
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): August 15, 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))
-
-

Item 2.02 – Results of Operations and Financial Condition

On August 15, 2016, Diffusion Pharmaceuticals Inc. (the “Company”) issued a press release announcing its financial results for its second quarter ended June 30, 2016. 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release dated August 15, 2016, announcing financial results for the second quarter ended June 30, 2016.



FOR IMMEDIATE RELEASE
OTCQX: DFFN

Diffusion Pharmaceuticals Provides Corporate Highlights and Reports Financial Second Quarter 2016 Results

Charlottesville, Virginia (August 15, 2016) - Diffusion Pharmaceuticals Inc. (OTCQX: 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 June 30, 2016 and provided an overview of recent corporate highlights. The results will be filed shortly 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 been making in advancing trans sodium crocetinate (TSC). The recently expanded patent estate of TSC demonstrates its broad applicability across multiple hypoxia driven indications impacting human health. In the near term, we plan to continue to expand the clinical development pipeline for TSC to include both glioblastoma (GBM) and pancreatic cancer. Also, we recently welcomed Isaac Blech, an experienced biotechnology entrepreneur and investor, to our Board of Directors as Vice Chairman."

Corporate Highlights

In August 2016, Mr. Isaac Blech joined Diffusion's Board of Directors as Vice Chairman. With over 35 years of biotech industry expertise, Mr. Blech has founded and served on the boards of a number of companies including Celgene Corporation, Nova Pharmaceutical Corporation, Pathogenesis Corporation, and Genetics Systems Corporation. Among the other boards Mr. Blech currently serves on are Cerecor, Inc., a CNS company, ContraFect Corporation, an infectious disease company, Medgenics, Inc., a biotechnology company, and Edge Therapeutics, Inc., a company that treats life-threatening neurological conditions.

In July 2016, the Company's abstract related to medical emergency indications for its lead clinical stage drug candidate TSC has been accepted for presentation at the American College of Emergency Physicians (ACEP) Research Forum being held October 16 – 18, 2016 in Las Vegas. The acceptance of the abstract highlights the potential broad applicability of TSC as a life-saving intervention to reverse hypoxia in many medical emergencies, including hemorrhagic shock, myocardial infarction, and stroke.

In June 2016, the Company's U.S. patent application, entitled "Bipolar Trans Carotenoid Salts and Their Uses," was allowed by the United States Patent and Trademark Office. This application, which is expected to issue in the second half of 2016, expands coverage of the therapeutic use TSC and other related compounds to five hypoxia-related conditions including congestive heart failure, chronic renal failure, acute lung injury, chronic obstructive pulmonary disease, and respiratory distress syndrome.

Three Months Ended June 30, 2016 Financial Results

Research and development expenses were \$1.4 million for the three months ended June 30, 2016, compared to \$0.9 million for the three months ended June 30, 2015. This increase was primarily a result of an increase in GBM program-related drug expenditures and expenses related to the TSC pancreatic cancer program.

2020 Avon Court, #4
Charlottesville, VA 22902
Tel 434.220.0718
Fax 434.220.0722
www.diffusionpharma.com

General and administrative expenses were \$2.3 million for the three months ended June 30, 2016, compared to \$0.3 million for the three months ended June 30, 2015. The increase was driven by a non-cash expense of \$0.9 million associated with financial advisory fees in connection with the Company's current capital raising efforts, as well as incremental costs associated with operating as a new public company.

Net loss was \$3.8 million, or \$0.04 per share, for the three months ended June 30, 2016, compared to a net loss of \$1.3 million, or \$0.06 per share, for the three months ended June 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 combined company's technology and product candidates, the anticipated timing of future clinical trials, the anticipated financial position, operating results and growth prospects of the combined 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

David Kalergis
Chief Executive Officer Diffusion
Pharmaceuticals Inc. (434) 220-0718
dkalergis@diffusionpharma.com

Stephanie Carrington ICR Inc.
(646) 277-1282
Stephanie.Carrington@icrinc.com