Section 1: 8-K (FORM 8-K)

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): December 10, 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**	**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 7.01.

Regulation FD Disclosure.

On December 10, 2019, Diffusion Pharmaceuticals Inc. (the "Company") issued a press release. 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.

The Company makes no admission as to the materiality of any information in the press release or in this report. This information is furnished pursuant to Item 7.01 of Form 8-K and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section, unless we specifically incorporate it by reference in a document filed under the Securities Exchange Act of 1934, nor shall it be deemed incorporated by reference in any filing under the Securities Exchange Act of 1933, as amended, except as previously set forth by specific reference in such a filing.

Item 9.01.

Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
Exhibit 99.1	Press release issued December 10, 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: December 10, 2019

DIFFUSION PHARMACEUTICALS INC.

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

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Section 2: EX-99.1 (EXHIBIT 99.1)

Exhibit 99.1

Diffusion Pharmaceuticals Inc.

Diffusion Pharmaceuticals Presents Data Suggesting Optimized TSC Dosing Regimen Increases Survival in Newly Diagnosed Inoperable Glioblastoma Patients

Presentation Made by Chief Scientific Officer John Gainer at the Inaugural Glioblastoma Drug Development Summit

CHARLOTTESVILLE, Va. (December 10, 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 the presentation of data signaling increased survival in inoperable glioblastoma multiforme (GBM) patients enrolled in the 19-patient lead-in portion of its open-label, dose-escalation Phase 3 study with Trans Sodium Crocetinate (TSC) plus standard of care (SOC). Chief Scientific Officer John Gainer, Ph.D. presented these findings today at the inaugural Glioblastoma Drug Development Summit in Boston, sponsored by Hanson Wade.

Dr. Gainer's presentation included earlier research demonstrating that TSC safely reduces tumor hypoxia by a novel mechanism of action, making the tumor up to 3 times more susceptible to radiation and chemotherapy. In Phase 2 testing of TSC in newly diagnosed inoperable GBM patients, a nearly 4-fold increase in 2-year survival was seen compared with historical controls.

The current Phase 3 INTACT (INvestigating Tsc Against Cancerous Tumors) study – an open-label, randomized, controlled trial – was designed to examine this finding in a fully powered safety and efficacy registration study. The study was further designed to test a new TSC dosing regimen under which, in addition to the 18 injections of TSC administered during the radiation therapy phase, patients receive 18 additional injections of TSC during the post-radiation chemotherapy phase, at doses up to 6-times higher than those received during radiation. The addition of this high-dose regimen was based on research performed by Dr. Gainer over the last three years in his laboratory at Diffusion's headquarters.

In the randomized portion of the INTACT trial, subjects will be 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 the 19-patient open-label, dose-escalation, lead-in portion of the INTACT trial, safety was demonstrated in all patients receiving TSC at all dosing levels. Further, the Company believes that, while the number of high dose patients (7) is small, the addition of the 18 higher-dose treatments of TSC may be having a positive effect on survival. In his talk, Dr. Gainer presented a Kaplan-Meier survival plot highlighting the difference in survival seen with the addition of high-dose TSC treatment compared with both SOC and the earlier Phase 2 study. The current data show an 86% "Fraction Surviving," with 38% for the completed Phase 2 TSC study and 13% for SOC.

The ability of patients to perform daily activities as measured by Karnofsky performance scores also increased from baseline following completion of high-dose treatment with TSC, with scores showing a differential of 15% improvement over the Phase 2 results at 18 weeks, which is the time at which a decline rather than an improvement normally occurs.

Dr. Gainer's slide presentation is available at http://investors.diffusionpharma.com/Presentations and includes graphics of these data.

"Even when taking into account the small number of patients enrolled, the difference in results with the new TSC dosing regimen compared with both the former TSC regimen and the standard of care is notable," said David Kalergis, Diffusion Pharmaceuticals CEO. "We are gratified by the continued clean safety profile of TSC. We also believe that observed survival differences of this magnitude send a meaningful signal about TSC, further de-risking the INTACT Phase 3 study during the randomized phase."

Mr. Kalergis continued, "Patients diagnosed with inoperable GBM have a dire prognosis and very limited treatment options. Given TSC's proven safety profile and observed efficacy signals, we need to make all efforts to provide a new treatment option to these patients."

The Company is seeking a partner to continue development of TSC in the inoperable 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 designs 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 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 signals of enhanced survival and patient performance. Diffusion's on-ambulance PHAST-TSC trial for acute stroke has begun patient enrollment. In addition, preclinical data supports the potential for 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.

Further, 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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