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 June 30, 2021

☐ **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)

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

Securities registered pursuant to Section 12(g) of the Act:
None

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 August 11, 2021 was 101,903,979 shares.

DIFFUSION PHARMACEUTICALS INC.
FORM 10-Q
JUNE 30, 2021

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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, many of which are explained or defined below:

Term	Definition
2015 Equity Plan	Diffusion Pharmaceuticals Inc. 2015 Equity Incentive Plan, as amended
2017 Tax Act	Tax Cuts and Jobs Act of 2017
401(k) Plan	Diffusion Pharmaceuticals Inc. 401(k) Defined Contribution Plan
Altitude Trial	our planned Phase 1b clinical trial evaluating the effects of TSC on V02 and PaO2 in normal healthy volunteers exposed to conditions that induce hypoxia
Annual Report	our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 16, 2021
ASC	Accounting Standard Codification of the FASB
ASUs	Accounting Standards Updates of the FASB
COVID Trial	our Phase 1b clinical trial evaluating TSC in hospitalized COVID-19 patients, completed in February 2021
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
DLCO	diffusion capacity of lung for carbon monoxide
Exchange Act	Securities Exchange Act of 1934, as amended
FASB	Financial Accounting Standards Board
February 2021 Offering	our public offering and sale of 33,658,538 shares of common stock completed in February 2021
G&A	general and administrative
GAAP	U.S. generally accepted accounting principles
ILD-DLCO Trial	our planned Phase 2a clinical trial evaluating the effects of TSC through the measure of DLCO through the lungs as a surrogate measure of oxygen transfer efficiency in patients with previously diagnosed interstitial lung disease who have a baseline DLCO test that is abnormal
January 2018 Offering	our public offering and sale of 1,131,375 shares of common stock and warrants to purchase up to 1,131,375 shares of common stock completed in January 2018
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 a previously outstanding warrant to purchase up to 5,000,000 shares of common stock at an exercise price of $0.35 per share 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
Nasdaq	Nasdaq Stock Market, LLC
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
Oxygenation Trials	collectively, the TCOM Trial, the Altitude Trial, and the ILD-DLCO Trial
PaO2	partial pressure of blood oxygen
Planned Phase 2 Hypoxia-related Indication Trial	a Phase 2, controlled, clinical outcome study evaluating TSC in an appropriate hypoxia-related indication that we intend to initiate in the first half of 2022
Quarterly Report	this Quarterly Report on Form 10-Q
R&D	research and development
Regulation S-K	Regulation S-K promulgated under the Securities Act
SEC	U.S. Securities and Exchange Commission
Securities Act	Securities Act of 1933, as amended
TCOM Trial	our Phase 1b clinical trial evaluating the effects of TSC on peripheral tissue oxygenation in healthy normal volunteers using a TCOM device, completed in March 2021
TCOM	transcutaneous oxygen measurement
TSC	trans sodium crocetinate
U.S.	United States
VO2	maximal oxygen consumption

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:

- the success and timing of our clinical and preclinical studies, including our ability to enroll subjects in our ongoing and planned 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;
- 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 and the potential for others to infringe upon our intellectual property rights;
- 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, suppliers, and outside consultants, to whom we outsource certain operational, staff and other functions;
- our ability to obtain additional financing in the future and continue as a going concern;
- our estimates regarding expenses, future revenues, capital requirements, and needs for additional financing;
- regulatory developments in the U.S., E.U., and other foreign jurisdictions;
- recently enacted and future legislation related to 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 Affordable Care 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;
- uncertainties related to general economic, political, business, industry, and market conditions, including the ongoing COVID-19 pandemic; and
- other risks and uncertainties, including those discussed under the heading "Risk Factors" in this Annual Report and elsewhere in our other 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 or incorporated by reference 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 risks 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 contains certain trademarks, trade names, and service marks of ours, including "DIFFUSIO$_2$N." 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)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 43,307,573	$ 18,515,595
Prepaid expenses, deposits and other current assets	552,086	260,825
Total current assets	43,859,659	18,776,420
Property and equipment, net	100,996	149,198
Intangible asset	8,639,000	8,639,000
Right of use asset	95,829	149,162
Other assets	15,578	15,771
Total assets	$ 52,711,062	$ 27,729,551
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 749,948	$ 545,844
Accrued expenses and other current liabilities	1,254,790	1,776,470
Current operating lease liability	95,829	113,469
Total current liabilities	2,100,567	2,435,783
Deferred income taxes	443,893	443,893
Noncurrent operating lease liability	—	35,693
Total liabilities	2,544,460	2,915,369
Commitments and Contingencies (Note 7)		
Stockholders' Equity:		
Common stock, $0.001 par value:		
Common stock, $0.001 par value: 1,000,000,000 shares authorized; 101,903,979 and 64,015,441 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	101,904	64,016
Additional paid-in capital	164,395,974	130,659,550
Accumulated deficit	(114,331,276)	(105,909,384)
Total stockholders' equity	50,166,602	24,814,182
Total liabilities and stockholders' equity	$ 52,711,062	$ 27,729,551

