# 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): August 13, 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**<br>**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 August 13, 2018, Diffusion Pharmaceuticals Inc. (the "Company") issued a press release announcing its financial results for its second quarter ended June 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 5.03 – Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year**

On August 13, 2008, the Company filed a Certificate of Retirement of the Company's Series A Convertible Preferred Stock (the "Certificate of Retirement") with the Secretary of State of the State of Delaware, which became effective upon its filing. The Certificate of Retirement (i) eliminated the previous designation of 13,750,000 shares of Series A Convertible Preferred Stock, none of which were outstanding at the time of filing, (ii) caused such shares of Series A Convertible Preferred Stock to resume the status of authorized but unissued shares of preferred stock of the Company and (iii) eliminated from the Company's Certificate of Incorporation, as amended, all reference to the Series A Convertible Preferred Stock. The foregoing summary of the Certificate of Retirement does not purport to be complete and is qualified in their entirety by reference to the full text of the Certificate of Retirement filed as Exhibit 3.1 hereto, which is incorporated herein by reference. Both prior to and upon the filing of the Certificate of Retirement, the Company had 30,000,000 shares of preferred stock authorized, none of which was or is issued or outstanding.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits.

| Exhibit Number | Description |
|---|---|
| 3.1 | Certificate of Retirement, dated August 13, 2018. |
| 99.1 | Press release dated August 13, 2018, announcing financial results for the second quarter ended June 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: August 14, 2018

**DIFFUSION PHARMACEUTICALS INC.**

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

(Back To Top)

# Section 2: EX-3.1 (EXHIBIT 3.1)

**Exhibit 3.1**

# Delaware

The First State



*I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF RETIREMENT OF "DIFFUSION PHARMACEUTICALS INC.", FILED IN THIS OFFICE ON THE THIRTEENTH DAY OF AUGUST, A.D. 2018, AT 11 O`CLOCK A.M.*

*A FILED COPY OF THIS CERTIFICATE HAS BEEN FORWARDED TO THE NEW CASTLE COUNTY RECORDER OF DEEDS.*

Jeffrey W. Bullock, Secretary of State

5768394 8100
SR# 20186135835

Authentication: 203235386
Date: 08-13-18

You may verify this certificate online at corp.delaware.gov/authver.shtml

State of Delaware
Secretary of State
Division of Corporations
Delivered 11:00 AM 08/13/2018
FILED 11:00 AM 08/13/2018
SR 20186135835 - File Number 5768394

# CERTIFICATE OF RETIREMENT

# OF

# DIFFUSION PHARMACEUTICALS INC.

## SERIES A CONVERTIBLE PREFERRED STOCK

Pursuant to Section 243 of the General Corporation Law of the State of Delaware

Diffusion Pharmaceuticals Inc., a corporation organized and existing under the General Corporation Law of the State of Delaware (hereinafter called the "Corporation"), does hereby certify:

FIRST: All of the outstanding shares of the Corporation's Series A Convertible Preferred Stock were converted into shares of the Corporation's common stock effective on or prior to January 22, 2018.

SECOND: Section 4(d) of the Certificate of Designation of Preferences, Rights and Limitations of the Series A Convertible Preferred Stock of the Corporation, filed with the Secretary of State of the State of Delaware on March 13, 2017, as amended, provides that any shares of the Corporation's Series A Convertible Preferred Stock converted into common stock of the Corporation or redeemed in accordance with the terms thereof shall be canceled and shall not be reissued.

THIRD: At a meeting of the Board of Directors of the Corporation on June 14, 2018, the Board of Directors duly adopted the following resolutions relating to the proposed retirement of all of the Series A Convertible Preferred Stock of the Corporation as set forth herein:

RESOLVED, that a Certificate of Retirement be executed and filed with the Secretary of State of the State of Delaware, which shall have the effect of retiring the Series A Convertible Preferred Stock and eliminating from the Certificate of Incorporation of the Corporation, as amended, all matters set forth therein with respect to the Series A Convertible Preferred Stock of the Corporation;

FOURTH: Accordingly, pursuant to Section 243(b) of the General Corporation Law of the State of Delaware, upon the effective date of the filing of this Certificate of Retirement, all of the 13,750,000 authorized shares of preferred stock of the Corporation designated as Series A Convertible Preferred Stock will be retired and the Certificate of Incorporation of the Corporation, as amended, shall be amended so as to eliminate therefrom all references to the Corporation's Series A Convertible Preferred Stock, and all 13,750,000 shares of preferred stock previously designated as Series A Convertible Preferred Stock shall resume the status of authorized, undesignated and unissued shares of preferred stock of the Corporation, par value $0.001 per share, of the Corporation.

IN WITNESS WHEREOF, Diffusion Pharmaceuticals Inc. has caused this certificate to be signed by David G. Kalergis, its Chief Executive Officer, this 13th day of August 2018.

