
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): March 31, 2017

DIFFUSION PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

000-24477
(Commission File
Number)

30-0645032
(I.R.S. Employer
Identification No.)

2020 Avon Court, #4
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))
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Item 2.02 – Results of Operations and Financial Condition

On March 31, 2017, Diffusion Pharmaceuticals Inc. (the “Company”) issued a press release announcing its financial results for its year ended December 31, 2016. 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release dated March 31, 2017, announcing financial results for the year ended December 31, 2016.

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: March 31, 2017

DIFFUSION PHARMACEUTICALS INC.

By: /s/ David G. Kalergis

Name: David G. Kalergis

Title: Chief Executive Officer

Diffusion Pharmaceuticals Provides Corporate Highlights and Reports 2016 Financial Results

Charlottesville, Virginia (March 31, 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 full year of 2016 and provided an overview of recent operational highlights.

David Kalergis, Chairman and Chief Executive Officer, stated: “The recently received proceeds from our private placement provide Diffusion with resources to move forward with our Phase 3 clinical program testing of trans sodium crocetin (TSC) in newly diagnosed GBM patients, as well as advance its use in other indications. Diffusion staff, expert consultants and key opinion leaders continue to work together to craft the most cost-effective programs with optimal chances for success.”

Corporate Highlights

- In November 2016, our common stock was approved for listing, and commenced trading on the NASDAQ Capital Market;
- In February 2017, data from our Phase 1/2 clinical trial evaluating the safety and efficacy of TSC in newly diagnosed glioblastoma multiforme was published in the print edition of the peer-reviewed Journal of Neurosurgery;
- In March 2017, we completed an initial closing of our Series A Convertible Preferred Stock offering to accredited investors in private placement;
- 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).

Year End 2016 Results

Research and development expenses were \$7.3 million during the year ended December 31, 2016, compared to \$3.9 million during the year ended December 31, 2015. This increase was primarily a result of an additional \$1.2 million in expenses related to animal toxicology studies, an increase of \$1.0 million in active product ingredient manufacturing costs and an additional \$0.5 million in costs related to the TSC pancreatic cancer program. Additionally, a \$1.0 million noncash impairment charge was recognized for the abandonment of future development efforts related to the RES-440 IPR&D asset. Salaries and wages expense and stock compensation expense increased by \$0.3 million and \$0.4 million, respectively, due to an increase in headcount. The overall increase in research and development expense was offset by a \$0.9 million decrease in spend related to GBM trials.

General and administrative expenses were \$11.1 million for the year ended December 31, 2016, compared to \$2.5 million for the year ended December 31, 2015. The increase was primarily attributable to \$4.1 million in professional fees incurred in connection with preparing to operate as a public company, merger and transaction related fees and fees related to investment bank advisory services. There was also a \$2.5 million noncash charge recognized upon settlement of a litigation matter. In addition, insurance expense increased by \$0.8 million due to an increase in directors and officer's insurance and salaries and wages and stock compensation expense increased by \$0.4 million and \$0.4 million, respectively, due to an increase in headcount.

Net loss was \$18.0 million for the year ended December 31, 2016, compared to a net loss of \$6.7 million for the year ended December 31, 2015. The increase in the net loss was primarily due to higher expenses associated with research and development and general and administrative costs.

Cash and cash equivalents were \$1.6 million as of December 31, 2016, compared to \$2.0 million as of December 31, 2015.

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. The Diffusion technology is a paradigm shift in the approach to the treatment of cancer and other diseases involving hypoxia, or oxygen deprivation, in that it facilitates the diffusion of oxygen into hypoxic tissue. Diffusion is developing its lead drug, *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. A strong efficacy signal was seen in the subset of inoperable patients, where survival of TSC-treated patients at 2 years was increased by 380% over the controls. The U.S. Food and Drug Administration has provided guidance on the design of a Phase 3 trial in newly diagnosed GBM. Additional planned studies include a Phase 2 trial in pancreatic cancer and a study in brain metastases. 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. We also believe that TSC has potential application in other indications involving hypoxia, such as stroke and neurodegenerative diseases, 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, 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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