See accompanying notes to unaudited interim consolidated financial statements.

Diffusion Pharmaceuticals Inc.
Consolidated Statements of Operations
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 1,972,673	$ 2,173,183	$ 4,889,051	$ 3,707,650
General and administrative	1,836,773	1,458,257	3,580,283	2,852,065
Depreciation	23,755	27,021	48,202	54,041
Loss from operations	3,833,201	3,658,461	8,517,536	6,613,756
Other income:				
Interest income	(55,228)	(25,913)	(95,644)	(60,013)
Loss from operations before income tax benefit	(3,777,973)	(3,632,548)	(8,421,892)	(6,553,743)
Income tax benefit	—	(507,325)	—	(869,705)
Net loss	$ (3,777,973)	$ (3,125,223)	$ (8,421,892)	$ (5,684,038)
Deemed dividend arising from warrant exchange	—	(1,950,378)	—	(1,950,378)
Net loss attributable to common stockholders	$ (3,777,973)	$ (5,075,601)	$ (8,421,892)	$ (7,634,416)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.04)	$ (0.10)	$ (0.09)	$ (0.18)
Weighted average shares outstanding, basic and diluted	101,903,979	51,978,286	92,713,142	43,242,891

See accompanying notes to unaudited interim consolidated financial statements.

Diffusion Pharmaceuticals Inc.
Consolidated Statement of Changes in Stockholders' Equity
Three and Six Months Ended June 30, 2021
(unaudited)

	Stockholders' Equity				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at April 1, 2021	101,903,979	$ 101,904	$ 164,098,694	$ (110,553,303)	$ 53,647,295
Stock-based compensation expense	—	—	297,280	—	297,280
Net loss	—	—	—	(3,777,973)	(3,777,973)
Balance at June 30, 2021	101,903,979	$ 101,904	$ 164,395,974	$ (114,331,276)	$ 50,166,602

	Stockholders' Equity				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at January 1, 2021	64,015,441	$ 64,016	$ 130,659,550	$ (105,909,384)	$ 24,814,182
Sale of common stock and warrants, net of issuance costs	33,658,538	33,658	31,060,644	—	31,094,302
Issuance of common stock upon exercise of warrants	4,230,000	4,230	2,197,220	—	2,201,450
Stock-based compensation expense	—	—	478,560	—	478,560
Net loss	—	—	—	(8,421,892)	(8,421,892)
Balance at June 30, 2021	101,903,979	$ 101,904	$ 164,395,974	$ (114,331,276)	$ 50,166,602

See accompanying notes to unaudited interim consolidated financial statements.

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

	Stockholders' Equity				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at April 1, 2020	34,604,436	$ 34,605	$ 112,149,913	$ (94,282,893)	$ 17,901,625
Sale 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	17,965,290	17,965	7,627,213	—	7,645,178
Stock-based compensation expense	—	—	113,444	—	113,444
Net loss	—	—	—	(3,125,223)	(3,125,223)
Balance at June 30, 2020	63,998,298	$ 63,999	$ 130,220,772	$ (97,408,116)	$ 32,876,655

	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
Sale 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	19,089,361	19,089	7,760,887	—	7,779,976
Stock-based compensation expense	—	—	304,824	—	304,824
Net loss	—	—	—	(5,684,038)	(5,684,038)
June 30, 2020	63,998,298	$ 63,999	$ 130,220,772	$ (97,408,116)	$ 32,876,655

See accompanying notes to unaudited interim consolidated financial statements.

