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): March 12, 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**	**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 1.01 Entry into a Material Definitive Agreement

In connection with the previously announced resignation of John L. Gainer as the Chief Scientific Officer of Diffusion Pharmaceuticals Inc. (the "Company"), the Company accepted Dr. Gainer's resignation by reason of retirement, and Dr. Gainer's employment relationship with the Company terminated pursuant to a separation letter agreement dated March 12, 2020 (the "Separation Agreement"). Pursuant to the Separation Agreement, Dr. Gainer is entitled to his regular pay and benefits through March 12, 2020, including any accrued benefits and any bonus for the 2019 fiscal year. All outstanding and unvested options held by Dr. Gainer as of the date of the Separation Agreement vested as of March 12, 2020, and all options that are outstanding and vested (including the options that vested as of March 12, 2020) will remain exercisable in accordance with their respective terms until the expiration date stated in the applicable option documents. As part of the Separation Agreement, Dr. Gainer has agreed to release the Company and certain related parties, including the Company's officers, directors and employees, from all claims and liabilities arising prior to the date of the Separation Agreement under federal and state laws, and has reaffirmed the confidentiality, non-competition, non-solicitation, non-disparagement and certain other customary provisions in his employment agreement. Dr. Gainer will continue to serve on the Company's board of directors and is entitled to receive yearly compensation for his services as a member of the board of directors.

The Separation Agreement further provides that Dr. Gainer will provide consulting services to the Company pursuant to a consulting agreement, by and between the Company and Dr. Gainer, dated as of March 12, 2020 (the "Consulting Agreement"). Pursuant to the terms of the Consulting Agreement, Dr. Gainer will provide expert advice and services to the Company for a one-year period in connection with the development of trans sodium crocetinate (TSC) as a therapeutic agent for hypoxic conditions. Dr. Gainer will receive a monthly consulting fee equal to $6,000 during the term of the Consulting Agreement.

The foregoing descriptions of the Separation Agreement and the Consulting Agreement are qualified in their entirety by reference to the full text of the Separation Agreement and the Consulting Agreement, which are filed as Exhibit 10.1 and Exhibit 10.2, respectively, to this Current Report on Form 8-K and are incorporated by reference herein.

On March 12, 2020, the Company issued a press release announcing Dr. Gainer's retirement from his position as the Company's Chief Scientific Officer. The press release is attached as Exhibit 99.1 to this report.

Item 2.02 – Results of Operations and Financial Condition

On March 17, 2020, the Company issued a press release announcing its financial results for its fourth quarter ended December 31, 2019. A copy of that press release and the attached financial schedules are attached as Exhibit 99.2 to this report and incorporated herein by reference.

The information in this Item 2.02 (including Exhibit 99.2) is being furnished pursuant to Item 2.02 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

10.1	Separation Agreement, dated March 12, 2020, by and between Diffusion Pharmaceuticals Inc. and John L. Gainer.
10.2	Consulting Agreement, dated March 12, 2020, by and between Diffusion Pharmaceuticals Inc. and John L. Gainer
99.1	Press release dated March 12, 2020, announcing John L. Gainer's retirement
99.2	Press release dated March 17, 2020, announcing financial results for the fourth quarter ended December 31, 2019

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: March 18, 2020

DIFFUSION PHARMACEUTICALS INC.

By: /s/ David G. Kalergis
Name: David G. Kalergis
Title: Chief Exectutive Officer

Diffusion Pharmaceuticals Inc.

