

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): **November 14, 2022**

**Adial Pharmaceuticals, Inc.**

(Exact name of registrant as specified in charter)

**Delaware**

(State or other jurisdiction  
of incorporation)

**001-38323**

(Commission File Number)

**82-3074668**

(IRS Employer  
Identification No.)

**1180 Seminole Trail, Ste 495  
Charlottesville, VA 22901**

(Address of principal executive offices and zip code)

**(434) 422-9800**

(Registrant's telephone number including area code)

**N/A**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of registrant under any of the following provisions *see* General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12(b) under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbols | Name of each exchange on which registered              |
|---------------------|-----------------|--|
| Common Stock        | ADIL            | The Nasdaq Stock Market LLC<br>(Nasdaq Capital Market) |
| Warrants            | ADILW           | The Nasdaq Stock Market LLC<br>(Nasdaq Capital Market) |

Indicate by check mark whether the registrant is an emerging growth company as defined in in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by checkmark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 2.02 Results of Operations and Financial Condition.**

On November 14, 2022, Adial Pharmaceuticals, Inc., a Delaware corporation (the "Company"), issued a press release that included financial information for the fiscal quarter ended September 30, 2022. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02 and in the press release attached as Exhibit 99.1 to this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 2.02 and in the press release attached as Exhibit 99.1 to this Current Report on Form 8-K shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

The following exhibits are furnished with this Current Report on Form 8-K:

| <b>Exhibit Number</b> | <b>Exhibit Description</b>  |
|-----------------------|---|
| 99.1                  | <a href="#">Press Release, issued by Adial Pharmaceuticals, Inc. on November 14, 2022</a>                   |
| 104                   | Cover Page Interactive Data File (the cover page XBRL tags are embedded within in the inline XBRL document) |

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: November 15, 2022

ADIAL PHARMACEUTICALS, INC.

By: /s/ Cary J. Claiborne

Name: Cary J. Claiborne

Title: President and Chief Executive Officer

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## Adial Pharmaceuticals Reports Third Quarter 2022 Financial Results and Provides Business Update

*Advancing submission of AD04 ONWARD™ phase 3 results to regulatory agencies Actively*

*exploring potential partnership opportunities for AD04 and Purnovate compounds*

*Promoted Cary Claiborne to President and Chief Executive Officer*

**Charlottesville, VA – November 14, 2022 – 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 third quarter of 2022.

Cary Claiborne, President and Chief Executive Officer of Adial, stated, “We are in the process of finalizing our regulatory strategy and are working aggressively to prepare submission of our ONWARD™ trial results to the appropriate regulatory authorities. Based on the encouraging Phase 3 data and positive feedback from both key opinion leaders, as well as our regulatory and scientific advisors, we remain highly encouraged by the outlook for AD04 and the potential for commercialization in both Europe and North America. We remain committed to our goal of bringing AD04 to market, as we believe it will provide a new option for the millions of people around the world suffering from Alcohol Use Disorder (AUD). Additionally, we submitted the ONWARD™ data to a major medical journal and are hopeful the results will be published in the near-term. Furthermore, we are in active discussions with potential partners for both AD04 and Purnovate. Overall, we have made significant strides during the third quarter and look forward to providing further updates as developments unfold.”

### Other Recent Developments

#### *Management*

Cary Claiborne was promoted to President and Chief Executive Officer of Adial from his previous role as Chief Operating Officer. Mr. Claiborne was appointed Chief Operating Officer of Adial in December 2021 after previously being named to the Board of Directors. Mr. Claiborne brings extensive experience in leadership roles with clinical and commercial stage, publicly traded biopharmaceutical companies. Most recently, Mr. Claiborne served as Chief Financial Officer and director of Indivior PLC, a publicly traded specialty pharmaceutical company developing medicines to treat addiction and serious mental illnesses. He led Indivior’s spin-off from its then parent company, Reckitt Benckiser, to become an independent, publicly traded company. Prior to joining Indivior, Mr. Claiborne served as the Chief Financial Officer of Sucampo Pharmaceuticals, Inc., a global biopharmaceutical company, which was later sold to Mallinckrodt. Before joining Sucampo, Mr. Claiborne served as Chief Financial Officer and Corporate Secretary of Osiris Therapeutics, Inc. during the company’s initial public offering.

