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): October 25, 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**	**22902**
(Address of principal executive offices)	(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 5.08 Shareholder Director Nominations

To the extent applicable, the information in Item 8.01 of this Current Report is incorporated by reference into this Item 5.08.

Item 7.01 Regulation FD Disclosure

Certain information concerning the business, clinical studies, development plans, and financial position of Diffusion Pharmaceuticals Inc. (the "Company" or "we") that we expect to use at certain conferences, meetings, and presentations is being made available on our website, www.diffusionpharma.com, under "Investors – Presentations." Representatives of the Company may use this presentation, in whole or in part, and possibly with non-material modifications, periodically in connection with conferences, meetings, and presentations to investors, analysts and others.

The information contained in the presentation is summary information that is intended to be considered in the context of the Company's filings with the Securities and Exchange Commission ("SEC") and other public announcements that we may make, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in the presentation except as required by applicable law, although the Company may do so from time to time as its management believes is warranted. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases, or through other public disclosure.

The Company makes no admission or representation as to the materiality of any information in the presentation or otherwise contained in this Item 7.01. The information contained in this Item 7.01 (including Exhibit 99.1) is furnished pursuant to the applicable instructions to Form 8-K and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of Section 18 of the Exchange Act, unless we specifically incorporate it by reference in a document filed under the Exchange Act, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as previously set forth by specific reference in such a filing.

Item 8.01 Other Events

Press Release

On October 25, 2022, the Company issued a press release announcing that its Board of Directors (the "Board") has authorized a thorough review and evaluation of a range of potential strategic opportunities in the interest of enhancing stockholder value including transactional opportunities to better leverage the potential of trans sodium crocetinate and the Company's other assets. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Annual Stockholders' Meeting

The Board has established December 16, 2022 as the date of the Company's 2022 annual meeting of stockholders (the "Annual Meeting"). Additional details regarding the Annual Meeting, which will be held virtually by means of remote communication, will be disclosed in the Company's definitive proxy statement for the Annual Meeting to be filed with the SEC.

As the date of the Annual Meeting differs by more than 30 days from the anniversary date of the Company's 2021 annual meeting, stockholders of the Company who wish to have a proposal, including nominations of persons for election to the Board and proposals under Rule 14a-8, considered for inclusion in the Company's proxy materials for the Annual Meeting must deliver such proposal by email to the Corporate Secretary at proxyrequests@diffusionpharma.com, on or before the close of business on November 7, 2022. To be eligible for inclusion in the proxy materials for the Annual Meeting, any such proposal must meet the requirements set forth in the rules and regulations of the SEC and the Company's bylaws, as amended.

Item 9.01 – Financial Statements and Exhibits

(d) Exhibits

Exhibit Number	**Description**
99.1	Press Release, issued October 25, 2022
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: October 27, 2022

DIFFUSION PHARMACEUTICALS INC.
By: /s/ William Elder
Name: William Elder
Title: General Counsel & Corporate Secretary

Exhibit 99.1

Diffusion Pharmaceuticals Announces Strategic Review Process to Evaluate Value-Enhancing Alternatives including Opportunities to Better Leverage TSC

CHARLOTTESVILLE, Va., October 25, 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 that its Board of Directors (the "Board") has authorized a thorough review and evaluation of a range of potential strategic opportunities in the interest of enhancing stockholder value including transactional opportunities to better leverage the potential of trans sodium crocetinate ("TSC") and the Company's other assets.

As part of the Company's previously disclosed, ongoing efforts to identify acquisition and partnership transactions that complement, supplement or de-risk the Company's current development programs and the Board's commitment to enhancing stockholder value, the Board has determined to expand its evaluation to a broader range of options which could include a joint venture, licensing, sale or divestiture of some of the Company's proprietary technologies or a sale of the Company, in addition to the previously announced opportunities under consideration. The Company has retained Canaccord Genuity LLC as its financial advisor and Dechert LLP as its legal counsel to assist in the review process.

"Over the past two years, we have obtained encouraging data on the potential effects of TSC on oxygenation, including the results of our Altitude, TCOM, and COVID-19 Trials. We continue to believe TSC has potential benefits for patients, particularly as an adjuvant treatment to standard of care therapy for hypoxic solid tumors, like glioblastoma multiforme," said Robert J. Cobuzzi, Jr., Ph.D., President and Chief Executive Officer of Diffusion. "We continue to seek opportunities to leverage our cash position and the significant skills and experience of our team to opportunistically identify novel product candidates that may deliver additional value for our stockholders. This includes strategic transactions that may increase the likelihood of TSC's successful development and simultaneously allow for a more effective and efficient use of our other resources."

There is no timeline for this review and there is no assurance that the Board's review will result in any transaction being consummated. Diffusion does not intend to comment on the process or make further disclosures until it determines an update is appropriate.

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 glioblastoma multiforme.

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 Company's ongoing strategic alternative review process; the potential therapeutic value of TSC in cancer and non-cancer indications; anticipated timelines for the initiation, completion, and announcement of outcomes from the Company's strategic alternative review process or its clinical studies; and the Company's near-term strategic priorities with respect to the development of TSC and otherwise. 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 outcome of the Company's ongoing strategic alternative review process; 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

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