial terms. Adovate was recently formed by William Stilley, co-founder and former CEO of Adial, for the sole purpose of acquiring, funding and advancing the Purnovate assets.

Adial received an upfront payment of \$450 thousand on the notification date (May 8, 2023). After a final acquisition agreement is signed Adial will receive approximately \$1.1 million for Purnovate expenditures incurred and paid by Adial after December 1, 2022. During the quarter Adial received \$350 thousand in advance payment for reimbursement of those expenditures. Any Purnovate expenses incurred subsequent to May 15, 2023, are now the responsibility of Adovate. In addition, the

Company will be entitled 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 single digit royalty and has received a 19.9% equity stake in Advovate.

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

Second Quarter 2023 Financial Results

- **Cash Position:** As of June 30, 2023, cash and cash equivalents were \$1.2 million compared to \$4.0 million as of December 31, 2022. The Company believes that its existing cash and cash equivalents, as well as the impact of the agreement to sell its Purnovate's Assets and Business, will fund its operating expenses into the first quarter of 2024. Under the agreement, the Company received non-dilutive funding and the sale has significantly reduced its current cash burn rate.
- **Research and Development expenses** decreased by \$250 thousand (37%) in the three months ended June 30, 2023 compared to the three months ended June 30, 2022. This decrease was driven partly by a reduction of approximately \$96 thousand in direct development costs of AD04 as trial activities, which were winding down in the second quarter of 2022, were no longer taking place in the second quarter of 2023, replaced by less expensive regulatory consultations and data analysis. In addition, a one-time accrual of \$155 thousand for a royalty due the University of Virginia Patent Foundation took place in the second quarter of 2022.
- **General and Administration expenses** decreased by \$1.5 million (59%) in the three months ended June 30, 2023 compared to the three months ended June 30, 2022. This decrease was primarily due to expense reductions of approximately \$0.9 million and lower equity compensation expense of approximately \$0.4 million, which were due to reduced bonus payments and headcount.
- **Net Income** was \$1.1 million for the three months ended June 30, 2023, compared to a net loss of \$3.8 million for the three months ended June 30, 2022. Net Income for the second quarter of 2023 included a gain of \$2.66 million as a result of the Purnovate Sale.

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 FDA approval translating to acceptance in other international markets, plans to conduct two Phase 3 trials with AD04 in parallel to support potential approval in the shortest timeframe possible, progressing with partnering discussions and providing further updates as appropriate, AD04’s ability to address a significant unmet need for patients suffering from alcohol use disorder, representing an addressable market of approximately \$40 billion in the U.S. alone, being well positioned to execute on the Company’s development strategy and reach meaningful milestones that will drive significant value for shareholders 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 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.

Contact:

Crescendo Communications, LLC
David Waldman / Alexandra Schilt
Tel: 212-671-1020
Email: ADIL@crescendo-ir.com

