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

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 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 November 6, 2019 was 4,693,290 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.
FORM 10-Q
SEPTEMBER 30, 2019

INDEX

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)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 6,139,770	$ 7,991,172
Prepaid expenses, deposits and other current assets	578,613	923,059
Total current assets	6,718,383	8,914,231
Property and equipment, net	279,441	350,281
Intangible asset	8,639,000	8,639,000
Right of use asset	269,716	—
Other assets	290,674	298,480
Total assets	$ 16,197,214	$ 18,201,992
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 502,473	$ 198,818
Accrued expenses and other current liabilities	605,037	605,226
Current operating lease liability	110,969	—
Total current liabilities	1,218,479	804,044
Deferred income taxes	1,301,173	1,786,389
Noncurrent operating lease liability	158,747	—
Total liabilities	2,678,399	2,590,433
Commitments and Contingencies (Note 7)		
Stockholders' Equity:		
Common stock, $0.001 par value:		
1,000,000,000 shares authorized; 4,693,290 and 3,376,230 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	4,694	3,377
Additional paid-in capital	101,486,119	95,532,881
Accumulated deficit	(87,971,998)	(79,924,699)
Total stockholders' equity	13,518,815	15,611,559
Total liabilities and stockholders' equity	$ 16,197,214	$ 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 September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development	$ 1,743,494	$ 1,169,810	$ 4,961,720	$ 4,386,491
General and administrative	1,290,371	1,589,621	3,559,551	4,748,090
Goodwill impairment	—	4,186,050	—	4,186,050
Depreciation	18,178	26,723	70,840	81,450
Loss from operations	3,052,043	6,972,204	8,592,111	13,402,081
Other income:				
Interest income	(21,991)	(37,981)	(59,596)	(120,784)
Loss from operations before income tax benefit	(3,030,052)	(6,934,223)	(8,532,515)	(13,281,297)
Income tax benefit	(225,960)	(214,493)	(485,216)	(482,425)
Net loss	$ (2,804,092)	$ (6,719,730)	$ (8,047,299)	$ (12,798,872)
Series A cumulative preferred dividends	—	—		(85,993)
Deemed dividend related to the make-whole provision for the conversion of Series A convertible preferred stock into common stock	—	—	—	(8,167,895)
Net loss attributable to common stockholders	$ (2,804,092)	$ (6,719,730)	$ (8,047,299)	$ (21,052,760)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.60)	$ (1.99)	$ (2.01)	$ (6.61)
Weighted average shares outstanding, basic and diluted	4,693,290	3,371,468	4,005,919	3,185,865

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 and Nine Months Ended September 30, 2018 and 2019
(unaudited)

	Convertible Preferred Stock		Stockholders' Equity				
	Series A		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance at July 1, 2018	—	$ —	3,371,469	$ 3,372	$94,930,731	$ (67,634,031)	$ 27,300,072
Stock-based compensation expense	—	—	—	—	327,396	—	327,396
Net loss	—	—	—	—	—	(6,719,730)	(6,719,730)
Balance at September 30, 2018	—	$ —	3,371,469	$ 3,372	$95,258,127	$ (74,353,761)	$ 20,907,738

	Convertible Preferred Stock		Stockholders' Equity				
	Series A		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
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
Common stock issued for advisory services	—	—	3,031	3	24,997	—	25,000
Stock-based compensation expense	—	—	—	—	971,832	—	971,832
Net loss	—	—	—	—	—	(12,798,872)	(12,798,872)
Balance at September 30, 2018	—	$ —	3,371,469	$ 3,372	$95,258,127	$ (74,353,761)	$ 20,907,738

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

Diffusion Pharmaceuticals Inc.
Condensed Consolidated Statement of Changes in Convertible Preferred Stock and Stockholders' Equity
Three and Nine Months Ended September 30, 2018 and 2019
(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
Issuance of common stock and warrants, net of issuance costs	1,317,060	1,317	5,567,633	—	5,568,950
Stock-based compensation expense	—	—	385,605	—	385,605
Net loss	—	—	—	(8,047,299)	(8,047,299)
Balance at September 30, 2019	4,693,290	$ 4,694	$ 101,486,119	$ (87,971,998)	$ 13,518,815

See accompanying notes to unaudited interim condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2019	**2018**
Operating activities:		
Net loss	$ (8,047,299)	$ (12,798,872)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	70,840	81,450
Stock-based compensation expense	385,605	971,832
Common stock issued for advisory services	—	25,000
Change in deferred income taxes	(485,216)	(482,425)
Goodwill impairment	—	4,186,050
Changes in operating assets and liabilities:		
Prepaid expenses, deposits and other assets	352,252	405,620
Accounts payable, accrued expenses and other liabilities	303,466	(134,202)
Net cash used in operating activities	(7,420,352)	(7,745,547)
Cash flows provided by financing activities:		
Repayment of convertible debt principal	—	(550,000)
Proceeds from the sale of common stock	5,731,779	10,846,062
Payment of offering costs	(162,829)	(428,542)
Net cash provided by financing activities	5,568,950	9,867,520
Net (decrease) increase in cash and cash equivalents	(1,851,402)	2,121,973
Cash and cash equivalents at beginning of period	7,991,172	8,896,468
Cash and cash equivalents at end of period	$ 6,139,770	$ 11,018,441
Supplemental disclosure of cash flow information		
Cash paid for interest	$ —	$ 40,142
Supplemental disclosure of non-cash investing and financing activities:		
Reclassification of accrued dividends related to the issuance of common stock to Series A convertible preferred stockholders	$ —	$ 1,148,307
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 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 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 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. In May 2019, the Company completed a registered direct public offering of 1,317,060 shares of its common stock, par value $0.001 per share (the "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 per unit 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.

