Section 1: 8-K (FORM 8-K)

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 13, 2017

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 400 **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. ☐

Item 2.02 – Results of Operations and Financial Condition

On November 13, 2017, Diffusion Pharmaceuticals Inc. (the "Company") issued a press release announcing its financial results for its third quarter ended September 30, 2017. 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 13, 2017, announcing financial results for the third quarter ended September 30, 2017.

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 13, 2017

DIFFUSION PHARMACEUTICALS INC.

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

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Section 2: EX-99.1 (EXHIBIT 99.1)

Exhibit 99.1

FINAL DRAFT
NOVEMBER 10, 2017

Diffusion Pharmaceuticals Reports Third Quarter 2017 Financial Results and Provides Business Update

- **FDA Clears Phase 3 Protocol for Patient Enrollment in GBM Brain Cancer Trial**
- **"First Patient In" Expected this Year**
- **Company Charter Amendment Addresses Nasdaq Listing Issue**
- **Additions to Board and Management Strengthen Company Buildout**

CHARLOTTESVILLE, Va. (November 13, 2017) – Diffusion Pharmaceuticals Inc. (Nasdaq: DFFN) ("Diffusion" or "the Company"), a clinical-stage biotechnology company focused on extending the life expectancy of cancer patients using the novel small molecule trans sodium crocetinate (TSC) in conjunction with standard radiation and chemotherapy, today reported financial results for the three and nine months ended September 30, 2017 and provided a business update.

David Kalergis, Chairman and Chief Executive Officer of Diffusion Pharmaceuticals, stated, "The FDA's authorization of patient enrollment in our TSC Glioblastoma (GBM) Phase 3 pivotal study marks a major milestone, and the Agency's agreement with our focus on inoperable GBM patients allows a greatly improved trial design. Because the inoperable GBM patients treated with TSC in the Phase 2 study showed a remarkable four-fold increase in overall survival at two years, the approved trial design can enroll fewer patients than the previous Phase 3 design and have a greater chance of reaching its overall survival endpoint. The thousands of patients diagnosed with inoperable GBM who are currently excluded from participation in most newly-diagnosed GBM clinical trials can now have renewed hope, with a novel treatment being developed specifically for them, to be used in conjunction with their standard of care radiation and chemotherapy treatments. We are ready to begin our GBM trial with a highly-regarded CRO engaged, sites identified and enough drug product on hand to conduct the entire trial. We are currently working with the sites' Institutional Review Boards and remain on track to begin enrolling patients by the end of 2017."

"In an effort to bring the Company into compliance with Nasdaq's listing requirements, our shareholders voted to modify the terms of our Series A Convertible Preferred Stock to allow dividends to be paid in either cash or common stock, thus allowing the common stock purchase warrants issued with our Series A Convertible Preferred Stock to be classified, for accounting purposes, as permanent equity rather than as a liability. We believe this change, which occurred subsequent to the close of the quarter, brings us into compliance with Nasdaq's $2.5 million stockholders' equity requirement. We are now awaiting confirmation from Nasdaq that we have demonstrated compliance with all applicable requirements for continued listing. This modification also permits additional financial flexibility as we advance our programs."

Mr. Kalergis continued, "We've also made important additions to our board and management during the third quarter. Robert Ruffolo, Jr. joined our board of directors, bringing comprehensive pharmaceutical industry experience and drug development knowledge, honed at Wyeth (now Pfizer) and SmithKline Beecham (now GlaxoSmithKline). William Hornung joined us as Chief Business Officer, with more than 20 years of finance and operations leadership experience in the biopharmaceutical industry with such companies as PTC Therapeutics, Elan Pharmaceuticals, The Liposome Company and Contravir Pharmaceuticals. Bill has already had a positive impact on our business development activities."

Recent Highlights

Research and Development

- Diffusion received final protocol guidance from the U.S. Food and Drug Administration (“FDA”) for the Phase 3 trial with its lead compound trans sodium crocetinate (“TSC”) in patients newly diagnosed with inoperable glioblastoma multiforme (“GBM”), a type of brain cancer.

