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 11, 2019

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))**

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. ☐

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**

Item 2.02 – Results of Operations and Financial Condition

On November 11, 2019, Diffusion Pharmaceuticals Inc. (the "Company") issued a press release announcing its financial results for its third quarter ended September 30, 2019. A copy of that press release and the attached financial schedules are attached as Exhibit 99.1 to this report and incorporated herein by reference.

The information in this report (including Exhibit 99.1) 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.

Exhibit Number	Description
99.1	Press release dated November 11, 2019, announcing financial results for the third quarter ended September 30, 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: November 12, 2019

DIFFUSION PHARMACEUTICALS INC.

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

Diffusion Pharmaceuticals Inc.

Diffusion Pharmaceuticals Reports Third Quarter 2019 Financial Results and Provides Business Update

Commenced Patient Enrollment in Phase 2 On-Ambulance TSC Clinical Trial for the Treatment of Stroke

Reported Favorable Safety Data in Glioblastoma Multiforme Phase 3 Run-in Study

CHARLOTTESVILLE, Va. (November 11, 2019) – 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 the three and nine months ended September 30, 2019 and provided a business update.

Recent business highlights include the following:

- Reported news that based on favorable safety data in the TSC dose-escalation run-in study, the Data Safety Monitoring Board (DSMB) recommended continuation of the INTACT trial using the highest dose administered, 1.5 mg/kg of TSC during the adjuvant treatment period. The INTACT trial is comparing SOC radiation therapy and chemotherapy plus TSC, against SOC alone. In Phase 2 testing, TSC demonstrated a nearly four-fold improvement in overall survival at two years for the subset of inoperable GBM patients, compared with the control group of GBM patients. Diffusion is seeking a partner to continue development of TSC in GBM.

- During October, the Company commenced enrollment in its on-ambulance Phase 2 clinical trial testing TSC for the treatment of acute stroke. In cooperation with researchers at the University of California Los Angeles (UCLA) and the University of Virginia (UVA), the 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. Results from the trial may be available in just under two years. The first patients were treated in Virginia. The Company is qualifying sites in Los Angeles and expects the study to begin enrollment there in the coming weeks.

"We are pleased with the progress during the third quarter and recent weeks in developing our lead compound to treat hypoxic conditions," said David Kalergis, chairman and chief executive officer of Diffusion. "A highlight was beginning patient enrollment in our PHAST-TSC Phase 2 study after detailed preparations to train the ambulance first responders and to certify each site. We expect enrollment to accelerate in the three sites participating in Virginia. Once the sites in Los Angeles are brought on board, the trial should be in full swing with data anticipated to be available in 18 to 24 months. The administration of TSC to stroke patients is an exciting opportunity to potentially safely mitigate some of the devastating effects of a stroke through immediate treatment while the patient is in the ambulance. In addition, the Notice of Intention to Grant a patent earlier this year from the European Patent Office for the use of TSC in combination with tPA – the only currently available drug for the treatment of ischemic stroke – further supports the commercial prospects of TSC."

Third Quarter Financial Results

Research and development expenses were $1.7 million for the third quarter of 2019, compared with $1.2 million for the third quarter of 2018. The increase was mainly attributable to a $0.6 million increase in expense related to the commencement of the Phase 2 stroke trial and an increase in manufacturing expense of $0.2 million, offset by a decrease of $0.2 million in expense related to the Phase 3 GBM trial and a $0.1 million decrease in salary and other expense.

General and administrative expenses were $1.3 million for the third quarter of 2019, compared with $1.6 million for the third quarter of 2018. The decline was mainly due to lower salaries and wages, along with lower stock compensation expense, partially offset by an increase in insurance and other costs.

Net cash used in operating activities during the first nine months of 2019 was $7.4 million, compared with $7.7 million used during the prior-year period.

Diffusion had cash and cash equivalents of $6.1 million as of September 30, 2019, compared with $8.0 million at December 31, 2018.

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 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 Sheets

	September 30, 2019	December 31, 2018
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 6,139,770	$ 7,991,172
Prepaid expenses, deposits and other current assets	578,613	923,059
Total current assets	6,718,383	8,914,231
Property and equipment, net	279,441	350,281
Intangible asset	8,639,000	8,639,000
Right of use asset	269,716	—
Other assets	290,674	298,480
Total assets	$ 16,197,214	$ 18,201,992
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 502,473	$ 198,818
Accrued expenses and other current liabilities	605,037	605,226
Current operating lease liability	110,969	—
Total current liabilities	1,218,479	804,044
Deferred income taxes	1,301,173	1,786,389
Noncurrent operating lease liability	158,747	—
Total liabilities	2,678,399	2,590,433
Stockholders' Equity:		
Common stock, $0.001 par value:		
1,000,000,000 shares authorized; 4,693,290 and 3,376,230 issued and outstanding at September 30, 2019 and December 31, 2018, respectively	4,694	3,377
Additional paid-in capital	101,486,119	95,532,881
Accumulated deficit	(87,971,998)	(79,924,699)
Total stockholders' equity	13,518,815	15,611,559
Total liabilities and stockholders' equity	$ 16,197,214	$ 18,201,992

Diffusion Pharmaceuticals Inc.
Consolidated Statements of Operations
(unaudited)

	Three Months ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development	$ 1,743,494	$ 1,169,810	$ 4,961,720	$ 4,386,491
General and administrative	1,290,371	1,589,621	3,559,551	4,748,090
Goodwill impairment	—	4,186,050	—	4,186,050
Depreciation	18,178	26,723	70,840	81,450
Loss from operations	3,052,043	6,972,204	8,592,111	13,402,081
Other income:				
Interest income	(21,991)	(37,981)	(59,596)	(120,784)
Loss from operations before income tax benefit	(3,030,052)	(6,934,223)	(8,532,515)	(13,281,297)
Income tax benefit	(225,960)	(214,493)	(485,216)	(482,425)
Net loss	$ (2,804,092)	$ (6,719,730)	$ (8,047,299)	$ (12,798,872)
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	$ (2,804,092)	$ (6,719,730)	$ (8,047,299)	$ (21,052,760)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.60)	$ (1.99)	$ (2.01)	$ (6.61)
Weighted average shares outstanding, basic and diluted	4,693,290	3,371,468	4,005,919	3,185,865