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 11, 2022

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.)

300 East Main Street, Suite 201 **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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	DFFN	NASDAQ Capital Market

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 August 11, 2022, Diffusion Pharmaceuticals Inc. (the "Company") issued a press release announcing financial results for the three-month period ended June 30, 2022 and a business update. A copy of that press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information included in or incorporated by reference into this Item 2.02 (including Exhibit 99.1) is being furnished pursuant to Item 2.02 of Form 8-K 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, issued August 11, 2022, announcing financial results for the three-month period ended June 30 2022 and business update
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: August 16, 2022

DIFFUSION PHARMACEUTICALS INC.

By: /s/ William Elder
Name: William Elder
Title: General Counsel & Corporate Secretary

Exhibit 99.1

Diffusion Pharmaceuticals Reports Second Quarter 2022 Financial Results and Provides Business Update

- *Aligned with FDA on Design of Phase 2 GBM Trial of TSC; Initiation Expected by End of 2022*
- *Reported Positive Effects in TSC Altitude Trial*
- *Ended Quarter with $28.5 million in Cash, Cash Equivalents and Marketable Securities*
- *Expected Cash Runway into First Quarter of 2024*

CHARLOTTESVILLE, Va., August 11, 2022--Diffusion Pharmaceuticals Inc. (NASDAQ: DFFN) ("Diffusion" or the "Company"), a biopharmaceutical company developing novel therapies that may enhance the body's ability to deliver oxygen to areas where it is needed most, today announced financial results for the quarter ended June 30, 2022, and provided a business update.

Development Updates

Aligned with FDA on Innovative Trial Design in Glioblastoma Multiforme ("GBM") Patients: In July 2022, Diffusion announced that it had aligned with the U.S. Food and Drug Administration ("FDA") on the design of an open-label, dose-escalation, Phase 2 safety and efficacy study of its lead product candidate, trans sodium crocetinate ("TSC"), administered with standard of care to patients newly diagnosed with glioblastoma multiforme. The trial, which has been designated *Study 200-208*, has been designed to incorporate an innovative use of positron emission tomography ("PET") to map hypoxia within the tumor. The use of PET is designed to allow the Company to directly quantify the effects of TSC on tumor hypoxia, and thereby test TSC's ability to enhance oxygen within the tumor microenvironment. These initial imaging readouts are expected to be available within one year of study initiation, thereby providing objective surrogate data readouts significantly faster than historical clinical trials in patients with GBM. The Company expects to initiate the trial by the end of 2022 with the first patient dosed in the first quarter of 2023.

Reported Positive Results from Altitude Trial: In June 2022, positive results were reported from the Company's Altitude Trial. The data suggested that a higher dose of TSC (2.5 mg/kg dose) decreased blood acidity (lower lactate accumulation) and enhanced metabolic recovery at 10 minutes after completion of exercise under the stressful conditions of simulated high altitude and exercise. Additionally, positive changes were observed in blood markers of oxygen utilization, indicating that TSC may enhance oxygen availability at the cellular level, reinforcing Diffusion's belief in the therapeutic potential of TSC.

"During the second quarter of 2022, we maintained significant momentum across our clinical and corporate programs achieving clinical and operational milestones we believe will help build Diffusion's long-term success. Specifically, we were pleased to report positive results from our Altitude Trial, which we believe support our plans for further development of TSC to treat hypoxic solid tumors like GBM," commented Robert Cobuzzi, Jr., Ph.D., President and Chief Executive Officer of Diffusion. "Additionally, we are very pleased to have reached alignment with the FDA on an innovative GBM Trial design, and our team is already working to initiate the trial. We believe TSC has the potential to enhance the effectiveness of available treatment of this devastating disease."

Business Updates

Appointed Raven Jaeger, M.S., as Chief Regulatory Officer: In May 2022, Diffusion appointed Ms. Raven Jaeger as the Company's Chief Regulatory Officer. Ms. Jaeger will, among other things, oversee the development and implementation of regulatory and related strategies to support the development and commercialization of Diffusion's product development candidates.

