
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): November 14, 2016

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 November 14, 2016, Diffusion Pharmaceuticals Inc. (the “Company”) issued a press release announcing its financial results for its third quarter ended September 30, 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 November 14, 2016, announcing financial results for the third quarter ended September 30, 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: November 14, 2016

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 Third Quarter 2016 Results

Charlottesville, Virginia (November 14, 2016) - 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 September 30, 2016 and provided an overview of recent corporate highlights. The third quarter results will be filed on the Quarterly Report on Form 10-Q with the SEC.

David Kalergis, Chairman and Chief Executive Officer, stated, "I am very excited about the progress that we have made in advancing the clinical development of our lead candidate, trans sodium crocetininate (TSC). The completion of the reverse stock split and subsequent uplisting to the Nasdaq Capital Market is an important step for the Company and I am extremely pleased that we have reached this stage of growth. The successful completion of our three month animal toxicology studies is also an important milestone in support of Diffusion's readiness to conduct a Phase 3 pivotal trial of TSC in newly diagnosed GBM patients. Our newly assembled Scientific Advisory Board will serve as a valuable resource as we prepare to begin this Phase 3 trial, and will also guide our research as we seek to develop TSC for therapeutic use in other hypoxia-related diseases."

Corporate Highlights

In August 2016, Diffusion announced a 1-for-10 reverse stock split in preparation for its proposed uplisting to Nasdaq Capital Market.

In September 2016, Diffusion announced the successful completion of animal toxicity studies in preparation for a Phase 3 pivotal trial of TSC in newly diagnosed GBM patients.

In September 2016, the Company also established a Scientific Advisory Board of distinguished experts to serve as a resource for the development of TSC in its many areas on therapeutic use for indications involving hypoxic conditions.

In November 2016, the Company subsequently announced that its shares of common stock were approved for listing on the Nasdaq Capital Market, effective November 9, 2016.

Three Months Ended September 30, 2016 Financial Results

Research and development expenses were \$1.9 million for the three months ended September 30, 2016, compared to \$0.9 million for the three months ended September 30, 2015. This increase was primarily a result of the \$1.0 million non-cash impairment charge upon the abandonment of the future development efforts of the RES-440 IPR&D asset acquired from RestorGenex.

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General and administrative expenses were \$3.9 million for the three months ended September 30, 2016, compared to \$0.4 million for the three months ended September 30, 2015. The increase was primarily attributable to a \$2.5 million non-cash litigation settlement with an investor in September 2016 and an increase in incremental costs in connection with operating as a public company.

Net loss was \$5.4 million, or \$0.53 per share, for the three months ended September 30, 2016, compared to a net loss of \$1.4 million, or \$0.64 per share, for the three months ended September 30, 2015. The increase in the net loss was due primarily to higher expenses associated with the increased research and development expenses and general and administrative expenses.

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 drug, *trans sodium crocetin* (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. The U.S. Food and Drug Administration has agreed upon 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.

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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