UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark one)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2020

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____.

Commission file number: **000-24477**

DIFFUSION PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Delaware	**30-0645032**
(State of other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

1317 Carlton Avenue, Suite 200
Charlottesville, VA 22902
(Address of principal executive offices, including zip code)

(434) 220-0718
(Registrant's telephone number including area code)

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: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).Yes ☐ No ☒

The number of shares of common stock outstanding at November 11, 2020 was 64,015,441 shares.

DIFFUSION PHARMACEUTICALS INC.
FORM 10-Q
SEPTEMBER 30, 2020

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Note Regarding Company References and Other Defined Terms

Unless the context otherwise requires, in this Quarterly Report, (i) references to the "Company," "we," "our," or "us" refer to Diffusion Pharmaceuticals Inc. and its subsidiaries and (ii) references to "common stock" refer to the common stock, par value $0.001 per share, of the Company. We have also used several other defined terms in this Quarterly Report, which are explained or defined below:

Term	Definition
100-303 COVID Trial	our Phase 1b clinical trial evaluating TSC in hospitalized COVID-19 patients, designated as Protocol 100-303, initiated in September 2020
2015 Equity Plan	Diffusion Pharmaceuticals Inc. 2015 Equity Incentive Plan
401(k) Plan	Diffusion Pharmaceuticals Inc. 401(k) Defined Contribution Plan
ASC	Accounting Standard Codification of the FASB
ASUs	Accounting Standards Updates of the FASB
COVID-19	Corona Virus Disease 2019, the novel coronavirus disease known as COVID-19, caused by SARS-CoV-2 infection
CRO	contract research organization
December 2019 Offering	our registered direct public offering and sale of 6,266,787 shares of common stock and concurrent private placement of warrants to purchase up to 6,266,787 shares of common stock completed in December 2019
Exchange Act	U.S. Securities Exchange Act of 1934, as amended
FASB	Financial Accounting Standards Board
FDA	U.S. Food and Drug Administration
Form 10-K	our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 17, 2020
G&A	general and administrative
GAAP	U.S. generally accepted accounting principles
GBM	glioblastoma multiforme brain cancer
INTACT Trial	our Phase 3 clinical trial evaluating TSC in a newly diagnosed inoperable GBM patient population, designated the "INvestigation of TSC Against Cancerous Tumors," initiated in December 2017
June 30 Form 10-Q	our Quarterly Report on Form 10-Q for the period ended June 30, 2020, filed with the SEC on August 7, 2020
May 2019 Offering	our registered direct public offering and sale of 1,317,060 shares of common stock and concurrent private placement of warrants to purchase up to 1,317,060 shares of common stock completed in May 2019
May 2020 Investor Warrant Exercise	the exercise of the Prior Warrant in May 2020 pursuant to a warrant exercise agreement
May 2020 Offering	our registered direct public offering and sale of 11,428,572 shares of common stock completed in May 2020
NIID	National Institute of Infectious Diseases in Bucharest, Romania
NOL	net operating loss
November 2019 Offering	our public offering and sale of 5,104,429 shares of common stock, pre-funded warrants to purchase up to 6,324,143 shares of common stock, and warrants to purchase up to 22,857,144 shares of common stock completed in November 2019
PHAST Trial	our Phase 2 clinical trial evaluating TSC in the treatment of acute ischemic or hemorrhagic stroke, designated the "Pre-Hospital Treatment of Acute Stroke-TSC," initiated in October 2019
Prior Warrant	a previously outstanding warrant to purchase up to 5,000,000 shares of common stock at an exercise price of $0.35 per share
Quarterly Report	this quarterly report on Form 10-Q
R&D	research and development
ROU	right-of-use
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2, the virus responsible for COVID-19
SEC	U.S. Securities and Exchange Commission
TSC	trans sodium crocetinate
U.S.	United States

Note Regarding Forward-Looking Statements

This Quarterly Report (including, for purposes of this *Note Regarding Forward-Looking Statements*, any information or documents incorporated herein by reference) includes express and implied forward-looking statements. By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change, and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition, liquidity and prospects may differ materially from the forward-looking statements contained in this Quarterly Report. In addition, even if our results of operations, financial condition, liquidity, and prospects are consistent with the forward-looking statements contained in this Quarterly Report, they may not be predictive of actual results or reflect unanticipated developments in future periods.

Forward-looking statements appear in a number of places throughout this Quarterly Report . We 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. Forward-looking statements also include statements regarding our intentions, beliefs, projections, outlook, analyses, or expectations concerning, among other things:

- our ability to obtain additional financing;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- the success and timing of our clinical and preclinical studies, including our ability to enroll subjects in our ongoing clinical studies at anticipated rates;
- our ability to obtain and maintain regulatory approval of our product candidates and, if approved, our products, including the labeling under any approval we may obtain;
- our plans and ability to develop and commercialize our product candidates and the outcomes of our research and development activities;
- the accuracy of our estimates of the size and characteristics of the potential markets for our product candidates, the rate and degree of market acceptance of any of our product candidates that may be approved in the future, and our ability to serve those markets;
- the success of products that are or may become available which also target the potential markets for our product candidates;
- our failure to recruit or retain key scientific or management personnel or to retain our executive officers;

- the performance of third parties, including contract research organizations, manufacturers, and outside consultants to whom we outsource certain operational and staff functions;
- obtaining and maintaining intellectual property protection for our product candidates and our proprietary technology;
- our ability to operate our business without infringing the intellectual property rights of others;
- regulatory developments in the U.S., European Union, and other foreign jurisdictions;
- recently enacted and future legislation regarding the healthcare system, including trends towards managed care and healthcare cost containment, the impact of any significant spending reductions or cost controls affecting publicly funded or subsidized healthcare programs, or any replacement, repeal, modification or invalidation of some or all of the provisions of the U.S. Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act;
- any significant breakdown, infiltration or interruption of our information technology systems and infrastructure;
- our ability to satisfy the continued listing requirements of the NASDAQ Capital Market or any other exchange on which our securities may trade in the future;
- our ability to continue as a going concern;
- uncertainties related to general economic, political, business, industry, and market conditions, including the recent U.S. presidential election;
- the ongoing COVID-19 pandemic; and
- other risks and uncertainties, including those discussed in Part II, Item 1A of this Quarterly Report, Part I, Item 1A of the Form 10-K and elsewhere in our public filings.

As a result of these and other factors, known and unknown, actual results could differ materially from our intentions, beliefs, projections, outlook, analyses, or expectations expressed in any forward-looking statements in this Quarterly Report. Accordingly, we cannot assure you that the forward-looking statements contained in this Quarterly Report will prove to be accurate or that any such inaccuracy will not be material. You should also understand that it is not possible to predict or identify all such factors, and you should not consider any such list to be a complete set of all potential risk or uncertainties. In light of the foregoing and the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

Any forward-looking statements that we make in this Quarterly Report speak only as of the date of such statement, and, except as required by applicable law or by the rules and regulations of the SEC, we undertake no obligation to update such statements to reflect events or circumstances after the date of this Quarterly Report or to reflect the occurrence of unanticipated events. 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.

Note Regarding Trademarks, Trade Names and Service Marks

This Quarterly Report may contain the following trademarks, trade names and service marks of ours: “DIFFUSIO2N.” All other trade names, trademarks and service marks appearing in this Quarterly Report are, to the knowledge of Diffusion, the property of their respective owners. To the extent any such terms appear without the trade name, trademark or service mark notice, such presentation is for convenience only and should not be construed as being used in a descriptive or generic sense.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Diffusion Pharmaceuticals Inc.
Consolidated Balance Sheets
(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
Commitments and Contingencies (Note 7)		
Stockholders' Equity:		
Common stock, $0.001 par value:		
1,000,000,000 shares authorized; 64,015,441 and 33,480,365 shares 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

See accompanying notes to unaudited interim consolidated financial statements.

Diffusion Pharmaceuticals Inc.
Consolidated Statements 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

See accompanying notes to unaudited interim consolidated financial statements.

