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, 2019

☐ **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)

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, 2019 was 3,379,345 shares.

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

DIFFUSION PHARMACEUTICALS INC.
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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.
Condensed Consolidated Balance Sheets
(unaudited)

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 5,333,714	$ 7,991,172
Prepaid expenses, deposits and other current assets	1,050,008	923,059
Total current assets	6,383,722	8,914,231
Property and equipment, net	332,009	350,281
Intangible asset	8,639,000	8,639,000
Right of use asset	313,364	—
Other assets	319,724	298,480
Total assets	$ 15,987,819	$ 18,201,992
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	480,016	198,818
Accrued expenses and other current liabilities	603,448	605,226
Current operating lease liability	110,001	—
Total current liabilities	1,193,465	804,044
Deferred income taxes	1,636,037	1,786,389
Noncurrent operating lease liability	203,363	—
Total liabilities	3,032,865	2,590,433
Commitments and Contingencies (Note 7)		
Stockholders' Equity:		
Common stock, $0.001 par value:		
1,000,000,000 shares authorized; 3,376,230 shares issued and outstanding at March 31, 2019 and December 31, 2018.	3,377	3,377
Additional paid-in capital	95,624,085	95,532,881
Accumulated deficit	(82,672,508)	(79,924,699)
Total stockholders' equity	12,954,954	15,611,559
Total liabilities and stockholders' equity	$ 15,987,819	$ 18,201,992

See accompanying notes to unaudited interim condensed consolidated financial statements.

Diffusion Pharmaceuticals Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended March 31,	
	2019	**2018**
Operating expenses:		
Research and development	$ 1,699,845	$ 1,825,568
General and administrative	1,200,728	1,497,839
Depreciation	18,272	28,018
Loss from operations	2,918,845	3,351,425
Other income:		
Interest income	(20,684)	(37,464)
Loss from operations before income tax benefit	(2,898,161)	(3,313,961)
Income tax benefit	(150,352)	—
Net loss	$ (2,747,809)	$ (3,313,961)
Series A cumulative preferred dividends	—	(85,993)
Deemed dividend related to the make-whole provision for the conversion of Series A preferred stock into common stock	—	(8,167,895)
Net loss attributable to common stockholders	$ (2,747,809)	$ (11,567,849)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.81)	$ (4.11)
Weighted average shares outstanding, basic and diluted	3,376,230	2,814,316

See accompanying notes to unaudited interim condensed consolidated financial statements.

Diffusion Pharmaceuticals Inc.

Condensed Consolidated Statement of Changes in Convertible Preferred Stock and Stockholders' Equity
Three Months Ended March 31, 2018 and 2019
(unaudited)

	Convertible Preferred Stock		Stockholders' Equity				
	Series A		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance at January 1, 2018	8,306,278	$ —	967,976	$ 968	$82,783,865	$ (61,554,889)	$ 21,229,944
Conversion of Series A convertible preferred stock to common stock	(8,306,278)	—	553,752	554	(554)	—	—
Issuance of common stock to Series A convertible preferred stockholders under make-whole adjustment feature	—	—	777,895	778	(778)	—	—
Issuance of common stock related to accrued dividends	—	—	68,815	69	1,148,238	—	1,148,307
Series A cumulative preferred dividend	—	—	—	—	(85,993)	—	(85,993)
Issuance of common stock and warrants, net of issuance costs	—	—	1,000,000	1,000	10,416,520	—	10,417,520
Stock-based compensation expense	—	—	—	—	324,667	—	324,667
Net loss	—	—	—	—	—	(3,313,961)	(3,313,961)
Balance at March 31, 2018	—	$ —	3,368,438	$ 3,369	$94,585,965	$ (64,868,850)	$ 29,720,484

