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 March 31, 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 May 8, 2020 was 45,989,932 shares.

DIFFUSION PHARMACEUTICALS INC.
FORM 10-Q
MARCH 31, 2020

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Unless the context otherwise requires, in this report, references to the "Company," "we," "our" or "us" refer to Diffusion Pharmaceuticals Inc. and its subsidiaries and references to "common stock" refer to the common stock, par value $0.001 per share, of the Company.

This report contains the following trademarks, trade names and service marks of ours: Diffusion. All other trade names, trademarks and service marks appearing in this quarterly report on Form 10-Q are the property of their respective owners. We have assumed that the reader understands that all such terms are source-indicating. Accordingly, such terms appear without the trade name, trademark or service mark notice 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)

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 10,828,228	$ 14,177,349
Prepaid expenses, deposits and other current assets	888,234	472,464
Total current assets	11,716,462	14,649,813
Property and equipment, net	225,346	252,366
Intangible asset	8,639,000	8,639,000
Right of use asset	223,757	247,043
Other assets	252,561	322,301
Total assets	$ 21,057,126	$ 24,110,523
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	655,298	1,251,412
Accrued expenses and other current liabilities	519,552	358,532
Current operating lease liability	111,970	111,477
Total current liabilities	1,286,820	1,721,421
Deferred income taxes	1,756,894	2,119,274
Noncurrent operating lease liability	111,787	135,566
Total liabilities	3,155,501	3,976,261
Commitments and Contingencies (Note 7)		
Stockholders' Equity:		
Common stock, $0.001 par value:		
1,000,000,000 shares authorized; 34,604,436 and 33,480,365 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	34,605	33,481
Additional paid-in capital	112,149,913	111,824,859
Accumulated deficit	(94,282,893)	(91,724,078)
Total stockholders' equity	17,901,625	20,134,262
Total liabilities and stockholders' equity	$ 21,057,126	$ 24,110,523

See accompanying notes to unaudited interim consolidated financial statements.

Diffusion Pharmaceuticals Inc.
Consolidated Statements of Operations
(unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 1,534,467	$ 1,699,845
General and administrative	1,393,808	1,200,728
Depreciation	27,020	18,272
Loss from operations	2,955,295	2,918,845
Other income:		
Interest income	(34,100)	(20,684)
Loss from operations before income tax benefit	(2,921,195)	(2,898,161)
Income tax benefit	(362,380)	(150,352)
Net loss	$ (2,558,815)	$ (2,747,809)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.07)	$ (0.81)
Weighted average shares outstanding, basic and diluted	34,507,496	3,376,230

See accompanying notes to unaudited interim consolidated financial statements.

Diffusion Pharmaceuticals Inc.
Consolidated Statements of Changes in Stockholders' Equity
Three Months Ended March 31, 2019 and 2020
(unaudited)

	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
Stock-based compensation expense	—	—	91,204	—	91,204
Net loss	—	—	—	(2,747,809)	(2,747,809)
Balance at March 31, 2019	3,376,230	$ 3,377	$ 95,624,085	$ (82,672,508)	$ 12,954,954

	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 upon exercise of warrants, net	1,124,071	1,124	133,674	—	134,798
Stock-based compensation expense	—	—	191,380	—	191,380
Net loss	—	—	—	(2,558,815)	(2,558,815)
Balance at March 31, 2020	34,604,436	$ 34,605	$ 112,149,913	$ (94,282,893)	$ 17,901,625

See accompanying notes to unaudited interim consolidated financial statements.

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

	Three Months Ended March 31,	
	2020	**2019**
Operating activities:		
Net loss	$ (2,558,815)	$ (2,747,809)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	27,020	18,272
Stock-based compensation expense	191,380	91,204
Change in deferred income taxes	(362,380)	(150,352)
Changes in operating assets and liabilities:		
Prepaid expenses, deposits and other assets	(346,030)	(119,644)
Accounts payable, accrued expenses and other liabilities	(455,489)	250,871
Net cash used in operating activities	(3,504,314)	(2,657,458)
Cash flows provided by financing activities:		
Proceeds received from the exercise of common stock warrants	393,425	—
Payment of financing costs that were previously classified in accounts payable	(238,232)	—
Net cash provided by financing activities	155,193	—
Net decrease in cash and cash equivalents	(3,349,121)	(2,657,458)
Cash and cash equivalents at beginning of period	14,177,349	7,991,172
Cash and cash equivalents at end of period	$ 10,828,228	$ 5,333,714
Supplemental disclosure of non-cash investing and financing activities:		
Offering costs in accounts payable and accrued expenses	$ 258,627	$ 28,549
Operating lease right of use asset and current and noncurrent liability	$ —	$ 334,205

See accompanying notes to unaudited interim consolidated financial statements.

