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 15, 2017

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.)

2020 Avon Court, #4 **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 May 15, 2017, Diffusion Pharmaceuticals Inc. (the "Company") issued a press release announcing its financial results for its first quarter ended March 31, 2017. A copy of that press release is 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 15, 2017, announcing financial results for the first quarter ended March 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: May 15, 2017

DIFFUSION PHARMACEUTICALS INC.

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

FOR IMMEDIATE RELEASE
NASDAQ: DFFN

Diffusion Pharmaceuticals Provides Corporate Highlights and Reports Financial First Quarter 2017 Results

Charlottesville, Virginia (May 15, 2017) - Diffusion Pharmaceuticals Inc. (NASDAQ: DFFN), a clinical stage biotechnology company focused on the development of novel small molecule therapeutics for cancer and other hypoxia-related diseases, today reported financial results for the three months ended March 31, 2017 and provided an overview of recent corporate highlights.

David Kalergis, Chairman and Chief Executive Officer, stated, "With the completion of our recent private placement, we believe we are now well positioned to advance our clinical development strategy for our lead product candidate, trans sodium crocetinate (TSC). We are in dialogue with the U.S. FDA regarding the design of a Phase 3 trial of TSC in newly diagnosed inoperable GBM patients, and plan to complete a protocol review in the third quarter of 2017. Assuming FDA sign-off on final protocol design, the study is planned to initiate by the end of 2017."

Corporate Highlights

In March 2017, U.S. Patent 9,604,899 entitled "Bipolar Trans Carotenoid Salts and Their Uses" was granted by the United States Patent and Trademark Office. This patent expands the coverage of the therapeutic use of TSC and other related compounds to five hypoxia-related conditions including congestive heart failure, chronic renal failure, acute lung injury (ALI), chronic obstructive pulmonary disease (COPD) and respiratory distress syndrome (RDS).

In March 2017, the Company raised aggregate gross proceeds of $25.0 million in an oversubscribed private placement of its Series A convertible preferred stock. At March 31, 2017, the Company had cash and cash equivalents of $12.2 million and an $8.3 million subscription receivable that was then received on April 3, 2017.

Three Months Ended March 31, 2017 Financial Results

Research and development expenses were $1.0 million for the three months ended March 31, 2017, compared to $2.4 million for the three months ended March 31, 2016. This decrease in research and development was attributable to a decrease in expenses related to the Company's pancreatic cancer program and animal toxicology studies.

General and administrative expenses were $1.6 million for the three months ended March 31, 2017, compared to $3.9 million for the three months ended March 31, 2016. The decrease in general and administrative expenses was primarily attributable to a decrease in costs attributable to the reverse merger transaction in January 2016.

The Company recognized $26.0 million in warrant related expenses (of which $25.6 million was non-cash related and fees netted against gross proceeds) associated with the private placement for the three months ended March 31, 2017, which consisted of the change in fair value of the common stock warrants from issuance, the excess fair value of the common stock warrants over the gross cash proceeds from the Series A preferred stock offering, and placement agent commissions and other offering costs.

Net loss was $28.6 million for the three months ended March 31, 2017, compared to a net loss of $6.2 million for the three months ended March 31, 2016. For the quarter ended March 31, 2017, the net loss included $26.0 million in warrant related expenses (of which $25.6 million was non-cash related and fees netted against gross proceeds) associated with the private placement. For the three months ended March 31, 2017, net loss attributable to common shares was $28.7 million, which was inclusive of the dividend payable on the Series A convertible preferred stock.

Net cash used in operating activities for the three months ended March 31, 2017 was $3.4 million compared to $4.6 million during the three months ended March 31, 2016.

About Diffusion Pharmaceuticals Inc.

Diffusion Pharmaceuticals Inc. is a clinical stage biotechnology company focused on extending the life expectancy of cancer patients by improving the effectiveness of current standard of care treatments including radiation therapy and chemotherapy. Diffusion is developing its lead product candidate, trans sodium crocetinate (TSC), for use in the many cancer types in which tumor hypoxia (oxygen deprivation) is known to diminish the effectiveness of current treatments. 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 treatments such as radiation therapy and chemotherapy, without the apparent addition of any serious side effects.

A Phase 2 clinical program, completed in the second quarter of 2015, evaluated 59 patients with newly diagnosed glioblastoma multiforme (GBM). This open label, historically controlled study demonstrated a favorable safety and efficacy profile for TSC combined with standard of care, including a 37% improvement in overall survival over 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 increased by 380% over the controls. At an End-Of-Phase 2 Meeting, the U.S. Food and Drug Administration provided Diffusion with extensive guidance on the design for a Phase 3 trial of TSC in newly diagnosed GBM patients. Assuming FDA sign-off on our final protocol design, focusing on the inoperable patients, the study is planned to initiate by the end of 2017. Due to its novel mechanism of action, TSC has safely re-oxygenated a range of tumor types in our preclinical and clinical studies. Diffusion believes its therapeutic potential is not limited to specific tumors, thereby making it potentially useful to improve standard-of-care treatments of other life-threatening cancers. Additional planned studies include a Phase 2 trial in pancreatic cancer and a study in 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, such as neurodegenerative diseases and emergency medicine, and an in-ambulance trial of TSC in stroke is under consideration.

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 protocol review, the anticipated financial position, operating results and growth prospects of the company 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. 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.

Diffusion Pharmaceuticals Contacts

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