	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

See accompanying notes to unaudited interim condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2019	**2018**
Operating activities:		
Net loss	$ (2,747,809)	$ (3,313,961)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	18,272	28,018
Stock-based compensation expense	91,204	324,667
Change in deferred income taxes	(150,352)	—
Non-cash interest expense	—	1,356
Changes in operating assets and liabilities:		
Prepaid expenses, deposits and other assets	(119,644)	(92,944)
Accounts payable, accrued expenses and other liabilities	250,871	(236,420)
Net cash used in operating activities	(2,657,458)	(3,289,284)
Cash flows provided by financing activities:		
Proceeds from the sale of common stock	—	10,846,062
Payment of offering costs	—	(253,765)
Net cash provided by financing activities	—	10,592,297
Net (decrease) increase in cash and cash equivalents	(2,657,458)	7,303,013
Cash and cash equivalents at beginning of period	7,991,172	8,896,468
Cash and cash equivalents at end of period	$ 5,333,714	$ 16,199,481
Supplemental disclosure of non-cash investing and financing activities:		
Reclassification of accrued dividends related to the issuance of common stock to the Series A convertible preferred stockholders	$ —	$ 1,148,307
Offering costs in accounts payable and accrued expenses	$ 28,549	$ 174,777
Series A cumulative preferred dividends	$ —	$ (85,993)
Operating lease right of use asset and current and noncurrent liability	$ 334,205	$ —

See accompanying notes to unaudited interim condensed 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 oncology and cardiovascular/stroke. 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 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 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 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.

On December 13, 2018, the Company effected a 1-for-15 reverse split of its common stock. As a result of the reverse stock split, every fifteen shares of common stock outstanding immediately prior to the reverse stock split were reclassified and combined into one share of Common Stock. No fractional shares were issued in connection with the reverse stock split. Stockholders who otherwise would have been entitled to receive fractional shares of common stock had their holdings rounded up to the next whole share. Proportional adjustments were made to the Company's outstanding warrants, stock options and other equity securities and to the Company's 2015 Equity Incentive Plan, as amended, to reflect the reverse stock split, in each case, in accordance with the terms thereof. The accompanying unaudited interim condensed consolidated financial statements and these notes give retroactive effect to this reverse stock split.

2. Liquidity

The Company has not generated any revenues from product sales and has funded operations primarily from the proceeds of public offerings of common stock and warrants, and private placements of 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 currently does not have any credit facilities or other commitments to which it could utilize for future funding 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 into such arrangements or if it entered into such arrangements at later stages in the product development process.

The Company has prepared its financial statements assuming that it will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred net losses since inception and it expects to generate losses from operations for the foreseeable future primarily due to research and development costs for its potential product candidates, which raises substantial doubt about the Company's ability to continue as a going concern. The Company currently has no sources of revenue and its ability to continue as a going concern is dependent on its ability to raise capital to fund its future business plans. Additionally, volatility in the capital markets and general economic conditions in the United States may be a significant obstacle to raising the required funds. These factors raise substantial doubt about its ability to continue as a going concern. The financial statements included herein do not include any adjustments that might be necessary should the Company be unable to continue as a going concern. If the going concern basis were not appropriate for these financial statements, adjustments would be necessary in the carrying value of assets and liabilities, the reported expenses and the balance sheet classifications used. The Company believes its cash and cash equivalents as of March 31, 2019 are sufficient to fund operations into July 2019.

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.

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, 2018, filed with the Securities and Exchange Commission on March 19, 2019, have not materially changed, except as set forth below.

Basis of Presentation

The accompanying unaudited interim condensed 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 condensed 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 condensed consolidated financial statements) considered necessary to present fairly the Company's financial position as of March 31, 2019, and its results of operations and cash flows for the three months ended March 31, 2019 and 2018. Operating results for the three months ended March 31, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2019. The unaudited interim condensed consolidated financial statements presented herein do not contain the required disclosures under GAAP for annual financial statements. The accompanying unaudited interim condensed 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, 2018 filed with the SEC on Form 10-K on March 19, 2019.

Use of Estimates

The preparation of the unaudited interim condensed 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. Actual results could differ from those estimates. Due to the uncertainty of factors surrounding the estimates or judgments used in the preparation of the unaudited interim condensed 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 condensed consolidated financial statements in the period they are determined necessary.

Fair Value of Financial Instruments

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

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, 2019 and 2018.

Research and Development

Major components of research and development costs include internal research and development (such as salaries and related employee benefits, equity-based compensation, supplies and allocated facility costs) and contracted services (research and development activities performed on the Company's behalf). Costs incurred for research and development are expensed as incurred.