1. Organization and Description of Business

Diffusion Pharmaceuticals Inc. (“Diffusion” or the “Company”), a Delaware corporation, is a clinical stage biotechnology company developing new treatments for life-threatening conditions by improving the body’s ability to bring oxygen to the areas where it is needed most. The Company is developing its lead product candidate, transcrocetinate sodium, also known as trans sodium crocetinate (“TSC”), for use in those life-threatening conditions in which cellular oxygen deprivation (“hypoxia”) is the basis for significant unmet medical needs. TSC is designed to safely and selectively target and re-oxygenate the micro-environment of hypoxic cells, and can potentially be used in many indications, including stroke, oncology and cardiovascular disease. In stroke, TSC helps promote the diffusion of oxygen into those brain cells in which oxygen-deprivation causes neuronal death resulting in patient mortality or morbidity. In cancer, TSC re-oxygenates treatment-resistant cancerous tissue, making the cancer cells up to three times more susceptible to the therapeutic effects of standard-of-care radiation therapy and chemotherapy. In addition to the TSC programs, the Company is exploring alternatives regarding how best to capitalize upon our product candidate RES-529, which may include possible out-licensing and other options. RES-529 is a novel PI3K/Akt/mTOR pathway inhibitor which has completed two Phase 1 clinical trials for age-related macular degeneration and is in preclinical development in oncology, specifically GBM. RES-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.

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 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 currently 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 believes its cash and cash equivalents as of March 31, 2020, along with the $4.8 million in proceeds received during the second quarter of 2020 related to warrant exercises, are sufficient to fund operations into the third quarter of 2021.

3. Basis of Presentation and Summary of Significant Accounting Policies

The Summary of Significant Accounting Policies included in the Company's Form 10-K for the year ended December 31, 2019, filed with the Securities and Exchange Commission on March 17, 2020, 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 U.S. generally accepted accounting principles ("GAAP") for interim financial information as found in the Accounting Standard Codification ("ASC") and Accounting Standards Updates ("ASUs") of the Financial Accounting Standards Board ("FASB"), and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (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 March 31, 2020, and its results of operations and cash flows for the three months ended March 31, 2020 and 2019. Operating results for the three months ended March 31, 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. The accompanying unaudited interim consolidated 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, 2019 filed with the SEC on Form 10-K on March 17, 2020.

Use of Estimates

The preparation of the 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 full extent to which the COVID-19 pandemic will directly or indirectly impact our 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 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international markets. We have made estimates of the impact of COVID-19 within our financial statements and there may be changes to those estimates in future periods. Due to the uncertainty of factors surrounding the estimates or judgments used in the preparation of the unaudited interim consolidated financial statements, actual results may materially vary from these 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 necessary.

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:

	March 31, 2020		
	(Level 1)	**(Level 2)**	**(Level 3)**
Assets			
Cash equivalents	$ 9,916,053	$ —	$ —

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

Intangible Asset

The Company's 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 RES-529 intangible asset recognized during both the three months ended March 31, 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 as of March 31, 2020 and 2019 have been excluded from the computation of diluted weighted average shares outstanding, as they would be anti-dilutive:

	March 31,	
	2020	**2019**
Common stock warrants	21,261,070	2,087,012
Stock options	1,182,629	256,057
Unvested restricted stock awards	98,100	—
	22,541,799	2,343,069

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. Other Accrued Expenses and Liabilities

Other accrued expenses and liabilities consisted of the following:

	March 31, 2020	**December 31, 2019**
Accrued payroll and payroll related expenses	$ 149,620	$ 182,708
Accrued professional fees	338,627	48,338
Accrued clinical studies expenses	9,100	57,378
Other accrued expenses	22,205	70,108
Total	$ 519,552	$ 358,532

5. Stockholders' Equity and Common Stock Warrants

2019 Common Stock Offerings

In December 2019, the Company completed an offering (the “December 2019 Offering”) of 6,266,787 shares of its common stock and warrants to purchase 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 a registered direct public offering (the “November 2019 Offering”) of 5,104,429 shares of its common stock, and 6,324,143 pre-funded warrants each 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 warrant 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. During the year ended December 31, 2019, 11,091,716 of those warrants were exercised for proceeds of $3.9 million.

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 a registered direct public offering (the “May 2019 Offering”) of 1,317,060 shares of common stock and a private placement of warrants to purchase 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 March 31, 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 common stock offering	1,181,375	$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	11,212,786	$0.35	-	$0.4375	May 2024
Common stock warrants issued related to the December 2019 Offering	6,580,126	$0.4335	-	$0.6981	December 2024 and June 2025
	21,261,070				

During the three months ended March 31, 2020, no warrants expired, and 1,124,071 warrants were exercised at an exercise price of $0.35 per warrant.