Diffusion Pharmaceuticals Inc.
Consolidated Statement of Changes in Stockholders' Equity
Three and Nine Months Ended September 30, 2019
(unaudited)

	Stockholders' Equity				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at July 1, 2019	4,693,290	$ 4,694	$ 101,340,798	$ (85,167,906)	$ 16,177,586
Stock-based compensation expense	—	—	145,321	—	145,321
Net loss	—	—	—	(2,804,092)	(2,804,092)
Balance at September 30, 2019	4,693,290	$ 4,694	$ 101,486,119	$ (87,971,998)	$ 13,518,815

	Stockholders' Equity				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at January 1, 2019	3,376,230	$ 3,377	$ 95,532,881	$ (79,924,699)	$ 15,611,559
Issuance of common stock and warrants, net of issuance costs	1,317,060	1,317	5,567,633	—	5,568,950
Stock-based compensation expense	—	—	385,605	—	385,605
Net loss	—	—	—	(8,047,299)	(8,047,299)
Balance at September 30, 2019	4,693,290	$ 4,694	$ 101,486,119	$ (87,971,998)	$ 13,518,815

See accompanying notes to unaudited interim consolidated financial statements.

Diffusion Pharmaceuticals Inc.
Consolidated Statement of Changes in Stockholders' Equity
Three and Nine Months Ended September 30, 2020
(unaudited)

	Stockholders' Equity				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at July 1, 2020	63,998,298	$ 63,999	$ 130,220,772	$ (97,408,116)	$ 32,876,655
Issuance of common stock upon exercise of warrants	17,143	17	7,483	—	7,500
Stock-based compensation expense	—	—	279,473	—	279,473
Net loss	—	—	—	(4,439,211)	(4,439,211)
Balance at September 30, 2020	64,015,441	$ 64,016	$ 130,507,728	$ (101,847,327)	$ 28,724,417

	Stockholders' Equity				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at January 1, 2020	33,480,365	$ 33,481	$ 111,824,859	$ (91,724,078)	$ 20,134,262
Issuance of common stock and warrants, net of issuance costs	11,428,572	11,429	10,330,202	—	10,341,631
Issuance of common stock upon exercise of warrants	19,106,504	19,106	7,768,370	—	7,787,476
Stock-based compensation expense	—	—	584,297	—	584,297
Net loss	—	—	—	(10,123,249)	(10,123,249)
Balance at September 30, 2020	64,015,441	$ 64,016	$ 130,507,728	$ (101,847,327)	$ 28,724,417

See accompanying notes to unaudited interim consolidated financial statements.

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

	Nine Months Ended September 30,	
	2020	**2019**
Operating activities:		
Net loss	$ (10,123,249)	$ (8,047,299)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	78,233	70,840
Stock-based compensation expense	584,297	385,605
Change in deferred income taxes	(1,675,381)	(485,216)
Changes in operating assets and liabilities:		
Prepaid expenses, deposits, and other assets	(224,224)	352,252
Accounts payable, accrued expenses, and other liabilities	1,202,283	303,466
Net cash used in operating activities	(10,158,041)	(7,420,352)
Cash flows provided by financing activities:		
Proceeds from the sale of common stock	10,827,100	5,731,779
Proceeds from the exercise of common stock warrants	8,046,103	—
Payment of issuance costs	(982,328)	(162,829)
Net cash provided by financing activities	17,890,875	5,568,950
Net increase (decrease) in cash and cash equivalents	7,732,834	(1,851,402)
Cash and cash equivalents at beginning of period	14,177,349	7,991,172
Cash and cash equivalents at end of period	$ 21,910,183	$ 6,139,770
Supplemental disclosure of non-cash investing and financing activities:		
Operating lease right of use asset and current and noncurrent liability	$ —	$ 334,205

See accompanying notes to unaudited interim consolidated financial statements.

Please see the "Note Regarding Company References and Other Defined Terms" included elsewhere in this Quarterly Report for the meanings of certain capitalized terms used throughout these notes accompanying our unaudited consolidated financial statements.

1. Organization and Description of Business

Diffusion Pharmaceuticals Inc., a Delaware corporation, 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.

TSC was designed to enhance the level of organization among water molecules by increasing the amount of hydrogen bonding. This creates a less dense matrix of water molecules, which facilitates the diffusion of oxygen molecules from areas of high to low oxygen concentrations, such as from oxygenated red blood cells into tissues where the oxygen is used to power the cells. In animal models, this diffusion-enhancing mechanism of action has been observed to affect hypoxic tissue preferentially while avoiding excessive oxygen-related tissue toxicity, also known as hyperoxia.

TSC previously has been demonstrated safe and tolerable in over 160 subjects included in the Company's clinical program across a variety of medical conditions often complicated by hypoxia, including the Company's clinical studies conducted in patients afflicted with GBM, peripheral artery disease with intermittent claudication, and stroke, as well as its ongoing 100-303 COVID Trial. In each of these conditions and many others, hypoxia is a significant contributor to morbidity and mortality, and a considerable treatment obstacle for medical providers.

In September 2020, the Company initiated the 100-303 COVID Trial, its ongoing Phase 1b clinical trial evaluating TSC in hospitalized COVID-19 patients and, on September 10, 2020, the Company announced the dosing of the first two patients in the trial. As of the date of this Quarterly Report, patient enrollment continues and no dose-limiting toxicities have been observed. However, given the complex design of the 100-303 COVID Trial, the sequential nature of patient enrollment thereunder, and the resulting challenges to expediting the trial when ordinary course delays are encountered, protocol the Company now expects the 100-303 COVID Trial to be completed with topline data available by the end of first quarter of 2021.

In addition to TSC, the Company's product candidate DFN-529, a novel, allosteric PI3K/Akt/mTOR pathway inhibitor, is in early-stage development. The Company previously completed two Phase 1 clinical trials evaluating DFN-529 in age-related macular degeneration, and DFN-529 was also previously in preclinical development in oncology, specifically GBM.

2. Liquidity

The Company has not generated any revenues from product sales and has funded operations primarily from the proceeds of public and private offerings of equity, convertible debt and convertible preferred stock. Substantial additional financing will be required by the Company to continue to fund its research and development activities. No assurance can be given that any such financing will be available when needed, or at all, or that the Company's research and development efforts will be successful.

The Company regularly explores alternative means of financing its operations and seeks funding through various sources, including public and private securities offerings, collaborative arrangements with third parties and other strategic alliances and business transactions. The Company does not have any commitments to obtain additional funds and may be unable to obtain sufficient funding in the future on acceptable terms, if at all. If the Company cannot obtain the necessary funding, it will need to delay, scale back or eliminate some or all of its research and development programs or enter into collaborations with third parties to commercialize potential products or technologies that it might otherwise seek to develop or commercialize independently; consider other various strategic alternatives, including a merger or sale of the Company; or cease operations. If the Company engages in collaborations, it may receive lower consideration upon commercialization of such products than if it had not entered such arrangements or if it entered into such arrangements at later stages in the product development process.

Operations of the Company are subject to certain risks and uncertainties including various internal and external factors that will affect whether and when the Company's product candidates become approved products and how significant their market share will be, some of which are outside of the Company's control. The length of time and cost of developing and commercializing the Company's product candidates and/or failure of them at any stage of the approval process will materially affect the Company's financial condition and future operations. The Company believes its cash and cash equivalents as of September 30, 2020 are sufficient to fund operations into the fourth quarter of 2022.

3. Basis of Presentation and Summary of Significant Accounting Policies

The Summary of Significant Accounting Policies included in the Form 10-K have not materially changed, except as set forth below.

Basis of Presentation

The accompanying unaudited interim consolidated financial statements of the Company have been prepared in accordance with GAAP for interim financial information as found in the ASC and ASUs of the FASB, and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the SEC. In the opinion of management, the accompanying unaudited interim consolidated financial statements of the Company include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the unaudited interim consolidated financial statements) considered necessary to present fairly the Company's financial position as of September 30, 2020, results of operations for the three and nine months ended September 30, 2020 and 2019 and cash flows for the nine months ended September 30, 2020 and 2019. Operating results for the nine months ended September 30, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020. The unaudited interim consolidated financial statements presented herein do not contain the required disclosures under GAAP for annual financial statements and should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended December 31, 2019 filed with the SEC as part of the Form 10-K on March 17, 2020.