March 12, 2020

John L. Gainer, PhD
125 Cameron Lane
Charlottesville, VA 22903

Dear John:

In a communication dated February 2, 2020, you announced to the Board of Directors of Diffusion Pharmaceuticals Inc. ("Board") your intent to retire from Diffusion Pharmaceuticals Inc. ("Company"). The Company has accepted your retirement. This letter termination agreement and general release ("Agreement") will confirm the separation from employment of Dr. John L. Gainer ("you" or "your") from the Company, under the following terms and conditions:

1. **Separation from Employment.** Your employment with the Company will terminate as of the date you sign this Agreement below (the "Separation Date"). You will receive your regular pay and benefits through the Separation Date. Any bonus for the year 2019 will also be paid. You will be entitled to the Accrued Benefits (as such term is defined in Section 4.2.1 of the Employment Agreement entered into as of October 18, 2016 between the Company and you ("Employment Agreement")). You and the Company agree that you are not entitled to any further compensation or benefits other than such Accrued Benefits and any bonus for the year 2019.

2. **Consulting Agreement.** As you requested, the Company is entering into a consulting agreement with you on or around the date of this Agreement ("Consulting Agreement"). In addition, the Board acknowledges your desire to remain on the Board, and you understand that any re-nomination to the Board for a subsequent term or terms will be within the purview of the Board' s Nominating and Corporate Governance Committee. You will receive the same yearly compensation (cash/options) as the other non-Diffusion employee members of the Board of Directors do, which will consist solely of (i) annual cash compensation of $35,000, payable evenly over the course of the year, (ii) annual discretionary stock options as shall be determined by the Compensation Committee of the Board in its sole discretion, and (iii) at the Board's sole discretion, payments for annual committee membership depending on committee participation.

3. **Options.** As of the Separation Date, (i) you hold options (the "Options") to purchase a total of 258,501 shares of the Company's common stock, par value $0.001 per share ("Common Stock") that were granted to you under the Diffusion Pharmaceuticals Inc. 2015 Equity Incentive Plan or other plans (collectively, as amended and/or restated from time to time, the " Plans"), (ii) Options covering 58,046 shares of Common Stock in the aggregate are vested and exercisable and (iii) Options covering 200,455 shares of Common Stock in the aggregate are not vested. Conditioned upon your execution of this Agreement , (a) all of your Options that are outstanding and unvested as of the Separation Date shall become immediately vested and exercisable and (b) all of your Options that are outstanding and vested as of the Separation Date (including those Options that become vested under clause (a) of this sentence) shall remain exercisable in accordance with their respective terms until the expiration date stated in the applicable Option agreement and the Plan (generally, the tenth anniversary of the grant date of the applicable Option).

4. **Complete General Release of Claims.** In consideration of the Company entering into the Consulting Agreement, and other good and valuable consideration to which you would not otherwise be entitled, you (on behalf of yourself, and your heirs, executors, and assigns) hereby irrevocably release and discharge the Company and its past, present and future subsidiaries, divisions, affiliates and parents; each of their respective current and former officers, directors , shareholders, employees, attorneys, agents , benefit plans, and/or owners, in their individual and official capacities; and any other person or entity claimed to be jointly or severally liable with the Company or any of the aforementioned persons or entities (the
"Released Parties") from any and all claims and/or causes of action, known or unknown , contingent or noncontingent, accrued or unaccrued, which you may have or could claim to have against the Released Parties up to and including the date you sign this Agreement. The general release in this paragraph includes, but is not limited to, (i) all claims arising from or during your employment or as a result of the termination of your employment with any of the Released Parties, (ii) all claims arising under federal, state or local laws prohibiting employment discrimination based upon race, age, sex, religion, disability, color, national origin or any other protected characteristic , including without limitation under Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act, the Virginia Human Rights Act, and the Virginians with Disabilities Act, and (iii) all claims arising under any federal, state, or local statute , rule, regulation or ordinance (including without limitation under the Virginia genetic testing and nondiscrimination law (Va. Code Ann§ 40.1-28.7:1), the Virginia HIV/AIDS confidentiality law (Va. Code Ann§ 32.1-36.1), the Virginia equal pay law (Va. Code Ann§ 40.1-28.6), and the Virginia statute on release of an employee's personal identifying information (Va. Code Ann
§ 40.1-28.7:4)) or under the common law of any jurisdiction. It is the intention of you and the
Company that the language relating to the description of released claims in this Section shall be given the broadest possible interpretation permitted by law. It is understood that nothing in this Agreement is to be construed as an admission on behalf of the Released Parties of any wrongdoing.

