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 10, 2020

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))

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

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 10, 2020, the Company issued a press release announcing its financial results for its second quarter ended June 30, 2020. 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

99.1 Press release dated August 10, 2020, announcing financial results for the second quarter ended June 30, 2020

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 10, 2020

DIFFUSION PHARMACEUTICALS INC.

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

Diffusion Pharmaceuticals Inc.

Diffusion Pharmaceuticals Reports Second Quarter 2020 Financial Results and Provides Business Update

Continues global clinical development of TSC for the treatment of COVID-19

CHARLOTTESVILLE, Va. (August 10, 2020) – Diffusion Pharmaceuticals Inc. (Nasdaq: DFFN) ("Diffusion" or "the Company"), a cutting-edge biotechnology company developing new treatments for life-threatening medical conditions by improving the body's ability to deliver oxygen to the areas where it is needed most, today reported financial results for the three and six months ended June 30, 2020 and provided a business update.

Highlights from the second quarter of 2020 and recent weeks include:

- Initiation of an international clinical development program in hospitalized patients with COVID-19. Low oxygen levels occur as a consequence of damage to the lungs from COVID-19, often resulting in mechanical ventilation and, if that is ineffective, multiple organ failure – the leading cause of death from COVID-19. Diffusion believes that the oxygen-enhancing mechanism of action of TSC could benefit such patients.

- The TSC/Covid-19 clinical development program will begin with an open-label lead-in trial which, if successful, will be followed by one or more randomized double-blinded clinical trials. The lead-in trial will test TSC in 24 hospitalized COVID-19 patients at the Romanian National Institute of Infectious Diseases (NIID). Diffusion expects to begin dosing in this study in the third quarter, with data read-out in the fourth quarter of 2020. In addition to safety, the lead-in trial will collect data on possible increased oxygenation, thereby helping the Company determine TSC dosing for follow-on studies.

- Following the recent successful completion of the 19-patient open-label, dose-escalation lead-in safety portion of the trial, the Company has continued pursuit of partnership efforts for its Phase 3 INTACT (INvestigating Tsc Against Cancerous Tumors) program with TSC plus standard of care (SOC) for patients newly diagnosed with inoperable glioblastoma multiforme (GBM).

- The Company's Phase 2 160-patient on-ambulance clinical trial testing TSC for the treatment of acute stroke continues, but on a limited basis because of the on-going pandemic. This program, featuring the PHAST-TSC (Pre-Hospital Administration of Stroke Therapy-TSC) trial, will ultimately involve a total of 23 hospitals across urban, suburban and rural areas in Los Angeles County and Central Virginia when conditions permit more robust operations.

- On May 29, 2020 the Company") announced that it received written notice from the Nasdaq Listing Qualifications Staff of the NASDAQ Stock Market LLC ("Nasdaq") stating that the Company regained compliance with the applicable Nasdaq minimum bid price continued listing standard and the matter was now closed.

- During the quarter, the Company sold common stock raising $10.3 million and also raised $7.6 million from the exercise of outstanding warrants, for net proceeds of $17.9 million during the reporting period.

“This is an exciting time for Diffusion as we prepare for first enrollment in our global clinical trial program using TSC for the treatment of hospitalized COVID-19 patients,” said David Kalergis, chairman and chief executive officer of Diffusion. “Given the severity of the worldwide pandemic, regulatory authorities in the U.S. and Europe have put in place measures to expedite the testing of therapeutics and have been generous in their guidance in light of emerging knowledge. Protocol changes based on this guidance have been incorporated into the development program so that data from any patient, wherever located, can be included to help support planned future regulatory filings in both the U.S. and Europe.

“We also raised funds during the quarter, which will largely be used to advance our TSC clinical development plan, with an emphasis on the COVID-19 program,” Mr. Kalergis continued. “At quarter-close we had more than $25 million in cash, the largest cash balance on hand since becoming a public company. In addition, to better help our investors, potential partners and the public stay informed, we are currently revamping our website to reflect the impact of our COVID-19 program on TSC’s development, with the revised website launch targeted for later this quarter.”

