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 12, 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 November 12, 2020, we issued a press release announcing our financial results for the three- and nine-month periods ended September 30, 2020. A copy of the press release is attached as Exhibit 99.1 to this Current Report and is incorporated herein by reference.

The information in this Item 2.02 (including the information incorporated herein by reference) is being furnished pursuant to Item 2.02 of Form 8-K and shall not be deemed "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 into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent expressly set forth by specific reference in such filing.

Item 9.01 – Financial Statements and Exhibits

(d) Exhibits

99.1 Press Release, dated November 12, 2020, announcing financial results for the three- and nine-month periods ended September 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: November 12, 2020

DIFFUSION PHARMACEUTICALS INC.

By: /s/ William Hornung
Name: William Hornung
Title: Chief Financial Officer

Diffusion Pharmaceuticals Inc.

Diffusion Pharmaceuticals Reports Third Quarter 2020 Financial Results and Provides Business Updates

Initiated and Advanced Clinical Trial Evaluating Lead Product Candidate in COVID-19 Patients

Announces Next Steps in Development Program for Lead Product Candidate

Ended Quarter with $21.9 million in Cash and Cash Equivalents

CHARLOTTESVILLE, Va. (November 12, 2020) – Diffusion Pharmaceuticals Inc. (Nasdaq: DFFN) ("Diffusion" or the "Company") today reported financial results for the three and nine months ended September 30, 2020 and provided certain updates on its development program for its lead product candidate, trans sodium crocetinate ("TSC"), which is being developed to enhance the diffusion of oxygen to tissues with low oxygen levels, also known as hypoxia, a serious complication of many of medicine's most intractable and difficult-to-treat conditions.

Third quarter results, recent developments, and anticipated next steps in the TSC development program include:

Third Quarter Results & Recent Developments

- Strengthened leadership team with additions and appointments to key management positions, including pharmaceutical industry veterans Jane Hollingsworth, as director, Robert Cobuzzi, Ph.D., as president and chief executive officer, and Chris Galloway, M.D., as chief medical officer, as well as Bill Elder, J.D., as general counsel.

- Ended quarter with $21.9 million in cash and cash equivalents.

- Announced dosing of first two patients in Phase 1b clinical trial evaluating TSC in hospitalized COVID-19 patients (the "100-303 COVID Trial") with primary endpoint of evaluating safety and tolerability of TSC administered every six hours for up to 15 days, a more frequent dosing regimen than has been used in the Company's previous clinical studies.

- As of November 11, 2020, patient enrollment continues, and no dose-limiting toxicities have been observed.

Near-Term Strategy

- Ongoing review of existing TSC development program with plans to modify the program and accomplish two principal strategic objectives:
    - Optimize the clinical dose and dosing frequency for TSC.
    - Evaluate TSC in clinical models designed to establish proof of concept for improvement in oxygenation following administration of TSC.

- Designing and initiating additional studies in effort to accomplish strategic objectives:

- Evaluating possibility of expanding 100-303 COVID Trial to include additional doses administered on the same regimen, assuming successful and timely completion of currently planned doses and final regulatory approval of pending protocol amendment to effect change.

- Designing additional clinical studies intended to evaluate (i) the effects of TSC using short-term experimental models of oxygenation with the expected primary objective of establishing proof of concept for improvement of tissue oxygen levels and certain other clinical parameters and (ii) depending on whether or not the Company decides to implement the expansion of the 100-303 COVID Trial, additional doses of TSC on a more frequent dosing regimen.

- Diffusion expects to fully fund these studies with cash-on-hand.

- Diffusion intends to provide certain additional details regarding the design of these new studies in January 2021 and to initiate the studies during the first quarter of 2021. The Company also now expects the 100-303 COVID Trial, whether or not the Company decides to implement the expansion described above, to be completed with topline data available by the end of first quarter of 2021.

Other Events

- Diffusion currently intends to participate in two virtual, biopharmaceutical and biotechnology industry conferences in mid-January 2021 – Biotech Showcase and the H.C. Wainwright 2021 Bioconnect Conference – and to provide its next update regarding its development program for TSC at that time.

- Launched new website design at www.diffusionpharma.com.

“Hypoxia can be a serious complication of a multitude of acute and chronic disease processes in patients of all ages and represents a continued area of unmet need that spans multiple therapeutic areas. I am excited about our development plans, which we believe will clarify TSC’s mechanism of action in controlled human studies of oxygenation. We intend to use these data to inform and evaluate our further development opportunities for TSC, as well as potential patient populations and indications,” said Chris Galloway, M.D., Chief Medical Officer of Diffusion.

“Diffusion has experienced a lot of changes over the past few months. While we continue to refine our vision for the Company, we are pleased with the progress we made during the third quarter and we are excited to begin implementing our plans during the coming months,” said Robert Cobuzzi, Ph.D., Chief Executive Officer of Diffusion. “We believe our near-term strategy will significantly improve the probability of development success for TSC by providing the opportunity to optimize dosing and obtain a clear clinical signal supporting the potential value of TSC’s mechanism of action across a broad range of conditions in which hypoxia remains a significant obstacle to effective treatment.”

Third Quarter Financial Results

Research and development ("R&D") expenses were $3.1 million during the third quarter of 2020, compared with $1.7 million during the third quarter of 2019. A significant portion of the increase, $1.4 million, was attributable to expenses related to the initiation of the Company's ongoing clinical trial evaluating TSC in COVID-19 patients. In addition, R&D expenses included $0.1 million related to winding down the Company's Phase 2 stroke trial.

