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, 2018

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))

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, 2018, Diffusion Pharmaceuticals Inc. (the "Company") issued a press release announcing its financial results for its third quarter ended September 30, 2018. 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 Item 2.02 (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 14, 2018, announcing financial results for the third quarter ended September 30, 2018.

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 14, 2018

DIFFUSION PHARMACEUTICALS INC.

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

November 14, 2018
FOR IMMEDIATE RELEASE

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Diffusion Pharmaceuticals Reports Third Quarter 2018 Financial Results and Provides Business Update

Highlights Include FDA Approval of Phase 2 On-Ambulance Clinical Trial for Treatment of Stroke and Appointment of New Chief Financial Officer

CHARLOTTESVILLE, VA. (November 14, 2018) – 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's needed most, today reported financial results for the three months ended September 30, 2018 and provided a business update.

The third quarter and recent weeks featured a number of developments, including approval from the U.S. Food and Drug Administration (FDA) to enroll patients in an ambulance-based Phase 2 clinical trial testing the Company's lead drug candidate, *Trans Sodium Crocinate* (TSC), for the treatment of acute stroke. The trial, named PHAST-TSC (Pre-Hospital Administration of Stroke Therapy-TSC), will involve 23 hospitals across urban, suburban, and rural areas in Los Angeles and Central Virginia, working closely with approximately 150 emergency medical transport groups and will be led by researchers at the University of Virginia (UVA) and the University of California Los Angeles (UCLA). TSC, which will be administered while the stroke victim is still in the ambulance, may offer new hope for these patients by increasing the amount of oxygen directed to affected tissue, potentially reducing cell death and improving patient outcomes. Results for the trial will potentially be available in just under two years, subject to receiving necessary funding.

The Company is also currently enrolling patients in its Phase 3 INTACT (INvestigation of TSC Against Cancerous Tumors) program, using TSC to target inoperable glioblastoma multiforme (GBM) brain cancer. Phase 2 of the INTACT program had previously seen a nearly four-fold improvement in overall survival for the subset of inoperable patients treated with TSC over the control group of GBM patients at two years.

During the third quarter, the Company also appointed William “Bill” Hornung – an executive with 20 years of experience, including with small, innovative, publicly-traded companies with origins in university research communities – to the position of Chief Financial Officer. Mr. Hornung previously served as the Company’s Chief Business Officer. The Company ended the quarter with $23.6 million in total assets, including cash and cash equivalents of $11.0 million.

“*At Diffusion, we’re building a world-class team of scientists, researchers, and business leaders dedicated to advancing the fight against life-threatening medical conditions in the United States and around the world,*” **said David Kalergis, Chairman and CEO of Diffusion.** “*While the past quarter has been an exciting time for the Company, we believe that the future is full of even more potential and promise as we continue our scientific efforts and pursue strategic partnerships. We’re also looking forward to beginning our FDA approved Phase 2 on-ambulance trial for the treatment of stroke and continuing our advanced efforts to treat patients with GBM brain cancer.*”

“*Over the past quarter, Diffusion has maintained our commitment to prudent fiscal management while dedicating resources to advancing our research priorities,*” **said Bill Hornung, Chief Financial Officer of Diffusion.** “*We believe that due to our existing assets, strong patent protection program, recent regulatory approvals, and continued thought leadership within the business and scientific communities, the Company is well positioned for future success.*”

Financial Results for the Three Months Ended September 30, 2018

We had cash and cash equivalents of $11.0 million as of September 30, 2018. The Company believes its cash and cash equivalents at September 30, 2018 are sufficient to fund operations through September 2019. We recognized $1.2 million in research and development expenses during the three months ended September 30, 2018 compared to $1.8 million during the three months ended September 30, 2017. The decrease in research and development expense was attributable to a $0.3 million decrease in expense related to our Phase 3 GMB trial and a decrease in manufacturing expense of $0.4 million, offset by a $0.1 million increase in salary and wages expense. The decrease in GBM expense was attributable to the fact that the current 8 patient dose escalation phase of the trial is less costly than the startup and implementation costs that were incurred during the three months ended September 30, 2017.

General and administrative expenses were $1.6 million during the three months ended September 30, 2018 compared to $1.6 million during the three months ended September 30, 2017. Although overall general and administrative expenses remained flat, there was a $0.2 million decrease in professional fees, offset by an increase in salary and wages expense of $0.2 million.

We recognized a non-cash goodwill impairment charge of $4.2 million during the three months ended September 30, 2018 as a result of a decrease in our market capitalization during the prior three months. There was no such charge during the three months ended September 30, 2017.

