

Adial Pharmaceuticals Reports 2025 Fiscal Year Financial Results and Provides Business Update

GLEN ALLEN, Va., March 06, 2026 (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 2025 fiscal year ended December 31, 2025.

Key Highlights:

• Regulatory Progress:

- Achieved positive clinical study results from the AD04-103 pharmacokinetics (PK) study supporting AD04's pharmacologic profile and regulatory strategy.
- Received a positive response from the U.S. Food and Drug Administration (FDA) regarding the Company's proposed in vitro bridging strategy.
- Successfully completed its End-of-Phase 2 (EOP2) meeting, advancing regulatory alignment toward Phase 3 development.

• Expanded Intellectual Property Portfolio:

- Strengthened IP coverage with multiple U.S. patents issued covering genotype-specific treatment of opioid disorders and expanded genetic-based approaches for treating and diagnosing Alcohol Use Disorder (AUD) and other dependencies.
- Filed a Patent Cooperation Treaty (PCT) application to protect core assets and extend international exclusivity by 14 years through at least 2045.

• Strategic Partnerships & Development Support:

- Engaged Cytel Inc., a global leader in advanced clinical trial design and statistical methodologies, to support AD04 Phase 3 planning.
- Partnered with Genomind to implement precision medicine testing solutions aligned with genotype-guided therapeutic strategy.

• U.S.-Based Manufacturing Secured:

- Secured U.S. manufacturing supply partnerships with Cambrex and Thermo Fisher Scientific for drug substance and drug product supply in support of late-stage development and future commercialization readiness.

"2025 was a pivotal year for Adial as we continued to advance AD04 scientifically, strategically, and within an evolving regulatory landscape," said Cary Claiborne, Chief Executive Officer of Adial Pharmaceuticals. "Our positive AD04-103 pharmacokinetic results, productive End-of-Phase 2 meeting with the FDA, and supportive FDA feedback on our in vitro bridging strategy provided meaningful validation of our clinical and regulatory approach. Engaging Cytel for advanced statistical design and partnering with Genomind for precision medicine testing further strengthens our ability to execute a rigorous and clinically relevant Phase 3 program."

"We were also encouraged by concurrent government and policy developments that align with the scientific rationale and real-world relevance of our development strategy. Bipartisan support in the U.S. Senate for expanding clinical trial endpoints beyond strict abstinence - including outcomes such as reduced cravings and disorder severity - reflects a more patient-centered approach to evaluating addiction therapeutics, consistent with how AD04 is designed to benefit patients. Such support was underscored by a Congressional directive advancing alternative clinical trial endpoints for substance use disorders, which strengthens the regulatory path forward for AD04 and reinforces the importance of broader, clinically meaningful measures in AUD development."

"In addition, recent FDA policy discussion indicating that, in certain scientifically justified cases, approval may be supported by one adequate and well-controlled study plus confirmatory evidence - rather than two independent pivotal

trials - highlights a potential shift toward more flexible yet scientifically robust development frameworks. Because Phase 3 trials represent the most capital-intensive stage of development, the ability to pursue a single well-designed pivotal study instead of two could potentially reduce late-stage clinical development costs by tens of millions of dollars, while also lowering associated site, CRO, and operational expenses. A one-study framework could materially improve capital efficiency and shorten development timelines by eliminating the need to initiate and complete a second confirmatory trial, thereby accelerating our potential path toward NDA submission."

"Taken together, these scientific validations, regulatory discussions, and governmental policy signals reinforce the strength of our strategy and the relevance of AD04's precision medicine approach. With an expanded intellectual property estate, key strategic partnerships, and secured U.S.-based manufacturing, we are well positioned to execute on our mission of delivering meaningful treatments for patients impacted by AUD."

Other Developments

Collaborations

On March 3, 2026, Adial announced that it entered into a collaboration framework agreement with Molteni Farmaceutici ("Molteni") for a proposed exclusive partnership covering the commercialization of AD04 in Europe.