5. **Covenant Not to Sue.** You agree and covenant not to institute or join any lawsuit (either individually, with others, or as part of a class), in any forum, pleading, raising or asserting any claim(s) barred or released by this Agreement. You understand that nothing in this Agreement precludes you from filing a charge with, cooperating with, communicating with , or providing information to the U.S. Equal Employment Opportunity Commission, U.S. Securities and Exchange Commission, or other government agency, or in connection with any proceedings by any such agency. You agree, however, that you will not seek or accept any relief obtained on your behalf by an y government agency, private party, class, or otherwise with respect to any claims released in this Agreement, provided that this Agreement does not limit your right to receive an award for information provided to any government agency.

6. Continuing Obligations.

(a) Surviving Provisions of the Employment Agreement. You acknowledge and agree that you remain bound by, and will abide by, Article 1, Article 5, Section 2.1, and Sections 4.4 through 4.17 of the Employment Agreement, which remain in effect. Without limiting the generality of the foregoing, you specifically agree that all works of authorship, in any format or medium, and whether published or unpublished, created wholly or in part by you, whether alone or jointly with others, (i) in the course of, in connection with, or as a result of your service with the Company or any of its affiliates (whether before or after the Separation Date), (ii) at the direction or request of the Company or any of its affiliates, or (iii) through the use of, or that is related to, facilities, equipment, confidential information, other invent ions, intellectual property, or other resources of the Company or any of its affiliates, are works made for hire as defined under the United States copyright law and shall be considered a Work for purposes of the Employment Agreement.

(b) Return of Property. You represent that you have returned (and have not retained) in good working condition any and all property, equipment, documents, and other information, confidential or otherwise, of the Company or any of its affiliates that was in your possession, custody, or control, except as necessary in connection with the performance of services under the Consulting Agreement.

(c) Material Non-Public Information. You acknowledge that the Company is a reporting company under the Securities Exchange Act of 1934, as amended, and its equity securities are currently traded on the NASDAQ Capital Market. You hereby acknowledge and agree that you shall not (i) trade in the securities of the Company while in possession of material, non-public information regarding the Company or (ii) communicate any such information to any other person under circumstances in which it is reasonably foreseeable that such person is likely to purchase or sell such securities.

7. **Miscellaneous.** You and the Company acknowledge and agree that this Agreement will be governed by the substantive laws of the State of Virginia, irrespective of conflicts of law principles, and you and the Company hereby agree that all disputes arising under or relating to this Agreement or the Consulting Agreement shall be resolved in accordance with Sections 5.2 and 5.3 of the Employment Agreement. This Agreement represents the total and complete understanding between you and the Company with respect to the subject matter hereof and supersedes all other prior or contemporaneous written or oral agreements or representations, if any, relating to such subjects. This Agreement may be modified only by a writing signed by both you and the Company. No waiver by you or the Company of any breach by the other party is to be deemed a waiver of any other provisions at any time. The Company, but not you, may assign its rights and obligations under this Agreement, and such rights and obligations inure to the benefit of, and are binding upon, the Company ' s successors and permitted assigns . You and the Company intend that the terms of this Agreement be considered severable, such that if any provision of this Agreement is adjudged to be invalid for whatever reason, such invalidity will not affect any other clause of this Agreement, and such clauses will remain in full force and effect. The principle of construction that all ambiguities are to be construed against the drafter will not be employed in the interpretation of this Agreement. Rather, it is agreed that this Agreement should not be construed for or against any party. The captions of this Agreement are not part of the provisions hereof and shall have no force or effect. This Agreement may be executed in counterparts and delivered by facsimile transmission or electronic transmission in "portable document format," each of which shall be an original and which taken together shall constitute one and the same document.

