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): August 14, 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** (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 August 14, 2017, Diffusion Pharmaceuticals Inc. (the "Company") issued a press release announcing its financial results for its second quarter ended June 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 August 14, 2017, announcing financial results for the second quarter ended June 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: August 14, 2017

DIFFUSION PHARMACEUTICALS INC.

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

Diffusion Pharmaceuticals Inc.

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

CHARLOTTESVILLE, Va. (August 14, 2017) – **Diffusion Pharmaceuticals Inc. (NASDAQ: DFFN)** ("Diffusion" or "the Company"), a clinical-stage biotechnology company focused on the development of novel small molecule therapeutics for cancer and other hypoxia-related diseases, today reported financial results for the three months ended June 30, 2017 and provided a business update.

Highlights of the second quarter of 2017 and recent weeks include:

- Advanced trans sodium crocetinate (TSC) for the treatment of newly diagnosed inoperable glioblastoma multiforme (GBM) in preparation for a planned Phase 3 trial with the engagement of a contract research organization and the completion of a major TSC production run
- Appointed long-standing pharmaceutical executive Robert R. Ruffolo, Jr., Ph.D. to the Company's board of directors
- Received $8.3 million from the second closing of a private placement of Series A convertible preferred stock
- Obtained stockholder approval for a potential offering of up to $20.0 million of Series B convertible preferred stock

David Kalergis, Chairman and Chief Executive Officer of Diffusion Pharmaceuticals, stated, "During the second quarter we made solid progress in advancing preparations for a planned Phase 3 trial of TSC in newly diagnosed inoperable GBM patients, and are on track to complete a protocol review in the third quarter of 2017. Assuming FDA sign-off on the final protocol design, we plan to begin enrolling patients into the study by the end of 2017."

"We have engaged a premier contract research organization to conduct the Phase 3 study and entered into agreements with top-tier partners to manage the MRI imaging, clinical data management, drug supply and other functions related to the trial," Mr. Kalergis added. "We completed a major production run of TSC and now have sufficient quantity of the drug to support the entire Phase 3 trial."

Second Quarter Financial Results

Research and development expenses for the second quarter of 2017 were $1.2 million, compared with $1.4 million for the second quarter of 2016. This decrease was attributable to lower expenses related to animal toxicology studies, partially offset by an increase in API and drug manufacturing costs.

General and administrative expenses for the second quarter of 2017 were $1.8 million, compared with $2.3 million for the second quarter of 2016. The decrease was primarily attributable to lower professional fees, partially offset by an increase in salary and salary-related expenses.

The Company recorded a loss from operations of $3.0 million for the second quarter of 2017, compared with a loss from operations of $3.8 million for the second quarter of 2016. The narrowed operating loss reflects lower research and development expenses, as well as lower general and administrative expenses.

We recognized a non-cash gain of $23.4 million in the second quarter of 2017 related to the change in fair value of warrant liabilities, which was attributable to a decrease in the fair market value of our common stock during the period. This non-cash gain resulted in net income for the second quarter, which is not indicative of ongoing operations.

Net cash used in operating activities for the first half of 2017 was $6.2 million, compared with $7.5 million during the first half of 2016.

In April 2017 we received the remaining $8.3 million related to our Series A financing and as of June 30, 2017, the Company had cash and cash equivalents of $7.4 million and a certificate of deposit of $10.0 million.

At our annual meeting of stockholders on June 15, 2017, stockholders approved a potential offering of up to $20.0 million of shares of our Series B convertible preferred stock, $0.001 par value per share ("Series B Preferred Stock"), at a price of $2.10 per share, with each share of Series B Preferred Stock being initially convertible into one share of our common stock, subject to adjustment. For each share of Series B Preferred Stock purchased in the offering, the investor will receive a five-year warrant to purchase one share of common stock with an exercise price of $2.31. There is no assurance we will successfully close such an offering at such terms due to the current trading price of our common stock or for any other reason.

Additional Information

This press release is neither an offer to sell, nor a solicitation of an offer to buy, any securities and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offer, solicitation or sale is unlawful. The Series B Preferred Stock and related warrants described herein have not been and will not be registered under the Securities Act, or any state securities laws, and unless so registered, may not be offered or sold in the United States except pursuant to an exemption from the registration requirements of the Securities Act, and applicable state securities laws.

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 ("SOC") treatments including radiation therapy and chemotherapy. Diffusion is developing its lead product candidate, trans sodium crocetinate (TSC), 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 addition 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 (GBM), 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. At an End-Of-Phase 2 Meeting, the U.S. Food and Drug Administration provided Diffusion with extensive guidance on the design for a Phase 3 trial of TSC in newly diagnosed GBM patients. Assuming FDA sign-off on the final protocol design focusing on inoperable patients, the study is planned to initiate by the end of 2017. Due to its novel mechanism of action, TSC has safely re-oxygenated a range of tumor types in our preclinical and clinical studies. Diffusion believes its therapeutic potential is not limited to specific tumors, thereby making it potentially useful to improve SOC treatments of other life-threatening cancers. Additional planned studies 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 neurodegenerative diseases and emergency medicine.