- Diffusion selected the first 17 clinical trial sites in the U.S. under one Institutional Review Board, with 100 sites planned for the Phase 3 GBM trial. We anticipate our first patient dosing for the Phase 3 GBM before the end of 2017.

- We engaged a contract research organization and completed a major TSC production run, providing sufficient Phase 3 drug product to conduct the entire trial.

Key Personnel and Other

- Appointed Robert Ruffolo, Jr. Ph.D. to the Company’s Board of Directors.

- Named William “Bill” Hornung as the Company’s Chief Business Officer, a new position.

- In an effort to regain Company compliance with Nasdaq’s stockholders’ equity requirement, obtained shareholder approval to amend a provision of our Certificate of Incorporation relating to the Series A convertible preferred stock, enabling the Company to revalue and re-classify Series A warrants from liabilities to stockholders' equity.

- Participated in multiple investor conferences to present the Company’s business and interface with the investment community.

Financial Results for the Three Months Ended September 30, 2017

We had cash, cash equivalents and a certificate of deposit totaling $11.2 million as of September 30, 2017.

We recognized $1.8 million in research and development expenses during the three months ended September 30, 2017 compared to $1.9 million during the three months ended September 30, 2016. The decrease in research and development expense was attributable to a $1.0 million non-cash impairment charge recognized in the third quarter of 2016, a $0.2 million decrease in expense associated with animal toxicology studies and a $0.1 million decrease in stock-based compensation expense. These amounts were partially offset by a $0.9 million increase in costs associated with our GBM trials, a $0.1 million increase in API and drug manufacturing costs and a $0.1 million increase in salary related expenses.

General and administrative expenses were $1.6 million during the three months ended September 30, 2017 compared to $3.9 million during the three months ended September 30, 2016. The decrease in general and administrative expense was primarily due to a $2.5 million decrease in non-cash litigation settlement fees, partially offset by an increase in salary and stock-based compensation expense of $0.1 million and an increase in professional fees of $0.1 million.

In connection with the private placement of our Series A convertible preferred stock and common stock warrants, we determined the warrants to be classified as liabilities and subject to remeasurement at each reporting period. As a result of the liability classification, during the three months ended September 30, 2017, we recorded a $8.4 million non-cash gain for the change in fair value of our common stock warrant liabilities which was primarily attributable to the decrease in the market price for our common stock.

As noted above, at a Special Stockholders meeting held on November 1, 2017, holders of both our common stock and Series A convertible preferred stock approved an amendment to our Certificate of Incorporation to permit us to pay dividends on the Series A convertible preferred stock in either cash or shares of our common stock, rather than just shares. This amendment allowed us to revalue our Series A warrant liability on November 1, 2017 and reclassify the liability, for accounting purposes, to stockholders' equity. As a result of the non-cash gain relating to the change in fair value of the warrant liabilities referred to above, we believe that this Certificate of Incorporation amendment will allow us to maintain our Nasdaq compliant status with respect to stockholders' equity for the foreseeable future. See Note 12 of our unaudited condensed consolidated financial statements filed in Form 10-Q as of September 30, 2017 for further details.

About Diffusion Pharmaceuticals Inc.

Diffusion Pharmaceuticals Inc. is a clinical-stage biotechnology company focused on extending the life expectancy of cancer patients by improving the effectiveness of current standard-of-care treatments including radiation therapy and chemotherapy. Diffusion is developing its lead product candidate, trans sodium crocetinate, for use in the many cancers where tumor hypoxia (oxygen deprivation) is known to diminish the effectiveness of SOC treatments. TSC targets the cancer's hypoxic micro-environment, re-oxygenating treatment-resistant tissue and making the cancer cells more vulnerable to the therapeutic effects of SOC treatments without the apparent occurrence of any serious side effects.

