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): November 19, 2019

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 November 19, 2019, Diffusion Pharmaceuticals Inc. (the "Company") issued a press release announcing early findings of the Company's Phase 3 study with Trans Sodium Crocetinate plus standard of care on glioblastoma multiforme brain cancer 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

Exhibit No.	**Description**
Exhibit 99.1	Press release issued November 19, 2019

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: November 19, 2019

DIFFUSION PHARMACEUTICALS INC.

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

Diffusion Pharmaceuticals Inc.

Diffusion Pharmaceuticals Presents Early Findings Showing Increased Survival in Lead-in Portion of Phase 3 Glioblastoma Study with TSC plus Standard of Care

Chief Scientific Officer Dr. John Gainer to Present at Inaugural Glioblastoma Drug Development Summit

CHARLOTTESVILLE, Va. (November 19, 2019) – Diffusion Pharmaceuticals Inc. (Nasdaq: DFFN), 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, announces increased survival in inoperable glioblastoma patients enrolled in the 19-patient, open-label, dose-escalation lead-in portion of its Phase 3 study with Trans Sodium Crocetinate (TSC) plus standard of care (SOC). John Gainer, Ph.D., the Company's chief scientific officer, will present details of these findings at the inaugural Glioblastoma Drug Development Summit being held in Boston December 10-11, and sponsored by Hanson Wade. Dr. Gainer's slide presentation will be posted to the Company's website at www.diffusionpharma.com immediately prior to the conference.

In an earlier Phase 2 study testing TSC in newly diagnosed glioblastoma multiforme (GBM) brain cancer patients, an almost fourfold increase in 2-year survival was seen versus historical controls in inoperable patients. The current Phase 3 INTACT (**IN**vestigating **T**sc **A**gainst **C**ancerous **T**umors) study – an open-label, randomized, controlled trial – is designed to examine this finding in a fully powered safety and efficacy registration study, which, if successful, could be the basis for US FDA approval.

In the INTACT trial, subjects are randomized at baseline to SOC for first-line treatment of GBM plus TSC, or to SOC alone. The SOC for GBM is temozolomide plus radiation therapy for 6 weeks, followed by 28 days of rest, then by 6 cycles of post-radiation temozolomide treatment. In a modification to the Phase 2 dosing regimen, patients in the INTACT trial will also receive high-dose TSC during the post-radiation chemotherapy phase.

A 19-patient, open-label, dose-escalation lead-in portion to the INTACT trial was recently completed, sending a positive safety signal across all patients receiving TSC. In addition, six of the seven patients who received the high dose TSC treatment are still alive, with a median survival at the present time of 14.3 months. This is compared with 9.2 months for the historical standard of patients with inoperable GBM. Since six of the TSC-treated patients are still alive, median survival time is actually increasing with the passage of time, suggesting the INTACT trial may confirm or better the efficacy findings seen in the Phase 2 study

Patients' abilities to perform their daily activities as measured by Karnofsky performance scores increased from the baseline following completion of high dose treatment with TSC. Investigators have also reported instances of inoperable GBM patients treated with the higher dose TSC regimen leaving hospice or returning to work after treatment in the open-label portion of the study.

"We are encouraged by these early findings showing that patients enrolled in the lead-in portion of the INTACT trial have experienced increased survival with our new protocol," said Dr. Gainer. "Although final conclusions will depend on the completion of the randomized portion of the trial, we believe that TSC helps to eradicate the low oxygen status of cancerous tumors, and it appears this may also result in a survival benefit compared with the current standard therapy."

The Company previously announced it is seeking a partner to continue development of TSC in the GBM indication and has begun patient enrollment in its Phase 2 on-ambulance trial with TSC for the treatment of stroke.

About Hanson Wade

Hanson Wade's goal is to accelerate progress within organizations and across industries. Its primary method for achieving this is by creating exclusive business conferences that gather together the world's smartest thinkers and doers. The inaugural Glioblastoma Drug Development Summit is designed with two critical and ambitious objectives: to help overcome the major biological challenges limiting effective Glioblastoma treatment; and to evaluate novel therapies and innovative trial design to prevent more tragic Phase 2 failures.

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 and 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 the target for TSC’s novel mechanism.

Its on-ambulance PHAST-TSC acute stroke protocol has begun patient enrollment. 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 brain cancer. Additional preclinical data supports the potential use of TSC as a treatment for other conditions where hypoxia plays a major role, such as myocardial infarction, respiratory diseases such as COPD, 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, the anticipated timing of future clinical trials, 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 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.

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