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, 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, including pursuant to the proposed Series B Preferred Stock offering; 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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(Tables to follow)

Diffusion Pharmaceuticals Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 7,413,399	$ 1,552,852
Certificate of deposit	10,000,000	—
Prepaid expenses, deposits and other current assets	287,893	50,844
Total current assets	17,701,292	1,603,696
Property and equipment, net	479,650	79,755
Intangible asset	8,639,000	8,639,000
Goodwill	6,929,258	6,929,258
Other assets	157,229	232,675
Total assets	$ 33,906,429	$ 17,484,384
Liabilities, Convertible Preferred Stock and Stockholders' Equity		
Current liabilities:		
Current portion of convertible debt	$ 2,430,000	$ 1,880,000
Accounts payable	1,039,002	1,684,158
Accrued expenses and other current liabilities	1,232,696	874,264
Common stock warrant liability	24,757,670	—
Total current liabilities	29,459,368	4,438,422
Convertible debt, net of current portion	—	550,000
Deferred income taxes	3,279,363	3,279,363
Other liabilities	—	31,915
Total liabilities	32,738,731	8,299,700
Commitments and Contingencies		
Convertible preferred stock, $0.001 par value:		
Series A - 13,750,000 shares authorized, 12,376,329 and 10,449,338 shares issued and outstanding, respectively at June 30, 2017; No shares authorized, issued or outstanding at December 31, 2016 (liquidation value of $21,107,663 at June 30, 2017)	—	—
Total convertible preferred stock	—	—
Stockholders' Equity:		
Common stock, $0.001 par value:		
1,000,000,000 shares authorized; 12,298,363 and 10,345,637 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	12,299	10,346
Additional paid-in capital	69,596,807	69,363,575
Accumulated deficit	(68,441,408)	(60,189,237)
Total stockholders' equity	1,167,698	9,184,684
Total liabilities, convertible preferred stock and stockholders' equity	$ 33,906,429	$ 17,484,384

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	**2016**	**2017**	**2016**
Operating expenses:				
Research and development	$ 1,179,544	$ 1,444,906	$ 2,187,115	$ 3,797,713
General and administrative	1,795,886	2,349,227	3,349,025	6,211,711
Depreciation	5,790	5,845	12,393	13,698
Loss from operations	2,981,220	3,799,978	5,548,533	10,023,122
Other expense (income):				
Interest expense, net	18,889	6,216	74,608	6,237
Change in fair value of warrant liability	(23,387,850)	—	(10,468,176)	—
Warrant related expenses	—	—	10,225,846	—
Other financing expenses	—	—	2,870,226	—
Net income (loss)	$ 20,387,741	$ (3,806,194)	$ (8,251,037)	$ (10,029,359)
Per share information:				
Net income (loss) per share of common stock, basic	$ 0.88	$ (0.37)	$ (0.83)	$ (0.99)
Net income (loss) per share of common stock, diluted	$ (1.00)	$ (0.37)	$ (1.56)	$ (0.99)
Weighted average shares outstanding, basic	10,828,063	10,263,703	10,582,521	10,130,042
Weighted average shares outstanding, diluted	13,872,632	10,263,703	12,339,386	10,130,042

Diffusion Pharmaceuticals Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)

	Six Months Ended June 30,	
	2017	**2016**
Operating activities:		
Net loss	$ (8,251,037)	$ (10,029,359)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	12,393	13,698
Loss on sale or disposal of assets	—	6,761
Stock-based compensation expense	681,449	731,633
Common stock issued for advisory services	—	1,409,363
Warrant related expense, change in fair value, and other financing expenses	2,627,896	—
Non-cash interest expense	85,309	4,754
Changes in operating assets and liabilities:		
Prepaid expenses, deposits and other assets	(68,189)	17,712
Accounts payable, accrued expenses and other liabilities	(1,249,735)	356,124
Net cash used in operating activities	(6,161,914)	(7,489,314)
Cash flows (used in) provided by investing activities:		
Purchases of property and equipment	(64,002)	(2,331)
Purchase of certificate of deposit	(10,000,000)	—
Cash received in reverse merger transaction	—	8,500,602
Net cash (used in) provided by investing activities	(10,064,002)	8,498,271
Cash flows provided by financing activities:		
Proceeds from the sale of Series A convertible preferred stock and warrants, net	22,129,774	—
Payment of offering costs for Series B	(43,311)	—
Net cash provided by financing activities	22,086,463	—
Net increase in cash and cash equivalents	5,860,547	1,008,957
Cash and cash equivalents at beginning of period	1,552,852	1,997,192
Cash and cash equivalents at end of period	$ 7,413,399	$ 3,006,149
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment in accounts payable and accrued expenses	$ (348,286)	$ —
Series B offering costs in accounts payable and accrued expenses	$ (50,103)	$ —
Series A cumulative preferred dividends	$ (546,305)	$ —
Conversion of accrued dividends related to convertible preferred stock	$ 70,890	$ —
Conversion of convertible notes and related accrued interest into common stock	$ —	$ 711,495
Consideration in connection with RestorGenex Corporation merger transaction	$ —	$ 21,261,000

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