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

	Six Months Ended June 30,	
	2021	**2020**
Operating activities:		
Net loss	$ (8,421,892)	$ (5,684,038)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	48,202	54,041
Stock-based compensation expense	478,560	304,824
Deferred income taxes	—	(869,705)
Changes in operating assets and liabilities:		
Prepaid expenses, deposits and other assets	(291,068)	(604,558)
Accounts payable, accrued expenses and other liabilities	(317,576)	151,411
Net cash used in operating activities	(8,503,774)	(6,648,025)
Cash flows provided by financing activities:		
Proceeds from the sale of common stock and warrants, net of issuance costs	31,094,302	10,827,100
Proceeds from the exercise of common stock warrants	2,201,450	8,038,603
Payment of financing costs	—	(833,428)
Net cash provided by financing activities	33,295,752	18,032,275
Net increase in cash and cash equivalents	24,791,978	11,384,250
Cash and cash equivalents at beginning of period	18,515,595	14,177,349
Cash and cash equivalents at end of period	$ 43,307,573	$ 25,561,599
Supplemental disclosure of non-cash investing and financing activities:		
Offering costs in accounts payable	$ —	$ 148,900

See accompanying notes to unaudited interim 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. In addition to TSC, the Company's product candidate DFN-529, a novel, allosteric PI3K/Akt/mTOR pathway inhibitor, is in early-stage development.

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 drugs 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 these product candidates and/or failure of them at any stage of the drug approval process will materially affect the Company's financial condition and future operations. The Company expects that its existing cash and cash equivalents as of June 30, 2021 will enable it to fund its operating expenses and capital expenditure requirements, including expected costs related to the planned Oxygenation Trials and the Planned Hypoxia-related Indication Trial(s), through 2023.

3. Basis of Presentation and Summary of Significant Accounting Policies

The Summary of Significant Accounting Policies included in the Company's Annual Report for the year ended December 31, 2020 have not materially changed.

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 promulgated by 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 June 30, 2021, results of operations for the three and six months ended June 30, 2021 and 2020 and cash flows for the six months ended June 30, 2021 and 2020. Operating results for the six months ended June 30, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021. The unaudited interim consolidated financial statements presented herein do not contain the required disclosures under GAAP for annual financial statements. The accompanying unaudited consolidated interim financial statements should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended December 31, 2020 filed with the SEC as part of the Company's Annual Report on Form 10-K on March 16, 2021.

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 the Company's estimates and assumptions used in the preparation of the unaudited interim consolidated financial statements for the three and six months ended June 30, 2021. However, the full extent to which the ongoing COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, including sales, expenses, reserves and allowances, clinical trials, 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 the Company's 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. The Company's future assessment of the magnitude and duration of COVID-19, as well as other factors, could result in material impacts to the Company's consolidated financial statements in future reporting periods.

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, including cash equivalents and accounts payable approximate fair value due to the short-term nature of those instruments.

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 six months ended June 30, 2021 and 2020.

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 June 30,	
	2021	**2020**
Common stock warrants	6,499,469	9,117,209
Stock options	3,052,887	1,427,829
Unvested restricted stock awards	153,000	98,100
	9,705,356	10,643,138

Recently Adopted Accounting Pronouncements

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): *Simplifying the Accounting for Income Taxes*. This guidance applies to all entities and aims to reduce the complexity of tax accounting standards while enhancing reporting disclosures. This guidance was effective for fiscal years beginning after December 15, 2020 and interim periods therein. The Company adopted ASU No. 2019-12 in the first quarter of 2021 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:

	June 30, 2021	**December 31, 2020**
Accrued payroll and payroll related expenses	542,598	653,899
Accrued professional fees	61,306	31,809
Accrued clinical studies expenses	634,870	1,055,398
Other accrued expenses	16,016	35,364
Total	$ 1,254,790	$ 1,776,470

5. Stockholders' Equity and Common Stock Warrants

February 2021 Common Stock Offering

In February 2021, the Company completed the February 2021 Offering in which it offered and sold 33,658,538 shares of its common stock in an underwritten, public offering for a purchase price to the public of $1.025 per share, inclusive of shares offered and sold pursuant to the exercise-in-full by the underwriter of its 30-day option to purchase additional shares. The February 2021 Offering resulted in aggregate net proceeds to the Company of $31.1 million, after deducting underwriting commissions, discounts, and expenses but prior to deducting other offering costs. In addition, at the closings of the February 2021 Offering, the Company issued to designees of the underwriter of the transaction warrants to purchase up to an aggregate of 1,682,927 shares of common stock to designees. The underwriter warrants have an exercise price of $1.28125 per share and a term of five years from the date of issuance.