Use of Estimates

The preparation of unaudited interim consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of assets and liabilities at the date the financial statements and reported amounts of expense during the reporting period. The COVID-19 pandemic had no material impact on our estimates and assumptions used in the preparation of the unaudited interim consolidated financial statements for the quarterly period ended September 30, 2020. However, the full extent to which the ongoing COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, including sales, expenses, reserves and allowances, clinical studies, research and development costs and employee-related amounts, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19, governmental and business responses to the pandemic, further actions taken to contain or treat COVID-19, the ongoing economic impact on local, regional, national and international markets, and the speed of the anticipated economic recovery. Due to the uncertainty of factors surrounding these estimates or judgments, actual results may materially vary from our estimates. Estimates and assumptions are periodically reviewed, and the effects of revisions are reflected in the unaudited interim consolidated financial statements in the period they are determined. Our future assessment of the magnitude and duration of COVID-19, as well as other factors, could result in material impacts to our consolidated financial statements in future reporting periods.

Fair Value of Financial Instruments

Fair value is the price that could be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. Fair value determination in accordance with applicable accounting guidance requires that a number of significant judgments be made. Additionally, fair value is used on a nonrecurring basis to evaluate assets for impairment or as required for disclosure purposes by applicable accounting guidance on disclosures about fair value of financial instruments. Depending on the nature of the assets and liabilities, various valuation techniques and assumptions are used when estimating fair value. The carrying amounts of certain of the Company's financial instruments, including cash equivalents and accounts payable are shown at cost, which approximates fair value due to the short-term nature of these instruments. The Company follows the provisions of FASB ASC Topic 820, *Fair Value Measurement*, for financial assets and liabilities measured on a recurring basis. The guidance requires fair value measurements be classified and disclosed in one of the following three categories:

- *Level 1:* Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.
- *Level 2:* Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liabilities.
- *Level 3:* Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity.

The following fair value hierarchy table presents information about the Company's cash equivalents measured at fair value on a recurring basis:

	September 30, 2020		
	Level 1	**Level 2**	**Level 3**
Assets			
Cash equivalents	$ 21,570,461	$ —	$ —

	December 31, 2019		
	Level 1	**Level 2**	**Level 3**
Assets			
Cash equivalents	$ 14,006,193	$ —	$ —

Intangible Asset

The Company's DFN-529 (formerly RES-529) intangible asset is assessed for impairment annually on October 1 of the Company's fiscal year or more frequently if impairment indicators exist. There was no impairment to the Company's DFN-529 intangible asset recognized during the three or nine months ended September 30, 2020 and 2019.

Net Loss Per Common Share

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during each period. Diluted net loss per share includes the effect, if any, from the potential exercise or conversion of securities, such as convertible debt, convertible preferred stock, common stock warrants, stock options and unvested restricted stock that would result in the issuance of incremental shares of common stock. In computing the basic and diluted net loss per share applicable to common stockholders, the weighted average number of shares remains the same for both calculations due to the fact that when a net loss exists, dilutive shares are not included in the calculation as the impact is anti-dilutive.

The following potentially dilutive securities outstanding have been excluded from the computation of diluted weighted average shares outstanding, as they would be anti-dilutive as of the dates indicated below:

	As of September 30,	
	2020	2019
Common stock warrants	9,100,112	3,469,825
Stock options	2,040,204	309,276
Unvested restricted stock awards	153,000	—
	11,293,316	3,779,101

Recently Adopted Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-13, *Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurements*, which changes the fair value measurement disclosure requirements of ASC 820. The goal of the ASU is to improve the effectiveness of ASC 820's disclosure requirements by providing users of the financial statements with better information about assets and liabilities measured at fair value in the financial statements and notes thereto. The Company adopted ASU No. 2018-13 in the first quarter of 2020 and the adoption did not have a material impact on the Company's consolidated financial statements.

4. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following as of the dates indicated below:

	September 30, 2020	December 31, 2019
Accrued payroll and payroll related expenses	751,704	182,708
Accrued professional fees	100,000	48,338
Accrued clinical studies expenses	280,845	57,378
Other accrued expenses	29,729	70,108
Total	$ 1,162,278	$ 358,532

5. Stockholders' Equity and Common Stock Warrants

2020 Common Stock Offering

In May 2020, the Company completed a public offering of 11,428,572 shares of common stock for a purchase price of $1.05 per share for net proceeds of $10.3 million after deducting commissions, discounts, and other offering costs. In addition, at the closing of the May 2020 Offering, the Company issued warrants to purchase up to 571,429 shares of common stock to designees of the placement agent for the May 2020 Offering. The placement agent's warrants have an exercise price of $1.3125 per share and a term of five years from the date of issuance.

Additionally, in May 2020, the Company entered into a warrant exercise agreement with an investor who held the Prior Warrant, a previously outstanding warrent to purchase up to an aggregate of 5,000,000 shares of our common stock at an exercise price of $0.35 per share. In consideration for the exercise of the Prior Warrant for cash and an additional $0.125 per each share of common stock in the Prior Warrant being exercised, the exercising investor received new unregistered warrants to purchase up to an aggregate of 5,000,000 shares of common stock in a private placement. The warrants are exercisable immediately at an exercise price of $0.5263 per share and exercisable until November 8, 2025. The Company recognized a deemed dividend of $2.0 million to reflect the consideration given as an inducement for the investor to exercise the warrants. This deemed dividend is recorded in the Company's statement of operations during the nine months ended September 30, 2020 as an increase to the net loss attributable to common stockholders for purposes of computing net loss per share, basic and diluted.

In connection with the May 2020 Investor Warrant Exercise, the Company issued warrants to purchase up to 250,000 shares of common stock to the placement agent with an exercise price of $0.5938 per share and otherwise have identical terms to the warrants issued to the investor.

2019 Common Stock and Warrant Offerings

In December 2019, the Company completed the December 2019 Offering, an offering of 6,266,787 shares of its common stock and warrants to purchase up to 6,266,787 shares of common stock. The shares of common stock and warrants were sold for a combined purchase price of $0.5585 per share for net proceeds of $3.0 million. The December 2019 Offering warrants are exercisable beginning on the date of their issuance until June 13, 2025 at an initial exercise price equal to $0.4335 per share.

In addition, at the closing of the December 2019 Offering, the Company issued warrants to purchase up to 313,339 shares of common stock to designees of the placement agent. The placement agent's warrants have an exercise price of $0.6981 per share and a term of five years from the date of issuance.

In November 2019, the Company completed the November 2019 Offering, a registered direct public offering of 5,104,429 shares of its common stock, and 6,324,143 pre-funded warrants each entitling the holder to purchase one share of common stock, together with warrants to purchase up to 22,857,144 shares of common stock, at a combined public offering price of $0.35 per share and associated warrants for total net proceeds of $3.3 million. The warrants were issued with an exercise price of $0.35 per share and are exercisable beginning on their date of issuance. Of the warrants issued, 11,428,572 have a term of 18 months and 11,428,572 have a term of five years.

In addition, at the closing of the November 2019 Offering, the Company issued warrants to purchase up to 571,429 shares of common stock to designees of the placement agent. The placement agent's warrants have an exercise price of $0.4375 per share and a term of five years from the date of issuance.

In May 2019, the Company completed the May 2019 Offering, a registered direct public offering of 1,317,060 shares of common stock and a private placement of warrants to purchase up to 1,317,060 shares of common stock. The shares of common stock and warrants were sold for a combined purchase price of $4.895 for total net proceeds of $5.6 million. The warrants are exercisable beginning on the date of their issuance until November 29, 2024 at an initial exercise price equal to $5.00.

In addition, at the closing of the May 2019 Offering, the Company issued warrants to purchase up to 65,853 shares of common stock to designees of the placement agent. The placement agent's warrants have an exercise price of $6.11875 per share and a term of five years from the date of issuance.

Common Stock Warrants

As of September 30, 2020, the Company had the following warrants outstanding to acquire shares of its common stock:

	Outstanding	Range of exercise price per share	Expiration dates
Common stock warrants issued in 2017 related to Series A convertible preferred stock offering	903,870	$33.30	March 2022
Common stock warrants issued in 2018 related to the January 2018 common stock offering	1,181,421	$12.00 - $15.00	January 2023
Common stock warrants issued related to the May 2019 Offering	1,382,913	$5.00 - $6.11875	November 2024
Common stock warrants issued related to the November 2019 Offering	497,140	$0.35 - $0.4375	May 2024
Common stock warrants issued related to the December 2019 Offering	313,339	$0.6981	December 2024
Common stock warrants issued related to the May 2020 Offering	571,429	$1.3125	May 2025
Common stock warrants issued related to May 2020 Investor Warrant Exercise	4,250,000	$0.5263 - $0.5938	November 2025
	9,100,112		

During the nine months ended September 30, 2020, no warrants expired and 19,106,504 warrants were exercised for gross proceeds of $8.0 million.