Second Quarter Financial Results

Research and development expenses were $2.2 million for the second quarter of 2020, compared with $1.5 million for second quarter of 2019. The increase was attributable to a $0.6 million increase in costs associated with follow on work for our 19 patient run-in Phase 3 trial for GBM, a $0.3 million increase in expense related to our open-label Phase 1b lead-in trial for TSC in COVID-19 patients, and a $0.3 million increase in associated manufacturing costs as we ramp up the trial. These increases were offset in part by a $0.5 million decrease in costs associated with the delay in our Phase 2 stroke trial due to the COVID-19 pandemic

General and administrative expenses were $1.5 million for the second quarter of 2020, compared with $1.1 million for the second quarter of 2019. The increase was mainly due to higher professional fees, salaries and wages.

Diffusion had cash and cash equivalents of $25.6 million as of June 30, 2020, compared with $14.2 million as of December 31, 2019. During the second quarter the Company completed an offering of 11.4 million shares of common stock for net proceeds of $10.3 million. In addition, the Company received proceeds of $7.6 million from the exercise of 13.0 million warrants and the exchange and exercise of a further 5.0 million warrants. Diffusion believes its cash and cash equivalents as of June 30, 2020 are sufficient to fund operating expenses and capital expenditures, including clinical trials, into the fourth quarter of 2021.

About Diffusion Pharmaceuticals Inc.

Diffusion Pharmaceuticals Inc. is an innovative biotechnology company developing new treatments that improve the body’s ability to deliver oxygen to the areas where it is needed most, offering new hope for the treatment of life-threatening medical conditions. Diffusion’s lead drug trans sodium crocetinate (TSC) was originally developed in conjunction with the U.S. Office of Naval Research, which was seeking a way to treat multiple organ failure and its resulting mortality caused by low oxygen levels from blood loss on the battlefield. Evolutions in research have led to Diffusion’s focus today on addressing some of medicine’s most intractable and difficult-to-treat diseases, including multiple organ failure from respiratory distress, stroke and glioblastoma multiforme (GBM) brain cancer. In each of these diseases, lack of available oxygen presents a significant obstacle for medical providers and is the target for TSC’s novel mechanism. The Company is currently partnering with both U.S. and European-based institutions in an expedited research program to develop TSC as a treatment for the low oxygen levels and associated multiple organ failure in COVID-19 patients.

In 2019, the Company reported favorable safety data in a 19-patient dose-escalation run-in to its Phase 3 INTACT program using TSC to target inoperable GBM. That trial is currently paused while the Company searches for a partner and prioritizes its resources to address COVID-19. Diffusion’s in-ambulance PHAST-TSC trial for acute stroke began enrolling patients last year. Given the responsibilities of the Company’s participating emergency medical services providers, enrollment in this trial, while not officially paused, is expected to be minimal until the COVID-19 pandemic abates.