Ended Quarter with $28.5 Million in Cash, Cash Equivalents and Marketable Securities with Expected Cash Runway into First Quarter of 2024

Research and development expenses in the second quarter of 2022 were $2.1 million, compared to $2.0 million in the prior year period. There was a decrease in costs associated with clinical trials and drug manufacturing, offset by an increase in salaries and wages and stock-based compensation related to increased headcount.
General and administrative expenses were $2.1 million during the second quarter of 2022 versus $1.8 million in the comparable quarter last year. The increase reflects a rise in professional fees related to the reverse stock split that occurred in April 2022, as well as increased salary expenses related to additional headcount.

As of June 30, 2022, Diffusion had $28.5 million in cash, cash equivalents, and marketable securities, which the Company currently expects will enable it to fund its operating expenses and capital expenditure requirements into the first quarter of 2024, without giving effect to any business development activities the Company may undertake.

About Diffusion Pharmaceuticals Inc.
Diffusion Pharmaceuticals Inc. is a biopharmaceutical company developing novel therapies to enhance the body's ability to deliver oxygen to areas where it is needed most. Diffusion's lead product candidate, TSC, is being investigated to enhance the diffusion of oxygen to tissues with low oxygen levels, also known as hypoxia, a serious complication of many of medicine's most intractable and difficult-to-treat conditions, including hypoxic solid tumors like GBM. For more information, please visit us at www.diffusionpharma.com.

Forward-Looking Statements
This press release includes express and implied forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including: the potential therapeutic value of TSC in cancer and non-cancer indications; anticipated timelines for the initiation, completion, and announcement of data from Study 200-208; the Company's ongoing and planned clinical trials; the Company's near-term strategic priorities with respect to the development of TSC and otherwise; and the Company's anticipated cash runway. The Company may, in some cases, use terms such as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately," or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Although the Company believes that it has a reasonable basis for each forward-looking statement contained herein, forward-looking statements by their nature involve risks and uncertainties, known and unknown, many of which are beyond the Company's control and, as a result, the Company's actual results could differ materially from those expressed or implied in any forward-looking statement. Particular risks and uncertainties include, among other things, those related to: the novelty of the Company's Oxygenation Trials' design and endpoints, the relevance of trends observed in those studies to any indication, including hypoxic solid tumors, and the therapeutic value of TSC; the optimal doses and dosing regimens of TSC in connection with the potential treatment of any particular disease or indication; the Company's ability to design, initiate, enroll, execute, and complete its ongoing and planned studies evaluating TSC, including Study 200-208; the likelihood and timing of regulatory approval of TSC, if any, for the treatment of solid tumors complicated by hypoxia or any other indication, or the nature of any feedback the Company may receive from the U.S. Food and Drug Administration or other regulatory bodies; the impact of global supply chain disruptions on the Company's drug product manufacturing capabilities, clinical development program, and associated timelines; the Company's ability to identify, evaluate and execute potential business development transactional opportunities, if any; the Company's ability to protect and expand its intellectual property portfolio; general economic, political, business, industry, and market conditions, including the ongoing COVID-19 pandemic, inflationary pressures, and geopolitical conflicts; and the other factors discussed under the heading "Risk Factors" in the Company's filings most recent Annual Report on Form 10-K and other filings with the U.S. Securities and Exchange Commission. Any forward-looking statements in this press release speak only as of the date hereof (or such earlier date as may be identified) and, except as required by applicable law, rule, or regulation, the Company undertakes no obligation to update any such statements after the date hereof.

Contacts

Investors:
Tiberend Strategic Advisors, Inc.
Daniel Kontoh-Boateng/Jonathan Nugent
dboateng@tiberend.com
jnugent@tiberend.com

Media:
Kate Barrette
RooneyPartners
Kbarrette@rooneypartners.com