6. Stock-Based Compensation

2015 Equity Plan

The 2015 Equity Plan provides for increases to the number of shares reserved for issuance thereunder each January 1 equal to 4.0% of the total shares of the Company's common stock outstanding as of the immediately preceding December 31, unless a lesser amount is stipulated by the Compensation Committee of the Company's board of directors. Accordingly, 1,339,215 shares were added to the reserve as of January 1, 2020, which shares may be issued in connection with the grant of stock-based awards, including stock options, restricted stock, restricted stock units, stock appreciation rights and other types of awards as deemed appropriate, in each case, in accordance with the terms of the 2015 Equity Plan. As of September 30, 2020, there were no shares of common stock available for future issuance under the 2015 Equity Plan. Further, the Company granted an option to purchase 70,000 shares of common stock to an employee during the nine months ended September 30, 2020 that were granted outside of the 2015 Equity Plan as an inducement material to the employee's acceptance of employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4).

The Company recorded stock-based compensation expense in the following expense categories of its unaudited interim consolidated statements of operations for the periods indicated:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	$ 19,838	$ 13,519	$ 136,236	$ 40,692
General and administrative	259,635	131,802	448,061	344,913
Total stock-based compensation expense	$ 279,473	$ 145,321	$ 584,297	$ 385,605

The following table summarizes the activity related to all stock options for the nine months ended September 30, 2020:

	Number of Options	Weighted average exercise price per share	Weighted average remaining contractual life (in years)
Balance at January 1, 2020	309,276	$ 55.78	
Granted	1,731,100	0.66	
Expired	(172)	142.50	
Outstanding at September 30, 2020	2,040,204	$ 9.01	9.1
Exercisable at September 30, 2020	992,779	$ 17.65	8.4

The weighted average grant date fair value of stock option awards granted during the nine months ended September 30, 2020 was $0.62. The total fair value of options vested during the three months ended September 30, 2020 and 2019 was $0.3 million and $0.2 million, respectively. The total fair value of options vested during the nine months ended September 30, 2020 and 2019 was $0.6 million and $0.5 million, respectively. No options were exercised during any of the periods presented. At September 30, 2020, there was $0.8 million of unrecognized compensation expense that will be recognized over a weighted-average period of 2.1 years.

Options granted were valued using the Black-Scholes option-pricing model and the weighted average assumptions used to value the options granted during the nine months ended September 30, 2020 and 2019 were as follows:

	2020	2019
Expected term (in years)	7.75	5.52
Risk-free interest rate	0.9%	2.2%
Expected volatility	119.7%	113.4%
Dividend yield	—%	—%

Restricted Stock Awards

During the nine months ended September 30, 2020, the Company granted 153,000 restricted stock awards to members of the board of directors of the Company. The weighted average grant date fair value of the restricted stock awards granted during the nine months ended September 30, 2020 was $0.65. The shares begin to vest 18 months after the grant date. The Company recognized approximately $4,000 and $12,000 in expense related to these awards during the three and nine months ended September 30, 2020, respectively. At September 30, 2020, there was approximately $88,000 of unrecognized compensation cost that will be recognized over a weighted average period of 2.66 years.

7. Commitments and Contingencies

Office Space Rental

The Company has a non-cancelable operating lease for office and laboratory space in Charlottesville, Virginia, which began in April 2017 and as of September 30, 2020, has a remaining lease term of approximately 1.6 years. In February 2016, the FASB issued ASU 2016-02, *Leases (ASC 842)*, and the Company adopted ASC 842 in the first quarter of 2019 and as a result of the adoption, the Company recognized a current operating lease liability of $0.1 million and a noncurrent operating lease liability of $0.2 million with a corresponding ROU asset of the combined amounts, which is based on the present value of the minimum rental payments of the lease. The discount rate used to account for the Company's operating lease under ASC 842 is the Company’s estimated incremental borrowing rate of 10%. The original term of the lease ends in the second quarter of 2022 and the Company has an option to extend for another five (5) years. This option to extend was not recognized as part of the Company's measurement of the ROU asset and operating lease liability as of September 30, 2020.

Rent expense related to the Company's operating lease for the three months ended September 30, 2020 and 2019 was approximately $31,000 and $30,000, respectively. Rent expense for the nine months ended September 30, 2020 and 2019 was approximately $91,000 and $80,000, respectively. Future minimum rental payments under the Company's non-cancelable operating lease at September 30, 2020 were as follows:

	Rental Commitments
2020	29,287
2021	118,519
2022	39,735
Total	187,541
Less: imputed interest	(12,873)
	$ 174,668

Research and Development Arrangements

In the course of normal business operations, the Company enters into agreements with universities and CROs, to assist in the performance of research and development activities and contract manufacturers to assist with chemistry, manufacturing, and controls related expenses. Expenditures to CROs represent a significant cost in clinical development for the Company. The Company could also enter into additional collaborative research, contract research, manufacturing, and supplier agreements in the future, which may require upfront payments and long-term commitments of cash.

Defined Contribution Retirement Plan

The Company has established a 401(k) defined contribution plan that covers all employees who qualify under the terms of the plan. Eligible employees may elect to contribute to the 401(k) Plan up to 90% of their compensation, limited by the IRS-imposed maximum. The Company provides a safe harbor match with a maximum amount of 4% of the participant’s compensation. The Company made matching contributions under the 401(k) Plan of approximately $11,000 and $16,000 for the three months ended September 30, 2020 and 2019, respectively and matched approximately $42,000 and $54,000 during the nine months ended September 30, 2020 and 2019, respectively.

Legal Proceedings

On August 7, 2014, a complaint was filed in the Superior Court of Los Angeles County, California by Paul Feller, the former Chief Executive Officer of the Company's legal predecessor under the caption *Paul Feller v. RestorGenex Corporation, Pro Sports & Entertainment, Inc., ProElite, Inc. and Stratus Media Group, GmbH* (Case No. BC553996). The complaint asserts various causes of action, including, among other things, promissory fraud, negligent misrepresentation, breach of contract, breach of employment agreement, breach of the covenant of good faith and fair dealing, violations of the California Labor Code and common counts. The plaintiff is seeking, among other things, compensatory damages in an undetermined amount, punitive damages, accrued interest and an award of attorneys’ fees and costs. On December 30, 2014, the Company filed a petition to compel arbitration and a motion to stay the action. On April 1, 2015, the plaintiff filed a petition in opposition to the Company’s petition to compel arbitration and a motion to stay the action. After a hearing for the petition and motion on April 14, 2015, the Court granted the Company’s petition to compel arbitration and a motion to stay the action. On January 8, 2016, the plaintiff filed an arbitration demand with the American Arbitration Association. On November 19, 2018 at an Order to Show Cause Re Dismissal Hearing, the Court found sufficient grounds not to dismiss the case, and an arbitration hearing was scheduled for November 2020. In August 2020, due to the ongoing COVID-19 pandemic and related restrictions on gatherings in the State of California, the arbitration hearing was postponed to the summer of 2021. The Company believes this matter is without merit and intends to defend the arbitration vigorously. However, because this matter is in an early stage, the Company is unable to predict its outcome and the possible loss or range of loss, if any, associated with its resolution or any potential effect the matter may have on the Company’s financial position. Depending on the outcome or resolution of this matter, it could have a material effect on the Company’s financial position.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations as of and for the periods ended September 30, 2020 and 2019 together with (i) the unaudited interim consolidated financial statements and accompanying notes included in Part I, Item 1 of this Quarterly Report and (ii) the audited consolidated financial statements and accompanying notes included in the Form 10-K. In addition, our actual results may differ materially from those anticipated in any forward-looking statements included in the following discussion. Please refer to the "Note Regarding Forward-Looking Statements" included elsewhere in this Quarterly Report for a discussion of certain risks and uncertainties associated with forward-looking statements. Please also see the "Note Regarding Company References and Other Defined Terms" included elsewhere in this Quarterly Report for the meanings of certain capitalized terms used throughout this discussion and analysis.

