

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 12, 2022

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.)

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 May 12, 2022, Diffusion Pharmaceuticals Inc. (the “Company”) issued a press release announcing financial results for the three-month period ended March 31, 2022. 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 May 12, 2022, announcing financial results for the three-month period ended March 31, 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: May 16, 2022

DIFFUSION PHARMACEUTICALS INC.

By: /s/ William Elder

Name: William Elder

Title: General Counsel & Corporate Secretary



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

- Completed Dosing in Altitude Trial; Topline Data Expected in June 2022
- Blinded, Interim Data to be Presented at UHMS Annual Scientific Meeting in May 2022
- Ended Quarter with \$32.6 Million in Cash, Cash Equivalents and Marketable Securities
 - Regained Compliance with Nasdaq Bid Price Rule

CHARLOTTESVILLE, Va., May 12, 2022 -- **Diffusion Pharmaceuticals Inc. (NASDAQ: DFFN)** (“Diffusion” or the “Company”), a biopharmaceutical company developing novel therapies that enhance the body’s ability to deliver oxygen to areas where it is needed most, today announced financial results for the quarter ended March 31, 2022, and provided a business update.

Business Updates

- **Completed Dosing in Altitude Trial:** The Company announced the last participant in this study of its lead product candidate, trans sodium crocetinate (“TSC”), completed dosing in April 2022 and topline data are expected in June 2022. Two abstracts, based on blinded, aggregated (placebo and treatment), interim physiological data from a subset of study participants, will be presented by the clinical investigators at the Undersea and Hyperbaric Medical Society’s Annual Scientific Meeting in Reno, Nevada being held from May 22-26, 2022.
 - **Continued Enrollment in TSC ILD-DLCO Trial:** Diffusion announced dosing of the first patients in December 2021 and enrollment continued during the first quarter of 2022. The Company currently anticipates completing dosing in the second half of 2022 and reporting topline results within two months of study completion.
 - **Expanded Scientific Advisory Board:** In February 2022, the Company announced the addition of five prominent radiation and medical oncologists to its Scientific Advisory Board (“SAB”) to further support development of TSC, as an adjunctive treatment for hypoxic solid tumors.
 - **Maintained Solid Cash Position:** As of March 31, 2022, Diffusion reported \$32.6 million in cash, cash equivalents, and marketable securities, which is expected to fund the Company’s operating expenses and capital expenditure requirements through 2023.
 - **Regained Nasdaq Compliance:** In May 2022, the Company announced that it had regained compliance with the Nasdaq Capital Market’s continued listing requirements, following the bid price of the Company’s common stock closing above \$1.00 for 10 consecutive trading days.
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“We believe 2022 has the potential to be a transformational year, as we anticipate the topline data readout from the Altitude Trial in June and the completion of patient dosing in our ILD-DLCO trial later this year,” commented Robert Cobuzzi, Jr., Ph.D., President and Chief Executive Officer of Diffusion. “With our strong cash position, experienced development team, and the appointment of our new and distinguished SAB members, we believe Diffusion is now effectively positioned to launch our Hypoxic Solid Tumor Program aimed at evaluating TSC as an adjunctive treatment for hypoxic solid tumors. Our team worked hard during the first quarter, evaluating various options in designing an appropriate clinical study protocol and amending our oncology investigational new drug application for TSC to support a start date for the first trial in the program in the second half of 2022. We look forward to providing updates on these development activities that we hope will drive both patient and shareholder value.”

Financial Results

- Research and development expenses in the first quarter of 2022 were \$2.4 million, compared to \$2.9 million in the prior year period. A significant portion of this decrease was attributable to the timing of clinical trials and drug manufacturing, offset by an increase in salaries, wages and stock-based compensation related to increased headcount.
- General and administrative expenses were \$2.1 million during the first quarter of 2022 versus \$1.7 million in the comparable quarter last year. The increase compared to the prior year period was mainly due to an increase in salaries, wages, and stock-based compensation related to increased headcount, as well as an increase in outside professional fees to support business activities during the quarter.
- As of March 31, 2022, Diffusion had cash, cash equivalents, and marketable securities of \$32.6 million, compared to \$46.6 million as of March 31, 2021.

About Diffusion Pharmaceuticals Inc.

Diffusion Pharmaceuticals Inc. is a biopharmaceutical company developing novel therapies that enhance the body’s ability to deliver oxygen to areas where it is needed most. Diffusion’s lead product candidate, TSC, is being developed 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. 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 regarding the Company's anticipated cash runway, anticipated timelines for the initiation, completion, and announcement of data from the Company's Oxygenation Trials and hypoxic solid tumor program, the relevance and significance of any such data, and the potential therapeutic value of TSC. 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 risk and uncertainties include, among other things, those related to: the Company's ability to design, initiate, enroll, execute, and complete its planned studies evaluating TSC; 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 supply chain and other supplier issues on the Company's clinical development program and associated timelines; 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.

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