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): April 3, 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**	**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))

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 April 3, 2018, Diffusion Pharmaceuticals Inc. (the "Company") issued a press release announcing its financial results for its fourth quarter and year ended December 31, 2017. 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 April 3, 2018, announcing financial results for the fourth quarter and year ended December 31, 2017.

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 3, 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 2017 Financial Results and Provides Business Update

- **Patient Enrollment in Phase 3 Inoperable GBM Brain Cancer Trial Underway**
- **Raised $12 Million in Underwritten Public Offering**
- **Preparing to Commence Clinical Trial with TSC in Stroke**
- **Expanded Intellectual Property Portfolio with New Key Patents**

CHARLOTTESVILLE, Va. (April 3, 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 2017 financial results and provides a business update. Diffusion's lead clinical trial program, the INvestigation of TSC Against Cancerous Tumors (INTACT) trial, is a Phase 3 study expected to enroll a total of 236 patients, with half in the treatment arm and half in the control arm. 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 began opening clinical sites for the INTACT trial in December as planned, and started enrolling and dosing patients in January while continuing to open more clinical sites," said David Kalergis, Chairman and Chief Executive Officer of Diffusion Pharmaceuticals. "We believe that the INTACT trial can provide a promising new treatment option for the thousands of patients who each year are newly diagnosed with inoperable GBM brain cancer and who, because of their poor prognosis, may be excluded from other clinical trials."

In January 2018 the Company conducted a public offering, raising gross proceeds of approximately $12.0 million from the sale of common stock and warrants. In conjunction with this capital raise, all the Company's preferred stock was converted into common stock, eliminating the obligation for future dividend payments and certain restrictive provisions contained therein.

In January 2018 the Company, along with researchers from the University of California Los Angeles (UCLA) and the University of Virginia (UVA), presented an abstract at the International Stroke Conference in Los Angeles describing a Phase 2 trial design to test TSC for use in acute stroke. The planned Phase 2, randomized, double-blind, placebo-controlled trial 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, potentially overcoming the current severe timing obstacle in the treatment of 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.

The Company further expanded its intellectual property portfolio in 2017, with the allowance of key patents that increased coverage of the therapeutic use of TSC and related compounds. The new areas include congestive heart failure, chronic renal failure, acute lung injury, chronic obstructive pulmonary disease and respiratory distress syndrome. Additional claims were also allowed relating to the treatment of a number of cancer types including brain and pancreatic, using TSC along with chemotherapy and radiation therapy.

Financial Results for the Year Ended December 31, 2017

We had cash and cash equivalents of $8.9 million as of December 31, 2017. Subsequent to the close of the year, on January 22, 2018 we closed an underwritten public offering of stock and warrants, raising approximately $12.0 million in gross proceeds.

We recognized $5.1 million in research and development expenses during 2017, compared with $7.3 million during 2016. This decrease was primarily attributable to a decrease of $1.3 million related to animal toxicology studies, a decrease of $0.9 million of pancreatic expenses, a decrease of $0.6 million related to stock-based compensation expense and a decrease of $0.3 million in manufacturing-related expenses. We also recognized a $1.0 million impairment charge upon our abandonment of future development efforts related to our RES-440 IPR&D asset in 2016. These decreases were offset by increases in GBM trial expenses of $1.6 million as we prepared for the Phase 3 clinical trial for TSC and increases in salaries and wages expenses of $0.2 million as a result of an increase in headcount. We currently expect our research and development expenses to increase significantly in future periods due to costs associated with our Phase 3 clinical trial for TSC, the Phase 2 trial for pre-hospital stroke therapy and overall efforts to advance the research and development of our technologies and product candidates.

General and administrative expenses were $6.2 million during 2017, compared with $11.1 million during 2016. The decrease was primarily due to a decrease of $3.2 million in professional fees incurred in 2016 in connection with preparations to operate as a public company and a $2.5 million decrease in non-cash litigation settlement fees, offset by increases in salary and wages and stock-based compensation expense of $0.4 million and $0.4 million, respectively, due to our increase in headcount.