Executive Summary

Third Quarter Developments & Near-Term Strategy

- ***Board & Management Additions and Changes***

  During the quarter ended September 30, 2020 and the early part of October 2020, our leadership team changed significantly. We appointed a new chief executive officer (Robert Cobuzzi, Ph.D.) and a new general counsel (William Elder, J.D.) in September 2020, followed by a new chief medical officer (Christopher Galloway, M.D.) in October 2020. We also welcomed a new director (Jane Hollingsworth) in August 2020.

- ***Selected Financial Highlights***

  As of September 30, 2020, we had cash and cash equivalents of $21.9 million, which we believe will enable us to fund our anticipated operating expenses and capital expenditures into the fourth quarter of 2022.

- ***Initiated and Advanced Previously Announced Trial Evaluating TSC in COVID-19 Patients***

  On September 10, 2020, we announced the dosing of the first two patients in our 100-303 COVID Trial evaluating TSC in hospitalized COVID-19 patients at the NIID in Bucharest, Romania. The primary endpoint of the 100-303 COVID Trial is to evaluate the safety and tolerability of TSC administered every six (6) hours for up to 15 days, a more frequent dosing regimen than has been used in our previous clinical studies.

  As of the date of this Quarterly Report, patient enrollment continues and no dose-limiting toxicities have been observed. However, given the complex design of the 100-303 COVID Trial protocol, the sequential nature of patient enrollment thereunder, and the resulting challenges to expediting the trial when ordinary course delays are encountered, we now expect the 100-303 COVID Trial to be completed with topline data available by the end of first quarter of 2021. Additional details regarding certain objectives, endpoints, and other aspects of the protocol and design of the 100-303 COVID Trial are described below under the heading, *"—TSC in Conditions Often Complicated by Hypoxia–TSC in COVID-19."*

- ***Anticipated Next Steps in TSC Development Program***

  Following the recent changes and additions to our leadership team, we initiated a thorough review of our existing development program for TSC. Although this review remains ongoing, we have commenced plans to modify the existing development program for TSC intending to accomplish two principal strategic objectives:

  o Optimize the clinical dose and dosing frequency for TSC; and

  o Evaluate TSC in clinical models designed to establish proof of concept for improvement in oxygenation.

  We believe that, if we are able to accomplish these two strategic objectives, it will allow us to mitigate a significant number of potential risks related to the subsequent stages of our development of TSC and focus our resources, time, and energy in a more efficient manner, particularly given the broad range of indications in which we believe TSC may have an adjunctive therapeutic benefit.

Accordingly, our plans include the following, which we refer to collectively as our Planned Studies:

- *Optimize Dose and Dose Frequency for TSC Administration*

  - TSC previously has been demonstrated safe and tolerable in over 160 subjects included in our clinical program across a variety of indications when administered once daily.

  - The protocol for the 100-303 COVID Trial includes four different doses administered every six (6) hours for up to 15 days. We are evaluating the possibility of expanding the number of dose groups in the 100-303 COVID Trial to include additional doses administered on the same regimen. We have submitted an amendment to the current protocol to the applicable regulatory body in Romania, but our final decision to implement and execute this expansion is contingent upon successful and timely determination by the trial's safety monitoring committee that highest dose provided for by the unamended protocol is safe and tolerable.

  - If we determine, for any reason, not to expand and include these additional doses in the 100-303 COVID Trial, we intend to evaluate the full range and frequency of doses of TSC in one or more of the studies described directly below.

- *Design and Initiate New Studies of TSC in Clinical Models of Hypoxia*

  - We are in the early stages of designing additional clinical studies which will be intended to evaluate the effects of TSC using short-term experimental models of oxygenation.

  - We expect the primary objective of these studies will be to quantify the magnitude of effect of TSC on tissue oxygen levels and certain other clinical parameters.

  - If successful, we believe that the data received from these studies would establish proof of concept for TSC's effects on oxygenation and, accordingly, assist in our efforts to optimize our clinical development strategy, including the identification of relevant patient populations and indications.

  - We expect to provide details on the design of these additional studies by mid-January 2021 and intend to initiate the studies in the first quarter of 2021.

We expect to fully fund our Planned Studies with cash-on-hand.

- ***Upcoming Events and Future Announcements***

We are registered to participate in two virtual, biopharmaceutical and biotechnology industry conferences in mid-January 2021: Biotech Showcase and the HC Wainwright Bioconnect Conference. We intend to provide our next update regarding our Planned Studies and our overall development program for TSC at that time.

Our Business

We are an innovative biopharmaceutical company developing novel therapies that enhance the body's ability to deliver oxygen to the areas where it is needed most. Our 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.

TSC was designed to enhance the level of organization among water molecules by increasing the amount of hydrogen bonding. This creates a less dense matrix of water molecules, which facilitates the diffusion of oxygen molecules from areas of high to low oxygen concentrations, such as from oxygenated red blood cells into tissues where the oxygen is used to power the cells. In animal models, this diffusion-enhancing mechanism of action has been observed to affect hypoxic tissue preferentially while avoiding excessive oxygen-related tissue toxicity, also known as hyperoxia.

TSC previously has been demonstrated safe and tolerable in over 160 subjects included in our clinical program across a variety of medical conditions often complicated by hypoxia, including our clinical studies conducted in patients afflicted with GBM, peripheral artery disease with intermittent claudication, and stroke, as well as our ongoing 100-303 COVID Trial. In each of these conditions and many others, hypoxia is a significant contributor to morbidity and mortality, and a considerable treatment obstacle for medical providers.

About Hypoxia

Under normal conditions, the body's supply of oxygen meets the demand at the tissue/cellular level to sustain life. The availability of sufficient oxygen enables efficient and sustainable generation of energy to support the metabolic demands of the cells. Hypoxia is a condition in which the body, or a region of the body, is deprived of sufficient oxygen to produce the energy it needs to survive. This state can only be sustained for very brief periods of time before tissue ischemia, damage and, eventually, cell death occurs. Hypoxic conditions occur in many of medicine's most intractable and difficult-to-treat conditions, complicating treatment of the underlying condition by medical providers.

TSC in Conditions Often Complicated by Hypoxia

TSC in COVID-19

In March 2020, the COVID-19 pandemic accelerated in the U.S. resulting in numerous delays and other challenges for biopharmaceutical companies conducting clinical studies in indications not related to COVID-19, including our Phase 2 PHAST-TSC Trial evaluating TSC in acute stroke. This is discussed in more detail below under the heading – *TSC in Stroke*. In early April 2020 we announced plans to initiate a clinical research program to evaluate TSC in patients with COVID-19 due to the anticipated persistence of the COVID-19 pandemic coupled with our belief in the potential of TSC to improve low tissue oxygen levels. We believe this decision was both opportunistic and a natural extension of the previous development work conducted with TSC, as COVID-19 often affects patients' respiratory systems, with some patients rapidly progressing to acute respiratory distress and multiple organ failure.

On September 10, 2020 we announced the dosing of the first two patients in the 100-303 COVID Trial, our ongoing Phase 1b clinical trial evaluating TSC in hospitalized COVID-19 patients at the NIID in Bucharest, Romania. The 100-303 COVID Trial is a single-center, open-label, pharmacokinetic, pharmacodynamic, multiple ascending dose study in hospitalized patients with confirmed SARS-CoV-2 infection and hypoxemia, defined for purposes of the trial as (i) low blood oxygen levels as measured by pulse oximetry ($SpO2 < 94\%$) when breathing room air or (ii) if such patient requires supplemental oxygen. Patients requiring mechanical ventilation or extracorporeal membrane oxygenation, however, are excluded from the 100-303 COVID Trial. As of the date of this Quarterly Report, patient enrollment continues in accordance with the trial protocol and no dose-limiting toxicities have been observed.