Common Stock Warrants

As of June 30, 2021, 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 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	May and December 2024
Common stock warrants issued related to the November 2019 Offering	213,570	$0.35	November 2024
Common stock warrants issued related to the December 2019 Offering	313,339	$0.4335 - $0.6981	December 2024 and June 2025
Common stock warrants issued related to the May 2020 Offering	571,429	$1.31	March 2025
Common stock warrants issued related to May 2020 Investor Warrant Exercise	250,000	$0.5938	November 2025
Common stock warrants issued related to the February 2021 Offering	1,682,927	$1.28	February 2026
	6,499,469		

During the six months ended June 30, 2021, 53,570 warrants expired and 4,230,000 warrants were exercised for aggregate proceeds of approximately $2.2 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, 2,560,618 shares were added to the reserve as of January 1, 2021, 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 June 30, 2021, there were 1,181,629 shares available for future issuance under the 2015 Equity Plan.

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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development	$ 59,567	$ 91,896	$ 92,567	$ 188,426
General and administrative	237,713	21,548	385,993	116,398
Total stock-based compensation expense	$ 297,280	$ 113,444	$ 478,560	$ 304,824

The following table summarizes the activity related to all stock option grants for the six months ended June 30, 2021:

	Number of Options	Weighted average exercise price per share	Weighted average remaining contractual life (in years)	Aggregate intrinsic value
Balance at January 1, 2021	2,240,204	$ 8.28		
Granted	924,115	1.10		
Forfeited	(111,432)	0.91		
Outstanding at June 30, 2021	3,052,887	$ 6.37	8.8	$ 219,228
Exercisable at June 30, 2021	1,563,224	$ 11.54	8.1	$ 195,252
Vested and expected to vest at June 30, 2021	3,052,887	$ 6.37	8.8	$ 219,228

The weighted average grant date fair value of stock option awards granted during the six months ended June 30, 2021 was $1.05. The total fair value of options vested during the three months ended June 30, 2021 and 2020 was $0.1 million and $0.1 million, respectively. The total fair value of options vested during the six months June 30, 2021 and 2020 was $0.3 million and $0.3 million, respectively. No options were exercised during any of the periods presented. At June 30, 2021, there was $1.1 million of unrecognized compensation expense that will be recognized over a weighted-average period of 2.22 years. During the six months ended June 30, 2021, the Company granted 385,267 performance-based stock options with an exercise price of $1.11 per share, subject to vesting based on the satisfaction of specified performance criteria. Compensation expense for the performance-based awards is recorded over the estimated service period for each milestone when the performance conditions are deemed probable of achievement. The Company recorded stock-based compensation expense of approximately $0.1 million and $0.2 million during the three and six months ended June 30, 2021, for service-based awards and performance conditions deemed probable of achievement and/or achieved.

Options granted were valued using the Black-Scholes option-pricing model and the weighted average assumptions used to value the options granted during the six months ended June 30, 2021 and 2020 were as follows:

	2021	2020
Expected term (in years)	10	5.59
Risk-free interest rate	1.5%	1.3%
Expected volatility	124.5%	115.1%
Dividend yield	—%	—%

Restricted Stock Awards

As of the six months ended June 30, 2021, the Company has granted an aggregate of 153,000 restricted stock awards to members of the board of directors of the Company. The shares begin to vest 18 months after the respective grant date. The Company recognized approximately $5,000 and $4,000 in expense related to these awards during the three months ended June 30, 2021 and 2020, respectively. The Company recognized approximately $10,000 and $8,000 in expense related to these awards during the six months ended June 30, 2021 and 2020, respectively. At June 30, 2021, there was approximately $72,000 of unrecognized compensation cost that will be recognized over a weighted average period of 1.96 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 June 30, 2021, has a remaining lease term of approximately 0.8 years. 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 right-of-use asset and operating lease liability as of June 30, 2021.