6. Stock-Based Compensation

2015 Equity Plan

The Diffusion Pharmaceuticals Inc. 2015 Equity Incentive Plan, as amended (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 March 31, 2020, there were 485,602 shares of common stock 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 March 31,	
	2020	2019
Research and development	$ 96,530	$ 13,596
General and administrative	94,850	77,608
Total stock-based compensation expense	$ 191,380	$ 91,204

The following table summarizes the activity related to all stock option grants for the three months ended March 31, 2020:

	Number of Options	Weighted average exercise price per share	Weighted average remaining contractual life (in years)	Aggregate intrinsic value
Balance at January 1, 2020	309,276	$ 55.78		$ —
Granted	873,500	0.47		
Expired	(147)	142.50		
Outstanding at March 31, 2020	1,182,629	$ 14.91	9.0	$ —
Exercisable at March 31, 2020	560,524	$ 30.60	8.2	$ —

The weighted average grant date fair value of stock option awards granted was $0.36 during the three months ended March 31, 2020. The total fair value of options vested during the three months ended March 31, 2020 and 2019 was $0.2 million and $0.2 million, respectively. No options were exercised during any of the periods presented. At March 31, 2020, there was $0.4 million of unrecognized compensation expense that will be recognized over a weighted-average period of 1.81 years.

Options granted were valued using the Black-Scholes model and assumptions used to value the options granted during the three months ended March 31, 2020 were as follows:

Expected term (in years)	5.70
Risk-free interest rate	1.7%
Expected volatility	113.7%
Dividend yield	—

Restricted Stock Awards

During the three months ended March 31, 2020, the Company granted 98,100 restricted stock awards to a member of the board of directors of the Company. The grant date fair value of each restricted stock award granted during the three months ended March 31, 2020 was $0.51. The shares begin to vest 18 months after the grant date. The Company recognized approximately $4,000 in expense related to this award during the three months ended March 31, 2020 and, at March 31, 2020, there was approximately $46,000 of unrecognized compensation cost that will be recognized over a weighted average period of 2.83 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 December 31, 2019, has a remaining lease term of approximately 2.3 years. 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 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 March 31, 2020.

Rent expense related to the Company's operating lease was approximately $30,000 and $20,000 for the three months ended March 31, 2020 and 2019, respectively. Future minimum rental payments under the Company's non-cancelable operating lease at was as follows as of March 31, 2020:

	Rental Commitments
2020 (remaining)	$ 87,691
2021	118,519
2022	39,735
Total	245,945
Less: imputed interest	(22,188)
Current and noncurrent operating lease liability	$ 223,757

Research and Development Arrangements

In the course of normal business operations, the Company enters into agreements with universities and contract research organizations, or 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 (the "401(k) 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 $17,000 and $18,000 for the three months ended March 31, 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 Company's former Chief Executive Officer 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 has been scheduled for November 2020. The Company believes this matter is without merit and intends to defend the arbitration vigorously. 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.

8. Subsequent Events

In April 2020, the Company announced the pre-IND submission to the U.S. Food and Drug Administration ("FDA") of a planned clinical program using TSC in COVID-19 patients displaying severe respiratory symptoms and low oxygen levels. Under federal regulations, the FDA has up to 60 days to hold an advisory meeting with the Company, but for COVID-19-related submissions, the FDA has announced its intention to significantly shorten this period under its Coronavirus Treatment Acceleration Program. Clinical trial start-up preparations are continuing as the Company awaits the FDA's response.

From April 1, 2020 through May 8, 2020, warrants were exercised to purchase 6,385,496 shares of the Company's common stock for gross proceeds of approximately $2.5 million.

On May 8, 2020, the Company completed a warrant exchange and related private placement (the "Exchange"). In the Exchange, an existing holder of the Company's warrants exercised warrants to purchase 5,000,000 shares of the Company's common stock and also purchased new unregistered warrants to purchase up to 5,000,000 shares of common stock (the "New Warrants"), for gross proceeds of approximately $2.4 million. The New Warrants have an exercise price of $0.5263 per share, are exercisable immediately upon issuance, and which have a term of exercise equal to five and one-half years. In connection with the Exchange, the Company issued warrants to purchase up to 250,000 shares of the Company's common stock (the "May 2020 PA Warrants") to the H.C. Wainwright & Co. LLC, as compensation for its role as placement agent in such Exchange. The May 2020 PA Warrants have an exercise price of $0.5938 per share, are exercisable immediately upon issuance, and have an exercise term equal to five and one-half years.

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 on Form 10-K for the fiscal year ended December 31, 2018. These risks could cause our actual results to differ materially from any future performance suggested below.