The primary objective of the 100-303 COVID Trial is to evaluate the safety and tolerability of TSC administered every six (6) hours for up to 15 days. Secondary endpoints include pharmacokinetic measurement of TSC levels after dosing, relative improvements in blood oxygen levels, and certain other clinical parameters related to COVID-19. The trial's ascending dose design provides for groups of six (6) patients to receive the protocol-specified dose of TSC via intravenous administration every six (6) hours for up to 15 days. Once a group of six (6) patients successfully completes treatment at a specified dose with no dose-limiting toxicities observed, the following group of six (6) patients can then be enrolled and receive the next, higher dose specified by the protocol, with four different doses provided for by the protocol as of the date of this Quarterly Report. However, as described in more detail above under the heading *"—Third Quarter Developments & Near Term Strategy – Anticipated Next Steps in TSC Development Program – Expanding the Ongoing 100-303 COVID Trial*," we are evaluating the possibility of expanding the 100-303 COVID Trial to include two additional doses, each in a group of six (6) patients, for a total of 36 patients across all doses. In addition, although the trial is not powered to evaluate efficacy, patients' blood oxygen levels and other COVID-19-specific clinical data will be collected throughout the trial and analyzed at the end of the trial.

The adjudication of dose-limiting toxicities, if any, is being performed by an external safety monitoring committee put in place to oversee the safety of the patients in the trial. Pursuant to the trial protocol, this committee meets after every three (3) patients complete a specified minimum number of days of dosing, at which time the safety data for these patients are collected and summarized for analysis by the committee. For the first group of three (3) patients, the protocol specified the safety monitoring committee was to meet only after the first three (3) patients completed the full treatment period of up to 15 days. Following the committee's review of the data for this first group of three (3) patients, with respect to all subsequent groups of three (3) patients, the protocol allows for the safety monitoring committee meeting to occur after the last of the three (3) patients in the group completes five (5) days of dosing and all relevant safety data have been collected and provided to the committee. In the interest of patient safety, enrollment of a subsequent group of three (3) patients into the trial cannot proceed until approval is granted by the safety monitoring committee based upon review of the data from the immediately preceding three (3) patient group.

As described above, the design of the 100-303 COVID Trail protocol is complex, patient enrollment thereunder is sequential in nature, and this results in certain challenges to expediting the trial when ordinary course delays are encountered. Accordingly, we now expect the 100-303 COVID Trial to be completed with topline data available by the end of first quarter of 2021, including with respect to any additional groups we may add to the trial as described above.

TSC in GBM

GBM is a particularly deadly form of brain cancer that each year affects approximately 12,000 patients in the U.S. and approximately 35,000 patients worldwide, and for which TSC has received an Orphan Drug Designation from the FDA. We believe TSC may be able to re-oxygenate hypoxic cancer tissue, making the cells more susceptible to the therapeutic effects of standard-of-care radiation therapy and chemotherapy.

We previously completed a Phase 2 clinical trial that evaluated 59 patients with newly diagnosed GBM. This open-label, historically controlled trial demonstrated a favorable safety and tolerability profile for TSC when combined with standard of care treatment for GBM. Although not prospectively defined, a subgroup analysis of inoperable patients suggested a higher proportion of TSC-treated patients survived at two years compared to those in the historical control group.

Based upon data from the inoperable patient subgroup in the Phase 2 trial, we initiated the Phase 3 INTACT Trial in the newly diagnosed inoperable GBM patient population in December 2017. The INTACT Trial was designed to enroll 236 patients in total, with 118 in the treatment arm and 118 in the control arm. The trial began with an FDA-mandated, open-label, dose-escalation safety run-in for which enrollment was completed and has closed. A total of 19 patients were enrolled in an attempt to ensure that at least 8 completed the FDA-specified 42-month exposure period. At a meeting in the third quarter of 2019, the data safety monitoring board for the INTACT Trial concluded that no adverse safety signal was present and unanimously recommended the trial continue as planned, with TSC to be used adjunctively with temozolomide, an anti-cancer chemotherapy drug, during the adjuvant treatment chemotherapy period. However, we determined we did not have the resources to support the randomized portion of the INTACT Trial. Further development of TSC in GBM is contingent upon our ability to raise additional capital or enter into a strategic partnership.

TSC in Stroke

A stroke occurs when blood flow to the brain is blocked (an "ischemic stroke") or a blood vessel in the brain ruptures (a "hemorrhagic stroke"), causing part of the brain to become damaged or to die. According to the U.S. Centers for Disease Control and Prevention, stroke is the fifth leading cause of death and a leading cause of adult disability in the U.S.

Based upon preclinical safety and efficacy data, as well as certain clinical safety data, we believe TSC has potential applications in both ischemic and hemorrhagic stroke. The hypoxic conditions in the brain of stroke patients may be a significant factor contributing to morbidity and mortality, and we believe TSC could enhance the diffusion of oxygen into brain tissue to reduce stroke-induced hypoxia and neuronal death.

In October 2019, we began enrolling patients in our randomized Phase 2 PHAST-TSC Trial to evaluate TSC in the treatment of acute ischemic or hemorrhagic stroke. The PHAST Trial was planned to enroll 160 total patients, evenly split between the TSC treatment arm and the control arm. All patients were to receive either TSC or placebo treatment while in the ambulance to ensure treatment as soon as possible after the onset of clinical symptoms. However, due to, among other factors, the delays and other challenges related to COVID-19 discussed above under the heading *–TSC in COVID-19*, and the substantial capital needs to complete the trial, we determined to begin winding down the PHAST-TSC Trial. Further development of TSC in stroke is contingent upon our ability raise additional capital or enter into a strategic partnership.

DFN-529 (formerly RES-529)

In addition to TSC, our product candidate DFN-529, a novel PI3K/Akt/mTOR pathway inhibitor, is in early-stage development. We previously completed two Phase 1 clinical trials evaluating DFN-529 in age-related macular degeneration, and DFN-529 was also previously in preclinical development in oncology, specifically GBM. In oncology, DFN-529 has shown activity in both in vitro and in vivo glioblastoma animal models and has been demonstrated to be orally bioavailable and capable of crossing the blood brain barrier. We continue to explore alternatives regarding how best to capitalize upon the value of DFN-529 and our associated intellectual property.

The COVID-19 Pandemic and its Impacts on Our Business

In March 2020, the World Health Organization declared the outbreak of COVID-19 a global pandemic. The spread of COVID-19 during 2020 has caused a worldwide economic downturn as well as significant volatility in the financial markets. We have experienced certain disruptions to our clinical operations, including with respect to patient enrollment in our clinical studies, specifically the PHAST Trial prior to our decision to begin winding down the trial.

As a result of the uncertainty caused by the COVID-19 pandemic, we have taken certain measures and responded to changes in our operational needs, including actions designed to provide a safe work environment for the patients and other third-parties involved in the conduct of our clinical studies. We have also made certain internal resource allocation decisions designed to streamline our clinical operations and increase our overall financial flexibility, including prioritizing our resources to the 100-303 COVID Trial and our other Planned Studies, beginning to wind-down the PHAST Trial and INTACT Trial, investing in technology solutions to support increased work-from-home capabilities for our employees and consultants, and suspending or eliminating certain other R&D activities and their related costs.

These changes are being and will be reviewed on an ongoing basis throughout the duration of the pandemic based on operating conditions and other factors. We will continue to take measures intended to address our changing needs and the evolving nature of the pandemic, and we may have to take further actions that we determine are in the best interests of the patients in our clinical studies, our employees, or other constituencies that we serve, or as required by federal, state or local authorities. As the pandemic continues to unfold, the extent of its effect on our operational and financial performance will depend in large part on future developments, which cannot be predicted with confidence at this time. Any such future developments or actions we may take in response thereto, including any prolonged material disruption to our ongoing or planned clinical studies, our other business operations, the industry in which we operate, or general economic, business or market conditions, could cause additional delays with respect to our product development activities and could negatively impact our consolidated financial position, consolidated results of operations, and consolidated cash flows.

Financial Operations Overview & Critical Accounting Policies

Revenues

We have not yet generated any revenue from product sales. We do not expect to generate revenue from product sales for the foreseeable future.

Research and Development Expenses

R&D expenses include, but are not limited to, third-party CRO arrangements and employee-related expenses, including salaries, benefits, stock-based compensation, and travel expense reimbursement. R&D activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical studies. As we advance our product candidates, we expect the amount of R&D costs will continue to increase for the foreseeable future. R&D costs are charged to expense as incurred.

General and Administrative Expense

G&A expenses consist principally of salaries and related costs for executive and other personnel, including stock-based compensation, other employee benefit costs, expenses associated with investment bank and other financial advisory services, and travel expenses. Other G&A expenses include, facility-related costs, communication expenses and professional fees for legal, patent prosecution and maintenance, consulting, accounting, and other professional services.

