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 10, 2020

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.)

1317 Carlton Avenue, Suite 200 **Charlottesville, Virginia** (Address of principal executive offices)	**22902** (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 September 10, 2020, Diffusion Pharmaceuticals Inc. (the "Company") issued a press release announcing the dosing of the first patients in the Company's open-label Phase 1b lead-in trial of its novel, oxygen-enhancing therapeutic, trans sodium crocetinate. A copy of the press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press Release issued September 10, 2020

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: September 10, 2020

Diffusion Pharmaceuticals, Inc.

By: /s/ William Hornung
Name: William Hornung
Title: Chief Financial Officer

Diffusion Pharmaceuticals Inc.

Diffusion Pharmaceuticals Doses First Two Patients with TSC in COVID-19 Clinical Trial

Twenty-four patient Phase 1b safety and tolerability study initiated in Romania

CHARLOTTESVILLE, Va. (September 10, 2020) – Diffusion Pharmaceuticals Inc. (NASDAQ: DFFN) ("Diffusion" or the "Company") today announced dosing of the first two patients in the Company's open-label Phase 1b lead-in trial of its novel, oxygen-enhancing therapeutic, trans sodium crocetinate ("TSC"), in 24 hospitalized COVID-19 patients. In addition to evaluating the safety and tolerability of TSC, this trial will collect preliminary data on TSC's effects on arterial blood oxygenation. The Company believes these pharmacodynamic data will provide proof of concept for TSC in hypoxemic patients, and these data will be used to guide design of the planned follow-on efficacy study.

The Phase 1b study is being conducted at the Romanian National Institute of Infectious Diseases. The planned follow-on efficacy trial will be a randomized, placebo-controlled safety and efficacy study of TSC in hospitalized COVID-19 patients that will be conducted in the United States and Europe after consultation with, and approval from, local regulatory authorities.

"Dosing TSC in oxygen-deprived, hospitalized COVID-19 patients is an important milestone for Diffusion." said Robert Cobuzzi, chief executive officer of Diffusion. "We anticipate learning a lot about TSC's effects on blood oxygen levels in COVID-19 patients, and we're excited about the potential to incorporate the knowledge gained from this study into the broader TSC development program."

About TSC and COVID-19

Patients with COVID-19 respiratory tract infections often present with significantly impaired oxygen levels. Diffusion and its affiliated researchers believe the oxygen-enhancing mechanism of action of TSC could benefit such patients. Preclinical data indicate TSC increases oxygen availability and provides a functional benefit in animal models of acute lung injury and hemorrhagic shock. Clinical data from more than 150 patients receiving TSC for other indications demonstrate that the drug has an acceptable safety profile in both healthy and critically ill patients.

About Diffusion Pharmaceuticals Inc.

Diffusion Pharmaceuticals Inc. is an innovative biotechnology company developing new treatments that improve the body's ability to deliver oxygen to the areas where it is needed most, offering new hope for the treatment of life-threatening medical conditions. Diffusion's lead drug, TSC, was originally developed in conjunction with the United States ("U.S.") Office of Naval Research, which was seeking a way to treat multiple organ failure and its resulting mortality caused by low oxygen levels from blood loss on the battlefield. Evolutions in research have led to Diffusion's focus today on addressing some of medicine's most intractable and difficult-to-treat diseases, including multiple organ failure from respiratory distress, stroke and glioblastoma multiforme ("GBM") brain cancer. In each of these diseases, lack of available oxygen presents a significant obstacle for medical providers and is the target for TSC's novel mechanism. The Company is currently partnering with U.S. and European institutions on an expedited research program to develop TSC as a treatment for the low oxygen levels and associated multiple organ failure in COVID-19 patients.

Preclinical data support the potential for TSC as a treatment for other conditions where low oxygen availability plays an important role, such as myocardial infarction, peripheral artery disease and neurodegenerative conditions such as Alzheimer's and Parkinson's disease. In addition to the development of TSC, RES-529, the Company's PI3K/AKT/mTOR pathway inhibitor that dissociates the mTORC1 and mTORC2 complexes, is in preclinical testing for GBM.

Diffusion is headquartered in Charlottesville, Virginia – a hub of advancement in the life science and biopharmaceutical industries.

Forward-Looking Statements

To the extent any statements made in this news release deal with information that is not historical, these are forward-looking statements under the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about the company's plans, objectives, expectations and intentions with respect to future operations and products, the potential of the company's technology and product candidates, and other statements that are not historical in nature, particularly those that utilize terminology such as "would," "will," "plans," "possibility," "potential," "future," "expects," "anticipates," "believes," "intends," "continue," "expects," other words of similar meaning, derivations of such words and the use of future dates. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Uncertainties and risks may cause the Diffusion's actual results to be materially different than those expressed in or implied by such forward-looking statements. Particular uncertainties and risks include: the timing of the enrolment and completion of the Phase 1b study, the pharmacodynamic data providing proof of concept for TSC in hypoxemic patients, and the use of these data to guide design of the planned follow-on efficacy study; the uncertainty as to whether the protocol for the planned United States and European follow-on efficacy study referenced above will be ultimately acceptable to the U.S. Food and Drug Administration ("FDA") and appropriate European regulators, that the FDA or European regulators will not require significant changes that might take significant time to implement, if at all, that any such required changes will be financially feasible or that administrative or other delays may arise; the uncertainty as to whether and when the FDA or European regulators might provide any additional guidance with respect to our study protocol or when the program might be able to commence, if at all; the uncertainty that as of yet the FDA has not approved a trial evaluating TSC for the treatment of ARDS, or if approved, such a trial may entail significant additional time, effort and expense, particularly in light of the difficulty of doing business during the COVID-19 pandemic; Diffusion's ability to maintain its Nasdaq listing, market conditions, the difficulty of developing pharmaceutical products, obtaining regulatory and other approvals and achieving market acceptance; general business and economic conditions; the sufficiency of the company's cash, the company's need for and ability to obtain additional financing or partnering arrangements; and the various risk factors (many of which are beyond Diffusion's control) as described under the heading "Risk Factors" in Diffusion's filings with the United States Securities and Exchange Commission. All forward-looking statements in this news release speak only as of the date of this news release and are based on management's current beliefs and expectations. Diffusion undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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