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): September 1, 2020

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.)

1317 Carlton Avenue, Suite 200 **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.

(d) On September 1, 2020, the Board of Directors (the "Board") of Diffusion Pharmaceuticals Inc. (the "Company") appointed Jane H. Hollingsworth as a director of the Company. Upon Ms. Hollingsworth's appointment as a director of the Company, the size of the Board was expanded from six to seven members. Ms. Hollingsworth was also appointed to serve on the audit, compensation and nominating & corporate governance committees of the Board.

Ms. Hollingsworth, age 61, currently serves as Managing Partner of Militia Hill Ventures ("Militia Hill"), an investment firm focused on building, growing and investing in high-quality life sciences companies, a role she has held since Militia Hill's founding in 2013. Prior to founding Militia Hill, Ms. Hollingsworth served as Executive Chair of Immunonome Inc., a cancer immunotherapy company, and co-founder and Chief Executive Officer of NuPathe, Inc. ("NuPathe"), a publicly-traded biopharmaceutical company focused on diseases of the central nervous system, prior to the acquisition of NuPathe by Teva Pharmaceuticals in 2014. She also currently serves on the board of various industry and community organizations, including DS Biopharma, Talee Bio, the University City Science Center, the Kimmel Center for the Performing Arts and Breatcancer.Org. Ms. Hollingsworth received her B.A. from Gettysburg College and her J.D. from Villanova University.

In connection with her appointment to the Board, on September 1, 2020, Ms. Hollingsworth was granted stock options to purchase 67,400 shares of the Company's common stock with an exercise price of $0.91 per share (the "Option Grant"), the closing price of the Company's common stock on September 1, 2020. Ms. Hollingsworth was also granted, on September 1, 2020, restricted stock units representing 54,900 shares of the Company's common stock (the "RSU Grant"). The Option Grant will vest in 18 equal monthly installments on the last calendar day of the next 18 months and the RSU Grant will vest in six (6) equal quarterly installments on the last calendar day of each quarter over the 18 month period beginning on March 1, 2022. In addition to the Option Grant and the RSU Grant, Ms. Hollingsworth will also receive an annual retainer and other compensation payable to the Company's non-employee directors as described in the Company's filings with the Securities and Exchange Commission.

There are no arrangements or understandings between Ms. Hollingsworth and any other persons pursuant to which Ms. Hollingsworth was selected as a director of the Company. There are also no family relationships between Ms. Hollingsworth and any director or executive officer of the Company.

Additional information regarding Ms. Hollingsworth's appointment as a director is contained in the press release attached hereto as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press Release, dated as of September 1, 2020, announcing the appointment of a new director.

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: September 4, 2020

Diffusion Pharmaceuticals, Inc.

By: /s/ William Hornung
Name: William Hornung
Title: Chief Financial Officer

Diffusion Pharmaceuticals Inc.

Diffusion Pharmaceuticals Appoints Jane H. Hollingsworth to its Board of Directors

Romanian Regulatory Approval Received to Begin Phase 1b COVID-19 Clinical Trial

CHARLOTTESVILLE, Va. (September 1, 2020) – Diffusion Pharmaceuticals Inc. (Nasdaq: DFFN) ("Diffusion" or "the Company"), a biotechnology company developing new treatments for life-threatening medical conditions by improving the body's ability to deliver oxygen to the areas where it is needed most, today announced the appointment of Jane H. Hollingsworth to its board of directors, effective immediately. Ms. Hollingsworth's appointment expands the board to seven directors. In addition to serving as a director, she will join the Nominating & Corporate Governance, Compensation and Audit Committees of the Board.

Ms. Hollingsworth brings to Diffusion more than 25 years of experience founding and leading life sciences companies. In 2013 she co-founded Militia Hill Ventures, a business focused on building, growing and investing in high-quality life sciences companies, and has served as its Managing Partner since that time.

Separately, the Company reported that full regulatory approval has been received from Romanian regulatory authorities to begin enrollment in its 24-patient, open label lead-in Phase 1b clinical trial in hospitalized COVID-19 patients at the Romanian National Institute of Infectious Diseases (NIID).

"Jane is a seasoned and accomplished executive who brings to our board considerable leadership experience and knowledge of the life sciences industry," said David G. Kalergis, Chairman and Chief Executive Officer of Diffusion. "Additionally, her extensive public company experience as both an executive and a director will contribute to Diffusion's growth plan. Jane will bring a valuable perspective to our board as we work to solve intractable medical problems, in particular in COVID-19 patients as we now are cleared by Romanian authorities to begin enrollment in the Romanian arm of our global COVID-19 clinical studies."

"The strong foundational science and work done to develop that science to date has Diffusion well positioned for its next stage of growth. I look forward to helping the team take advantage of that foundation to bring new, better treatments to patients and great value to all Diffusion stakeholders," commented Ms. Hollingsworth.