Rent expense related to the Company's operating lease for the three months ended June 30, 2021 and 2020 was approximately $29,000 and $30,000, respectively. Rent expense for the six months ended June 30, 2021 and 2020 was approximately $60,000. Future minimum rental payments under the Company's non-cancelable operating lease at June 30, 2021 were as follows:

	Rental Commitments
2021	69,365
2022	39,735
Total	109,100
Less: imputed interest	(13,271)
	$ 95,829

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 $24,000 and $14,000 for the three months ended June 30, 2021 and 2020, respectively and matched approximately $40,000 and $31,000 during the six months ended June 30, 2021 and 2020, 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 August 16, 2021. The Company believes this matter is without merit and intends to defend the arbitration vigorously. However, at this 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, results of operations and cash flows.

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

You should read the following discussion of our financial condition and results of operations together with the unaudited interim consolidated financial statements and the notes thereto included elsewhere in this report and other financial information included in this report. The following discussion may contain predictions, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under "*Part I — Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—Special Note Regarding Forward-Looking Statements*" in this report and under "*Part I — Item 1A. Risk Factors*" in our Annual Report and under "*Part II—Other Information – Item 1A. Risk Factors*" *in our Quarterly Report* on Form 10-Q for the quarterly period ended March 31, 2021. These risks could cause our actual results to differ materially from any future performance suggested below.

Diffusion Pharmaceuticals: Enhancing Oxygen, Fueling Life

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. In addition to TSC, our product candidate DFN-529, a novel, allosteric PI3K/Akt/mTOR pathway inhibitor, is in early-stage development.

TSC Second Quarter Development Update

In May 2021, we announced final results of our COVID Trial, which we initiated in 2020 due to a belief in the potential of TSC to improve low tissue oxygen levels, a common complication of COVID-19. The study's primary objective was to evaluate the safety and tolerability of TSC administered on a more frequent dosing regimen not previously tested in a clinical trial setting, and the secondary and exploratory endpoints for the trial included time to improvement in World Health Organization ordinal scale by day 7 and through day 29, time on oxygen supplementation, and hospital length of stay. Although the study was not designed or powered to evaluate efficacy, the study's external safety monitoring committee observed that patients receiving the 1.5 mg/kg dose had improved outcomes in these secondary and exploratory endpoints compared to those receiving lower doses.

In June 2021, the Company reported a positive trend in oxygenation from the TCOM Trial. The TCOM Trial was designed to evaluate the effect of TSC versus placebo on peripheral tissue oxygenation in healthy normal volunteers. Topline results based upon analyses of primary endpoint data indicated, as compared to placebo, a positive dose-response trend in TCOM readings after TSC administration that persisted through the measurement period with no evidence of hyperoxygenation. TSC was also safe and well-tolerated at all doses tested.

The TCOM Trial was a randomized, double-blind, placebo controlled, pharmacokinetic and pharmacodynamic study of TSC that enrolled and dosed 30 healthy volunteers. Trial participants were randomized into one of six subgroups, each of which received a single intravenous dose of placebo or one of five different doses of TSC ranging from 0.5 mg/kg to 2.5 mg/kg. All trial participants received supplemental oxygen during equivalent, one-hour monitoring periods before and after TSC or placebo was administered while subjects were continuously monitored with TCOM sensors applied to their lower extremity. The primary endpoint evaluated the relative change in TCOM readings from baseline after TSC administration compared to placebo.

TSC Development Plans for 2021 and 2022

We remain focused on our over-arching clinical development plan announced in November 2020 designed to accomplish two principal strategic objectives: (1) Optimize the clinical dose and dosing frequency for TSC; and (2) Evaluate TSC in clinical models designed to establish proof of concept for improvement in oxygenation. As part of this plan, we are currently focused on the execution of our three, short-term Oxygenation Trials to explore the relationship between TSC dose and change in oxygenation. These studies are being conducted in the U.S. during 2021in and will be funded with cash-on-hand.

The positive trend observed in the TCOM Trial is being used to guide dose selection in the additional Oxygenation Trials planned for the latter part of 2021 -- the Altitude Trial, followed by the ILD-DLCO Trial.

Altitude Trial: TSC's Effects Under Induced Hypoxic Conditions

This trial will be a double-blind, randomized, placebo-controlled study which will evaluate the effects of TSC on maximal oxygen consumption, or VO2, and partial pressure of blood oxygen, or PaO2, in normal healthy volunteers subjected to incremental levels of physical exertion while exposed to hypoxic and hypobaric conditions (i.e., simulated altitude). The study is designed to evaluate the effect of TSC on oxygen availability and consumption compared to placebo. We anticipate initiating and completing the Altitude Trial in the fourth quarter of 2021, with topline results available within one to two months of study completion.