Business Overview

We are a clinical stage biotechnology company developing new treatments for life threatening conditions by improving the body's ability to bring oxygen to the areas where it is needed most. We are developing our lead product candidate, transcrocetinate sodium, also known as trans sodium crocetinate ("TSC"), for use in those life-threatening conditions in which cellular oxygen deprivation ("hypoxia") is the basis for significant unmet medical needs. TSC is designed to safely and selectively target and re-oxygenate the micro-environment of hypoxic cells, and can potentially be used in many indications, including stroke, oncology, multiple organ failure and cardiovascular disease. In stroke, TSC helps promote the diffusion of oxygen into those brain cells in which oxygen-deprivation causes neuronal death resulting in patient mortality or morbidity. In cancer, TSC re-oxygenates treatment-resistant cancerous tissue, making the cancer cells up to three times more susceptible to the therapeutic effects of standard-of-care radiation therapy and chemotherapy. In multiple organ failure, we have begun a cooperative research effort with University of Virginia Health (UVA) and the Integrated Translational Research Institute of Virginia (iTHRIV), to evaluate TSC in patients with Acute Respiratory Distress Syndrome (ARDS) associated with COVID-19 infection. iTHRIV is a National Institutes of Health (NIH)-funded Clinical and Translational Awards (CTSA) program.

A range of tissue types, including both normal and cancerous cells, has been shown to be safely re-oxygenated in our preclinical and clinical studies using TSC's novel mechanism of action. We believe TSC's ability to re-oxygenate normal (i.e. non-cancerous) tissue that has become oxygen-deprived provides opportunities for new therapeutic approaches to conditions ranging from stroke and emergency medicine - including multiple organ failure associated with Acute Respiratory Distress Syndrome (ARDS) - to cardiovascular and neurodegenerative diseases. In the treatment of cancerous tissue, we believe TSC's therapeutic potential to lessen the tumors treatment resistance to radiation and chemo-therapy is not limited to one specific tumor type, thereby making it potentially useful to improve standard-of-care treatments in many life-threatening cancers. Given TSC's safety profile and animal data, we could, with appropriate funding, move directly into Phase 2 studies for TSC in other cancers. The successful completion of trials for TSC or any other potential product candidate in these or any other indication is dependent upon our ability to further raise necessary capital.

We believe that TSC has potential applications in stroke and emergency medicine. In stroke, a Phase 2 trial in cooperation with the University of California Los Angeles (UCLA) and the University of Virginia (UVA) to test TSC in the treatment of acute ischemic or hemorrhagic stroke is currently enrolling patients. Stroke is the 5th leading cause of death in the U.S. and the No. 1 cause of adult disability. Our stroke trial, which features in-ambulance dosing of TSC, is named the "PreHospital Acute Stroke Therapy - TSC" (PHAST - TSC) study, and is expected to enroll 160 patients, with 80 in the treatment arm and 80 in the control arm. We believe in-ambulance dosing of TSC will significantly cut the time in which the stroke-related oxygen deprivation to brain cells goes untreated, potentially leading to a better outcome for stroke victims treated in this manner. Near term enrollment in this trial is expected to be minimal for the duration of the COVID-19 pandemic.

Patients with COVID-19 infections are at risk for developing ARDS, which can lead to death from systemic hypoxemia (general lack of oxygen to body tissue and vital organs). We, along with researchers affiliated with UVA and iTHRIV, believe the oxygen-enhancing mechanism of action of TSC could benefit COVID-19 patients by mitigating the multiple organ failure that often accompanies systemic hypoxemia, and are, together, exploring avenues to advance TSC's development as quickly as possible for this use. Preclinical data indicate TSC increases oxygen availability in animal models of acute lung injury, mitigating the negative effects of systemic hypoxemia. Preclinical publications also indicate TSC's ability to mitigate systemic hypoxemia in other animal models, including hemorrhagic shock. Clinical data from 150 patients receiving TSC for other indications demonstrate that the drug has an acceptable safety profile in both healthy and critically ill patients.

We, together with UVA/iTHRIV, have engaged in initial discussions with the U.S. Food and Drug Administration (FDA) to assess possible regulatory pathways for the evaluation of TSC in ARDS-related COVID-19 patients.

