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): **September 26, 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, 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:

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 September 26, 2022, Adial Pharmaceuticals, Inc. (the "Company") issued a press release announcing that Purnovate, Inc. ("Purnovate"), a subsidiary of the Company, achieved positive in vivo data for PNV-5030 as a potential treatment for chronic pain.

The information in this Item 7.01 and in the press release furnished 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 and 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 furnished 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.

Item 8.01. Other Events.

On September 26, 2022, the Company issued a press release announcing that Purnovate achieved positive in vivo data for PNV-5030 as a potential treatment for chronic pain. The study was conducted in four groups of ten rats, which underwent surgical injury of the sciatic nerve. After ten days of recovery, mechanical allodynia (measured in grams of pressure) was performed using a 50% withdrawal threshold, an accepted animal model for measuring pain.

Certain highlights of the study included the following:

- PNV-5030 treatment was administered orally with a 15mg/kg dose.

- At 30 minutes post dose, PNV-5030 reduced pain by 43% compared to the control group, while acetaminophen (APAP) doses did not have a significant effect (4.7g vs 2.7g, respectively, $p<0.05$). PNV-5030 also demonstrated a 49% improvement in pain reduction over acetaminophen (APAP-25mg/kg) (4.7g vs 2.4g, respectively, $p<0.05$).

- At 60 minutes post dose, PNV-5030 reduced pain by 76% compared to the control group (5.3g vs 1.8g, respectively, $p<0.05$). PNV-5030 also demonstrated a 53% improvement in pain reduction over acetaminophen (APAP-25mg/kg) (5.3g vs 2.4g, respectively, $p<0.05$).

- At 120 minutes post dose, PNV-5030 reduced pain by 62% compared to the control group, while acetaminophen (APAP) doses did not have a significant effect (4.7g vs 1.8g, respectively, $p<0.05$).

- At 180 minutes post dose, PNV-5030 reduced pain by 56% compared to the control group (3.4g vs 1.5g, respectively, $p<0.05$). PNV-5030 also demonstrated a 56% improvement in pain reduction over acetaminophen (APAP-25mg/kg) (3.4g vs 1.5g, respectively, $p<0.05$).

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of Adial Pharmaceuticals, Inc. dated September 26, 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: September 26, 2022

ADIAL PHARMACEUTICALS, INC.

By: /s/ Cary J. Claiborne
Name: Cary J. Claiborne
Title: President and Chief Executive Officer

Exhibit 99.1

An Adial Company

Adial Pharmaceuticals Announces Positive In Vivo Data for Purnovate's PNV-5030 as a Potential Treatment for Chronic Pain

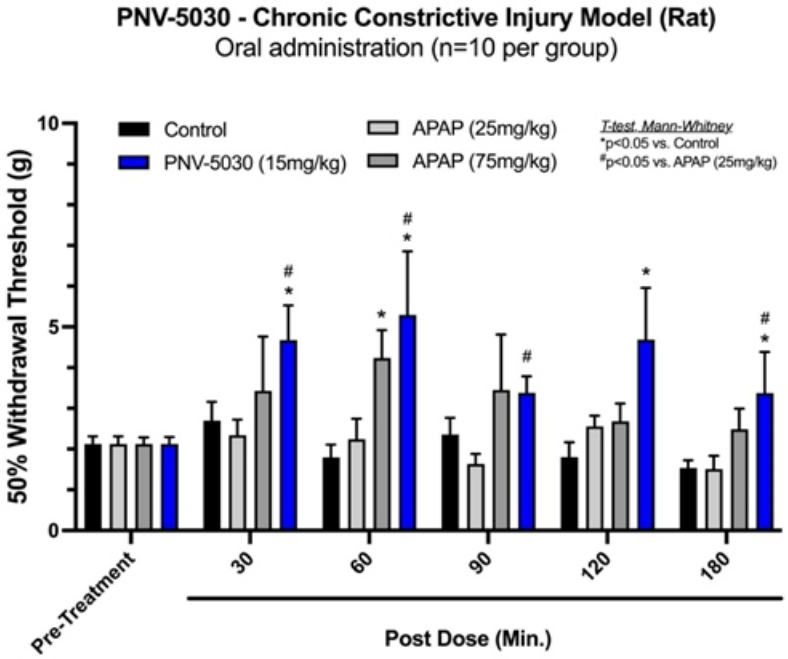
PNV-5030 significantly reduced pain compared to both placebo and acetaminophen