DIFFUSION PHARMACEUTICALS INC.

By: _____

Name: David G. Kalergis
Title: Chief Executive Officer

(Back To Top)

# Section 3: EX-99.1 (EXHIBIT 99.1)

**Exhibit 99.1**

## Diffusion Pharmaceuticals Reports Second Quarter 2018 Financial Results and Provides Business Update

- **Enrollment continues in Phase 3 GBM brain cancer trial**
- **Key European patent validated covering oral formulation of TSC**
- **Preparing for Phase 2 stroke trial with in-ambulance administration of TSC**

**CHARLOTTESVILLE, Va. (August 13, 2018) – Diffusion Pharmaceuticals Inc. (Nasdaq: DFFN)** ("Diffusion" or "the Company"), a clinical-stage biotechnology company focused on improving patient outcomes in unmet medical needs using its novel small molecule trans sodium crocetinate (TSC), reports financial results for the three months ended June 30, 2018 and provides a business update.

Commenting on the second quarter, David Kalergis, Chairman and Chief Executive Officer, said, "We have continued to screen and enroll patients with inoperable glioblastoma multiforme (GBM) into our INTACT Phase 3 pivotal trial. Following the dose escalation run-in portion, this planned 236-patient study will enroll half the patients in the treatment arm consisting of standard-of-care radiation and chemotherapy plus TSC, and half in the control arm, which is standard-of-care alone. We designed INTACT based on our Phase 2 study that demonstrated a nearly four-fold increase in overall survival at two years in inoperable GBM patients."

Mr. Kalergis continued, "During the quarter, U.S. Patent 9,950,067 issued relating to methods of treating cancer using bipolar trans carotenoids including TSC. European patent 2575487 was validated for oral formulations of bipolar trans carotenoids and includes novel compositions in tablet, pill or capsule form. Further, US Patent 10,016,384, also relating to oral formulations of bipolar trans carotenoids, issued on July 10, 2018. We believe TSC holds great promise in treating a number of diseases in addition to cancer and are pleased to be able to protect a patient-friendly oral formulation suitable for more chronic uses. Our intellectual property protection further supports the value of TSC as we discuss partnership opportunities in various indications and geographies."

Diffusion is continuing preparations for a Phase 2 randomized, double-blind, placebo-controlled trial with TSC in acute stroke in cooperation with UCLA and the University of Virginia, and is in discussions with potential partners. Financing permitting, we expect to begin enrolling patients in early 2019 with data in about 18 months thereafter. The study calls for the administration of TSC by specially-trained Emergency Medical Technicians to ambulance-transported patients within two hours of the onset of a suspected acute stroke. In-ambulance administration could overcome the current severe timing delay in administering therapy to stroke victims, serving a market of up to 800,000 patients a year who suffer acute stroke.

**Financial Results for the Three Months Ended June 30, 2018**

We had cash and cash equivalents of $12.9 million as of June 30, 2018. We believe that our cash and cash equivalents will enable us to fund our obligated operating expenses and capital expenditure requirements into September 2019.

We recognized $1.4 million in research and development expenses during the three months ended June 30, 2018, compared with $1.2 million during the three months ended June 30, 2017. The increase was mainly attributable to a $0.8 million increase in expenses related to our Phase 3 GBM trial, offset by a $0.6 million decrease in expense associated with manufacturing costs.

General and administrative expenses for the three months ended June 30, 2018 were $1.7 million, compared with $1.8 million for the three months ended June 30, 2017. The decrease in general and administrative expense was primarily due to a $0.3 million decrease in professional fees, partially offset by an increase in salary and wages expense of $0.2 million.

Net cash used in operating activities for the first half of 2018 was $5.8 million, compared with $6.2 million during the same period in the prior year.

**About Diffusion Pharmaceuticals Inc.**

Diffusion Pharmaceuticals Inc. is a clinical-stage biotechnology company focused on improving patient outcomes in unmet medical needs using its novel small molecule trans sodium crocetinate (TSC). Diffusion is developing TSC for use in conditions where hypoxia (oxygen deprivation) is known to diminish the effectiveness of standard of care (SOC) treatments. In oncology, 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. In non-oncology indications, therapeutic benefit would be achieved directly through re-oxygenation of tissue threatened with cell death from hypoxia.

The INvestigation of TSC Against Cancerous Tumors (INTACT) Phase 3 randomized, controlled registration trial with TSC and SOC chemotherapy and radiation, compared with SOC alone in 236 patients who have been newly diagnosed with inoperable glioblastoma multiforme (GBM) brain cancer, is underway. In this study, TSC with concomitant temozolomide is being assigned to the first 8 subjects enrolled, and these patients will undergo radiation therapy plus temozolomide and TSC treatment through the normal six-week RT treatment period. During the subsequent temozolomide treatment period these subjects will be assigned TSC at ascending doses and studied in parallel for 2 full 28-day cycles. The Data Safety Monitoring Board will examine the resultant data and based on their observations may recommend the continued use of the starting TSC dose or another dose for those patients remaining to be randomized into the study.