Interest Income

Interest income consists of interest earned from our cash and cash equivalents.

Income Tax Benefit

We recognize income tax benefit to utilize indefinite deferred tax liabilities as a source of income against indefinite lived portions of our deferred tax assets. Our NOLs and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. NOL and tax credit carryforwards may become subject to an annual limitation in the event of a greater than 50% cumulative change in the ownership interest of significant stockholders over a three year period, as defined under Sections 382 and 383 of the Internal Revenue Code as well as similar state provisions. These limitations may, in certain cases, limit the amount of income tax benefit that can be utilized annually to offset taxable income or tax liabilities in future periods. The amount of the annual limitation is determined based on the Company's value immediately prior to the ownership change, and subsequent ownership changes may further affect the limitation in future years. In 2019, due to the significant changes to our stockholder base as a result of the equity financing we completed during that year, we performed an analysis under Section 382 of the Internal Revenue Code and, as a result, reduced the magnitude of our NOL carryforwards to account for the ownership changes. In addition, the cumulative benefit of our NOLs was remeasured, resulting in tax expense recognized during the year ended December 31, 2019. We have not yet performed an analysis to determine whether or not ownership changes that have occurred in year ending December 31, 2020 give rise to any further limitations.

Critical Accounting Policies

As of September 30, 2020, our Critical Accounting Policies included in the Form 10-K have not changed, except as otherwise set forth in *Note 3 – Basis of Presentation and Summary of Significant Accounting Policies – Recently Adopted Accounting Pronouncements* in the notes accompanying the financial statements included in Part I, Item 1 of this Quarterly Report.

Results of Operations

Three Months Ended September 30, 2020 Compared to Three Months Ended September 30, 2019

The following table sets forth our results of operations for the three months ended September 30, 2020 and 2019.

	Three Months Ended September 30, 2020		
	2020	**2019**	**Change**
Operating expenses:			
Research and development	$ 3,137,553	$ 1,743,494	$ 1,394,059
General and administrative	2,112,375	1,290,371	822,004
Depreciation	24,192	18,178	6,014
Loss from operations	(5,274,120)	(3,052,043)	2,222,077
Other income:			
Interest income	29,233	21,991	7,242
Loss from operations before income tax benefit	(5,244,887)	(3,030,052)	(2,214,835)
Income tax benefit	805,676	225,960	579,716
Net loss	$ (4,439,211)	$ (2,804,092)	$ (1,635,119)

We recognized $3.1 million in R&D expenses during the three months ended September 30, 2020 compared to $1.7 million during the three months ended September 30, 2019. A significant portion of this increase was attributable to R&D expenses related to the 100-303 COVID Trial initiated in September 2020 and our related ramp-up, including a $0.4 million increase in manufacturing costs and a $1.0 million increase in clinical trial and other R&D expenses. The overall increase in R&D expense also includes a $0.1 million increase in costs associated with the PHAST Trial, primarily costs related to winding down the trial. These increases in R&D expenses were offset in part by a $0.1 million decrease in R&D related salaries, wages and stock-based compensation expense.

G&A expenses were $2.1 million during the three months ended September 30, 2020 compared to $1.3 million during the three months ended September 30, 2019. The increase in G&A expenses 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 our former Chief Executive Officer in September 2020.

We recognized income tax benefits of $0.8 million and $0.2 million during the three months ended September 30, 2020 and 2019, respectively. In both periods, the recognized benefit reflects the utilization of indefinite deferred tax liabilities as a source of income against indefinite lived portions of our deferred tax assets.

Nine Months Ended September 30, 2020 Compared to Nine Months Ended September 30, 2019

The following table sets forth our results of operations for the nine months ended September 30, 2020 and 2019.

	Nine Months Ended September 30,		
	2020	**2019**	**Change**
Operating expenses:			
Research and development	$ 6,845,203	$ 4,961,720	$ 1,883,483
General and administrative	4,964,440	3,559,551	1,404,889
Depreciation	78,233	70,840	7,393
Loss from operations	(11,887,876)	(8,592,111)	3,295,765
Other income:			
Interest income	89,246	59,596	29,650
Loss from operations before income tax benefit	(11,798,630)	(8,532,515)	(3,266,115)
Income tax benefit	1,675,381	485,216	1,190,165
Net loss	$ (10,123,249)	$ (8,047,299)	$ (2,075,950)

We recognized $6.8 million in R&D expenses during the nine months ended September 30, 2020 compared to $5.0 million during the nine months ended September 30, 2019. A significant portion of this increase was attributable to R&D expenses related to the 100-303 COVID Trial initiated in September 2020 and our related ramp-up, including a $0.8 million increase in manufacturing costs and a $1.3 million increase in clinical trial and other related R&D expenses. The overall increase in R&D expense also includes a $0.1 million increase in costs associated with the INTACT Trial, primarily related to winding down that trial. These increases in R&D expenses were offset in part by a $0.2 million decrease in R&D related salaries, wages and stock-based compensation expense and a $0.3 million decrease in costs associated with our PHAST Trial as we wind down that trial as well.

G&A expenses were $5.0 million during the nine months ended September 30, 2020 compared to $3.6 million during the nine months ended September 30, 2019. The increase in G&A expense was primarily due to a $0.7 million increase in professional fees and a $0.6 million increase in salaries, wages and stock-based compensation expense, including non-recurring expenses related to the retirement, resignation and separation of our former Chief Executive Officer in September 2020.

We recognized income tax benefits of $1.7 million and $0.5 million during the nine months ended September 30, 2020 and 2019, respectively. In both periods, the recognized benefit reflects the utilization of indefinite deferred tax liabilities as a source of income against indefinite lived portions of our deferred tax assets.

Financial Condition, Liquidity and Capital Resources

Summary

As of September 30, 2020, we had cash and cash equivalents of $21.9 million. We have incurred operating losses since inception, have not generated any product revenue and have not achieved profitable operations. We incurred net losses of $4.4 million and $10.1 million for the three and nine months ended September 30, 2020, respectively. Our accumulated deficit as of September 30, 2020 was $101.8 million, and we expect to continue to incur substantial losses in future periods. We anticipate that our operating expenses will increase substantially as we continue to advance the development of TSC, including any costs related to:

- our ongoing 100-303 COVID Trial and our other Planned Studies;

- any additional studies we may undertake, including other preclinical and clinical studies to support the filing of any new drug application with the FDA with respect to TSC;

- other research, development and manufacturing activities designed to develop and optimize products and dose forms for which we may obtain regulatory approval;

- the maintenance, expansion, and protection our global intellectual property portfolio;

- the hiring of additional clinical, manufacturing, scientific, sales or other personnel;

- other operational, financial and management information systems and personnel.

We intend to use our existing cash and cash equivalents for working capital and to fund the research and development of TSC, including our Planned Studies. We believe that our cash and cash equivalents as of September 30, 2020, will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2022.

To date, we have funded our operations and short-term liquidity needs primarily through the issuance and sale of common stock, warrants, convertible debt, and convertible preferred stock. For example, in May 2020, we completed an offering of 11,428,572 shares of our common stock for a purchase price of $1.05 per share for net proceeds of $10.3 million after deducting commissions, discounts and other offering costs. Additionally, during the nine months ended September 30, 2020, warrants to purchase 19,106,504 shares of our common stock were exercised for proceeds of $8.0 million. We expect to continue funding our operations through similar means for the foreseeable future, assuming the availability of additional capital, though we may enter into strategic partnerships or other alternative transactions in order to fund our ongoing capital requirements.

Cash Flows

The following table sets forth our cash flows for the nine months ended September 30, 2020 and 2019:

	Nine Months Ended September 30,	
	2020	**2019**
Net cash (used in) provided by:		
Operating activities	$ (10,158,041)	$ (7,420,352)
Financing activities	17,890,875	5,568,950
Net increase (decrease) in cash and cash equivalents	$ 7,732,834	$ (1,851,402)

Operating Activities

Cash flows from operating activities represent our sources and uses of cash related to all of our activities other than financing activities and investing activities. For the nine months ended September 30, 2020, our net cash used in operating activities increased by $2.8 million from the corresponding prior year period, from $7.4 million to $10.2 million.