Our oncology program targets TSC against treatment-resistant brain cancer. A Phase 2 clinical program, completed in the second quarter of 2015, evaluated 59 patients with newly diagnosed glioblastoma multiforme ("GBM"), a particularly deadly form of primary brain cancer. GBM affects approximately 12,000 patients annually in the United States and approximately 35,000 patients annually worldwide. This open label, historically controlled study demonstrated a favorable safety and efficacy profile for TSC when combined with GBM's standard of care, including a 37% improvement in overall survival over the control group at two years. A particularly strong efficacy signal was seen in the inoperable patients, where survival of TSC-treated patients at two years was increased by almost four-fold over the controls. In December 2017, we initiated the INvestigation of TSC Against Cancerous Tumors (INTACT) Phase 3 trial in the newly diagnosed inoperable GBM patient population. The trial is 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 8 patient safety run-in for which enrollment has completed and is now closed. With the FDA's permission, a total of 19 patients were enrolled to ensure that at least 8 complete data sets meeting the FDA's specified 4-month exposure period would be available for review. The INTACT Trial Data Safety Monitoring Board (DSMB) met in the third quarter of 2019 and, based on their analysis, recommended that the study be continued. The DSMB concluded that no adverse safety signal had been observed, and unanimously recommended continuing the study as planned using the highest tested dose of TSC - 1.5 mg/kg - during the adjuvant treatment chemotherapy period with temozolomide. We believe that a preliminary efficacy signal was also received. A total of 10 patients were enrolled into the higher dose cohorts and 9 in the lower dose cohorts. In the higher dose patients, where the best results were expected, 3 discontinued treatment before meeting the FDA exposure period criteria. Of the 7 patients who met the criteria, 5 remain alive as of March 12, 2020. Commencement of enrollment in the randomization portion of the INTACT Phase 3 Trial is contingent upon our entering into a strategic partnership providing the necessary resources to undertake the full trial.

In addition to the TSC programs, we are exploring alternatives regarding how best to capitalize upon our product candidate RES-529, which may include possible out-licensing and other options. RES-529 is a novel PI3K/Akt/mTOR pathway inhibitor which has completed two Phase 1 clinical trials for age-related macular degeneration and was in preclinical development in oncology, specifically GBM. RES-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.

COVID-19 Pandemic

The spread of COVID-19 during 2020 has caused an economic downturn on a global scale, as well as significant volatility in the financial markets. In March 2020 the World Health Organization declared COVID-19 a pandemic. As of May 11, 2020, we have experienced some disruptions to clinical operations, including with respect to patient enrollment in our clinical trials. In this time of uncertainty as a result of the COVID-19 pandemic, we are continuing to conduct trials at certain clinical trial sites while taking precautions to provide a safe work environment for our trial participants and employees. However, some in-person visits are currently on hold and other activities are being conducted remotely to the extent possible. We have also made internal resource allocation decisions in order to deliver on key business objectives and to increase our financial flexibility, including, for example, by pausing the development of certain preclinical research programs, delaying the start of certain longer-term clinical studies, limiting staff hiring and reducing the number of contract workers, and delaying or limiting information technology and facilities infrastructure projects. We may have to take further actions that we determine are in the best interests of our trial participants and employees or as required by federal, state, or local authorities.

As the pandemic continues to unfold, the extent of the pandemic's effect on our operational and financial performance will depend in large part on future developments, which cannot be predicted with confidence at this time. Future developments include changes in the duration, scope and severity of the pandemic, the actions taken to contain or mitigate its impact, the impact on governmental programs and budgets, the development of treatments or vaccines, and the resumption of widespread economic activity. Any prolonged material disruption on recruiting or retaining patients in our clinical trials, the ability of our suppliers to provide materials for our product candidates, or the regulatory review process could cause additional delays with respect to product development activities and could negatively impact our consolidated financial position, consolidated results of operations and consolidated cash flows.

Financial Summary

As of March 31, 2020, we had cash and cash equivalents of $10.8 million. We have incurred operating losses since inception, have not generated any product sales revenue and have not achieved profitable operations. We incurred a net loss of $2.6 million for the three months ended March 31, 2020. Our accumulated deficit as of March 31, 2020 was $94.3 million, and we expect to continue to incur substantial losses in future periods. We anticipate that our operating expenses will increase as we continue to advance our lead, clinical-stage product candidate, TSC. We anticipate that our expenses will substantially increase as we:

- begin one or more clinical programs using TSC in COVID-19 patients;
- continue our Phase 2 clinical trial for TSC in stroke;
- continue the research, development and scale-up manufacturing capabilities to optimize products and dose forms for which we may obtain regulatory approval;
- conduct other preclinical and clinical studies to support the filing of a New Drug Application ("NDA") for TSC with the FDA;
- maintain, expand and protect our global intellectual property portfolio;
- hire additional clinical, manufacturing, and scientific personnel; and
- add, acquire or develop operational, financial and management information systems and personnel, including personnel to support our drug development and potential future commercialization efforts.

