

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 18, 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Appointment of Chief Regulatory Officer

On May 18, 2022, Raven Jaeger, M.S., was appointed as the Chief Regulatory Officer of Diffusion Pharmaceuticals Inc. (the “Company,” “Diffusion” or “we”).

Prior to joining Diffusion, Ms. Jaeger, 44, served from April 2018 to May 2022 in positions of increasing seniority at BridgeBio, Inc., a publicly traded biopharmaceutical company developing treatments for genetic diseases and cancers with clear genetic drivers, as well as several of its affiliate companies, most recently serving as Senior Vice President, Regulatory Affairs. From 2011 to April 2018, Ms. Jaeger served in a variety of positions, most recently as Director, Regulatory Affairs, at Leadiant Biosciences Inc. (f/k/a Sigma-Tau Pharmaceuticals), a biopharmaceutical company specializing in the development of treatments for rare diseases. Prior to her time at Leadiant, Ms. Jaeger served in a variety of regulatory roles at ICON Clinical Research (f/ka ICON Development Solutions) and Nabi Biopharmaceuticals, Inc. She received a B.S. in natural sciences area with an emphasis in biology and biophysics from The Johns Hopkins University and her M.S. in biotechnology management from the University of Maryland University College.

In connection with her appointment as Chief Regulatory Officer, Ms. Jaeger will receive an initial annual base salary of \$400,000 and has an initial target bonus opportunity equal to 35% of her base salary, which will be pro-rated for calendar year 2022. Ms. Jaeger’s annual salary will be subject to increase at the discretion of the Company’s board of directors. In addition, in connection with Ms. Jaeger’s appointment, she will also receive (i) a sign-on bonus of \$60,000, subject to clawback by the Company under certain circumstances if Ms. Jaeger does not complete one full year of employment with the Company, and (ii) an incentive stock option grant to purchase 8,000 shares of the Company’s common stock. The option will have a 10-year term and will vest on a monthly basis over the 36-month period following the date of grant, subject to Ms. Jaeger’s continuous employment with the Company through each applicable vesting date, and will be subject to acceleration or forfeiture upon the occurrence of certain events. Ms. Jaeger will also be eligible to participate in the Company’s broad-based employee benefit plans, including the Company’s 2015 Equity Incentive Plan, as amended. The Company intends to enter into an employment agreement with Ms. Jaeger to reflect the compensation and certain other terms of her employment.

There are no arrangements or understandings between Ms. Jaeger and any other person pursuant to which Ms. Jaeger was selected as the Chief Regulatory Officer. Ms. Jaeger does not have any direct or indirect material interest in any transaction requiring the disclosure of the information required by Item 404(a) of Regulation S-K. There is no material plan, contract or arrangement to which Ms. Jaeger is a party or in which she participates that was entered into, or any grant or award to Ms. Jaeger or modification thereto, under any such plan, contract or arrangement in connection with her appointment as Chief Regulatory Officer other than as described herein. There are also no family relationships between Ms. Jaeger and any director or executive officer of the Company.

Item 7.01 Regulation FD Disclosure

Certain information concerning the business, clinical studies, development plans, and financial position of the Company 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

On May 18, 2022, the Company issued a press release announcing the appointment of Ms. Jaeger as Chief Regulatory Officer of the Company. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 – Financial Statements and Exhibits**(d) Exhibits**

Exhibit Number	Description
99.1	Press Release, issued May 18, 2022, announcing appointment of Raven Jaeger, M.S., as Chief Regulatory Officer
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 23, 2022

DIFFUSION PHARMACEUTICALS INC.

By: /s/ William Elder

Name: William Elder

Title: General Counsel & Corporate Secretary



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Diffusion Pharmaceuticals Announces Appointment of Raven Jaeger, M.S., as Chief Regulatory Officer

Appointment brings 20 years of regulatory affairs experience and exceptional leadership capabilities

CHARLOTTESVILLE, Va. May 18, 2022 – Diffusion Pharmaceuticals Inc. (NASDAQ: DFFN) (“Diffusion” or the “Company”), a biopharmaceutical company developing therapies that enhance the body’s ability to deliver oxygen to areas where it is needed most, today announced that Raven Jaeger, M.S., has joined the Company as its Chief Regulatory Officer effective immediately. Ms. Jaeger will be responsible for development and implementation of regulatory and related strategies to support the development and commercialization of Diffusion’s product development candidates, including the Company’s lead candidate, trans sodium crocetininate (TSC), which is planned for development as an adjunct to standard of care therapy for hypoxic solid tumors.

Robert Cobuzzi, Jr., Ph.D., President and Chief Executive Officer of Diffusion, stated, “I am thrilled to have Raven join the Diffusion team. She brings with her a wealth of experience managing unique and complex global development programs focused on the treatment of rare diseases across multiple therapeutic areas, including oncology, neurology, metabolic and autoimmune diseases, vaccines, cardiology, and various liver diseases. Raven’s skills and experiences complement and enhance our team at Diffusion, and she will play a key near-term role in refining and implementing our product development strategy. I look forward to working closely with Raven as Diffusion prepares for the next phase of TSC’s development.”

Ms. Jaeger joins Diffusion from BridgeBio Pharma, Inc. where she was most recently Senior Vice President, Regulatory Affairs. During her time there, she successfully built and led a regulatory affairs team responsible for global regulatory strategy and operations for multiple development programs within several affiliate companies, whereby she led her team to gaining the first US FDA regulatory approval for the company. Previously, Ms. Jaeger was the head of Regulatory Affairs at Leadiant Biosciences, Inc., and supported multiple programs at ICON Development Solutions and at Nabi Biopharmaceuticals, Inc. She brings with her experience in obtaining multiple drug and biologic approvals in the the rare disease space, two of which resulted in the granting of a rare pediatric disease voucher, and she was integral in obtaing other key regulatory designations including Orphan Drug Designation, Fast Track Designation, Breakthrough Therapy Designation, and Rare Pediatric Disease Designation. Ms Jaeger began her career at the National Institute of Mental Health and the National Institutes of Health Center for Scientific Review. She holds an M.S. in biotechnology management from the University of Maryland and a B.S. in natural sciences with an emphasis in biology and biophysics from The Johns Hopkins University.



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Ms. Jaeger commented, "I am excited to begin working with the Diffusion team. It's a great team and a dynamic time for the Company. I look forward to using my expertise to guide Diffusion's regulatory strategy as we prepare to start development of TSC to improve the treatment of hypoxic solid tumors and to support the business development to bring more treatments to patients with unmet medical needs in the future."

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 near-term strategic priorities 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; the Company's ability to maintain compliance with the continued listing standards of Nasdaq; general economic, political, business, industry, and market conditions, including the ongoing COVID-19 pandemic; 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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