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, 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
ſ	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 November 14, 2022, Diffusion Pharmaceuticals Inc. (the "Company") issued a press release announcing financial results for the three-month period ended September 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 November 14, 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: November 18, 2022

DIFFUSION PHARMACEUTICALS INC.

By: /s/ William Elder

Name: William Elder

Title: General Counsel & Corporate Secretary



Diffusion Pharmaceuticals Sees Significant Progress in its Strategic Review Process

Diffusion in Active Bidding Stage and Encouraged by Response to the Strategic Review Process

Diffusion Board of Directors Rejects Woefully Inadequate, Unsolicited Offer for the Company by client of Investment Bank LifeSci Capital

LifeSci-affiliated Fund Commences Proxy Contest for Control of the Diffusion Board Following Rejection of Client's Offer

Company Believes LifeSci Proxy Campaign is Attempt to Circumvent Strategic Review Process

Date of Diffusion's 2022 Annual Meeting of Stockholders Set for December 30, 2022

CHARLOTTESVILLE, Va., November 14, 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 provided an update on the Company's previously announced review and evaluation of strategic opportunities and its 2022 annual meeting of stockholders (the "2022 Annual Meeting") to be held on December 30, 2022.

Diffusion Aggressively Pursuing Clear Strategy to Deliver Superior Value for Stockholders Led by Board

As announced on October 25, 2022, Diffusion's Board of Directors (the "Board") is conducting a thorough evaluation of a comprehensive range of strategic opportunities to enhance stockholder value, including a sale, merger, divestiture, recapitalization or other strategic transaction, expanding on the Company's previously disclosed business development efforts.

The Company has made significant progress since publicly announcing the strategic review process less than three weeks ago, building upon efforts over the course of the past year to identify a potential strategic transaction that will enhance value for Diffusion stockholders in this period of challenging market conditions. Since the Company's public announcement, its management team has conducted meetings with multiple parties representing a broad range of interests and diverse array of potential transactions. Working together with its financial advisor, Canaccord Genuity LLC, and legal advisor, Dechert LLP, Diffusion is evaluating each interested party and opportunity in an effort to identify the most compelling, value-enhancing transaction for all stockholders. This includes assessing the potential for both short- and long-term value through the continued development of high potential therapies using the extensive skills and industry experience of the Company's Board and management team.

The Company continues to believe that its lead product candidate, TSC, has the potential to deliver benefits to patients, particularly as an adjuvant treatment to standard of care therapy for hypoxic solid tumors, like glioblastoma multiforme, as well as long-term value for stockholders. However, the Company believes it is in the interest of all Diffusion stockholders to seek a near-term opportunity to leverage both the Company's cash position and the significant skills and experience of its team to allow for a more effective use of resources, unlock the potential for TSC and enhance value for all Diffusion stockholders.



While the Company cannot provide any assurance as to the ultimate outcome of this strategic review process, the Company reports that it is in the active bidding stage and very encouraged by the overall response to the announcement of the Strategic Review Process. The Company's Board and management team are highly motivated to complete this process as soon as possible.

Board Rejects Woefully Inadequate, Unsolicited Offer for the Company; Affiliate of the Investment Bank Life Sci Capital Commences Proxy Contest for Control of the Diffusion Board

Despite the Board's ongoing efforts, a group of stockholders affiliated with LifeSci Capital (together with its affiliates and representatives, "LifeSci"), which holds itself out as a boutique investment bank focused on the life sciences industry, has embarked on a campaign to capture for itself the significant value and potential of the Company's assets at the expense of other stockholders.

Beginning in the late spring of this year, LifeSci approached the Company about the possibility of pursuing unidentified potential transactions with unidentified counterparties but refused to enter into a customary non-disclosure agreement or identify the principals on whose behalf it was supposedly acting. Then, on October 16, 2022, a LifeSci representative presented the Diffusion Board with an unsolicited offer to purchase Diffusion purportedly on behalf of a LifeSci client.

