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): May 26, 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**	**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 May 26, 2020, Diffusion Pharmaceuticals Inc. (the "Company") issued a press release announcing that the Company received an accelerated FDA response to its proposed trans sodium crocetinate (TSC) COVID-19 clinical trial program. A copy of the press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 – Financial Statements and Exhibits

(d) Exhibits

99.1 Press release issued May 26, 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: May 26, 2020

DIFFUSION PHARMACEUTICALS INC.

By: /s/ David G. Kalergis
Name: David G. Kalergis
Title: Chief Executive Officer

Diffusion Pharmaceuticals Receives Accelerated FDA Response to Proposed TSC COVID-19 Clinical Trial Program

First U.S. study to feature double-blinded, controlled, randomized trial design with safety and oxygenation endpoints

FDA recommends incorporating remdesivir, where available

CHARLOTTESVILLE, Va. (May 26, 2020) – Diffusion Pharmaceuticals Inc. (NASDAQ: DFFN) ("Diffusion" or "the Company") announces it has received an accelerated response from the U.S. Food and Drug Administration (FDA) to the Company's Pre-Investigational New Drug (PIND) meeting request. The PIND was filed on April 27, seeking FDA guidance on the Company's proposed clinical development program for the use of trans sodium crocetinate (TSC) in COVID-19 patients displaying severe respiratory symptoms and low oxygen levels.

The FDA's accelerated response to the PIND meeting request recommended that the first U.S. TSC COVID-19 study employ a double-blinded, controlled, randomized clinical trial design to address the wide variability in standard of care due to the rapidly evolving COVID-19 experience. The FDA also recommended incorporating, where available, the drug remdesivir, which has been newly approved for emergency use, into TSC clinical trials as a component of standard of care for patients hospitalized with severe disease. The FDA agreed with the safety and oxygenation marker endpoints proposed by the Company for early trials of TSC in COVID-19 patients and suggested a range of potential functional outcomes which might be used as primary endpoints in possible later-stage trials supporting product approval.

"We are gratified that in their accelerated response to our PIND for studies of TSC in COVID-19 patients the FDA has suggested this randomized, blinded clinical trial design allowing oxygenation endpoints in our initial U.S. trial, rather than the smaller unblinded safety trial we had expected," said David Kalergis, chief executive officer of Diffusion. "This more robust first U.S. study is fully funded by existing Company resources, and, with FDA guidance now in hand, we intend to move forward quickly under current expedited FDA and hospital-specific policies. Meanwhile, we expect a June 2020 first patient enrollment for the European arm of our TSC COVID-19 program being conducted at the Romanian National Institute of Infectious Diseases. We further expect the European trial to provide first human data regarding TSC's oxygenation-enhancing potential in this disease by the end of the summer."

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 over 150 patients receiving TSC for other indications demonstrate that the drug has an acceptable human 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 trans sodium crocetinate (TSC) was originally developed in conjunction with the 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.

In 2019, the Company reported favorable safety data in a 19-patient dose-escalation run-in to its Phase 3 INTACT program, using TSC to target inoperable GBM. That trial is currently paused, while the Company prioritizes its resources to address COVID-19. Diffusion's in-ambulance PHAST-TSC trial for acute stroke began enrolling patients last year. Given the heightened responsibilities of the Company's emergency medical services providers, enrollment in this trial, while not officially paused, is expected to be minimal until the COVID-19 pandemic abates. The Company is currently partnering with both U.S. and European-based institutions in 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 supports 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 – and is led by CEO David Kalergis, a 30-year industry veteran and company co-founder.

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 uncertainty as to whether the FDA will approve the IND submission for commencement of a trial in the U.S.; or that the FDA will not require significant changes that might take significant time to implement, if at all, or that any such required changes will be financially feasible; there can be no assurance as to when the program in the U.S. 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 possibly entailing significant additional time, effort and expense, particularly in light of the difficulty of doing business during the COVID-19 pandemic; whether Diffusion has sufficient funding to complete the trial described; the uncertainty as to whether the protocol for the Romanian trial will be ultimately acceptable to the Romanian healthcare regulatory authorities or that such regulators will not require significant changes that might take significant time to implement, if at all, or that any such required changes will be financially feasible; moreover, if this or a revised protocol is acceptable to the Romanian regulators, there can be no assurance as to when they might provide such guidance or when the program might be able to commence, if at all; the uncertainty that as of yet the Romanian regulators have not approved a trial evaluating TSC for the treatment of ARDS, or if approved, such a trial possibly entailing 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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