General and administrative ("G&A") expenses were $2.1 million during the third quarter of 2020, compared with $1.3 million during the third quarter of 2019. The increase was primarily due to a $0.2 million increase in professional fees and a $0.6 million increase in salaries, wages and stock-based compensation expenses, including non-recurring expenses related to the retirement, resignation and separation of the Company's former Chief Executive Officer in September 2020.

The Company recognized income tax benefits of $0.8 million and $0.2 million during the third quarters of 2020 and 2019, respectively. In both periods, the recognized benefit reflects the Company's utilization of indefinite deferred tax liabilities as a source of income against indefinite lived portions of its deferred tax assets.

Diffusion had cash and cash equivalents of $21.9 million as of September 30, 2020, compared with $14.2 million as of December 31, 2019, and believes its cash and cash equivalents are sufficient to fund operating expenses and capital expenditures into the fourth quarter of 2022.

About Diffusion Pharmaceuticals Inc.

Diffusion Pharmaceuticals Inc. is an innovative biopharmaceutical company developing novel therapies that enhance the body's ability to deliver oxygen to the areas where it is needed most. The Company's lead product candidate, TSC, is being developed to enhance the diffusion of oxygen to tissues with low oxygen levels, also known as hypoxia, a serious complication of many of medicine's most intractable and difficult-to-treat conditions. For more information please visit us on the web at www.diffusionpharma.com.

Forward-Looking Statements

This press release includes express and implied forward-looking statements including, without limitation, statements regarding the Company's ongoing clinical trials and development plans for its product candidates and the Company's financial condition, liquidity, and capital resources. By their nature, forward-looking statements involve risks and uncertainties because they relate to and depend on, among other things, events, competitive dynamics, and industry change. The Company may, in some cases, use terms such as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately," or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Although the Company believes that it has a reasonable basis for each forward-looking statement contained herein, as a result of certain risks and uncertainties, known and unknown, the Company's actual results could differ materially from any intentions, beliefs, projections, outlook, analyses, or expectations expressed herein. Particular risk and uncertainties include, among other things, those related to: the Company's ability to design, initiate, execute, and complete its ongoing and planned studies evaluating TSC; the Company's ability to achieve its near-term strategic objectives, in the near-term or at all; the Company's ability to obtain additional financing; the success and timing of the Company's clinical trials and preclinical studies, including its ability to enroll subjects in such trials and studies at anticipated rates; the Company's ability to develop and commercialize TSC or any other product candidate; the ongoing COVID-19 pandemic; general economic, political, business, industry, and market conditions, including the recent United States ("U.S.") presidential election; and the other factors discussed under the heading "Risk Factors" in the Company's filings with the U.S. Securities and Exchange Commission ("SEC"). Any forward-looking statements in this press release speak only as of the date hereof (or such earlier date as may be identified) and, except as required by applicable law, rule or regulation, the Company undertakes no obligation to update any such statements after the date hereof. Comparisons of current and any prior period results are not intended to express any ongoing or future trends or indications of future performance, unless explicitly expressed as such, and should only be viewed as historical data. For all forward-looking statements, the Company claims the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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(Tables to follow)

Diffusion Pharmaceuticals Inc.
Consolidated Balance Sheet
(unaudited)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 21,910,183	$ 14,177,349
Prepaid expenses, deposits and other current assets	766,932	472,464
Total current assets	22,677,115	14,649,813
Property and equipment, net	174,133	252,366
Intangible asset	8,639,000	8,639,000
Right of use asset	174,668	247,043
Other assets	252,057	322,301
Total assets	$ 31,916,973	$ 24,110,523
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,411,717	$ 1,251,412
Accrued expenses and other current liabilities	1,162,278	358,532
Current operating lease liability	112,953	111,477
Total current liabilities	2,686,948	1,721,421
Deferred income taxes	443,893	2,119,274
Noncurrent operating lease liability	61,715	135,566
Total liabilities	3,192,556	3,976,261
Stockholders' Equity:		
Common stock, $0.001 par value:		
1,000,000,000 shares authorized; 64,015,441 and 33,480,365 issued and outstanding at September 30, 2020 and December 31, 2019, respectively	64,016	33,481
Additional paid-in capital	130,507,728	111,824,859
Accumulated deficit	(101,847,327)	(91,724,078)
Total stockholders' equity	28,724,417	20,134,262
Total liabilities and stockholders' equity	$ 31,916,973	$ 24,110,523

Diffusion Pharmaceuticals Inc.
Consolidated Statement of Operations
(unaudited)

	Three Months ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$ 3,137,553	$ 1,743,494	$ 6,845,203	$ 4,961,720
General and administrative	2,112,375	1,290,371	4,964,440	3,559,551
Depreciation	24,192	18,178	78,233	70,840
Loss from operations	(5,274,120)	(3,052,043)	(11,887,876)	(8,592,111)
Other income:				
Interest income	29,233	21,991	89,246	59,596
Loss from operations before income tax benefit	(5,244,887)	(3,030,052)	(11,798,630)	(8,532,515)
Income tax benefit	805,676	225,960	1,675,381	485,216
Net loss	$ (4,439,211)	$ (2,804,092)	$ (10,123,249)	$ (8,047,299)
Deemed dividend arising from warrant exchange	—	—	(1,950,378)	—
Net loss attributable to common stockholders	$ (4,439,211)	$ (2,804,092)	$ (12,073,627)	$ (8,047,299)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.07)	$ (0.60)	$ (0.24)	$ (2.01)
Weighted average shares outstanding, basic and diluted	64,011,342	4,693,290	50,216,239	4,005,919