During her time at Militia Hill Ventures, Ms. Hollingsworth served as Executive Chair of Immunome Inc., a cancer immunotherapy company, and Talee Bio, a gene therapy company focused on cystic fibrosis that she co-founded. Prior to that she was co-founder and CEO of NuPathe Inc., a publicly-traded biopharmaceutical company focused on diseases of the central nervous system, and co-founder and EVP of Auxilium Pharmaceuticals, a biopharmaceutical company focused on urology and rare diseases. Ms. Hollingsworth began her career in the life sciences industry by serving as Vice President, Secretary and General Counsel of IBAH, Inc., a publicly-traded, multinational clinical research organization.

Ms. Hollingsworth received a B.A. from Gettysburg College and a J.D. from Villanova University.

About Diffusion Pharmaceuticals Inc.

Diffusion Pharmaceuticals Inc. is an innovative biotechnology company developing new treatments that improve the body's ability to deliver oxygen to the areas where it is needed most, offering new hope for the treatment of life-threatening medical conditions. Diffusion's lead drug TSC was originally developed in conjunction with the U.S. Office of Naval Research, which was seeking a way to treat multiple organ failure and its resulting mortality caused by low oxygen levels from blood loss on the battlefield. Evolutions in research have led to Diffusion's focus today on addressing some of medicine's most intractable and difficult-to-treat diseases, including multiple organ failure from respiratory distress, stroke and glioblastoma multiforme ("GBM") brain cancer. In each of these diseases, lack of available oxygen presents a significant obstacle for medical providers and is the target for TSC's novel mechanism. The Company is currently partnering with U.S. and European institutions on an expedited research program to develop TSC as a treatment for the low oxygen levels and associated multiple organ failure in COVID-19 patients.

In 2019 the Company reported favorable safety data in a 19-patient dose-escalation run-in to its Phase 3 INTACT program using TSC to target inoperable GBM. That trial is currently paused while the Company prioritizes its resources to address COVID-19. Diffusion's in-ambulance PHAST-TSC trial for acute stroke began enrolling patients last year. In response to logistical problems involving COVID-19 and on-ambulance treatment and other factors, enrollment in this trial has been suspended for at least the duration of the pandemic while the Company focuses its resources on developing TSC for use in the treatment of hospitalized COVID-19 patients.

Preclinical data support the potential for TSC as a treatment for other conditions where low oxygen availability plays an important role, such as myocardial infarction, peripheral artery disease and neurodegenerative conditions such as Alzheimer's and Parkinson's disease. In addition to the development of TSC, RES-529, the Company's PI3K/AKT/mTOR pathway inhibitor that dissociates the mTORC1 and mTORC2 complexes, is in preclinical testing for GBM.

Diffusion is headquartered in Charlottesville, Virginia – a hub of advancement in the life science and biopharmaceutical industries – and is led by CEO David Kalergis, a 30-year industry veteran and company co-founder.

Forward-Looking Statements

To the extent any statements made in this news release deal with information that is not historical, these are forward-looking statements under the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about the company's plans, objectives, expectations and intentions with respect to future operations and products, the potential of the company's technology and product candidates, and other statements that are not historical in nature, particularly those that utilize terminology such as "would," "will," "plans," "possibility," "potential," "future," "expects," "anticipates," "believes," "intends," "continue," "expects," other words of similar meaning, derivations of such words and the use of future dates. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Uncertainties and risks may cause the Diffusion's actual results to be materially different than those expressed in or implied by such forward-looking statements. Particular uncertainties and risks include: the uncertainty as to whether the protocol for the planned United States-based arm of the study referenced above will be ultimately acceptable to the U.S. Food and Drug Administration (FDA), that the FDA will not require significant changes that might take significant time to implement, if at all, that any such required changes will be financially feasible or that administrative or other delays may arise; the uncertainty as to whether and when the FDA might provide any additional guidance with respect to our study protocol or when the program might be able to commence, if at all; the uncertainty that as of yet the FDA has not approved a trial evaluating TSC for the treatment of ARDS, or if approved, such a trial may entail significant additional time, effort and expense, particularly in light of the difficulty of doing business during the COVID-19 pandemic; Diffusion's ability to maintain its Nasdaq listing, market conditions, the difficulty of developing pharmaceutical products, obtaining regulatory and other approvals and achieving market acceptance; general business and economic conditions; the sufficiency of the company's cash, the company's need for and ability to obtain additional financing or partnering arrangements; and the various risk factors (many of which are beyond Diffusion's control) as described under the heading "Risk Factors" in Diffusion's filings with the United States Securities and Exchange Commission. All forward-looking statements in this news release speak only as of the date of this news release and are based on management's current beliefs and expectations. Diffusion undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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