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): July 27, 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 July 27, 2020, Diffusion Pharmaceuticals Inc. (the "Company") issued a press release announcing that the Company has received guidance from the U.S. Food and Drug Administration for the Company's international Phase 1b/2b COVID-19 clinical program with trans sodium crocetinate (TSC). 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 July 27, 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: July 29, 2020

DIFFUSION PHARMACEUTICALS INC.

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

Diffusion Pharmaceuticals Receives FDA Guidance for International Phase 1b/2b COVID-19 Clinical Program with TSC

Guidance being incorporated into global study protocol
Enrollment of first patient now expected in August

CHARLOTTESVILLE, Va. (July 27, 2020) – Diffusion Pharmaceuticals Inc. (NASDAQ: DFFN) ("Diffusion" or "Company"), a biotechnology company developing novel therapeutics for the treatment of unmet medical needs, today announced receipt of guidance from the U.S. Food and Drug Administration (FDA) on the Company's recently-filed Investigational New Drug (IND) application for trans sodium crocetinate (TSC) in COVID-19 patients. This guidance suggests certain study design changes with regard to endpoints and statistical considerations that Diffusion believes will enhance the prospect of regulatory approvals upon program completion, should the clinical results be favorable.

Because these changes will be harmonized throughout the overall TSC global development program, they are being submitted for clearance by the Romanian National Agency for Medicines and Medical Devices (NAMMD). NAMMD has regulatory oversight over the Company's first planned clinical trial, an open-label Phase 1b lead-in trial in 24 hospitalized COVID-19 patients at the Romanian National Institute of Infectious Diseases (NIID).

The Company previously announced expectations that the first patient would be enrolled in the Phase 1b study by the end of July. Considering the FDA's suggested protocol modifications and an additional NAMMD review cycle, the Company now expects the first patient will be enrolled by the end of August, with first data available early in the fourth quarter of 2020.

"Getting the clinical trial protocol right is imperative as it will support regulatory reviews and determinations," said David Kalergis, chief executive officer of Diffusion. "We are grateful for the FDA's guidance. Incorporating their views into the Romanian arm of the program will delay the program start by just a few weeks, yet should have no material impact on overall program timelines."

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 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. 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.

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 responsibilities of the Company's participating emergency medical services providers, enrollment in this trial, while not officially paused, is expected to be minimal until the COVID-19 pandemic abates.

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 – 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; the uncertainty as to whether the protocol for the Romanian trial will be ultimately acceptable to the Romanian healthcare regulatory authorities and local ethics committees 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; whether Diffusion can enroll and complete the trials and provide data on the timelines indicated; whether Diffusion can efficiently transition from the Phase 1b to Phase 2b portion of the Romanian trials and to the 2b U.S. trial; whether the data from the Romanian trials can be combined with data generated in any U.S. trials; whether Diffusion has sufficient funding to complete the trials described; 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 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.

Contacts:
David Kalergis, CEO
Diffusion Pharmaceuticals Inc.
(434) 825-1834
dkalergis@diffusionpharma.com
or
LHA Investor Relations
Kim Sutton Golodetz
(212) 838-3777
kgolodetz@lhai.com

# # #