We intend to use our existing cash and cash equivalents for working capital and to fund the research and development of TSC. We believe that our cash and cash equivalents as of March 31, 2020, along with the $4.8 million in proceeds received in the second quarter of 2020 related to warrant exercises, will enable us to fund our operating expenses and capital expenditure requirements (including our clinical trials) into the third quarter of 2021.

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

Research and development costs include, but are not limited to, third-party contract research arrangements, employee-related expenses, including salaries, benefits, stock-based compensation and travel expense reimbursement. Research and development 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 trials. As we advance our product candidates, we expect the amount of research and development costs will continue to increase for the foreseeable future. Research and development costs are charged to expense as incurred.

General and Administrative Expense

General and administrative expenses consist principally of salaries and related costs for executive and other personnel, including stock-based compensation, expenses associated with investment bank and other financial advisory services, and travel expenses. Other general and administrative expenses include professional fees, facility-related costs, communication expenses and professional fees for legal, patent prosecution and maintenance, and consulting and accounting 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 the Company's deferred tax assets.

Results of Operations for Three Months Ended March 31, 2020 Compared to Three Months Ended March 31, 2019

The following table sets forth our results of operations for the three months ended March 31, 2020, and 2019.

	Three Months Ended March 31,		
	2020	2019	Change
Operating expenses:			
Research and development	$ 1,534,467	$ 1,699,845	$ (165,378)
General and administrative	1,393,808	1,200,728	193,080
Depreciation	27,020	18,272	8,748
Loss from operations	2,955,295	2,918,845	36,450
Other income:			
Interest income	(34,100)	(20,684)	(13,416)
Loss from operations before income tax benefit	(2,921,195)	(2,898,161)	(23,034)
Income tax benefit	(362,380)	(150,352)	(212,028)
Net loss	$ (2,558,815)	$ (2,747,809)	$ 188,994

We recognized $1.5 million in research and development expenses during the three months ended March 31, 2020 compared to $1.7 million during the three months ended March 31, 2019. The decrease in research and development expense was mainly attributable to a $0.4 million decrease in expense related to our Phase 3 GBM trial. The lead-in portion of the Phase 3 GBM trial was completed in the fourth quarter of 2019. This decrease was offset by a $0.1 million increase in manufacturing costs and an increase of $0.1 million in expense related to our Phase 2 stroke trial.

General and administrative expenses increased by $0.2 million during the three months ended March 31, 2020 compared to the three months ended March 31, 2019, mainly due to an increase in professional fees and salaries and wages.

The increase in interest income for the three months ended March 31, 2020 compared to the three months ended March 31, 2019 is primarily attributable to having a larger cash and cash equivalents balance earning more interest during the three months ended March 31, 2020 compared to the three months ended March 31, 2019.

We recognized income tax benefit of $0.4 million and $0.2 million during the three months ended March 31, 2020 and 2019, respectively, to reflect the utilization of indefinite deferred tax liabilities as a source of income against indefinite lived portions of the our deferred tax assets.

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 March 31, 2020, we had $10.8 million in cash and cash equivalents, working capital of $10.4 million and an accumulated deficit of $94.3 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 three months ended March 31, 2020 and 2019:

	Three Months Ended March 31,	
Net cash (used in) provided by:	**2020**	**2019**
Operating activities	$ (3,504,314)	$ (2,657,458)
Financing activities	155,193	—
Net decrease in cash and cash equivalents	$ (3,349,121)	$ (2,657,458)

Operating Activities

Net cash used in operating activities of $3.5 million during the three months ended March 31, 2020 was primarily attributable to our net loss of $2.6 million, our net change in operating assets and liabilities of $0.8 million and our change in deferred income taxes of $0.4 million. This amount was offset by $0.2 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 accounts payable and accrued expenses 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 $2.7 million during the three months ended March 31, 2019 was primarily attributable to our net loss of $2.7 million and our change in deferred income taxes of $0.2 million. This amount was offset by our net change in operating assets and liabilities of $0.1 million and $0.1 million in stock-based compensation expense and depreciation expense. The net change in our operating assets and liabilities is primarily attributable to an increase in our accounts payable and accrued expenses due to the timing of our payments to our vendors, slightly offset by an increase in our prepaid expenses, deposits and other current assets.

Financing Activities

Net cash provided by financing activities was $0.2 million during the three months ended March 31, 2020, which was attributable to the $0.4 million in proceeds received from the exercise of common stock warrants, offset by approximately $0.2 million in payments for offering costs.

We had no financing activities during the three months ended March 31, 2019.