At the end of the reporting period, the Company compares payments made to third-party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that the Company estimates has been made as a result of the services provided, the Company may record net prepaid or accrued expenses relating to these costs. Upfront payments made to third parties who perform research and development services on the Company's behalf are expensed as services are rendered.

Leases

In February 2016, the FASB issued a new standard related to leases to increase transparency and comparability among organizations by requiring the recognition of operating lease right-of-use ("ROU") assets and lease liabilities on the balance sheet. Most prominent among the changes in the standard is the recognition of ROU assets and lease liabilities by lessees for those leases classified as operating leases. Under the standard, disclosures are required to meet the objective of enabling users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. See note 7 for further details.

Net Loss Per 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, 2019 and 2018 have been excluded from the computation of diluted weighted average shares outstanding, as they would be anti-dilutive:

	March 31,	
	2019	**2018**
Convertible debt	—	14,325
Common stock warrants	2,087,012	2,113,815
Stock options	256,057	203,586
Unvested restricted stock awards	—	102
	2,343,069	2,331,828

Amounts in the table reflect the Common Stock equivalents of the noted instruments.

Recently Issued But Not Yet 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 guidance is applicable to public business entities for fiscal years beginning after December 15, 2019 and interim periods within those years. The Company is currently evaluating the potential impact of the adoption of this standard on its related disclosures.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* to increase transparency and comparability among organizations by requiring the recognition of operating lease right-of-use ("ROU") assets and lease liabilities on the balance sheet. Most prominent among the changes in the standard is the recognition of ROU assets and lease liabilities by lessees for those leases classified as operating leases. Under ASC 842, disclosures are required to meet the objective of enabling users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases.

The Company adopted ASC 842, effective January 1, 2019 using a modified retrospective approach and elected to apply the available practical expedients. The standard had an impact on the Company's unaudited interim condensed consolidated balance sheet but did not have an impact on the Company's unaudited interim condensed consolidated statements of operations or consolidated statements of cash flows upon adoption. The most significant impact of ASC 842 was the recognition of a $0.3 million ROU asset and corresponding lease liability for the Company's single operating lease.

On January 1, 2019, the Company adopted ASU 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU No. 2018-07") which simplifies the accounting for share-based payments granted to nonemployees for goods and services. The ASU supersedes ASC 505-50 *Equity-based Payments to Non-employees* and expands the scope of ASC 718 to include *all* share-based payment arrangements related to the acquisition of goods and services from both nonemployees and employees. The adoption of ASU No. 2018-17 did not have an impact on the unaudited interim condensed consolidated financial statements of the Company.

4. Other Accrued Expenses and Liabilities

Other accrued expenses and liabilities consisted of the following:

	March 31, 2019	December 31, 2018
Accrued payroll and payroll related expenses	258,877	409,889
Accrued professional fees	96,124	69,231
Accrued clinical studies expenses	170,755	34,000
Other accrued expenses	77,692	92,106
Total	$ 603,448	$ 605,226

5. Stockholders' Equity and Common Stock Warrants

2018 Common Stock Offering

In January 2018, the Company entered into an Underwriting Agreement (the "Agreement") pursuant to which it issued 1,000,000 shares of Common Stock and warrants to purchase 1,000,000 shares of Common Stock with an initial exercise price of $12.00 per share for cash proceeds of $10.8 million. In addition, as compensation for its services, the Company granted to the underwriter in the transaction an option (the "Over-Allotment Option") to purchase, in the aggregate, 150,000 shares of Common Stock (the "Option Shares") and warrants to purchase up to 150,000 shares of Common Stock (the "Option Warrants"). The underwriter exercised its right to purchase a portion of the Option Warrants and received an additional 131,375 warrants to purchase Common Stock with an initial exercise price $12.00 per share.

In addition, at the closing, the Company issued to designees of the underwriter warrants to purchase up to 50,000 shares of Common Stock. The underwriter's warrants have an exercise price of $15.00 per share, a term of five years from the date of issuance and otherwise substantially similar terms to the form of the investor warrant.

