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): May 10, 2018

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))

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 2.02 – Results of Operations and Financial Condition

On May 10, 2018, Diffusion Pharmaceuticals Inc. (the "Company") issued a press release announcing its financial results for its first quarter ended March 31, 2018. A copy of that press release and the attached financial schedules are attached as Exhibit 99.1 to this report and incorporated herein by reference.

The information in this report (including Exhibit 99.1) is being furnished pursuant to Item 2.02 and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description
99.1	Press release dated May 10, 2018, announcing financial results for the first quarter ended March 31, 2018.

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: May 10, 2018

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 Reports First Quarter 2018 Financial Results and Provides Business Update

- **Patient screening and enrollment are underway in Phase 3 inoperable GBM brain cancer trial**
- **Key U.S. Patent Issued**
- **Clinical trial preparations are ongoing for Phase 2 trial with TSC in stroke**

CHARLOTTESVILLE, Va. (May 10, 2018) – Diffusion Pharmaceuticals Inc. (Nasdaq: DFFN) ("Diffusion" or "the Company"), a clinical-stage biotechnology company focused on extending the life expectancy of cancer patients using the novel small molecule trans sodium crocetinate (TSC) in conjunction with standard radiation and chemotherapy, reports financial results for the three months ended March 31, 2018 and provides a business update.

"During the first quarter patients continued to be screened and enrolled into our lead clinical program, the INvestigation of TSC Against Cancerous Tumors (INTACT) trial for the treatment of inoperable glioblastoma multiforme, or GBM," said David Kalergis, Chairman and Chief Executive Officer of Diffusion Pharmaceuticals. "In January the first patients were dosed in this 236-patient Phase 3 study. The protocol calls for half of patients to be enrolled in the treatment arm, which is standard of care radiation and chemotherapy, plus TSC, and half to be enrolled in the control arm, which is standard of care alone. The design of INTACT is based on an almost four-fold increase in overall survival at two years demonstrated in inoperable GBM patients in the preceding Phase 2 study. We are hopeful that similar survival will be demonstrated in our pivotal Phase 3 study and that TSC will provide an effective treatment for these patients, for whom current options are limited."

The Company continues to prepare for a Phase 2, randomized, double-blind, placebo-controlled trial with TSC in acute stroke. The contemplated study, based on an abstract that was presented in January at the International Stroke Conference, calls for the administration of TSC by specially-trained Emergency Medical Technicians to ambulance-transported patients within two hours of the onset of a suspected acute stroke. The in-ambulance administration could potentially overcome the current severe timing delay in administering therapy to stroke patients. The trial, which has been named the Pre-Hospital Ambulance Stroke Trial - TSC (PHAST-T), is expected to commence in late 2018, subject to funding.

Diffusion is pleased to announce the granting of U.S. patent number 9,950,067, which expands the Company's coverage of the use of TSC and related compounds in cancer therapy. The claims of the new U.S. patent relate to the treatment of a number of cancer types such as brain cancer (including glioblastoma) and pancreatic cancer, using TSC in conjunction with radiation therapy and chemotherapy. "This new U.S. patent further strengthens our IP portfolio in cancer treatment and is relevant to our technology in the Phase 3 study," stated General Counsel and IP Counsel Thomas Byrne.

“Intellectual property is an important component of our growth strategy, and we are pleased this patent has issued,” Mr. Kalergis added. “We are expecting additional patent allowances in the near future that will further augment our IP.”

Financial Results for the Three Months Ended March 31, 2018

We had cash and cash equivalents of $16.2 million as of March 31, 2018. We believe that our cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through June 2019.

We recognized $1.8 million in research and development expenses during the three months ended March 31, 2018, compared with $1.0 million during the three months ended March 31, 2017. The increase was mainly attributable to a $1.1 million increase in expense related to our Phase 3 GBM trial, offset by a $0.3 million decrease in manufacturing costs.

General and administrative expenses for the three months ended March 31, 2018 were $1.5 million compared with $1.6 million for the three months ended March 31, 2017. Salaries and wages increased by $0.2 million due to the increase in headcount, which was offset by a decrease in professional fees of approximately $0.3 million.

In connection with the private placement of our Series A preferred stock and common stock warrants in March of 2017, we determined the warrants to be classified as liabilities and subject to remeasurement at each reporting period. As a result, we recognized $10.2 million in excess fair value of the common stock warrants over the gross proceeds from our private placement. We also recognized $2.9 million in placement agent commission and other offering costs. In total, for the three months ended March 31, 2017, we recorded a $12.9 million expense for the change in fair value of our common stock warrant liabilities, which was primarily attributable to the increase in the market price for our Common Stock. There were no such charges in 2018 as the warrants were reclassified into equity in November of 2017.

About Diffusion Pharmaceuticals Inc.

Diffusion Pharmaceuticals Inc. is a clinical-stage biotechnology company focused on improving patient outcomes in unmet medical needs using its novel small molecule trans sodium crocetinate (TSC). Diffusion is developing TSC for use in conditions where hypoxia (oxygen deprivation) is known to diminish the effectiveness of standard of care (SOC) treatments. In oncology, TSC targets the cancer's hypoxic micro-environment, re-oxygenating treatment-resistant tissue and making the cancer cells more vulnerable to the therapeutic effects of SOC treatments without the apparent occurrence of any serious side effects. In non-oncology indications, therapeutic benefit would be achieved directly through re-oxygenation of the tissue threatened with cell death from hypoxia.