Please sign the enclosed copy of this letter in the space provided and return it to me. By signing this Agreement, you acknowledge that you have carefully reviewed this Agreement, that you have had an opportunity to consult with counsel of your choice, that you have entered into this Agreement freely and voluntarily and without reliance on any promises not expressly contained herein, that you have been afforded an adequate time to review carefully the terms of this Agreement, that you are releasing any claims that you may have against the Company and related entities , and that this Agreement will not be deemed void or avoidable by claims, of duress, deception, mistake of fact, or otherwise.

Sincerely,
/s/ David Kalergis
David Kalergis
Chief Executive Officer

I have reviewed the Agreement as set forth above and, intending to be legally bound by my signature below, knowingly and voluntarily accept all of its terms and conditions.

/s/ John L. Gainer
John L. Gainer

March 12, 2020
Date

Diffusion Pharmaceuticals Inc.

Consulting Agreement

This Agreement is made between Diffusion Pharmaceuticals Inc. ("Diffusion" or "Client"), with a principal place of business at 1317 Carlton Avenue, Charlottesville, Virginia 22902, and John L. Gainer, PhD ("Consultant"), with a residence at 125 Cameron Lane, Charlottesville, VA 22903. This Agreement became effective as of March 12, 2020, and will end on March 11, 2021, unless renewed in writing by all parties hereto or terminated earlier in accordance with this Agreement.

NOW THEREFORE, the parties hereto, intending to be legally bound in consideration of the mutual covenants and agreements set forth herein, hereby agree as follows:

Services To Be Performed

Consultant shall serve as a consultant, providing expert advice and services to Client, as requested by the CEO of Client, in connection with the development of trans sodium crocetinate (TSC) as a therapeutic agent for hypoxic conditions ("Services.")

Payment

In consideration for the Services to be performed by Consultant, while this Agreement remains in effect, Client agrees to pay to Consultant a fee at a rate of $3,000 twice per month (i.e., $6 ,000 per month), prorated for any partial period, plus related expenses as described below.

Independent Consultant Status

Consultant is an independent consultant and is not Client's employee. Consultant and Client agree to the following rights:

- Consultant has the right to perform services for others during the term of this Agreement, but will not provide similar services for any competitor of Client.
- Consultant has the sole right to control, supervise and direct the method, means, and manner by which the Services will be performed.
- Consultant has the right to perform the Services at the place, location or time of his choosing.
- Client shall not require Consultant to devote any specific amount of time to performing the Services, but must devote such time as may be reasonably necessary to perform the Services requested or as mutually agreed.

State and Federal Taxes

1317 Carlton Ave, Suit e 200
Charlottesville, Wi. 22902
Tel 434.220.0718
Fax 434.220.0722
www.diffusionphannacom

Consultant shall pay all taxes incurred while performing services under this Agreement, including any/all applicable income taxes and in the event Consultant is not a corporation, self-employment (Social Security) taxes.

Client will not:

- Withhold FICA (Social Security and Medicare taxes) from Consultant's payments or make FICA payments on Consultant's behalf,
- Make state or federal unemployment compensation contributions on Consultant's behalf, or
- Withhold state or federal income tax from any payments to Consultants.

Confidential Information and Intellectual Property

Consultant acknowledges and agrees that he remains bound by, and will abide by, Sections 4.4 through 4.17 of the Employment Agreement entered into as of October 18, 2016 between the Client and Consultant ("Employment Agreement"), including without limitation the protection of confidential information, ownership of inventions, works for hire, non-competition, non-solicitation, non-acceptance, and other obligations set forth in such sections, each of which remain in full force and effect.

Return of Property

Consultant agrees that he will return all property, equipment, documents, and other information, confidential or otherwise, of the Client no later than the termination of this Agreement (or upon the earlier request of the Client), and without retaining any copies, notes or excerpts thereof, that is in his actual or constructive possession or which is subject to his control at such time. To the extent Consultant has retained any such property, equipment, documents, and other information, confidential or otherwise, on any electronic or computer equipment belonging to Consultant or under his control, Consultant agrees to so advise the Client and to follow the Client's instructions in permanently deleting all such property, equipment, documents, and other information, confidential or otherwise, and all copies.