During its evaluation of equity classification for the Common Stock warrants, the Company considered the conditions as prescribed within ASC 815-40, *Derivatives and Hedging, Contracts in an Entity's own Equity* ("ASC 815-40"). The conditions within ASC 815-40 are not subject to a probability assessment. The warrants do not fall under the liability criteria within ASC 480 "*Distinguishing Liabilities from Equity*" as they are not puttable and do not represent an instrument that has a redeemable underlying security. The warrants do meet the definition of a derivative instrument under ASC 815, but are eligible for the scope exception as they are indexed to the Company's own stock and would be classified in permanent equity if freestanding.

As a result of the Company's Common Stock offering in January 2018, all outstanding shares of the Company's Series A convertible preferred stock converted into 1,400,462 shares (the "Conversion Shares") of Common Stock of which (i) 553,752 shares were issued for the automatic conversion of Series A convertible preferred stock (ii) 68,815 shares were issued upon settlement of accrued dividends and (iii) 777,895 shares were issued for the settlement of the "make-whole" adjustment feature. A deemed dividend of $8.2 million was recorded against additional paid-in-capital for the value of the common shares issued for the settlement of the make-whole adjustment feature.

Common Stock Warrants

As of March 31, 2019, 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 before 2016	1,767	$562.50 - $735.00	2019
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
	2,087,012		

During the three months ended March 31, 2019, no warrants expired and no warrants were exercised.

6. Stock-Based Compensation

2015 Equity Plan

The Diffusion Pharmaceuticals Inc. 2015 Equity 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, 135,049 shares were added to the reserve as of January 1, 2019, 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, 2019, there were 77,340 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 condensed consolidated statements of operations for the periods indicated:

	Three Months Ended March 31,	
	2019	2018
Research and development	$ 13,596	$ 16,372
General and administrative	77,608	308,295
Total stock-based compensation expense	$ 91,204	$ 324,667

The following table summarizes the activity related to all stock option grants for the three months ended March 31, 2019:

	Number of Options	Weighted average exercise price per share	Weighted average remaining contractual life (in years)	Aggregate intrinsic value
Balance at January 1, 2019	203,736	$ 88.14		$ 143
Granted	59,670	2.10		
Forfeited	(7,202)	123.38		
Expired	(147)	276.00		
Outstanding at March 31, 2019	256,057	$ 66.99	7.19	$ 96,716
Exercisable at March 31, 2019	175,720	$ 93.36	6.19	$ 8,651

The weighted average grant date fair value of stock option awards granted was $1.77 during the three months ended March 31, 2019. The total fair value of options vested during the three months ended March 31, 2019 and 2018 was $0.2 million and $0.3 million, respectively. No options were exercised during any of the periods presented. At March 31, 2019, there was $0.6 million of unrecognized compensation expense that will be recognized over a weighted-average period of 1.51 years.

Options granted were valued using the Black-Scholes model and assumptions used to value the options granted during the first three months of 2019 were as follows:

Expected term (in years)	5.77
Risk-free interest rate	2.5%
Expected volatility	114.4%
Dividend yield	—

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 of 2017 and as of March 31, 2019, has a remaining lease term of approximately 3.1 years. As disclosed in Note 3, 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 Right-Of-Use (“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 5 years. This option to extend was not recognized as part of the Company's measurement of the ROU asset and operating lease liability as of March 31, 2019.

Rent expense related to the Company's operating lease was approximately $20,000 and $28,000 for the three months ended March 31, 2019 and 2018, respectively. Future minimum rental payments under the Company's non-cancelable operating lease was as follows as of March 31, 2019:

	Rental Commitments March 31, 2019
2019	$ 86,149
2020	116,464
2021	118,519
2022	39,735
Total	360,867
Less: imputed interest	47,503
Current and noncurrent operating lease liability	$ 313,364

Future minimum rental payments under the Company's non-cancelable operating lease was as follows as of December 31, 2018:

	Rental Commitments December 31, 2018
2019	$ 114,409
2020	116,464
2021	118,519
2022	39,735
Total	$ 389,127

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.

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 2019. 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.

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 condensed 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 potentially be used in many indications, including oncology and cardiovascular/stroke. 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 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.