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 our lead product candidate, TSC, for use in the treatment of ARDS, stroke, GBM, and other hypoxia related indications. Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts of cash to advance the clinical development of our product candidates. At the current time, the bulk of our cash resources for clinical development is dedicated to the Phase 2 trial for TSC in acute stroke, and if approved by the FDA, clinical work for TSC in the treatment of ARDS in COVID-19 patients. While we believe we have adequate cash resources to continue operations into the third quarter of 2021, we will need to raise additional funds in order to complete these trials. We do not expect to commence any clinical trials beyond these trials unless we are able to raise additional capital, enter into strategic collaborations, or make alternative financing arrangements for any such trials. To date, we have funded our ongoing business operations and short-term liquidity needs, primarily through the sale and issuance of preferred stock, common stock and convertible debt. We expect to continue this practice for the foreseeable future, however, we may enter into strategic partnerships or transactions in order to fund our ongoing capital requirements.

As of March 31, 2020, we did not have credit facilities under which we could borrow funds or any other sources of committed capital. We will seek to raise additional funds through various sources, such as equity and debt financings, or through strategic collaborations or licensing agreements. 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, or that potential delays in clinical trials due to the impact of COVID-19 could increase the anticipated cost of completing our clinical trials. 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 our product candidates and our operations, or we may need to obtain funds through collaborators 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 any additional capital in the near-term and/or we cannot significantly reduce our expenses 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 sale of our common stock, the interests of our current stockholders may be diluted. Also, the Company's outstanding warrants, if exercised, or any future warrants, if exercised, 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 or reduce the value of our common stock or any outstanding classes of preferred 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. 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.

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 a material effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources. As a result, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these arrangements.

Critical Accounting Policies

The Critical Accounting Policies included in our Form 10-K for the year ended December 31, 2019, filed with the SEC pursuant to Section 13 or 15(d) under the Securities Act on March 17, 2020 have not changed.

Cautionary Note Regarding Forward-Looking Statements

This report includes forward-looking statements. 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 appear in a number of places throughout this Quarterly Report and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned preclinical development and clinical trials, the timing of and our ability to make regulatory filings and obtain regulatory and other approvals for our product candidates, our intellectual property position, our ability to maintain our Nasdaq listing, the degree of clinical utility of our products, particularly in specific patient populations, our ability to develop commercial functions, expectations regarding clinical trial data, general business and market conditions, our results of operations, the sufficiency of the Company’s cash, the Company’s need for and ability to obtain additional financing or partnering arrangements, financial condition, liquidity, prospects, growth and strategies, the industry in which we operate and the trends that may affect the industry or us.

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 or incorporated by reference 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 and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained or incorporated by reference in this Quarterly Report. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained or incorporated by reference in this Quarterly Report, they may not be predictive of results or developments in future periods.

Actual results could differ materially from our forward-looking statements due to a number of factors, including risks related to:

- our ability to obtain additional financing;
- our estimates regarding expenses, capital requirements and needs for additional financing;
- the success and timing of our preclinical studies and clinical trials, including our ability to enroll an adequate number of patients in a timely fashion;
- the difficulties in obtaining and maintaining regulatory approval of our products and product candidates, and the labeling under any approval we may obtain;
- our plans and ability to develop and commercialize our product candidates;
- our failure to recruit or retain key scientific or management personnel or to retain our executive officers;
- the accuracy of our estimates of the size and characteristics of the potential markets for our product candidates and our ability to serve those markets;
- regulatory developments in the United States and foreign countries;

- the rate and degree of market acceptance of any of 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;
- recently enacted and future legislation regarding the healthcare system;
- our ability to maintain our listing on the Nasdaq Capital Market;
- our ability to continue as a going concern;
- the success of competing products that are or may become available;
- risks associated with the COVID-19 pandemic, which may adversely impact our preclinical studies and clinical trials; and
- the performance of third parties, including contract research organizations, and manufacturers.

You should also read carefully the factors described in the "Risk Factors" section of our Annual Report on Form 10-K filed with the SEC on March 17, 2020, as amended, and elsewhere in our public filings to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements contained or incorporated by reference in this Quarterly Report on Form 10-Q will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of 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.

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, 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 results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

This Item 3 is not applicable to us as a smaller reporting company and has been omitted.

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 Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended) that occurred during the quarter ended March 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

For this item, please refer to Note 7, Commitments and Contingencies to the Notes to the Unaudited Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, 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 Part I, Item IA - "Risk Factors," in our Annual Report on Form 10-K for the year ended December 31, 2019, which could materially affect our business, financial condition or future results.

Events outside of our control, including public health crises such as the COVID-19 pandemic, could negatively affect our business and our operating results.

The novel coronavirus ("COVID-19") pandemic has resulted in significant financial market volatility, and its impact on the global economy and our operations remains uncertain. A continuation or worsening of the pandemic could have a material adverse impact on our business, results of operations and financial condition and on the market price of our common stock.