Documentation

Consultant must maintain unambiguous and thorough documentation of the Services such that any knowledgeable person with qualifications similar to those of Consultant will be capable of understanding and continuing the work performed by Consultant. Consultant agrees that all such documentation will be the property of Client and must be surrendered to Client upon demand and no later than the termination of this Agreement.

Expenses

Consultant shall be responsible for tracking all expenses incurred while performing the Services and submitting them in writing to Client. Expenses include meals; entertainment; automobile and other similar expenses while traveling at Client's request.

Fringe Benefits

Consultant is not eligible to participate in any employee health, pension, sick pay, vacation pay or other fringe benefit plans of Client and hereby waives any right of participation to the extent Consultant may be deemed eligible.

Insurance

Client shall not provide any insurance coverage of any kind for Consultant.

Terminating the Agreement

Notwithstanding any other provision of this Agreement, either party may terminate this Agreement at any time by giving five days written notice to the other party of the intent to terminate. Upon the termination of this Agreement, Consultant will be paid for the Services through the date of termination, but will not be entitled to any further compensation.

Exclusive Agreement

This document and any Attachments constitute the entire Agreement between the parties relating to the subject matter hereof, and no promises or representations, other than those contained here and those implied by law, have been made by Client or Consultant. Notwithstanding the foregoing, Consultant and Client agree that the letter termination agreement and general release entered into on or around the date hereof between the Client and Consultant, and Article 1, Article 5, Section 2.1, and Sections 4.4 through
4.17 of the Employment Agreement, survive and remain in full force and effect. Any modifications to this Agreement must be in writing and signed by Client and Consultant.

Severability

In the event any provision of this Agreement is deemed to be void, invalid, or unenforceable, that provision shall be severed from the remainder of this Agreement so as not to cause the invalidity or unenforceability of the remainder of this Agreement. All remaining provisions of this Agreement shall then continue in full force and effect. If any provision shall be deemed invalid due to its scope or breadth, such provision shall be deemed valid to the extent of the scope and breadth permitted by law .

Applicable Law

The laws of the state of Virginia will govern this Agreement, irrespective of conflicts of law principles.

Paragraph Headings

The headings of particular paragraphs and subparagraphs are inserted only for convenience and are not part of this Agreement and are not to act as a limitation on the scope of the particular paragraph to which the heading refers.

Notices

All notices and other communications in connection with this Agreement shall be in writing and shall be considered given as follows:

- When delivered personally to the recipient's address as stated on this Agreement,
- Three days after being deposited in the United States mail, with postage prepaid to the recipient's address as stated on this Agreement, or
- When sent by fax or telex to the last fax or telex number of the recipient known to the person giving notice. Notice is effective when the recipient delivers a written confirmation of receipt.

No Partnership or Authority

Consultant does not have authority to enter into contracts on Client's behalf. This Agreement does not create a partnership relationship.

Electronically Transmitted Signatures

Consultant and Client agree that this Agreement may be executed in counterparts and will be considered signed when the signature of a party is delivered by facsimile transmission or by e-mail in portable document format. Signatures transmitted by facsimile or by e-mail in portable document format shall have the same effect as original signatures.

Signatures
Client:
Name of Client: Diffusion Pharmaceuticals Inc.
By: /s/ David G. Kalergis
(Signature)

David G. Kalergis, MBA/JD
(Typed or Printed Name)

Title: Chief Executive Officer

Date: February 10, 2020

Consultant:
Name of Consultant: John L. Gainer, PhD.