The collaboration framework, which is subject to execution of a final definitive agreement, outlines the strategic and financial terms of a planned partnership between Adial and Molteni, covering clinical, regulatory, manufacturing, and commercial terms. The anticipated definitive agreement would include upfront and milestone payments, as well as royalties on European net sales payable to Adial, with total potential value estimated at nearly \$60 million if AD04 successfully advances and launches in Europe. This marks Adial's first step toward establishing a European commercial pathway for AD04 in partnership with Molteni, a longstanding specialty pharmaceutical company with extensive capabilities and distribution across Europe.

Nasdaq

On February 24, 2026, Adial announced that it received notice from Nasdaq on February 23, 2026, that the Company has regained compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2). The Company has now successfully resolved its Nasdaq compliance issue and Nasdaq has advised that the matter is now closed.

Intellectual Property

On January 14, 2026, Adial announced the publication of the international patent application for AD04, filed in July 2024. The patent, once granted, is expected to protect Adial's core assets by an additional 14 years through at least 2045.

Adovate

On May 13, 2025, Adial announced that it had received a six-figure development milestone payment from [Adovate, LLC](#) ("Adovate"), following the commencement of a Phase 1 clinical trial evaluating Adovate's lead compound for asthma, ADO-5030.

Fiscal Year 2025 Financial Results

- Cash and cash equivalents were \$5.9 million as of December 31, 2025, compared to \$3.8 million as of December 31, 2024. The Company believes that its existing cash and cash equivalents will fund its operating expenses into the second half of 2026 based on currently committed development plans.
- Research and development expenses decreased by approximately \$609 thousand (19%) during the year ended

December 31, 2025, compared to the year ended December 31, 2024. The key driver of the decrease was lower clinical activity and lower compensation expense for the year ended December 31, 2025 as compared to the same period in 2024.

- General and administrative expenses increased by approximately \$125,000 (2%) during the year ended December 31, 2025 compared to the year ended December 31, 2024. This increase was mainly due to higher compensation expense for the year ended December 31, 2025 as compared to the same period in 2024.
- Net Loss was \$8.0 million for the year ended December 31, 2025, compared to a net loss of \$13.2 million for the year ended December 31, 2024. The decrease in net loss was primarily driven by lower R&D spending and a one-time non-cash inducement expense of \$4.5 million in 2024.

About Adial Pharmaceuticals, Inc.

Adial Pharmaceuticals is a clinical-stage biopharmaceutical company focused on the development of treatments for addictions 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. Adial is currently planning to conduct a new Phase 3 clinical trial program for the treatment of AUD in subjects with certain target genotypes identified using the Company's proprietary diagnostic genetic test. The Company's recent ONWARD Phase 3 clinical trial showed promising results in reducing drinking in heavy drinking patients, with 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 continuing to advance AD04 scientifically, strategically, and within an evolving regulatory landscape, strengthening the Company's ability to execute a rigorous and clinically relevant Phase 3 program, being encouraged by concurrent government and policy developments that align with the scientific rationale and real-world relevance of the Company's development strategy, advancing alternative clinical trial endpoints for substance use disorders, strengthening the regulatory path forward for AD04 and reinforcing the importance of broader, clinically meaningful measures in AUD development, the potential shift toward more flexible yet scientifically robust development frameworks, pursuing a single well-designed pivotal study instead of two reducing late-stage clinical development costs by tens of millions of dollars, while also lowering associated site, CRO, and operational expenses, materially improving capital efficiency and shortening development timelines with a one-study framework by eliminating the need to initiate and complete a second confirmatory trial, accelerating the Company's potential path toward NDA submission, the scientific validations, regulatory discussions, and governmental policy signals reinforcing the strength of the Company's strategy and the relevance of AD04's precision medicine approach, being well positioned to execute on the Company's mission of delivering meaningful treatments for patients impacted by AUD, establishing an exclusive partnership with Molteni covering the commercialization of AD04 in Europe, executing a final definitive agreement regarding the partnership, the definitive agreement including upfront and milestone payments, as well as royalties on European net sales payable to Adial, with total potential value estimated at nearly \$60 million if AD04 successfully advances and launches in Europe,

the patent for AD04, once granted, protecting the Company's core assets by an additional 14 years through at least 2045, existing cash and cash equivalents funding operating expenses into the second half of 2026 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, including our ability to finalize and enter into a definitive agreement regarding the planned partnership with Molteni, 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, 2024, 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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