A Phase 2 TSC clinical trial was completed in the second quarter of 2015 and evaluated 59 patients with newly diagnosed GBM. 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 including stroke, where the Company recently announced its Pre-Hospital Ambulance Stroke Trial - TSC (PHAST-T) study to be conducted in co-operation with the University of California Los Angeles (UCLA) and the University of Virginia (UVA) to test TSC in stroke patients in an in-ambulance clinical trial setting.

**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; 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.**
**Consolidated Balance Sheets**
**(unaudited)**

| | June 30, 2018 | December 31, 2017 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 12,934,703 | $ 8,896,468 |
| Prepaid expenses, deposits and other current assets | 772,736 | 769,946 |
| Total current assets | 13,707,439 | 9,666,414 |
| Property and equipment, net | 405,925 | 460,652 |
| Intangible asset | 8,639,000 | 8,639,000 |
| Goodwill | 6,929,258 | 6,929,258 |
| Other assets | 262,214 | 450,491 |
| Total assets | $ 29,943,836 | $ 26,145,815 |
| **Liabilities, Convertible Preferred Stock and Stockholders' Equity** | | |
| Current liabilities: | | |
| Current portion of convertible debt | $ — | $ 550,000 |
| Accounts payable | 175,772 | 511,956 |
| Accrued expenses and other current liabilities | 512,246 | 1,628,851 |
| Total current liabilities | 688,018 | 2,690,807 |
| Deferred income taxes | 1,955,746 | 2,223,678 |
| Other liabilities | — | 1,386 |
| Total liabilities | 2,643,764 | 4,915,871 |
| Commitments and Contingencies | | |
| Convertible preferred stock, $0.001 par value: | | |
| Series A - 13,750,000 shares authorized at both June 30, 2018 and December 31, 2017. No shares and 12,376,329 shares issued at June 30, 2018 and December 31, 2017, respectively. No shares and 8,306,278 outstanding at June 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 June 30, 2018 and December 31, 2017, respectively. | 50,571 | 14,520 |
| Additional paid-in capital | 94,883,532 | 82,770,313 |
| Accumulated deficit | (67,634,031) | (61,554,889) |
| Total stockholders' equity | 27,300,072 | 21,229,944 |
| Total liabilities, convertible preferred stock and stockholders' equity | $ 29,943,836 | $ 26,145,815 |

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2018** | **2017** | **2018** | **2017** |
| Operating expenses: | | | | |
| Research and development | $ 1,391,113 | $ 1,179,544 | $ 3,216,681 | $ 2,187,115 |
| General and administrative | 1,660,630 | 1,795,886 | 3,158,469 | 3,349,025 |
| Depreciation | 26,709 | 5,790 | 54,727 | 12,393 |
| Loss from operations | 3,078,452 | 2,981,220 | 6,429,877 | 5,548,533 |
| Other expense (income): | | | | |
| Interest (income) expense, net | (45,339) | 18,889 | (82,803) | 74,608 |
| Change in fair value of warrant liabilities | — | (23,387,850) | — | (10,468,176) |
| Warrant related expenses | — | — | — | 10,225,846 |
| Other financing expenses | — | — | — | 2,870,226 |
| (Loss) income from operations before income tax benefit | (3,033,113) | 20,387,741 | (6,347,074) | (8,251,037) |
| Income tax benefit | (267,932) | — | (267,932) | |
| Net (loss) income | $ (2,765,181) | $ 20,387,741 | $ (6,079,142) | $ (8,251,037) |
| Accretion of Series A cumulative preferred dividends | — | (487,460) | (85,993) | (546,305) |
| Deemed dividend related to the make-whole provision for the conversion of Series A preferred stock into common | — | — | (8,167,895) | — |
| Net (loss) income attributable to common stockholders | $ (2,765,181) | $ 19,900,281 | $ (14,333,030) | $ (8,797,342) |
| Per share information: | | | | |
| Net (loss) income per share of common stock, basic | $ (0.05) | $ 0.88 | $ (0.31) | $ (0.83) |
| Net (loss) income per share of common stock, diluted | $ (0.05) | $ (1.00) | $ (0.31) | $ (1.56) |
| Weighted average shares outstanding, basic | 50,546,021 | 10,828,063 | 46,357,478 | 10,582,521 |
| Weighted average shares outstanding, diluted | 50,546,021 | 13,872,632 | 46,357,478 | 12,339,386 |

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(Back To Top)