By: /s/ John L. Gainer
(Signature)

Taxpayer ID Number: _____

Date: March 12, 2020

Exhibit 99.1

Diffusion Pharmaceuticals Announces Retirement of Chief Science Officer John L. Gainer

Dr. Gainer to remain on board of directors

CHARLOTTESVILLE, Va. (March 12, 2020) – Diffusion Pharmaceuticals Inc. (NASDAQ: DFFN) ("Diffusion" or "the Company"), a cutting-edge biotechnology company developing new treatments for life-threatening medical conditions by improving the body's ability to bring oxygen to the areas where it is needed most, today announced the retirement of Professor John L. Gainer, Ph.D., the company's chief science officer. Dr. Gainer will continue to serve as both an advisor to the Company and as a member of the board of directors. In recognition of the advancement of the TSC technology into the clinic, the Company has begun a search for a Chief Medical Officer as a replacement for the former Chief Science Officer position.

Professor Gainer is the inventor of the trans bipolar carotenoid family of molecules from which the Company's lead compound Trans Sodium Crocetinate, or TSC, was derived. He co-founded Diffusion Pharmaceuticals in 2001 with David Kalergis, the company's chairman and chief executive officer, serving on the board of directors. He was named chief science officer in 2005 after his retirement as Professor Emeritus at the University of Virginia Department of Chemical Engineering, where he had served as a faculty member since 1966.

"On behalf of everyone at Diffusion Pharmaceuticals, we want to wish Professor Gainer the best with his well-deserved retirement," said Mr. Kalergis. "We are pleased that we will have the benefit of John's wisdom as both an advisor to the Company and as a board member, while we search for a new Chief Medical Officer to advance his work to offer treatment to patients suffering from diseases associated with a lack of oxygen."

About Diffusion Pharmaceuticals Inc.

Diffusion Pharmaceuticals Inc. is an innovative biotechnology company developing new treatments that improve the body's ability to bring 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 Office of Naval Research, which was seeking a way to treat hemorrhagic shock caused by massive blood loss on the battlefield.

Evolutions in research have led to Diffusion's focus today: Fueling Life by taking on some of medicine's most intractable and difficult-to-treat diseases, including stroke and GBM brain cancer. In each of these diseases, hypoxia – oxygen deprivation of essential tissue in the body – has proved to be a significant obstacle for medical providers and is the target for TSC's novel mechanism.

In July 2019 the Company reported favorable safety data in a 19-patient dose-escalation run-in study to its Phase 3 INTACT program, using TSC to target inoperable GBM. Further findings from the dose-escalation run-in study, released in December 2019, also showed possible signals of enhanced survival and patient performance. Diffusion's on-ambulance PHAST-TSC trial for acute stroke has begun patient enrollment. In addition, preclinical data supports the potential for TSC as a treatment for other conditions where hypoxia plays a major role, such as myocardial infarction, respiratory diseases such as COPD, peripheral artery disease, and neurodegenerative conditions such as Alzheimer's and Parkinson's disease.

Further, 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: 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.

Contacts:
David Kalergis, CEO
Diffusion Pharmaceuticals Inc.
(434) 220-0718
dkalergis@diffusionpharma.com
or
LHA Investor Relations
Kim Sutton Golodetz
(212) 838-3777
kgolodetz@lhai.com

# # #

Diffusion Pharmaceuticals Inc.

Diffusion Pharmaceuticals Reports 2019 Financial Results and Provides Business Update

- *$16.2 Million in Gross Proceeds Raised*
- *Now Enrolling in Acute Stroke Trial*
- *GBM Data Presented*
- *New Board Appointment*

CHARLOTTESVILLE, Va. (March 17, 2020) – Diffusion Pharmaceuticals Inc. (Nasdaq: DFFN), a cutting-edge biotechnology company developing new treatments for life-threatening medical conditions by improving the body's ability to bring oxygen to the areas where it is needed most, today reported financial results for 2019 and provided a business update.