A range of tissue types, including both cancerous and normal cells, has been shown to be safely re-oxygenated in our preclinical and clinical studies using TSC's novel mechanism of action. In oncology, we believe TSC's therapeutic potential 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 in many such cancers. Likewise, we believe TSC's ability to re-oxygenate normal tissue that has become oxygen-deprived provides opportunities for new therapeutic approaches to conditions ranging from stroke and emergency medicine to cardiovascular indications. The successful completion of trials for TSC or any other potential product candidate in these or any other indication are dependent upon our ability to further raise necessary capital.

Our most advanced 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. 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. Patient enrollment began in January 2018. The trial will enroll 236 patients in total, with 118 in the treatment arm and 118 in the control arm. The trial is beginning with an 8 patient safety run-in which the Company expects to be finished in the second quarter of 2019. Commencement of 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 236 patient trial.

Other cancerous tumor targets upon which the Company's technology is focused include pancreatic cancer and brain metastasis, for which an FDA Orphan Designation has been granted to TSC. We believe that TSC programs for such cancers are Phase 2 ready, as safety profiles have been demonstrated in other oncology programs, protocols have been written, FDA interaction has taken place, and key opinion leaders have been engaged. Further research and development of TSC as a potential treatment for these indications is largely dependent on the necessary financial resources becoming available.

We believe that TSC has potential application in other indications involving hypoxia, notably stroke and emergency medicine, as well as cardiovascular and neurodegenerative diseases. A Phase 2 trial program in cooperation with UCLA and the University of Virginia to test TSC in the treatment of acute stroke has received approval for enrollment by the FDA, with the first enrolled patient expected in the third quarter of 2019. This trial, which will feature in-ambulance dosing of TSC, is named the PreHospital Acute Stroke Therapy -TSC (PHAST - TSC) 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 could 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. In the fourth quarter of 2018, we received FDA permission to begin patient enrollment in the PHAST - TSC Phase 2 trial and expect to begin enrollment in third quarter of 2019, following completion of the institutional review board and contracting activities.

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.

Financial Summary

As of March 31, 2019, we had cash and cash equivalents of $5.3 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 $2.7 million for the three months ended March 31, 2019. Our accumulated deficit as of March 31, 2019 was $82.7 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:

- continue our Phase 3 clinical trial for TSC in GBM and begin 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") with the FDA;
- maintain, expand and protect our global intellectual property portfolio;
- hire additional clinical, manufacturing, and scientific personnel; and
- add 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, 2019, will enable us to fund our operating expenses and capital expenditure requirements into July 2019. However, we will need to secure additional funding in the future, from one or more equity or debt financings, collaborations, or other sources, in order to carry out all of our planned research and development activities with respect to TSC and our other product candidates.

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 are charged to expense as incurred. These costs include, but are not limited to, expenses related 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.

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 consists of the interest earned from our cash and cash equivalents.

Income Tax Benefit

Since inception, we had incurred net losses and until 2018, we had not recorded any U.S. federal or state income tax benefits for the losses as they had been offset by valuation allowances. As a result of the change in net operating loss carryforward period associated with the Tax Cuts and Jobs Act ("the 2017 Tax Act"), we recognize income tax benefit to reflect the adjustment 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.

Results of Operations for Three Months Ended March 31, 2019 Compared to Three Months Ended March 31, 2018

The following table sets forth our results of operations for the three months ended March 31, 2019, and 2018.

	Three Months Ended March 31,		
	2019	**2018**	**Change**
Operating expenses:			
Research and development	$ 1,699,845	$ 1,825,568	$ (125,723)
General and administrative	1,200,728	1,497,839	(297,111)
Depreciation	18,272	28,018	(9,746)
Loss from operations	2,918,845	3,351,425	(432,580)
Other income:			
Interest income	(20,684)	(37,464)	16,780
Loss from operations before income tax benefit	(2,898,161)	(3,313,961)	415,800
Income tax benefit	(150,352)	—	(150,352)
Net loss	$ (2,747,809)	$ (3,313,961)	$ 566,152

We recognized $1.7 million in research and development expenses during the three months ended March 31, 2019 compared to $1.8 million during the three months ended March 31, 2018. The slight decrease in research and development expense was mainly attributable to a $0.5 million decrease in expense related to our Phase 3 GBM trial, offset by a $0.4 million increase in expense related to the commencement of our Phase 2 stroke trial.