ILD-DLCO Trial: TSC's Effects on Oxygen Transfer Efficiency

This trial will be a double-blind, randomized, placebo-controlled study which will evaluate the effects of TSC on the diffusion of carbon monoxide through the lungs, or DLCO, in patients with previously diagnosed interstitial lung disease who have an abnormal baseline DLCO test result. DLCO will act as a surrogate measure of oxygen transfer efficiency, or uptake, from the alveoli of the lungs, through the plasma, and onto hemoglobin within red blood cells. The study will be statistically powered to evaluate the difference in effect of TSC on improvement in DLCO, as well as distance covered in a standard six-minute walk test.

We now anticipate initiating the ILD-DLCO Trial in the late fourth quarter of 2021 and completing the trial in the first quarter of 2022, with topline results available within one to two months of study completion.

Planned Phase 2 Hypoxia-related Indication Trial

We expect to announce in the fourth quarter of 2021 the initial indication in which TSC will be studied to support the planned pathway for regulatory approval and to initiate the Planned Phase 2 Hypoxia-related Indication Trial during the first half of 2022, funded with cash-on-hand.

Organizational Update

During the second quarter, we enhanced our operating team with the addition of new employees in the areas of administration, quality assurance, clinical operations, and finance. In addition, in connection with our annual meeting of stockholders in June 2021, Jane Hollingsworth was elected as the new Chair of our board of directors and Diana Lanchoney, M.D. and Eric Francois were newly elected to our board of directors.

We believe the totality of these organizational additions has already had a significant, positive impact on our ability to develop, implement and execute on our corporate strategy and development plans and position us well to build shareholder value through our next stage of growth.

Financial Summary

As of June 30, 2021, we had cash and cash equivalents of $43.3 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 $3.8 million and $8.4 million for the three and six months ended June 30, 2021, respectively. Our accumulated deficit as of June 30, 2021 was $114.3 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 and planned clinical trials, including the Oxygenation Trials and our Planned Hypoxia-related Indication Trial(s);
- any additional studies we may undertake, including other preclinical and clinical studies to support the filing of any NDA with the FDA;
- other research, development, and manufacturing activities designed to develop and optimize formulation, manufacturing processes, dosage, dose forms, and other characteristics prior to regulatory approval;
- the maintenance, expansion, and protection our global intellectual property portfolio;
- the hiring of additional clinical, manufacturing, scientific, sales, or other personnel; and
- investments in operational, financial, and management information systems.

We intend to use our existing cash and cash equivalents for working capital and to fund the research and development of TSC, including the Altitude Trial and the ILD-DLCO Trial. We expect that our cash and cash equivalents as of June 30, 2021 will enable us to fund our operating expenses and capital expenditure requirements, including expected costs related to the planned Oxygenation Trials and our Planned Hypoxia-related Indication Trial(s) through 2023.

Financial Operations Overview

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 Expense

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 is 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 50.0% 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 the year ended December 31, 2020 or during the three or six months ended June 30, 2021 give rise to any further limitations.

Results of Operations for Three Months Ended June 30, 2021 Compared to Three Months Ended June 30, 2020

The following table sets forth our results of operations for the three months ended June 30, 2021 and 2020.

	Three Months Ended June 30, 2021		
	2021	**2020**	**Change**
Operating expenses:			
Research and development	$ 1,972,673	$ 2,173,183	$ (200,510)
General and administrative	1,836,773	1,458,257	378,516
Depreciation	23,755	27,021	(3,266)
Loss from operations	3,833,201	3,658,461	174,740
Other income:			
Interest income	(55,228)	(25,913)	(29,315)
Loss from operations before income tax benefit	(3,777,973)	(3,632,548)	(145,425)
Income tax benefit	—	(507,325)	507,325
Net loss	$ (3,777,973)	$ (3,125,223)	$ (652,750)

We recognized approximately $2.0 million in R&D expenses during the three months ended June 30, 2021 compared to approximately $2.2 million during the three months ended June 30, 2020. This decrease was attributable to $0.7 million related to the wind-down of our trial evaluating TSC in the treatment of glioblastoma multiforme brain cancer. Additionally, costs related to our COVID Trial decreased by $0.2 million during the three months ended June 30, 2021. These decreases were offset by increases of $0.3 million in salaries and wages, increases of $0.2 million for costs related to our TCOM trial, which was initiated and completed in March 2021, and increases of $0.2 million in other research and development expenses.

