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 1, 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 April 1, 2020, Diffusion Pharmaceuticals Inc. (the "Company") issued a press release announcing that the Company is evaluating its novel small molecule Trans Sodium Crocetinate against acute respiratory distress syndrome in COVID-19 patients. 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 April 1, 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: April 1, 2020

DIFFUSION PHARMACEUTICALS INC.

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

Exhibit 99.1

Diffusion Pharmaceuticals Evaluating TSC Against Acute Respiratory Distress Syndrome (ARDS) in COVID-19 Patients

Partnering with University of Virginia Health and iTHRIV

CHARLOTTESVILLE, Va. (April 1, 2020) – Diffusion Pharmaceuticals Inc. (NASDAQ: DFFN) ("Diffusion" or "the Company"), a cutting-edge biotechnology company developing new treatments for life-threatening medical conditions by improving the body's ability to deliver oxygen to the areas where it is needed most, today announced that it has begun a cooperative research effort with University of Virginia Health (UVA) and the Integrated Translational Research Institute of Virginia (iTHRIV), to evaluate the Company's novel small molecule Trans Sodium Crocetinate (TSC) in patients with Acute Respiratory Distress Syndrome (ARDS) associated with COVID-19 infection. iTHRIV is a National Institutes of Health (NIH)-funded Clinical and Translational Awards (CTSA) program. Dr. Andrew Southerland, Associate Professor of Neurology and Public Health Sciences at UVA, will serve as lead Principal Investigator, working with co-investigators in the UVA Division of Pulmonary & Critical Care Medicine.

Patients with COVID-19 infections are at risk for developing ARDS, which can lead to death from systemic hypoxemia (general lack of oxygen to body tissue and vital organs). Diffusion, and researchers affiliated with UVA and iTHRIV, believe the oxygen-enhancing mechanism of action of TSC could benefit COVID-19 patients by mitigating the multiple organ failure that often accompanies systemic hypoxemia, and are, together, exploring avenues to advance TSC's development as quickly as possible for this use.

TSC is currently under clinical development by the Company for other enhanced-oxygen-related uses including the treatment of acute stroke and glioblastoma multiforme (GBM) brain cancer. Preclinical data indicate TSC increases oxygen availability in animal models of acute lung injury, mitigating the negative effects of systemic hypoxemia. Preclinical publications also indicate TSC's ability to mitigate systemic hypoxemia in other animal models, including hemorrhagic shock. Clinical data from 150 patients receiving TSC for other indications demonstrate that the drug has an acceptable safety profile in both healthy and critically ill patients.

The Company and UVA/iTHRIV have together begun discussions with the U.S. Food and Drug Administration (FDA) to assess possible regulatory pathways for the evaluation of TSC in ARDS-related COVID-19 patients.

"We are in desperate need of novel therapies to help combat the morbidity and mortality associated with COVID-19 infection," said Dr. Southerland. "Given our experience partnering with Diffusion Pharmaceuticals to study TSC in clinical trials for other conditions, we believe there is strong biological plausibility that the drug could help COVID-19 patients suffering from ARDS. Our robust infrastructure of research and clinical expertise at UVA positions us well to help bring TSC to COVID-19 trials as soon as possible to determine if it can help patients."

"TSC's oxygen-enhancing mechanism may help address the often-fatal multiple organ failure from ARDS in COVID-19 patients," said Diffusion's CEO, David Kalergis, JD/MBA. "In addition to UVA/iTHRIV, the Company has begun coordination with researchers from other institutions who have asked to participate in this new program. We have also begun discussions with the FDA. We will issue public updates as warranted by this fast-moving situation."

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 Office of Naval Research, which was seeking a way to treat multiple organ failure and its resulting mortality caused by the systemic hypoxemia from blood loss on the battlefield. Evolutions in research have led to Diffusion's focus today: Fueling Life by taking on some of medicine's most intractable and difficult-to-treat diseases, including multiple organ failure, stroke and glioblastoma multiforme (GBM) brain cancer. In each of these diseases, hypoxia – oxygen deprivation of essential tissue in the body – has proved to be a significant obstacle for medical providers and is the target for TSC's novel mechanism.

In July 2019 the Company reported favorable safety data in a 19-patient dose-escalation run-in study to its Phase 3 INTACT program, using TSC to target inoperable GBM. Further findings from the dose-escalation run-in study, released in December 2019, also showed possible signals of enhanced survival and patient performance. Diffusion's in-ambulance PHAST-TSC trial for acute stroke began enrolling patients last year. Given the heightened responsibilities of the Company's partnering emergency medical services providers, enrollment in this trial is expected to be minimal until the Covid-19 pandemic abates. The Company is also currently partnering with the University of Virginia and iTHRIV in a research program to develop its novel small molecule Trans Sodium Crocetinate (TSC) as a treatment for Acute Respiratory Distress Syndrome (ARDS) from COVID-19 infection, specifically targeting the associated multiple organ failure.

Preclinical data supports the potential for TSC as a treatment for other conditions where hypoxia plays a major role, such as myocardial infarction, peripheral artery disease, and neurodegenerative conditions such as Alzheimer's and Parkinson's disease. In addition, 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: as of yet the FDA not having approved a trial evaluating TSC for the treatment of ARDs, or if approved, such a trial possibly entailing significant additional time, effort and expense; 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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