In connection with the private placement of our Series A convertible preferred stock and common stock warrants in March 2017, we determined the warrants to be classified as liabilities and subject to remeasurement at each reporting period. As such, during 2017 we recorded a $22.1 million non-cash gain for the change in fair value of our common stock warrant liabilities, which was primarily attributable to the decrease in the market price for our common stock. We also recognized $10.2 million in excess fair value of the common stock warrants over the gross proceeds from our private placement and $2.9 million in placement agent commissions and other offering costs.

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 temozolimide 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.

Contacts:
David Kalergis, CEO
Diffusion Pharmaceuticals Inc.
(434) 220-0718
dkalergis@diffusionpharma.com
or
LHA Investor Relations
Kim Sutton Golodetz
(212) 838-3777
kgolodetz@lhai.com

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Diffusion Pharmaceuticals Inc.
Consolidated Balance Sheets

	December 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 8,896,468	$ 1,552,852
Prepaid expenses, deposits and other current assets	769,946	50,844
Total current assets	9,666,414	1,603,696
Property and equipment, net	460,652	79,755
Intangible asset	8,639,000	8,639,000
Goodwill	6,929,258	6,929,258
Other assets	450,491	232,675
Total assets	$ 26,145,815	$ 17,484,384
Liabilities, Convertible Preferred Stock and Stockholders' Equity		
Current liabilities:		
Current portion of convertible debt	$ 550,000	$ 1,880,000
Accounts payable	511,956	1,684,158
Accrued expenses and other current liabilities	1,628,851	874,264
Total current liabilities	2,690,807	4,438,422
Convertible debt, net of current portion	—	550,000
Deferred income taxes	2,223,678	3,279,363
Other liabilities	1,386	31,915
Total liabilities	4,915,871	8,299,700
Commitments and Contingencies		
Convertible preferred stock, $0.001 par value:		
Series A - 13,750,000 shares authorized, 12,376,329 and 8,306,278 shares issued and outstanding, respectively at December 31, 2017; No shares authorized, issued or outstanding at December 31, 2016 (liquidation value of $16,778,682 at December 31, 2017)	—	—
Stockholders' Equity:		
Common stock, $0.001 par value:		
1,000,000,000 shares authorized; 14,519,629 and 10,345,637 shares issued and outstanding at December 31, 2017 and December 31, 2016, respectively	14,520	10,346
Additional paid-in capital	82,770,313	69,363,575
Accumulated deficit	(61,554,889)	(60,189,237)
Total stockholders' equity	21,229,944	9,184,684
Total liabilities, convertible preferred stock and stockholders' equity	$ 26,145,815	$ 17,484,384

Diffusion Pharmaceuticals Inc.
Consolidated Statements of Operations

	Year Ended December 31,	
	2017	**2016**
Operating expenses:		
Research and development	$ 5,088,621	$ 7,252,241
General and administrative	6,191,845	11,094,146
Depreciation	67,981	25,342
Loss from operations	11,348,447	18,371,729
Interest expense, net	48,006	29,686
Change in fair value of warrant liabilities	(22,072,322)	—
Warrant related expenses	10,225,846	—
Other financing expenses	2,870,226	—
Loss from operations before income tax benefit	(2,420,203)	(18,401,415)
Income tax benefit	(1,055,685)	(364,796)
Net loss	$ (1,364,518)	$ (18,036,619)
Accretion of Series A cumulative preferred dividends	(1,252,394)	—
Net loss attributable to common stockholders	$ (2,616,912)	$ (18,036,619)
Per share information:		
Net loss per share of common stock, basic	$ (0.21)	$ (1.76)
Net loss per share of common stock, diluted	$ (1.94)	$ (1.76)
Weighted average shares outstanding, basic	12,447,641	10,232,791
Weighted average shares outstanding, diluted	12,755,316	10,232,791

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