G&A expenses were $1.8 million during the three months ended June 30, 2021 compared to $1.5 million during the three months ended June 30, 2020. The increase in G&A expenses was primarily due to a $0.3 million increase in salaries, wages and stock-based compensation expenses, including additional amounts related to increased headcount and costs associated with the separation of former executives which will not recur in future years. Additionally, insurance and other general and administrative expenses increased by $0.1 million during the period. These increases were offset by a decrease of $0.1 million in professional service fees.

We recognized an income tax benefit of $0.5 million during the three months ended June 30, 2020 to reflect the utilization of indefinite deferred tax liabilities as a source of income against indefinite lived portions of our deferred tax assets. Prior to 2021, we recognized the full income tax benefit allowed by the 2017 Tax Act to utilize indefinite deferred tax liabilities as a source of income against indefinite lived portions of our deferred tax assets. No additional benefit was recognized during the three months ended June 30, 2021 as the benefit was fully realized in prior periods.

Results of Operations for Six Months Ended June 30, 2021 Compared to Six Months Ended June 30, 2020

The following table sets forth our results of operations for the six months ended June 30, 2021 and 2020.

	Six Months Ended June 30,		
	2021	**2020**	**Change**
Operating expenses:			
Research and development	$ 4,889,051	$ 3,707,650	$ 1,181,401
General and administrative	3,580,283	2,852,065	728,218
Depreciation	48,202	54,041	(5,839)
Loss from operations	8,517,536	6,613,756	1,903,780
Other income:			
Interest income	(95,644)	(60,013)	(35,631)
Loss from operations before income tax benefit	(8,421,892)	(6,553,743)	(1,868,149)
Income tax benefit	—	(869,705)	869,705
Net loss	$ (8,421,892)	$ (5,684,038)	$ (2,737,854)

We recognized $4.9 million in R&D expenses during the six months ended June 30, 2021 compared to $3.7 million during the six months ended June 30, 2020. A significant portion of this increase was attributable to $0.8 million of costs related to our TCOM trial, which was initiated and completed in March 2021, and $0.5 million of costs incurred related to our COVID Trial, which was initiated in September 2020 and completed in February 2021. Manufacturing costs also increased by $0.6 million to support these trials. Additionally, salaries and wages increased by $0.5 million. These increases were offset by decreases of $0.8 million and $0.3 million related to the wind-down of our trials evaluating TSC in the treatment of glioblastma multiforme brain cancer and stroke, respectively.

G&A expenses were $3.6 million during the six months ended June 30, 2021 compared to $2.9 million during the six months ended June 30, 2020. The increase in G&A expense was primarily due to a $0.6 million increase in salaries, wages and stock-based compensation expense, including additional amounts related to increased headcount and costs associated with the separation of former executives which will not recur in future years. Additionally, insurance and other general and administrative expenses increased by $0.1 million during the period.

We recognized an income tax benefit of $0.9 million during the six months ended 2020, to reflect the utilization of indefinite deferred tax liabilities as a source of income against indefinite lived portions of our deferred tax assets. Prior to 2021, we recognized the full income tax benefit allowed by the 2017 Tax Act to utilize indefinite deferred tax liabilities as a source of income against indefinite lived portions of our deferred tax assets. No additional benefit was recognized during the six months ended June 30, 2021 as the benefit was fully realized in prior periods.

Liquidity and Capital Resources

Working Capital

To date, we have funded our operations primarily through the sale and issuance of preferred stock, common stock and convertible promissory notes. As of June 30, 2021, we had $43.3 million in cash and cash equivalents, working capital of $41.8 million and an accumulated deficit of $114.3 million. We expect to continue to incur net losses for the foreseeable future. We intend to use our existing cash and cash equivalents to fund our working capital and research and development of our product candidates.

Cash Flows

The following table sets forth our cash flows for the six months ended June 30, 2021 and 2020:

	Six Months Ended June 30,	
Net cash (used in) provided by:	**2021**	**2020**
Operating activities	$ (8,503,774)	$ (6,648,025)
Financing activities	33,295,752	18,032,275
Net increase in cash and cash equivalents	$ 24,791,978	$ 11,384,250

Operating Activities

Net cash used in operating activities of $8.5 million during the six months ended June 30, 2021 was primarily attributable to our net loss of $8.4 million and our net change in operating assets and liabilities of $0.6 million. This amount was offset by $0.5 million in stock-based compensation expense and depreciation expense. The net change in our operating assets and liabilities is primarily attributable to a decrease in our accrued expenses and other current liabilities due to the timing of our payments to our vendors and employees as well as an increase in our prepaid expenses, deposits and other current assets.

