

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): March 24, 2020

**DIFFUSION PHARMACEUTICALS INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of incorporation)

**000-24477**  
(Commission File  
Number)

**30-0645032**  
(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	DIFFN	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 March 24, 2020, Diffusion Pharmaceuticals Inc. (the “Company”) issued a press release announcing that the Company anticipates enrollment in its ambulance-based stroke trial will be slowed due to the impact of the coronavirus. 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 March 24, 2020](#)

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**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: March 24, 2020

**DIFFUSION PHARMACEUTICALS INC.**

By: /s/ David G. Kalergis

Name: David G. Kalergis

Title: Chief Executive Officer



**Diffusion Pharmaceuticals Anticipates Enrollment in its Ambulance-based Stroke Trial Will be Slowed Due to the Impact of the Coronavirus**  
*Overtaxed healthcare systems will delay enrollment in some geographic locations*

**CHARLOTTESVILLE, Va. (March 24, 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 bring oxygen to the areas where it is needed most, today announced that it expect delays in enrollment in the Company’s ambulance-based PHAST-TSC phase 2 clinical trial in acute stroke due to the coronavirus. The LA County Fire Department has informed us that, due to the necessity to respond to the pandemic, it is suspending future training of first responders who had been scheduled to participate in the trial protocol. Such disruptions are expected to delay the Company’s previously announced timeline for study completion.

“The coronavirus pandemic is affecting the conduct of clinical trials throughout the world, and the PHAST-TSC program is no exception,” said Diffusion’s CEO, David Kalergis, JD/MBA. “We are following the FDA’s recent guidelines for conducting clinical trials during this emergency, and are planning ways to make up lost time once the pandemic abates.”

**About Diffusion Pharmaceuticals Inc.**

Diffusion Pharmaceuticals Inc. is an innovative biotechnology company developing new treatments that improve the body’s ability to bring 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 Office of Naval Research, which was seeking a way to treat hemorrhagic shock caused by massive 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 stroke, GBM brain cancer and respiratory distress. 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. The Company is currently enrolling patients in its PHAST-TSC phase 2 clinical trial in acute stroke. 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.

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.

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## 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: 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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