

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 3, 2020**

**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, Suite 495**

**Charlottesville, Virginia 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:

<b>Title of each class</b>	<b>Trading Symbols</b>	<b>Name of each exchange on which registered</b>
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 (17 CFR §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark 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 7.01. Regulation FD Disclosure.**

On November 3, 2020, Adial Pharmaceuticals, Inc. (the “Company”) issued a press release (the “Press Release”) providing an update regarding its landmark ONWARD™ Phase 3 pivotal trial (the “Trial”) investigating the Company’s lead drug candidate, AD04, as a therapeutic agent for the treatment of Alcohol Use Disorder (AUD) in persons with certain target genotypes related to the serotonin transporter and receptor genes.

A copy of the Press Release is attached as Exhibit 99.1 to this 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 Company’s registration statements or other filings with the Commission.

**Item 8.01. Other Events.**

On November 3, 2020, the Company issued the Press Release providing the following highlighted updates on the Trial:

- All 25 planned investigative sites are active.
- 40% of expected Trial patient screenings have been completed and the Trial is more than 25% enrolled relative to planned enrollment.
- The enrollment rate has increased for four consecutive months and the Trial is projected to be fully enrolled during Q2 2021.
- Data readout is expected in Q4 2021 or earlier.
- AD04 has been well tolerated with no serious adverse events having been reported.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

The following exhibit is furnished with this Current Report on Form 8-K:

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press Release issued by Adial Pharmaceuticals, Inc. on November 3, 2020</a>

**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 3, 2020

**ADIAL PHARMACEUTICALS, INC.**

By: /s/ William B. Stilley, III

Name: William B. Stilley

Title: President and Chief Executive Officer



**Adial Pharmaceuticals Provides Update on its ONWARD™  
Pivotal Phase 3 Trial of AD04 for Treatment of Alcohol Use Disorder**

*ONWARD™ Projected to be Fully Enrolled During Q2 2021*

Charlottesville, VA – November 03, 2020 – Adial Pharmaceuticals, Inc. (NASDAQ: ADIL; ADILW) , a clinical-stage biopharmaceutical company focused on the development of treatments for addictions, today provided an update on its landmark ONWARD™ Phase 3 pivotal trial. ONWARD™ is investigating Adial's lead drug candidate, AD04, as a therapeutic agent for the treatment of Alcohol Use Disorder (AUD) in persons with certain target genotypes related to the serotonin transporter and receptor genes.

**Key ONWARD™ highlights include:**

- All 25 planned investigative sites are active.
- 40% of expected Trial patient screenings have been completed and the Trial is more than 25% enrolled relative to planned enrollment.
- The enrollment rate has increased for four consecutive months and the Trial is projected to be fully enrolled during Q2 2021.
- Data readout is expected in Q4 2021 or earlier.
- AD04 has been well tolerated with no serious adverse events having been reported.

“We are encouraged by the steady progress of our ONWARD™ Phase 3 trial and we are on track to complete enrollment during Q2 2021,” commented William Stilley, Chief Executive Officer of Adial Pharmaceuticals. “AUD accounts for nearly six percent of all deaths worldwide and is the leading cause of death among men and women in their prime (ages 15 to 49). AUD also represents a dramatically underserved market, as current therapies have limited efficacy and significant side effects. We believe AD04 may represent a paradigm shift in treating this population. Among patients with the target genotype, we estimate the market for AD04 to be in excess of \$35 billion in the United States where we are pursuing expedited review programs for AD04. The European market is expected to be similar in size. It has also been reported that the AUD crisis continues to escalate given the prolonged nature of the COVID-19 pandemic. We remain determined to advance ONWARD™ and look forward to providing further updates as we achieve key milestones.”

**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 therapeutic agent for the treatment of Alcohol Use Disorder (AUD) and is currently being investigated in a Phase 3 clinical 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. [www.adialpharma.com](http://www.adialpharma.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 the Trial being projected to be fully enrolled during Q2 2021, data readout being expected in Q4 2021 or earlier, AD04 representing a paradigm shift in treating the population afflicted with AUD, the market for AD04 being in excess of \$35 billion in the United States, the Company continuing its pursuit of U.S. expedited review programs for AD04, the European market being similar in size to the market in the United States, the AUD crisis continuing to escalate given the prolonged nature of the COVID-19 pandemic and providing further updates as the Company achieves key milestones, 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, our ability to enroll patients and 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 its product candidates in the marketplace and the successful development, marketing or sale of 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 its 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, 2019, 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 / Natalya Rudman  
Tel: 212-671-1021  
Email: [adil@crescendo-ir.com](mailto:adil@crescendo-ir.com)

---