Net cash used in operating activities of $6.6 million during the six months ended June 30, 2020 was primarily attributable to our net loss of $5.7 million, our deferred income taxes of $0.9 million and our net change in operating assets and liabilities of $0.5 million. These amounts were offset by $0.3 million in stock-based compensation expense, and $0.1 million in depreciation expense. The net change in our operating assets and liabilities is primarily attributable to an increase in our prepaid expenses, deposits and other current assets, which was slightly offset by an increase in accounts payable.

Financing Activities

Net cash provided by financing activities was $33.3 million during the six months ended June 30, 2021, which was attributable to net proceeds of $31.1 million received from the sale of our common stock and $2.2 million in proceeds received from the exercise of common stock warrants.

Net cash provided by financing activities was $18.0 million during the six months ended June 30, 2020, which was attributable to the $10.8 million in gross proceeds received upon the sale of our common stock and warrants plus $8.0 million in gross proceeds received from the exercise of common stock warrants. These cash inflows were offset in part by the payment of $0.8 million in financing costs.

Capital Requirements

We expect to continue to incur substantial expenses and generate significant operating losses as we continue to pursue our business strategy of developing TSC. Our operations have consumed substantial amounts of cash since inception and we expect to continue to spend substantial amounts of cash to advance the clinical development of TSC, DFN-529, and our other product candidates. As of the date of this Quarterly Report, most of our cash resources for clinical development are dedicated to our Oxygenation Trials and our Planned Hypoxia-related Indication Trial. While we believe we have adequate cash resources to continue operations through 2023, we anticipate that we will need additional funding in order to complete development of TSC which, if available, could be obtained through additional capital raising transactions, entry into strategic partnerships or collaborations, or alternative financing arrangements.

As of June 30, 2021, we did not have any credit facilities in place under which we could borrow funds or any other sources of committed capital. In the future, we may seek to raise additional funds through various sources. 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 such additional financing will be sufficient to meet our needs or be on terms acceptable to us. This risk may increase if economic and market conditions deteriorate. If we are unable to obtain additional financing when needed, we may need to terminate, significantly modify, or delay the development of TSC or our product candidates, or we may need to obtain funds through collaborations or otherwise on terms that may require us to relinquish rights to our technologies or product candidates that we might otherwise seek to develop or commercialize independently. If we are unable to raise adequate additional capital as and when required in the future, we could be forced to cease development activities and terminate our operations, and you could experience a complete loss of your investment.

To the extent that we raise additional capital in the future through the sale of our common stock or securities convertible or exchangeable for common stock such as common stock warrants, convertible preferred stock, or convertible debt instruments, the interests of our current stockholders may be diluted or otherwise impacted. 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. Debt financing, if available, 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.

Critical Accounting Policies

The Critical Accounting Policies included in our Form 10-K for the year ended December 31, 2020, filed with the SEC pursuant to Section 13 or 15(d) under the Securities Act on March 16, 2021 have not changed.

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 quarter ended June 30, 2021 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

As of the date of this Quarterly Report, there have been no material changes to our risk factors previously disclosed in our Annual Report and our subsequent quarterly reports on 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
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 June 30, 2021 formatted in Inline 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
104	Cover Page Interactive Data File (embedded within the Inline XBRL and contained in Exhibit 101)	

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: August 11, 2021

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., Ph.D., 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: August 11, 2021

/s/ Robert J. Cobuzzi, Jr., Ph.D.
Robert J. Cobuzzi, Jr., Ph.D.
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 K. 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: August 11, 2021

/s/ William K. Hornung
William K. Hornung
Chief Financial Officer
(Principal Financial and 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 quarter ended June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert J. Cobuzzi, Jr., Ph.D, 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; 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., Ph.D
Robert J. Cobuzzi, Jr., Ph.D
President and Chief Executive Officer
August 11, 2021

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 quarter ended June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, William K. 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; 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 K. Hornung
William K. Hornung
Chief Financial Officer (Principal Financial and Accounting Officer)
August 11, 2021