The INvestigation of TSC Against Cancerous Tumors (INTACT) Phase 3 randomized, controlled registration trial with TSC and SOC chemotherapy and radiation, compared with SOC alone in 236 patients who have been newly diagnosed with inoperable glioblastoma multiforme (GBM) brain cancer, is underway. In this study, TSC with concomitant temozolomide is being assigned to the first 8 subjects enrolled, and these patients will undergo radiation therapy plus temozolomide and TSC treatment through the normal six-week RT treatment period. During the subsequent temozolomide treatment period these subjects will be assigned TSC at ascending doses and studied in parallel for 2 full 28-day cycles. The Data Safety Monitoring Board will examine the resultant data and based on their observations may recommend the continued use of the starting TSC dose or another dose for those patients remaining to be randomized into the study.

A Phase 2 TSC clinical trial was completed in the second quarter of 2015 and evaluated 59 patients with newly diagnosed GBM. This open-label, historically controlled study demonstrated a favorable safety and efficacy profile for TSC combined with SOC, including a 37% improvement in overall survival compared with the control group at two years. A particularly strong efficacy signal was seen in the subset of inoperable patients where survival of TSC-treated patients at two years was nearly four-fold higher compared with the controls.

Due to its novel mechanism of action, TSC has safely re-oxygenated a range of tumor types in preclinical and clinical studies. Diffusion believes the therapeutic potential of TSC is not limited to specific tumors, thereby making it potentially useful to improve SOC treatments of other life-threatening cancers. Additional studies under consideration include Phase 2 trials in pancreatic cancer and brain metastases, with study initiation subject to receipt of additional funding or collaborative partnering. The Company also believes that TSC has potential application in other indications involving hypoxia including stroke, where the Company recently announced its Pre-Hospital Ambulance Stroke Trial - TSC (PHAST-T) study to be conducted in co-operation with the University of California Los Angeles (UCLA) and the University of Virginia (UVA) to test TSC in stroke patients in an in-ambulance clinical trial setting.

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 company's actual results to be materially different than those expressed in or implied by such forward-looking statements. Particular uncertainties and risks include: general business and economic conditions; the company's need for and ability to obtain additional financing; and the difficulty of developing pharmaceutical products, obtaining regulatory and other approvals and achieving market acceptance, 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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Difusion Pharmaceuticals Inc.
Consolidated Balance Sheets

	March 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 16,199,481	$ 8,896,468
Prepaid expenses, deposits and other current assets	890,891	769,946
Total current assets	17,090,372	9,666,414
Property and equipment, net	432,634	460,652
Intangible asset	8,639,000	8,639,000
Goodwill	6,929,258	6,929,258
Other assets	275,714	450,491
Total assets	$ 33,366,978	$ 26,145,815
Liabilities, Convertible Preferred Stock and Stockholders' Equity		
Current liabilities:		
Current portion of convertible debt	$ 550,000	$ 550,000
Accounts payable	419,103	511,956
Accrued expenses and other current liabilities	453,713	1,628,851
Total current liabilities	1,422,816	2,690,807
Deferred income taxes	2,223,678	2,223,678
Other liabilities	—	1,386
Total liabilities	3,646,494	4,915,871
Commitments and Contingencies		
Convertible preferred stock, $0.001 par value:		
Series A - 13,750,000 shares authorized at both March 31, 2018 and December 31, 2017. No shares and 12,376,329 shares issued at March 31, 2018 and December 31, 2017, respectively. No shares and 8,306,278 outstanding at March 31, 2018 and December 31, 2017, respectively.	—	—
Total convertible preferred stock	—	—
Stockholders' Equity:		
Common stock, $0.001 par value:		
1,000,000,000 shares authorized; 50,526,547 and 14,519,629 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively.	50,526	14,520
Additional paid-in capital	94,538,808	82,770,313
Accumulated deficit	(64,868,850)	(61,554,889)
Total stockholders' equity	29,720,484	21,229,944
Total liabilities, convertible preferred stock and stockholders' equity	$ 33,366,978	$ 26,145,815

Diffusion Pharmaceuticals Inc.
Consolidated Statements of Operations

	Three Months Ended March 31,	
	2018	**2017**
Operating expenses:		
Research and development	$ 1,825,568	$ 1,007,571
General and administrative	1,497,839	1,553,139
Depreciation	28,018	6,603
Loss from operations	3,351,425	2,567,313
Other expense		
Interest (income) expense, net	(37,464)	55,719
Change in fair value of warrant liabilities	—	12,919,674
Warrant related expenses	—	10,225,846
Other financing expenses	—	2,870,226
Net loss	$ (3,313,961)	$ (28,638,778)
Accretion of Series A cumulative preferred dividends	(85,993)	(58,845)
Deemed dividend related to the make-whole provision for the conversion of Series A preferred stock into common	(8,167,895)	—
Net loss attributable to common stockholders	$ (11,567,849)	$ (28,697,623)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.27)	$ (2.78)
Weighted average shares outstanding, basic and diluted	42,122,395	10,337,726

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