A Phase 2 clinical program was completed in the second quarter of 2015 and evaluated 59 patients with newly diagnosed glioblastoma multiforme, a type of brain cancer. This open-label, historically controlled study demonstrated a favorable safety and efficacy profile for TSC combined with SOC, including a 37% improvement in overall survival compared with the control group at two years. A particularly strong efficacy signal was seen in the subset of inoperable patients where survival of TSC-treated patients at two years was nearly four-fold higher compared with the controls. Due to its novel mechanism of action, TSC has safely re-oxygenated a range of tumor types in preclinical and clinical studies. Diffusion believes the therapeutic potential of TSC is not limited to specific tumors, thereby making it potentially useful to improve SOC treatments of other life-threatening cancers. Additional studies under consideration include Phase 2 trials in pancreatic cancer and brain metastases, with study initiation subject to receipt of additional funding or collaborative partnering. The Company also believes that TSC has potential application in other indications involving hypoxia, such as stroke, neurodegenerative diseases and emergency medicine, and is considering ways to further investigate these areas.

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 protocol review, satisfying Nasdaq continued listing standards 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; Nasdaq's acceptance of the warrant reclassification to enable satisfaction of its continued listing standards; the company's need for and ability to obtain additional financing; and 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.

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Diffusion Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	September 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 1,216,000	$ 1,552,852
Certificate of deposit	10,020,164	—
Prepaid expenses, deposits and other current assets	1,004,361	50,844
Total current assets	12,240,525	1,603,696
Property and equipment, net	479,647	79,755
Intangible asset	8,639,000	8,639,000
Goodwill	6,929,258	6,929,258
Other assets	38,813	232,675
Total assets	$ 28,327,243	$ 17,484,384
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Current portion of convertible debt	$ 550,000	$ 1,880,000
Accounts payable	409,423	1,684,158
Accrued expenses and other current liabilities	1,415,707	874,264
Common stock warrant liability	16,316,054	—
Total current liabilities	18,691,184	4,438,422
Convertible debt, net of current portion	—	550,000
Deferred income taxes	3,279,363	3,279,363
Common stock warrant liability	—	—
Other liabilities	—	31,915
Total liabilities	21,970,547	8,299,700
Commitments and Contingencies		
Convertible preferred stock, $0.001 par value:		
Series A - 13,750,000 shares authorized, 12,376,329 and 8,324,032 shares issued and outstanding, respectively at September 30, 2017; No shares authorized, issued or outstanding at December 31, 2016 (liquidation value of $16,814,360 at September 30, 2017)	—	—
Total convertible preferred stock	—	—
Stockholders' Equity:		
Common stock, $0.001 par value:		
1,000,000,000 shares authorized; 14,503,976 and 10,345,637 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	14,504	10,346
Additional paid-in capital	69,686,744	69,363,575
Accumulated deficit	(63,344,552)	(60,189,237)
Total stockholders' equity	6,356,696	9,184,684
Total liabilities, convertible preferred stock and stockholders' equity	$ 28,327,243	$ 17,484,384

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	**2016**	**2017**	**2016**
Operating expenses:				
Research and development	$ 1,759,305	$ 1,941,743	$ 3,946,420	$ 5,739,456
General and administrative	1,559,399	3,852,406	4,908,424	10,070,878
Depreciation	27,374	5,822	39,767	19,520
Loss from operations	3,346,078	5,799,971	8,894,611	15,829,854
Other expense (income):				
Interest (income) expense, net	(1,318)	1,378	73,290	854
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	—
Income (loss) from operations before income tax benefit	5,096,856	(5,801,349)	(3,154,181)	(15,830,708)
Income tax benefit	—	(364,796)	—	(364,796)
Net income (loss)	$ 5,096,856	$ (5,436,553)	$ (3,154,181)	$ (15,465,912)
Per share information:				
Net income (loss) per share of common stock, basic	$ 0.21	$ (0.53)	$ (0.35)	$ (1.52)
Net income (loss) per share of common stock, diluted	$ 0.20	$ (0.53)	$ (1.83)	$ (1.52)
Weighted average shares outstanding, basic	13,937,869	10,333,898	11,709,128	10,198,491
Weighted average shares outstanding, diluted	14,714,853	10,333,898	12,525,707	10,198,491

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