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): **February 9, 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 7.01 Regulation FD Disclosure.

On February 9, 2022, Adial Pharmaceuticals, Inc. (the "Company") issued a press release announcing 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.

PNV-5032 Relevant Information

- Greater than 1000-fold selective over the adenosine A1 receptor in potency assays
- Demonstrated solubility more than 100 times greater than other selective adenosine compounds of the same class currently known to the Company
- Solubility of an inhaled product allows dissolution in the aerosolized mist for fine distribution over the bronchioles and can be important in facilitating bronchiole membrane penetration
- Findings indicate drug development potential of molecules of this class, possibly to treat asthma
- Covered by a composition of matter patent application for patent protection through 2042 with expected statutory extension to 2047

The information in this Item 7.01 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 7.01 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.

The press release attached as Exhibit 99.1 to this Current Report on Form 8-K includes "safe harbor" language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained therein are "forward-looking" rather than historical.

The Company undertakes no duty or obligation to update or revise the information contained in this Current Report on Form 8-K, although it may do so from time to time if its management believes it is appropriate. Any such updating may be made through the filing of other reports or documents with the Securities and Exchange Commission, through press releases or through other public disclosures.

Item 8.01. Other Events.

On February 9, 2022, the Company issued a press release announcing 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.

PNV-5032 Relevant Information

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Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release issued by Adial Pharmaceuticals, Inc. on February 9, 2022
104	Cover Page Interactive Data File (the cover page XBRL tags are 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: February 9, 2022

ADIAL PHARMACEUTICALS, INC.

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

Adial Pharmaceuticals Announces Positive *In Vivo* Data for Purnovate's PNV-5032 as a Potential Treatment for Asthma

Charlottesville, VA – February 9, 2022 – Purnovate, Inc., a wholly owned subsidiary of Adial Pharmaceuticals, Inc. (NASDAQ: ADIL; ADILW) ("Adial" or the "Company"), today 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.

PNV-5032 Relevant Information

- Greater than 1000-fold selective over the adenosine A1 receptor in potency assays
- Demonstrated solubility more than 100 times greater than other selective adenosine compounds of the same class currently known to the Company
- Solubility of an inhaled product allows dissolution in the aerosolized mist for fine distribution over the bronchioles and can be important in facilitating bronchiole membrane penetration
- Findings indicate drug development potential of molecules of this class, possibly to treat asthma
- Covered by a composition of matter patent application for patent protection through 2042 with expected statutory extension to 2047

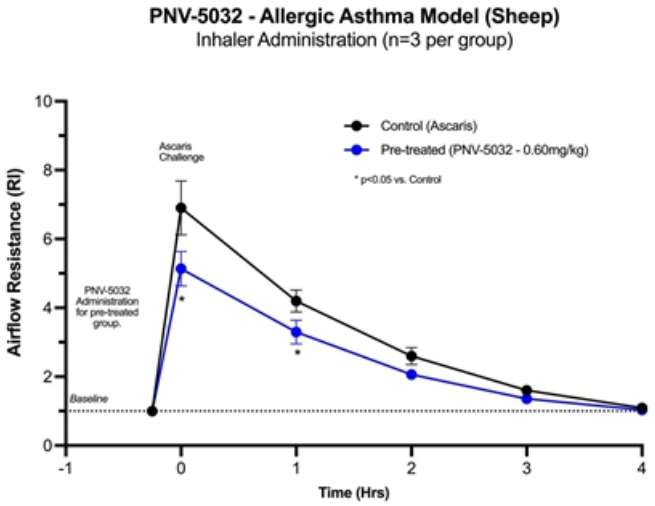
Study Design

Sheep, which respond to allergens and adenosine challenges in a manner similar to humans, were initially challenged with an aerosolized dose of *Ascaris Sum* allergens. Sheep are naturally allergic to these antigens, derived from intestinal roundworms, and each animal responded with severe bronchoconstriction, a clinically relevant symptom shared with asthma patients.

After a washout/recovery period of a few weeks, PNV-5032 was nebulized and administered prophylactically to the sheep. Fifteen minutes later, the sheep received another aerosolized dose of *Ascaris Sum* allergens. Breath-by-breath determination of mean pulmonary flow resistance was measured with the esophageal balloon technique over four hours post challenge, corresponding to the early asthmatic reaction. Each animal served as its own control.

Study Results

A significant 25% reduction in airflow resistance in the PNV-5032 group was observed as compared to the control group (5.1+/- 0.3 vs 6.9+/- 0.5 cm H_2O/L/s, respectively).



William Stilley, Adial's Chief Executive Officer, stated, "According to the World Health Organization, asthma affected an estimated 262 million people in 2019 and caused 461,000 deaths worldwide. However, there are still limited therapeutic options, such as bronchodilators and steroids, which can have a number of side effects such as susceptibility to thrush, voice changes, bruising and cardiovascular abnormalities, among others. PNV-5032 reduced airflow resistance by 25% in an animal test of allergen-induced asthma, which is highly encouraging. We plan to conduct further testing, with a goal of commencing first-in-human trials in 2023."

Mr. Stilley continued, "Our Purnovate platform has demonstrated broad therapeutic potential across a range of indications, as illustrated by our recently reported *in vivo* data in both pain and cancer. Based on the pharmacologic actions of our new adenosine analogs, we see broad applicability across a number of other prevalent ailments such as diabetes, wound/burn healing, Parkinson's disease, inflammatory bowel disease, and infectious diseases. We look forward to further exploring and advancing the full potential of this platform. Meanwhile, we are nearing completion of the ONWARD™ pivotal Phase 3 clinical trial and remain on track to report top line data in the coming months."

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 adenosine analogs to treat diseases and disorders such as pain, asthma, wound/burn healing, inflammation, infectious disease, cancer and

diabetes.

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.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 Purnovate's PNV-5032 as a potential treatment for asthma, patent protection to 2042 and expected extension for patent protection until 2047, plans to conduct further testing, with a goal of commencing first-in-human trials in 2023, Purnovate's having broad therapeutic potential across a range of indications, remaining on track to report top line data from the ONWARD™ pivotal Phase 3 clinical trial in the coming months, 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 commence clinical trials for PNV-5032 when anticipated, our ability to complete clinical trials on time and achieve desired results and benefits as expected and similar to those from in vivo studies, 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 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, 2020, 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