The Diffusion Board of Directors, after deliberation and in consultation with its advisors, and in the exercise of its fiduciary duty to protect the interests of all Company stockholders, rejected the offer as woefully inadequate. The Board did, however, encourage LifeSci to join the ongoing strategic review process. Rather than engaging in the competitive process designed to enhance value for all Diffusion stockholders, LifeSci once again refused to enter into the customary non-disclosure agreement signed by other participants in the process and instead went silent. Then, on November 7, 2022, LifeSci notified the Company that it plans to commence a proxy contest on its own behalf and nominate its own slate of directors for election the 2022 Annual Meeting, with the intention of requesting that stockholders vote to replace Diffusion's highly skilled and experienced directors with nominees that the Company believes lack relevant industry expertise and possess inferior skillsets to the current Board members.

While Diffusion remains open to engaging constructively with all Company stockholders, including LifeSci, the Company believes LifeSci is determined to pursue a costly and self-serving campaign, the effect of which could undermine the strategic review process, divert management's attention from expeditiously completing that process and the Company's TSC development activities, and ultimately destroy stockholder value. Nevertheless, the Diffusion Board intends to vigorously oppose this effort by LifeSci and to protect stockholder value.

2022 Annual Meeting

To, among other things, afford the Company more time to devote to progressing the strategic review process in a manner best designed to enhance stockholder value, the Board has determined that Diffusion's 2022 Annual Meeting of stockholders will be held on December 30, 2022, approximately, two weeks later than previously announced.

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 <u>www.diffusionpharma.com</u>.

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 timing and potential outcome of 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 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 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 GBM; the Company's ability to design, initiate, enroll, execute, and complete its 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; the Company's access to capital resources: 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.

Diffusio₂n

Contacts

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Important Additional Information Regarding Proxy Solicitation

Diffusion intends to file a definitive proxy statement and associated WHITE proxy card with the U.S. Securities and Exchange Commission (the "SEC") in connection with the solicitation of proxies for Diffusion's 2022 Annual Meeting (the "Proxy Statement"). Stockholders as of the record date of November 1, 2022 are eligible to vote at the Annual Meeting. Diffusion, its directors and certain of its executive officers will be participants in the solicitation of proxies from stockholders in respect of the 2022 Annual Meeting. Information regarding the names of Diffusion's directors and executive officers and their respective interests in Diffusion by security holdings or otherwise is set forth in Diffusion's proxy statement for the 2021 Annual Meeting of Stockholders, filed with the SEC on April 30, 2021, and the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 18, 2022. To the extent holdings of such participants in Diffusion's securities have changed since the amounts set forth in the 2021 proxy statement, such changes have been reflected on Statements of Change in Ownership on Form 4 or Annual Statement of Changes in Beneficial Ownership on Form 5 filed with the SEC. Details concerning the nominees of Diffusion's Board of Directors for election at the 2022 Annual Meeting will be included in the Proxy Statement. BEFORE MAKING ANY VOTING DECISION, INVESTORS AND STOCKHOLDERS OF THE COMPANY ARE URGED TO READ ALL RELEVANT DOCUMENTS FILED WITH OR FURNISHED TO THE SEC, INCLUDING THE COMPANY'S DEFINITIVE PROXY STATEMENT AND ACCOMPANYING WHITE PROXY CARD, AND ANY SUPPLEMENTS THERETO, WHEN THEY BECOME AVAILABLE, BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. Investors and stockholders will be able to obtain a copy of the definitive Proxy Statement and other relevant documents filed by Diffusion with the SEC free of charge from the SEC's website, www.sec.gov., or by directing a request by mail to Diffusion Pharmaceuticals Inc., Attention: Corporate Secretary, at 300 East Main Street, Suite 201, Charlottesville, Virginia 22902, via e-mail to

proxyrequests@diffusionpharma.com, or by visiting the investor relations section of Diffusion's website, investors.diffusionpharma.com.