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): April 11, 2022

DIFFUSION PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Delaware	**000-24477**	**30-0645032**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

300 East Main Street, Suite 201 **Charlottesville, Virginia**	**22902**
(Address of principal executive offices)	(Zip Code)

(434) 220-0718
(Registrant's telephone number, including area code)

Not applicable
(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 the 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 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 Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	DFFN	NASDAQ Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined 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 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 8.01 Other Events.

On April 11, 2022, Diffusion Pharmaceuticals Inc. (the "Company") issued a press release announcing the dosing of the final participant in the Company's Altitude Trial evaluating the Company's lead product candidate, trans sodium crocetinate, in normal healthy volunteers subjected to incremental levels of physical exertion while exposed to hypoxic and hypobaric conditions at a simulated altitude of 15,000 feet above sea level. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 – Financial Statements and Exhibits

(d) Exhibits

Exhibit Number	**Description**
99.1	Press Release, issued April 11, 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, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: April 12, 2022

DIFFUSION PHARMACEUTICALS INC.
By: /s/ William Elder
Name: William Elder
Title: General Counsel & Corporate Secretary

Exhibit 99.1

Diffusion Pharmaceuticals Completes Dosing in Altitude Trial

Topline data expected within two months

Blinded, interim data to be presented at the Undersea & Hyperbaric Medical Society's Annual Scientific Meeting in May 2022

CHARLOTTESVILLE, Va., April 11, 2022--Diffusion Pharmaceuticals Inc. (NASDAQ: DFFN) ("Diffusion" or the "Company"), a biopharmaceutical company developing novel therapies that enhance the body's ability to deliver oxygen to areas where it is needed most, today announced the final participant has completed dosing in its Altitude Trial.

The Altitude Trial is a double-blind, randomized, placebo-controlled crossover study, designed to evaluate the effects of TSC on maximal oxygen consumption, or VO2, and partial pressure of arterial blood oxygen, or PaO2, in normal healthy volunteers subjected to incremental levels of physical exertion while exposed to hypoxic and hypobaric conditions at a simulated altitude of 15,000 feet above sea level. A total of 30 volunteers were enrolled in the trial with each participant serving as their own control by completing the experiment twice in a random, blinded order, once after placebo administration and the other time after receiving a single dose of TSC at one of three dose levels.

"I would like to express our gratitude to the esteemed investigators and the participants in this clinical study," said Chris Galloway, M.D., Chief Medical Officer of Diffusion. "We look forward to obtaining topline results within the next two months, and believe that positive results, if obtained, will support the broad clinical potential of TSC to enhance oxygenation across a spectrum of conditions complicated by hypoxia."

Topline, unblinded data from the Altitude Trial will be available within two months. In the meantime, the clinical investigators have submitted two presentation abstracts for the Undersea & Hyperbaric Medical Society's Annual Scientific Meeting in Reno, Nevada scheduled for May 22nd to 26th based on blinded, aggregated (placebo and treatment) physiology data from the first fifteen participants in the study.

The results of the Altitude Trial will be used to further inform the design of clinical trials aimed at supporting the development and approval of TSC as a treatment for conditions complicated by hypoxia. While the Company intends to continue developing data to support TSC's broad potential uses, it recently announced its intent to focus its near-term efforts on evaluating TSC as an adjunct to standard of care in the treatment of hypoxic solid tumors as a first indication.

About Diffusion Pharmaceuticals Inc.

Diffusion Pharmaceuticals Inc. is a biopharmaceutical company developing novel therapies that enhance the body's ability to deliver oxygen to areas where it is needed most. Diffusion's lead product candidate, TSC, is being developed to enhance the diffusion of oxygen to tissues with low oxygen levels, also known as hypoxia, a serious complication of many of medicine's most intractable and difficult-to-treat conditions, including hypoxic solid tumors. For more information, please visit us at www.diffusionpharma.com.

Forward-Looking Statements

This press release includes express and implied forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including regarding the Company's near-term strategic priorities, anticipated timelines for the announcement of data from the Altitude Trial, the outcome of the Altitude Trial and significance of any such data, and the potential therapeutic value of TSC. The Company may, in some cases, use terms such as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately," or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Although the Company believes that it has a reasonable basis for each forward-looking statement contained herein, forward-looking statements by their nature involve risks and uncertainties, known and unknown, many of which are beyond the Company's control and, as a result, the Company's actual results could differ materially from those expressed or implied in any forward-looking statement. Particular risk and uncertainties include, among other things, those related to: the likelihood and timing of regulatory approval of TSC, if any, for the treatment of solid tumors complicated by hypoxia or any other indication, or the nature of any feedback the Company may receive from the U.S. Food and Drug Administration or other regulatory bodies; the Company's ability to protect and expand its intellectual property portfolio; the Company's ability to maintain compliance with the continued listing standards of Nasdaq; general economic, political, business, industry, and market conditions, including the ongoing COVID-19 pandemic; and the other factors discussed under the heading "Risk Factors" in the Company's filings most recent Annual Report on Form 10-K and other filings with the U.S. Securities and Exchange Commission. Any forward-looking statements in this press release speak only as of the date hereof (or such earlier date as may be identified) and, except as required by applicable law, rule, or regulation, the Company undertakes no obligation to update any such statements after the date hereof.

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