General and administrative expenses decreased by $0.3 million during the three months ended March 31, 2019 compared to the three months ended March 31, 2018. Salaries and wages decreased by $0.1 million and stock compensation expense decreased by $0.2 million.

The decrease in interest income for the three months ended March 31, 2019 compared to the three months ended March 31, 2018 is primarily attributable to having a larger cash and cash equivalents balance earning more interest during the three months ended March 31, 2018 compared to the three months ended March 31, 2019.

As a result of the change in net operating loss carryforward period associated with the 2017 Tax Act, we recognized an income tax benefit of $0.2 million during the three months ended March 31, 2019 to reflect the utilization of indefinite deferred tax liabilities as a source of income against indefinite-lived portions of 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, 2019, we had $5.3 million in cash and cash equivalents, working capital of $5.2 million and an accumulated deficit of $82.7 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, 2019 and 2018:

	Three Months Ended March 31,	
Net cash (used in) provided by:	**2019**	**2018**
Operating activities	$ (2,657,458)	$ (3,289,284)
Financing activities	—	10,592,297
Net (decrease) increase in cash and cash equivalents	$ (2,657,458)	$ 7,303,013

Operating Activities

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.

Net cash used in operating activities of $3.3 million during the three months ended March 31, 2018 was primarily attributable to our net loss of $3.3 million and our net change in operating assets and liabilities of $0.3 million. This amount was offset by $0.4 million in stock-based compensation expense and depreciation expense. The net change in our operating assets and liabilities is primarily attributable to the decrease in our accounts payable and accrued expenses due to the payments of employee bonuses and payments to our vendors.

Financing Activities

Net cash provided by financing activities was $10.6 million during the three months ended March 31, 2018 which was attributable to the $10.8 million in proceeds received upon the sale of our Common Stock, offset by $0.2 million in payments for related offering costs. We had no such financing activities during the three months ended March 31, 2019.

Reverse Stock Split

On December 13, 2018, we filed a Certificate of Amendment to our Certificate of Incorporation with the Secretary of State of the State of Delaware to effect a 1-to-15 reverse stock split (the “Reverse Stock Split”) of our common stock. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who otherwise would have been entitled to receive fractional shares of our common stock had their holdings rounded up to the next whole share. Proportional adjustments were made to our outstanding warrants, stock options, and other equity securities and to our 2015 Equity Incentive Plan, as amended, to reflect the Reverse Stock Split, in each case, in accordance with the terms thereof. Unless the context otherwise requires, all share and per share amounts in this quarterly report on Form 10-Q have been adjusted to reflect the Reverse Stock Split.

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 GBM, stroke 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 and to commercialize any product candidates for which we receive regulatory approval. At the current time, the bulk of our cash resources for clinical development is dedicated to the Phase 3 trial for TSC in inoperable GBM and the Phase 2 trial for TSC in acute stroke. While we believe we have adequate cash resources to continue operations into July 2019, 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 a strategic partnership, 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, 2019, 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. 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. If we issue additional 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, 2018, filed with the SEC pursuant to Section 13 or 15(d) under the Securities Act on March 19, 2019 have not changed aside from goodwill no longer being a critical accounting policy.

Special 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 and maintain regulatory approvals for our product candidates, our intellectual property position, the degree of clinical utility of our products, particularly in specific patient populations, our ability to develop commercial functions, expectations regarding clinical trial data, our results of operations, cash needs, 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;
- 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; 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 19, 2019, 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, 2019 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 Condensed 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, 2018, which could materially affect our business, financial condition or future results.

As of the date of this Quarterly Report on Form 10-Q, there have been no material changes with respect to the Company's risk factors previously disclosed on Form 10-K for the year ended December 31, 2018.

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 March 31, 2019, formatted in XBRL (Extensible Business Reporting Language): (i) the Unaudited Condensed Consolidated Balance Sheets, (ii) the Unaudited Condensed Consolidated Statements of Operations, (iii) the Unaudited Condensed Consolidated Statement of Changes in Stockholders' Equity (Deficit), (iv) the Unaudited Condensed Consolidated Statements of Cash Flows, and (v) Notes to Unaudited Condensed 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 9, 2019

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 9, 2019

/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 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: May 9, 2019

/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 March 31, 2019 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 9, 2019

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, 2019 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)
May 9, 2019