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): **May 16, 2022**

Adial Pharmaceuticals, Inc.
(Exact name of registrant as specified in charter)

Delaware
(State or other jurisdiction of incorporation)

001-38323	**82-3074668**
(Commission File Number)	*(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)

(Former Name and Former Address)

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:

☐ 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	NASDAQ
Warrants	ADILW	NASDAQ

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 May 16, 2022, Adial Pharmaceuticals, Inc., a Delaware corporation (the "Registrant"), issued a press release that included financial information for its quarter ended March 31, 2022. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K. The information contained in the press release is being furnished to the Securities and Exchange Commission (the "Commission") and shall not be deemed incorporated by reference into any of the Registrant's registration statements or other filings with the Commission.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	**Exhibit Description**
99.1	Press Release, issued by Adial Pharmaceuticals, Inc., dated May 16, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: May 16, 2022

ADIAL PHARMACEUTICALS, INC.

By: /s/ William B. Stilley, III
Name: William B. Stilley
Title: President and Chief Executive Officer

Adial Pharmaceuticals Provides Business Update and Reports First Quarter 2022 Financial Results

Nears completion of ONWARD™ Phase 3 pivotal trial of AD04 for the treatment of Alcohol Use Disorder; on track to report Phase 3 results in the current quarter

Ended first quarter with cash and cash equivalents of $12.7 million

Charlottesville, VA – May 16, 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 first quarter of 2022.

William Stilley, Adial's Chief Executive Officer, stated, "As previously reported, we completed the last patient visit in the ONWARD™ Phase 3 pivotal trial for AD04 for the treatment of alcohol use disorder (AUD) during the first quarter of 2022, exceeding our prior enrollment targets. We have now also completed the necessary safety protocol follow-up, and we are actively addressing other trial closing procedures related to our clinical sites and statistical analysis. We remain on track to report top line results this quarter, assuming no unanticipated delays with the remaining activities or compilation of the statistical data. Overall, we are highly encouraged by the outlook for the trial based on the prior encouraging Phase 2b data, as well as the current, blinded safety data and trial retention rate, which suggest a well-tolerated therapy."

Mr. Stilley continued, "We ended the first quarter of 2022 with more than $12 million of cash and cash equivalents. As a result, we are well funded to advance partnering discussions, as well as regulatory and other steps necessary as we prepare for potential commercialization of AD04. AUD is the leading cause of death for individuals ages 15 to 49 and represents a potential $36 billion dollar market in the U.S. alone, with 35 million individuals estimated to be suffering from AUD. We believe the potential number of patients is even larger in Europe, where we are concluding the current Phase 3 trial. Notably, Europe has the highest per capita alcohol consumption in the world with an estimated 55 million people with AUD. Sadly, there are limited options for patients suffering from AUD due to the significant side effects of conventional therapies and the fact that these treatments have been largely ineffective. In contrast, AD04 appears to be well tolerated and is designed for easy administration as an oral tablet. Moreover, we believe our companion genetic test will be an important tool in helping destigmatize this devastating disease and encourage patients to both attempt therapy and stay on therapy once started. We also see tremendous potential for AD04 in other related indications such as opioid use disorder."

"In parallel with the ONWARD trial, we are also advancing programs developed using our adenosine platform, through our wholly-owned subsidiary, Purnovate, Inc. Pre-clinical data has been encouraging across a range of potential indications such as pain, asthma, diabetes, and cancer, and we have announced collaborations to develop therapies with world-leading adenosine experts at the University of Virginia for burn/wound healing, and the University of California San Diego for inflammatory bowel disease and infectious diseases. We look forward to advancing Purnovate compounds into clinical trials next year, and plan to actively pursue potential additional partnerships to efficiently and cost-effectively advance the clinical trials and maximize the commercial potential of these assets."

First Quarter 2022 Financial Results

- Cash Position: As of March 31,2022, cash and cash equivalents were $12.7 million as compared to $6.1 million as of December 31, 2021.
- Research and Development expenses decreased by $1.5 million to $0.6 million for first quarter of 2022 as compared to $2.1 million in the first quarter of 2021. The decrease was driven by lower costs related to our ONWARD Phase 3 trial as it neared completion.
- General and Administration expenses decreased by $0.3 million to $2.4 million for the first quarter of 2022 as compared to $2.8 million in the first quarter of 2021.
- Net Loss was $2.9 million for the first quarter of 2022 as compared to a net loss of $4.8 million in the first quarter of 2021. Net loss per share for the first quarter of 2022 was $0.13, compared to a net loss of $0.30 per share in the first quarter of 2021.

Other recent business highlights

- Adial received a Notice of Allowance on its U.S. Patent for the Treatment for Opioid Use Disorder, using AD04. This patent application covers the treatment of patients with a specific genetic biomarker for the serotonin-3 receptor.
- Purnovate announced positive in vivo data for PNV-5032, as a potential treatment for asthma. PNV-5032 demonstrated a significant inhibition of pulmonary flow resistance, which is a measure of asthmatic response, in an in vivo model.
- Purnovate entered into a research collaboration agreement with the University of California San Diego to further evaluate the Company's proprietary adenosine analogs as a potential treatment for inflammatory diseases, including inflammatory bowel disease and infectious diseases.
- Adial held a meeting and has been in communication with the Finnish Medicines Agency (FIMEA) regarding finalizing the statistical analysis plan and protocol for the ONWARD trial. FIMEA was chosen by the Company as the lead regulatory agency for ONWARD due to their experience in the field of AUD. As previously stated, the primary endpoint is reduction of heavy drinking days in the last two months of the trial as compared to baseline. Secondary endpoints include reduction of total alcohol consumed and change in depression as measured by the Patient Health Questionnaire-9, a widely accepted tool to measure for depression. The Company submitted a protocol amendment to comply with the guidance from FIMEA.
- In 2021, Adial received its first patent for the genetic test to identify patients for treatment of AD04. This test is expected to be a "companion diagnostic test," meaning it would receive approval contemporaneous with AD04, assuming approval, and would also be a profit center for the Company. As previously, reported, we believe the potential total market for the test in the U.S. to be over $80 billion.

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) and is currently being investigated in the Company's landmark ONWARD™ pivotal Phase 3 clinical trial for the potential treatment of AUD in subjects with certain target genotypes, which are to be identified using the Company's proprietary companion diagnostic genetic test. A Phase 2b clinical trial of AD04 for the treatment of AUD showed promising results in reducing frequency of drinking, quantity of drinking and heavy drinking (all with statistical significance), and no overt safety concerns (there were no statistically significant serious adverse events reported). 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 through its wholly owned subsidiary, Purnovate, Inc. Additional information is available at 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 on track to report top line results for the ONWARD™ Phase 3 pivotal trial for AD04 this quarter, the outlook for the trial suggesting a well-tolerated therapy, AUD representing a $36 billion dollar market in the U.S. alone with 35 million individuals suffering from AUD, the potential number of patients being even larger in Europe, Europe having 55 million people with AUD, AD04 appearing to be well tolerated, the Company's companion genetic test being an important tool in helping destigmatize AUD and encourage patients to both attempt therapy and stay on therapy once started, the potential for AD04 in other related indications, advancing Purnovate compounds into clinical trials next year, pursuing potential additional partnerships to efficiently and cost-effectively advance the clinical trials and maximize the commercial potential of the Purnovate assets, the Company's patent for the genetic test to identify patients for treatment of AD04 receiving approval contemporaneous with AD04 and being a profit center for the Company, the potential total market for the test in the U.S. being over $80 billion 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.

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