Net cash used in operating activities of $10.2 million during the nine months ended September 30, 2020 was primarily attributable to our net loss of $10.1 million and our change in deferred income taxes of $1.7 million. These amounts were partially offset by a net change in operating assets and liabilities of $1.4 million, $0.6 million in stock-based compensation expense, and $0.1 million in depreciation expense. The net change in our operating assets and liabilities was primarily attributable to an increase in accounts payable and accrued expenses and was slightly offset by an increase in our prepaid expenses, deposits and other current assets.

Net cash used in operating activities of $7.4 million during the nine months ended September 30, 2019 was primarily attributable to our net loss of $8.0 million and our change in deferred income taxes of $0.5 million. These amounts were partially offset by our net change in operating assets and liabilities of $0.7 million, $0.4 million in stock-based compensation expense, and $0.1 million in depreciation expense. The net change in our operating assets and liabilities was primarily attributable to a decrease in our prepaid expenses, deposits and other current assets and an increase in accounts payable.

Investing Activities

Cash flows from investing activities represent our sources and uses of cash from our investments, including purchases and sales of equipment and other assets. During each of the nine months ended September 30, 2020 and 2019, we had no cash flows from investing activities.

Financing Activities

Cash flows from financing activities represent our sources and uses of cash from investors and banks. For the nine months ended September 30, 2020, our net cash provided by financing activities increased by $12.3 million from the corresponding prior year period, from $5.6 million to $17.9 million.

Net cash provided by financing activities of $17.9 million during the nine months ended September 30, 2020, was primarily attributable to $10.8 million in gross proceeds received in connection with the May 2020 Offering and $8.0 million in gross proceeds received in connection with the exercise of previously outstanding warrants to purchase common stock. These cash inflows were offset in part by the payment of $1.0 million in financing costs.

Net cash provided by financing activities of $5.6 million during the nine months ended September 30, 2019, was primarily attributable to $5.7 million in proceeds received in connection with the May 2019 Offering, offset in part by payments of approximately $0.2 million for related financing costs.

Capital Requirements

Our operations have consumed substantial amounts of cash since inception and we expect to continue to incur substantial expenses and generate significant operating losses as we continue to pursue our business strategy of developing our lead product candidate, TSC. As of September 30, 2020, most of our cash resources for clinical development were dedicated to the 100-303 COVID Trial and, except as set forth above under *Executive Summary - Developments and Strategy* with respect to our Planned Studies, we have not committed to any other clinical studies as of the date of this Quarterly Report.

While we believe we have adequate cash resources to continue operations into the fourth quarter of 2022, we will need to raise additional funds in order to complete our development of TSC and, as of September 30, 2020, we did not have any credit facilities under which we could borrow funds or any other sources of committed capital. We may seek to raise additional funds through various sources, including equity and debt financings or through strategic collaborations and license agreements. However, we can give no assurances that we will be able to secure additional sources of funds to support our operations or, if such funds are available to us, that any such additional financing will be sufficient to meet our needs or will be on terms acceptable to us. We also can give no assurances that potential delays in our clinical study timelines, due to the impact of the ongoing COVID-19 pandemic or otherwise, will not increase the anticipated cost of completing our planned clinical studies or any of other clinical studies we may commence in the future, and this risk may increase if general economic and market conditions deteriorate in the future. If we are unable to obtain additional financing when needed, we may need to terminate, significantly modify, or delay the development of our product candidates and our operations more generally, or we may need to obtain funds through collaborators or other sources that require us to relinquish rights to our product candidates or technologies that we might otherwise prefer to retain or seek to develop or commercialize independently. If we are unable to raise sufficient additional capital to meet our needs and are forced to terminate our operations, investors may experience a complete loss of their investment.

To the extent that we raise additional capital through the issuance and sale of our common stock, the interests of our current stockholders may be diluted. In addition, we have in the past issued warrants to purchase shares of common stock which, if exercised by the holders thereof, will dilute the interests of our current stockholders. If we issue preferred stock or convertible debt securities, it could affect the rights of our common stockholders which could reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock or convertible debt securities may include voting rights, preferences as to dividends and liquidation, conversion and redemption rights, sinking fund provisions, and restrictions on our ability to merge with or sell our assets to a third party. If we enter into a debt financing arrangement, if available, such arrangement may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional funds through strategic collaborations in the future, we may have to provide a license or otherwise relinquish valuable rights to our product candidates or other technologies, future revenue streams, or intellectual property.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined by the rules and regulations of the SEC that have or are reasonably likely to have an effect on our financial condition, or any changes thereto, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors. As a result, we are not materially exposed to any financing, liquidity, market, or credit risk that could arise if we had engaged in any such arrangements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a “smaller reporting company” as defined by Item 10 of Regulation S-K promulgated by the SEC under the U.S. Securities Act of 1933, as amended, we are not required to provide the information required by this Item 3.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) that are designed to provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules and forms and that such information is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and we are required to apply our judgment in evaluating the cost-benefit relationship of possible internal controls. Our management evaluated, with the participation of our principal executive officer and principal financial officer, the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered in this report. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of such period to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding disclosure.

Change in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as such term is defined in Exchange Act Rule 13a-15(f) that occurred during the period ended September 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Please refer to Note 7, Commitments and Contingencies in the notes accompanying the unaudited interim consolidated financial statements included in Part I, Item 1 of this Quarterly Report, which is incorporated herein by reference.

ITEM 1A. RISK FACTORS

In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the factors discussed in (i) Part I, Item 1A - "Risk Factors," in the Form 10-K and (ii) Part II, Item 1A - "Risk Factors," in the June 30 Form 10-Q, which could materially affect our business, financial condition or future results.

As of the date of this Quarterly Report, there have been no material changes to our risk factors previously disclosed in the Form 10-K other than as set forth in the June 30 Form 10-Q.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Unregistered Sales of Equity Securities

None.

Issuer Purchases of Equity Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

See attached Exhibit Index.

DIFFUSION PHARMACEUTICALS INC.
QUARTERLY REPORT ON FORM 10-Q
EXHIBIT INDEX

Exhibit No.	Description	Method of Filing
10.1	Separation Agreement, dated as of September 8, 2020, by and between Diffusion Pharmaceuticals Inc. and David G. Kalergis	Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on September 9, 2020
10.2	Employment Agreement, dated as of September 8, 2020, by and between Diffusion Pharmaceuticals Inc. and Robert J. Cobuzzi, Jr.	Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed on September 9, 2020
10.3	Employment Agreement, dated as of September 23, 2020, by and between Diffusion Pharmaceuticals Inc. and William R. Elder	Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on September 25, 2020
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)	Filed herewith
31.2	Certification of principal financial officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)	Filed herewith
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
32.2	Certification of principal financial officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
101	The following materials from Diffusion's quarterly report on Form 10-Q for the quarter ended September 30, 2020 formatted in XBRL (Extensible Business Reporting Language): (i) the Unaudited Consolidated Balance Sheets, (ii) the Unaudited Consolidated Statements of Operations, (iii) the Unaudited Consolidated Statement of Changes in Stockholders' Equity (Deficit), (iv) the Unaudited Consolidated Statements of Cash Flows, and (v) Notes to Unaudited Consolidated Financial Statements	Filed herewith

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, thereunto duly authorized.

Date: November 12, 2020

DIFFUSION PHARMACEUTICALS INC.

By: /s/ Robert J. Cobuzzi, Jr.
Robert J. Cobuzzi, Jr.
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ William Hornung
William Hornung
Chief Financial Officer
(Principal Financial Officer and
Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002 AND SEC RULE 13a-14(a)

I, Robert J. Cobuzzi, Jr., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Diffusion Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2020

/s/ Robert J. Cobuzzi Jr.

Robert J. Cobuzzi Jr.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002 AND SEC RULE 13a-14(a)

I, William Hornung, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Diffusion Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2020

/s/ William Hornung

William Hornung
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Diffusion Pharmaceuticals Inc. (the "Company") for the period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert J. Cobuzzi, Jr. President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Robert J. Cobuzzi, Jr.
Robert J. Cobuzzi, Jr.
President and Chief Executive Officer (Principal Executive Officer)
November 12, 2020

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Diffusion Pharmaceuticals Inc. (the "Company") for the period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, William Hornung, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ William Hornung
William Hornung
Chief Financial Officer (Principal Financial Officer)
November 12, 2020