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's needed most —offering new hope for the treatment of life-threatening medical conditions.

Diffusion's lead drug, Trans Sodium Crocinate (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* – when essential tissue in your body is deprived of oxygen – has proved to be a significant obstacle for medical providers and the target for TSC's novel mechanism.

In 2018, the Company began enrolling patients in its Phase 3 INTACT program, using TSC to target inoperable GBM brain cancer. It's on-ambulance Phase 2 acute stroke protocol was granted FDA clearance to proceed in September, 2018. Additional pre-clinical 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.

In addition, RES-529, the Company's PI3K/AKT/mTOR pathway inhibitor that dissociates the mTORC1 and mTORC2 complexes, is in the preclinical testing phase for GBM.

Diffusion is headquartered in Charlottesville, Virginia—an emerging 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 company's actual results to be materially different than those expressed in or implied by such forward-looking statements. Particular uncertainties and risks include: general business and economic conditions; the company's need for and ability to obtain additional financing or partnering arrangement; the difficulty of developing pharmaceutical products, obtaining regulatory and other approvals and achieving market acceptance; 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.

Diffusion Pharmaceuticals Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 11,018,441	$ 8,896,468
Prepaid expenses, deposits and other current assets	551,337	769,946
Total current assets	11,569,778	9,666,414
Property and equipment, net	379,202	460,652
Intangible asset	8,639,000	8,639,000
Goodwill	2,743,208	6,929,258
Other assets	263,480	450,491
Total assets	$ 23,594,668	$ 26,145,815
Liabilities, Convertible Preferred Stock and Stockholders' Equity		
Current liabilities:		
Current portion of convertible debt	$ —	$ 550,000
Accounts payable	129,057	511,956
Accrued expenses and other current liabilities	816,620	1,628,851
Total current liabilities	945,677	2,690,807
Deferred income taxes	1,741,253	2,223,678
Other liabilities	—	1,386
Total liabilities	2,686,930	4,915,871
Commitments and Contingencies		
Convertible preferred stock, $0.001 par value:		
Series A - No shares and 13,750,000 shares authorized at September 30, 2018 and December 31, 2017, respectively. No shares and 12,376,329 shares issued at September 30, 2018 and December 31, 2017, respectively. No shares and 8,306,278 shares outstanding at September 30, 2018 and December 31, 2017, respectively.	—	—
Total convertible preferred stock	—	—
Stockholders' Equity:		
Common stock, $0.001 par value:		
1,000,000,000 shares authorized; 50,572,001 and 14,519,629 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively.	50,571	14,520
Additional paid-in capital	95,210,928	82,770,313
Accumulated deficit	(74,353,761)	(61,554,889)
Total stockholders' equity	20,907,738	21,229,944
Total liabilities, convertible preferred stock and stockholders' equity	$ 23,594,668	$ 26,145,815

Diffusion Pharmaceuticals Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Operating expenses:				
Research and development	$ 1,169,810	$ 1,759,305	$ 4,386,491	$ 3,946,420
General and administrative	1,589,621	1,559,399	4,748,090	4,908,424
Goodwill impairment	4,186,050	—	4,186,050	—
Depreciation	26,723	27,374	81,450	39,767
Loss from operations	6,972,204	3,346,078	13,402,081	8,894,611
Other expense (income):				
Interest (income) expense, net	(37,981)	(1,318)	(120,784)	73,290
Change in fair value of warrant liability	—	(8,441,616)	—	(18,909,792)
Warrant related expenses	—	—	—	10,225,846
Other financing expenses	—	—	—	2,870,226
(Loss) income from operations before income tax benefit	(6,934,223)	5,096,856	(13,281,297)	(3,154,181)
Income tax benefit	(214,493)	—	(482,425)	—
Net (loss) income	$ (6,719,730)	$ 5,096,856	$ (12,798,872)	$ (3,154,181)
Series A cumulative preferred dividends	—	(366,641)	(85,993)	(912,946)
Undistributed earnings to participating securities	—	(1,838,354)	—	—
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) income attributable to common stockholders	$ (6,719,730)	$ 2,891,861	$ (21,052,760)	$ (4,067,127)
Per share information:				
Net (loss) income per share of common stock, basic	$ (0.13)	$ 0.21	$ (0.44)	$ (0.35)
Net (loss) income per share of common stock, diluted	$ (0.13)	$ 0.20	$ (0.44)	$ (1.83)
Weighted average shares outstanding, basic	50,572,001	13,937,869	47,777,757	11,709,128
Weighted average shares outstanding, diluted	50,572,001	14,714,853	47,777,757	12,525,707

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