Preclinical data support the potential for TSC as a treatment for other conditions where low oxygen availability plays an important role, such as myocardial infarction, peripheral artery disease, and neurodegenerative conditions such as Alzheimer's and Parkinson's disease. In addition to the development of TSC, 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, 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 uncertainty as to whether the FDA will approve the IND submission for commencement of a trial in the U.S.; or that the FDA will not require significant changes that might take significant time to implement, if at all, or that any such required changes will be financially feasible; there can be no assurance as to when the program in the U.S. might be able to commence, if at all; the uncertainty that as of yet the FDA has not approved a trial evaluating TSC for the treatment of ARDS, or if approved, such a trial possibly entailing significant additional time, effort and expense, particularly in light of the difficulty of doing business during the COVID-19 pandemic; the uncertainty as to whether the protocol for the Romanian trial will be ultimately acceptable to the Romanian healthcare regulatory authorities and local ethics committees or that such regulators will not require significant changes that might take significant time to implement, if at all, or that any such required changes will be financially feasible; moreover, if this or a revised protocol is acceptable to the Romanian regulators, there can be no assurance as to when they might provide such guidance or when the program might be able to commence, if at all; the uncertainty that as of yet the Romanian regulators have not approved a trial evaluating TSC for the treatment of ARDS, or if approved, such a trial possibly entailing significant additional time, effort and expense, particularly in light of the difficulty of doing business during the COVID-19 pandemic; whether addressing regulatory guidance now, while working within the parameters of current regulatory processes, will enhance the prospect of regulatory approvals upon program completion; whether Diffusion can enroll and complete the trials and provide data on the timelines indicated; whether Diffusion can efficiently transition from the Romanian lead-in trial to the larger global trial; whether the data from the Romanian trials can be combined with data generated in any U.S. trials; whether Diffusion has sufficient funding to complete the trials described; Diffusion's ability to maintain its Nasdaq listing, market conditions, 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.

Contacts:
David Kalergis, CEO
Diffusion Pharmaceuticals Inc.
(434) 220-0718
dkalergis@diffusionpharma.com

LHA Investor Relations
Kim Sutton Golodetz
(212) 838-3777
kgolodetz@lhai.com

(Tables to follow)

Diffusion Pharmaceuticals Inc.
Consolidated Balance Sheet
(unaudited)

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 25,561,599	$ 14,177,349
Prepaid expenses, deposits and other current assets	1,147,174	472,464
Total current assets	26,708,773	14,649,813
Property and equipment, net	198,325	252,366
Intangible asset	8,639,000	8,639,000
Right of use asset	194,879	247,043
Other assets	252,149	322,301
Total assets	$ 35,993,126	$ 24,110,523
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,354,948	$ 1,251,412
Accrued expenses and other current liabilities	317,075	358,532
Current operating lease liability	109,808	111,477
Total current liabilities	1,781,831	1,721,421
Deferred income taxes	1,249,569	2,119,274
Noncurrent operating lease liability	85,071	135,566
Total liabilities	3,116,471	3,976,261
Stockholders' Equity:		
Common stock, $0.001 par value:		
1,000,000,000 shares authorized; 63,998,298 and 33,480,365 issued and outstanding at June 30, 2020 and December 31, 2019, respectively	63,999	33,481
Additional paid-in capital	130,220,772	111,824,859
Accumulated deficit	(97,408,116)	(91,724,078)
Total stockholders' equity	32,876,655	20,134,262
Total liabilities and stockholders' equity	$ 35,993,126	$ 24,110,523

Diffusion Pharmaceuticals Inc.
Consolidated Statement of Operations
(unaudited)

	Three Months ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$ 2,173,183	$ 1,518,381	$ 3,707,650	$ 3,218,226
General and administrative	1,458,257	1,068,452	2,852,065	2,269,180
Depreciation	27,021	34,390	54,041	52,662
Loss from operations	3,658,461	2,621,223	6,613,756	5,540,068
Other income:				
Interest income	(25,913)	(16,921)	(60,013)	(37,605)
Loss from operations before income tax benefit	(3,632,548)	(2,604,302)	(6,553,743)	(5,502,463)
Income tax benefit	(507,325)	(108,904)	(869,705)	(259,256)
Net loss	$ (3,125,223)	$ (2,495,398)	$ (5,684,038)	$ (5,243,207)
Deemed dividend arising from warrant exchange	(1,950,378)	—	(1,950,378)	—
Net loss attributable to common stockholders	$ (5,075,601)	$ (2,495,398)	$ (7,634,416)	$ (5,243,207)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.10)	$ (0.63)	$ (0.18)	$ (1.43)
Weighted average shares outstanding, basic and diluted	51,978,286	3,940,684	43,242,891	3,658,457

# # #