On March 12, 2020, the World Health Organization declared COVID-19 to be a pandemic. In an effort to contain and mitigate the spread of COVID-19, many countries worldwide have imposed quarantines, business closures and unprecedented restrictions on travel. The outbreak and government measures taken in response, have had a significant impact, both direct and indirect, on economic activity, as worker shortages have occurred, supply chains have been disrupted, facilities and production have been suspended and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services has fallen.

As a result of the COVID-19 pandemic, we may experience disruptions that could severely impact our business and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical trial site activities, including difficulties in recruiting clinical trial staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (i.e., those that are deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies for productions of our product candidates from our third party suppliers due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruptions in preclinical studies due to restricted or limited operations at laboratory facilities; and
- interruption or delays to our clinical activities.

Any negative impact that the COVID-19 pandemic has on recruiting or retaining patients in our clinical trials, the ability of our suppliers to provide materials for our product candidates, or the regulatory review process could cause additional delays with respect to product development activities, which could materially and adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, affect our ability to raise additional capital, and have a material adverse effect on our financial results. In addition, our clinical trial patients who contract COVID-19 may have adverse health outcomes that could impact the results of our clinical trials.

The COVID-19 pandemic has resulted in significant financial market volatility and uncertainty in recent weeks and continues to rapidly evolve. The extent to which the outbreak impacts our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, on our business, results of operations and financial condition, and on the market price of our common stock.

We face risks related to the planned clinical program to test TSC as a treatment for COVID-19, which has not been approved by the FDA or any other regulatory authority.

In response to the recent global outbreak of COVID-19, on April 24, 2020, we submitted a Pre-Investigational New Drug Application (Pre-IND) to the FDA related to a planned clinical program using TSC in COVID-19 patients displaying severe respiratory symptoms and low oxygen levels. Under federal regulations, the FDA has up to 60 days to hold an advisory meeting with us, but for COVID-19-related submissions, the FDA has notified us of its intention to accelerate its review of the Pre-IND submission under its Coronavirus Treatment Acceleration Program. Clinical trial start-up preparations are continuing as we await the FDA's response. The estimated timing of regulatory approval is based on factors beyond our control, including but not limited to, unforeseen scheduling difficulties and unfavorable results at various stages in the pre-market application process. This FDA approval or clearance process may be time-consuming and costly. Moreover, there is no guarantee that the pre-IND submission will ultimately be acceptable to the FDA for an IND submission or that the FDA will not require significant changes that might take significant time to implement, if at all, or that any such required changes will be financially feasible for the Company. Even if the Pre-IND or a revised protocol is acceptable to the FDA for an IND submission, there can be no assurance as to when the FDA might provide such guidance or when the program might be able to commence, if at all. We intend to work closely with the FDA to determine the best path forward to obtain approval, but we cannot guarantee that these efforts will be successful. Even if FDA approval for trials evaluating TSC for the treatment of ARDS is ultimately granted and we are able to move forward with clinical trials, such trials may entail significant additional time, effort and expense, particularly in light of the difficulty of doing business during the COVID-19 pandemic. In addition, there is no assurance of favorable results from any clinical trials, or that one or more of such trials will be completed in the currently anticipated timelines or at all. Further, we may make a strategic decision to discontinue clinical testing of TSC in COVID-19 patients, including in the event that other parties are successful in developing a more effective treatment for COVID-19.

We have committed significant capital and resources to begin funding and supplying the clinical trials for the COVID-19 program. If we are unable to obtain regulatory approvals, or if clinical trials fail to demonstrate the clinical safety profile or the efficacy of TSC for the treatment of ARDS in COVID-19 patients, or if we make a strategic decision to discontinue testing TSC as a treatment for COVID-19 patients, we will be unable to recoup our significant expenses incurred to date and in the future related to the clinical program and the FDA approval process.

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 March 12, 2020, by and between Diffusion Pharmaceuticals Inc, and John L. Gainer	Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 18, 2020
10.2	Consulting Agreement, dated March 12, 2020, by and between Diffusion Pharmaceuticals Inc, and John L. Gainer	Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 18, 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 March 31, 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, (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: May 11, 2020

DIFFUSION PHARMACEUTICALS INC.

By: /s/ David G. Kalergis
David G. Kalergis
Chairman and Chief Executive Officer
(Principal Executive Officer)

By: /s/ William Hornung
William Hornung
Chief Financial Officer
(Principal Financial and 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, David G. Kalergis, 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: May 11, 2020

/s/ David G. Kalergis

David G. Kalergis
Chairman 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: May 11, 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 quarter ended March 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David G. Kalergis, Chairman 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/ David G. Kalergis
David G. Kalergis
Chairman and Chief Executive Officer
May 11, 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 quarter ended March 31, 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; 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
May 11, 2020