Recent business highlights include the following:

- Commenced enrollment in its on-ambulance Phase 2 clinical trial testing TSC for the treatment of acute stroke, with patients treated at sites affiliated with the University of Virginia (UVA) and the University of California Los Angeles (UCLA). This 160-patient trial, named PHAST-TSC (Pre-Hospital Administration of Stroke Therapy-TSC), will involve 23 hospitals across urban, suburban and rural areas in Los Angeles County and Central Virginia. The Company is continuing the process of qualifying sites in Los Angeles in cooperation with researchers at UCLA and is rapidly ramping up for increased patient enrollment.

- Completed the 19-patient open-label, dose-escalation lead-in portion of its Phase 3 INTACT (INvestigating Tsc Against Cancerous Tumors) trial with Trans Sodium Crocetinate (TSC) plus standard of care (SOC) for patients with inoperable glioblastoma multiforme (GBM), and announced encouraging results from patients who completed the study per protocol. In addition, favorable safety data in the dose-escalation run-in study supported the Data Safety Monitoring Board's recommendation to continue the Phase 3 study.

- Bolstered its global intellectual property position with the issuance of two patents in Europe during the year, for a total of 50 issued patents outside the U.S. and 16 patents issued in the U.S. These patents protect composition of matter and uses of TSC in multiple indications, including in combination with tissue plasminogen activator (tPA) to treat ischemic stroke. tPA is the only treatment approved by the U.S. Food and Drug Administration for the treatment of stroke.

- Strengthened the Company's board of directors with the appointment of Robert Cobuzzi, Jr., Ph.D. Dr. Cobuzzi is an accomplished life sciences professional with 25 years of cross-functional leadership experience including more than a decade with Endo International, Plc.

"We achieved multiple important milestones throughout 2019 and in particular during the fourth quarter, with the start of enrollment in our PHAST-TSC Phase 2 study," said David Kalergis, chairman and chief executive officer of Diffusion. "This trial start followed detailed preparations during the course of the year to train the ambulance first responders and to certify each site. Our UVA-affiliated site is up and enrolling, and enrollment has also now begun at UCLA-affiliated sites. We expect to complete the study and report topline data during 2022, subject to receipt of adequate funding.

“A recent presentation of early data from our Phase 3 GBM study was well received by conference attendees. We presented data suggesting that adding 18 injections of TSC during the post-radiation chemotherapy phase at doses up to six-times higher than those received during radiation, per the INTACT protocol, may be having a positive effect on survival without adding increased safety risks. We are encouraged by this data, and believe it enhances the prospects of attracting a partner to continue advancing this much-needed option for patients. Commencement of enrollment in the randomization portion of the INTACT trial is contingent upon entering into a strategic partnership,” Mr. Kalergis added.

“We look forward to achieving additional milestones in 2020,” continued Mr. Kalergis. “We anticipate enrollment in PHAST-TSC will continue during the year, with the expectation of completing this study before mid-2021. We have many patent applications pending worldwide and expect to further solidify our global TSC intellectual property estate. Given the early data from our GBM run-in study, we are hopeful we will secure a partner to continue the trial.”

2019 Financial Results

Research and development expenses were $6.6 million for 2019, compared with $5.8 million for 2018. The increase was attributable to a $1.9 million increase in expenses related to the Company’s Phase 2 stroke trial and a $0.3 million increase in manufacturing expense, partially offset by a $1.3 million decrease in expense related to its Phase 3 GBM trial. The lead-in portion of this trial was completed in the fourth quarter of 2019. The Company expects higher R&D expenses during 2020 compared with 2019, which will consist primarily of expenses associated with PHAST-TSC.

General and administrative expenses were $4.8 million for 2019, compared with $6.2 million for 2018. The decrease was primarily due to a $0.7 million decrease in stock-based compensation expense, a $0.4 million decrease in salaries and wages, and a $0.2 million decrease in professional fees and other expenses.

Diffusion had cash and cash equivalents of $14.2 million as of December 31, 2019, compared with $8.0 million at December 31, 2018. Net cash used in operating activities during 2019 was $9.9 million, compared with $10.8 million used during 2018. During 2019, the Company raised $16.2 million in gross proceeds via three separate offerings of stock and warrants. The Company believes it has adequate cash resources to continue operations into January of 2021.