William Stilley was appointed to the newly created position of Chief Executive Officer of Purnovate, Inc., a wholly owned subsidiary of the Company. In this position, Mr. Stilley will lead the development strategies for the Purnovate assets in order to unlock their value to the Company and its shareholders. Mr. Stilley also continues to provide his knowledge and experience to the Company as a whole as a member of Adial’s board of directors.

#### *Purnovate*

The Company continues to advance its pre-clinical programs based on its broad adenosine platform, through the Company’s wholly-owned subsidiary, Purnovate, Inc. During the quarter, the Company announced positive in-vivo data from its animal study of mice treated with Purnovate’s PNV-6005 as a potential treatment for inflammatory bowel diseases. PNV-6005 significantly prevented weight loss as compared to the control group (greater than 50% inhibition of weight loss) and significantly prevented colon damage as evidenced by reduction of shortening of colon lengths in the PNV-6005 treated group (almost total prevention), as well as a decrease in inflammation as assessed histologically. Additionally, the Company reported positive in vivo data for PNV-5030 in a rat pain model, achieving statistically significant reductions in pain of between 43% and 76% compared to the control group across all timepoints measured.

### Third Quarter 2022 Financial Results

- Cash Position: As of September 30, 2022, cash and cash equivalents were \$5.8 million as compared to \$6.1 million as of December 31, 2021.
- Research and Development expenses decreased by \$0.4 million (26%) to \$1.3 million for the third quarter of 2022, compared to \$1.7 million in the third quarter of 2021. The decrease was driven by lower costs related to the ONWARD Phase 3 trial as clinical activities were substantially complete last quarter. Research and Development expenses decreased by \$3.0 million (50%) for the nine months ended September 30, 2022, compared to the nine months ended September 30, 2021.
- General and Administration expenses decreased by \$0.4 million (18%) to \$1.9 million for the third quarter of 2022 as compared to \$2.4 million in the third quarter of 2021. General and administrative expenses decreased by \$0.2 million for the nine months ended September 30, 2022, compared to the nine months ended September 30, 2021.
- Net Loss was \$3.1 million for the third quarter of 2022 as compared to a net loss of \$4.3 million in the third quarter of 2021. Net loss per share for the third quarter of 2022 was \$0.12, compared to a net loss of \$0.22 per share for the third quarter of 2021.

### About Adial Pharmaceuticals, Inc.

Adial Pharmaceuticals is a clinical-stage biopharmaceutical company focused on the development of treatments for addictions. 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](http://www.adial.com).

## **About Purnovate, Inc.**

Purnovate, Inc., a wholly owned subsidiary of Adial Pharmaceuticals, Inc., is a pharmaceutical development and chemistry company focused on inventing and developing selective, potent, stable, and soluble drug candidates targeting the adenosine receptors to treat diseases and disorders such as pain, asthma, cancer, diabetes, non-alcoholic steatohepatitis (NASH), and inflammatory diseases and disorders such as burn/wound healing, inflammatory bowel disorder and infectious disease.

## **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 remaining highly encouraged by the outlook for AD04 and the potential for commercialization in both Europe and North America, remaining committed to the Company’s goal of bringing AD04 to market, AD04 providing a new option for the millions of people around the world suffering from Alcohol Use Disorder (AUD), results of the ONWARD™ data being published in a major medical journal, potential partners for both AD04 and Purnovate, providing further updates as developments unfold 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 complete clinical trials on time and achieve desired results and benefits as expected, our ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, 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 establish and maintain collaborations, our ability to obtain or maintain the capital or grants necessary to fund our research and development activities, 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, 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.*

## **Contact:**

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