Charlottesville, VA – September 26, 2022 – Adial Pharmaceuticals, Inc. (NASDAQ: ADIL; ADILW) ("Adial" or the "Company"), today announced that Purnovate, Inc., a subsidiary of Adial focused on developing novel molecules targeting the adenosine receptors for the treatment of major unmet medical needs, achieved positive in vivo data for PNV-5030, as a potential treatment for chronic pain.

The study was conducted in four groups of ten rats, which underwent surgical injury of the sciatic nerve. After ten days of recovery, mechanical allodynia (measured in grams of pressure) was performed using a 50% withdrawal threshold, an accepted animal model for measuring pain.

Study highlights:

- PNV-5030 treatment was administered orally with a 15mg/kg dose.
- At 30 minutes post dose, PNV-5030 reduced pain by 43% compared to the control group, while acetaminophen (APAP) doses did not have a significant effect (4.7g vs 2.7g, respectively, $p<0.05$). PNV-5030 also demonstrated a 49% improvement in pain reduction over acetaminophen (APAP-25mg/kg) (4.7g vs 2.4g, respectively, $p<0.05$).
- At 60 minutes post dose, PNV-5030 reduced pain by 76% compared to the control group (5.3g vs 1.8g, respectively, $p<0.05$). PNV-5030 also demonstrated a 53% improvement in pain reduction over acetaminophen (APAP-25mg/kg) (5.3g vs 2.4g, respectively, $p<0.05$).
- At 120 minutes post dose, PNV-5030 reduced pain by 62% compared to the control group, while acetaminophen (APAP) doses did not have a significant effect (4.7g vs 1.8g, respectively, $p<0.05$).
- At 180 minutes post dose, PNV-5030 reduced pain by 56% compared to the control group (3.4g vs 1.5g, respectively, $p<0.05$). PNV-5030 also demonstrated a 56% improvement in pain reduction over acetaminophen (APAP-25mg/kg) (3.4g vs 1.5g, respectively, $p<0.05$).



Dr. Julien Dimastromatteo, Purnovate's Vice President, Research, commented, "We are encouraged by the results of this study, which demonstrated PNV-5030 reduced pain in an animal model of chronic pain, as compared to both placebo and acetaminophen. This data further reinforces prior *in vivo* data demonstrating similar outcomes in treating other types of pain. As a result, we look forward to advancing PNV-5030 towards first-in-human clinical trials."

"PNV-5030 has demonstrated compelling data in animal models of both acute and chronic pain," said William Stilley, CEO of Purnovate. "Moreover, we believe the success of PNV-5030, Purnovate's first lead compound, validates our adenosine platform, which has already been used to generate drug candidates that have shown efficacy in pre-clinical models across a wide range of indications, from pain to ulcerative colitis, asthma and even cancer. The broad potential of the platform lends itself well to pursuing potential partnerships and other strategic opportunities."

PNV-5030 has been tested to be more than 1000-fold selective over the adenosine A1 receptor. Historically, when selectivity has been achieved over the A1 receptor, water solubility has decreased, making biodistribution, which is the ability to achieve tissue distribution in the human body (made largely of water) difficult to achieve. However, PNV-5030 has demonstrated solubility more than 50 times greater than other known selective adenosine compounds of the same class and has shown it achieves the necessary biodistribution. Solubility is often an important characteristic of successful drug candidates, and insufficient solubility has historically been a development limitation for

adenosine analogues. The solubility profiles of the new compounds under development at Purnovate provide the opportunity to unlock the potential of this class of drugs to treat a broad array of diseases.

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. For more information, visit www.adial.com/purnovate/.

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.

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-5030 as a potential treatment for chronic pain, namely PNV-5030's potential to significantly reduce pain compared to both placebo and acetaminophen. Any forward-looking statements included herein reflect our current views, and they involve certain risks and uncertainties, including, among others, our ability to further validate the potential of PNV-5030 as a treatment for chronic pain, 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 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, 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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