About Diffusion Pharmaceuticals Inc.

Diffusion Pharmaceuticals Inc. is an innovative biotechnology company developing new treatments that improve the body’s ability to bring 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 Office of Naval Research, which was seeking a way to treat hemorrhagic shock caused by massive blood loss on the battlefield.

Evolutions in research have led to Diffusion’s focus today: *Fueling Life* by taking on some of medicine’s most intractable and difficult-to-treat diseases, including stroke and GBM brain cancer. In each of these diseases, hypoxia – oxygen deprivation of essential tissue in the body – has proved to be a significant obstacle for medical providers and the target for TSC’s novel mechanism.

In September 2018 its on-ambulance PHAST-TSC acute stroke protocol was granted FDA clearance to proceed and the Company is prepared began enrolling patients in this Phase 2 study in October 2019. In July 2019 the Company reported favorable safety data in a 19-patient dose-escalation run-in study to its Phase 3 INTACT program, using TSC to target inoperable GBM brain cancer. Additional preclinical data supports the potential use of TSC as a treatment for other conditions where hypoxia plays a major role, such as myocardial infarction, respiratory diseases such as COPD, peripheral artery disease, and neurodegenerative conditions such as Alzheimer’s and Parkinson’s disease.

In addition, 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, the anticipated timing of future clinical trials, 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 difficulty of developing pharmaceutical products, obtaining regulatory and other approvals and achieving market acceptance; general business and economic conditions; 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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(Tables to follow)

Diffusion Pharmaceuticals Inc.
Consolidated Balance Sheet

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 14,177,349	$ 7,991,172
Prepaid expenses, deposits and other current assets	472,464	923,059
Total current assets	14,649,813	8,914,231
Property and equipment, net	252,366	350,281
Intangible asset	8,639,000	8,639,000
Right of use asset	247,043	—
Other assets	322,301	298,480
Total assets	$ 24,110,523	$ 18,201,992
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,251,412	$ 198,818
Accrued expenses and other current liabilities	358,532	605,226
Current operating lease liability	111,477	—
Total current liabilities	1,721,421	804,044
Deferred income taxes	2,119,274	1,786,389
Noncurrent operating lease liability	135,566	—
Total liabilities	3,976,261	2,590,433
Stockholders' Equity:		
Common stock, $0.001 par value:		
1,000,000,000 shares authorized; 33,480,365 and 3,376,230 issued and outstanding at December 31, 2019 and December 31, 2018, respectively	33,481	3,377
Additional paid-in capital	111,824,859	95,532,881
Accumulated deficit	(91,724,078)	(79,924,699)
Total stockholders' equity	20,134,262	15,611,559
Total liabilities and stockholders' equity	$ 24,110,523	$ 18,201,992

Diffusion Pharmaceuticals Inc.
Consolidated Statement of Operations

	Year Ended December 31,	
	2019	**2018**
Operating expenses:		
Research and development	$ 6,619,597	$ 5,751,940
General and administrative	4,834,284	6,167,177
Goodwill impairment	—	6,929,258
Depreciation	97,915	110,371
Loss from operations	11,551,796	18,958,746
Other exoense (income):		
Interest (income) expense, net	(85,302)	(151,647)
Loss from operations before income tax benefit	(11,466,494)	(18,807,099)
Income tax expense (benefit)	332,885	(437,289)
Net loss	$ (11,799,379)	$ (18,369,810)
Series A cumulative preferred dividends	—	(85,993)
Deemed dividend related to the make-whole provision for the conversion of Series A convertible preferred stock into common stock	—	(8,167,895)
Net loss attributable to common stockholders	$ (11,799,379)	$ (26,623,698)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (1.76)	$ (8.21)
Weighted average shares outstanding, basic and diluted	6,706,509	3,242,301

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