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 September 30, 2019 are sufficient to fund operations into the first quarter of 2020.

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 September 30, 2019, its results of operations for the three and nine months ended September 30, 2019 and 2018 and cash flows for the nine months ended September 30, 2019 and 2018. Operating results for the nine months ended September 30, 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 deemed 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 the nine months ended September 30, 2019 and 2018.

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 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 September 30, 2019 and 2018 have been excluded from the computation of diluted weighted average shares outstanding, as they would be anti-dilutive:

	Nine Months Ended September 30,	
	2019	**2018**
Common stock warrants	3,469,825	2,087,501
Stock options	309,276	214,353
	3,779,101	2,301,854

Recently Issued But Not Yet Adopted Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-03, *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. 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 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 Non-employee Share-Based Payment Accounting* ("ASU No. 2018-07") which simplifies the accounting for share-based payments granted to non-employees 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 non-employees 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. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	September 30, 2019	December 31, 2018
Accrued payroll and payroll related expenses	392,907	409,889
Accrued professional fees	47,857	69,231
Accrued clinical studies expenses	85,962	34,000
Other accrued expenses	78,311	92,106
Total	$ 605,037	$ 605,226

5. Stockholders' Equity and Common Stock Warrants

2019 Common Stock and Warrant Offering

In May 2019, the Company completed a registered direct public 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 such offering described in the foregoing paragraph, 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, 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.

Common Stock Warrants

As of September 30, 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 prior to 2016	1,667	$562.50			December 2019
Common stock warrants issued related to Series A convertible preferred stock offering	903,870	$33.30			March 2022
Common stock warrants issued in 2018	1,181,375	$12.00	-	$15.00	January 2023
Common stock warrants issued in 2019	1,382,913	$5.00	-	$6.11875	2024
	3,469,825				

During the nine months ended September 30, 2019, 100 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 September 30, 2019, there were 19,740 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	$ 13,519	$ 16,202	$ 40,692	$ 48,848
General and administrative	131,802	311,194	344,913	922,984
Total stock-based compensation expense	$ 145,321	$ 327,396	$ 385,605	$ 971,832

The following table summarizes the activity related to all stock options for the nine months ended September 30, 2019:

	Number of Options	Weighted average exercise price per share	Weighted average remaining contractual life (in years)
Balance at January 1, 2019	203,736	$ 88.14	
Granted	117,270	2.62	
Forfeited	(11,583)	83.81	
Expired	(147)	276.00	
Outstanding at September 30, 2019	309,276	$ 55.78	7.23
Exercisable at September 30, 2019	211,867	$ 78.92	6.30

The weighted average grant date fair value of stock option awards granted was $2.16 during the nine months ended September 30, 2019. The total fair value of options vested during the three months ended September 30, 2019 and 2018 was $0.2 million and $0.3 million, respectively. The total fair value of options vested during the nine months ended September 30, 2019 and 2018 was $0.5 million and $0.9 million, respectively. No options were exercised during any of the periods presented. At September 30, 2019, there was $0.4 million of unrecognized compensation expense that will be recognized over a weighted-average period of 1.2 years.

Options granted were valued using the Black-Scholes option-pricing model and the weighted average assumptions used to value the options granted during the nine months ended September 30, 2019 and 2018 were as follows:

	2019	2018
Expected term (in years)	5.52	5.57
Risk-free interest rate	2.2%	2.4%
Expected volatility	113.4%	114.7%
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 September 30, 2019, has a remaining lease term of approximately 2.6 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 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 September 30, 2019.

Rent expense related to the Company's operating lease for the three months ended September 30, 2019 and 2018 was approximately $30,000 and $28,000, respectively. Rent expense for the nine months ended September 30, 2019 and 2018 was approximately $80,000 and $84,000, respectively. Future minimum rental payments under the Company's non-cancelable operating lease at September 30, 2019 was as follows:

	Rental Commitments
2019	$ 28,774
2020	116,464
2021	118,519
2022	39,735
Total	303,492
Less: imputed interest	(33,776)
	$ 269,716

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

	Rental Commitments
2019	$ 114,409
2020	116,464
2021	118,519
2022	39,735
	$ 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 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.

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 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.

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 tissue that has become oxygen-deprived provides opportunities for new therapeutic approaches to conditions ranging from stroke and emergency medicine to cardiovascular and neurodegenerative diseases. 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 for TSC in many such 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. A Phase 2 trial 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. We enrolled our first patient in the study in October 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. Subject to receipt of adequate funding to support the PHAST – TSC trial, we expect to receive data readout during the first half of 2021.

Our primary 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, the Company 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 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 8 complete data sets. The INTACT Trial Data Safety Monitoring Board (DSMB) met in the third quarter of 2019 and 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. 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. 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

In May 2019, we completed a registered direct public 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 such 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, a term of five years from the date of issuance and otherwise substantially similar terms to the form of the investor warrant.

At September 30, 2019, we had cash and cash equivalents of $6.1 million. We have incurred operating losses since inception, have not generated any product revenue and have not achieved profitable operations. We incurred net losses of $2.8 million and $8.0 million for the three and nine months ended September 30, 2019, respectively. Our accumulated deficit as of September 30, 2019 was $88.0 million, and we expect to continue to incur substantial losses in future periods. We anticipate that our operating expenses will increase substantially as we continue to advance our lead, clinical-stage product candidate, TSC. We anticipate that our expenses will substantially increase as we:

- 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 any 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.

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 September 30, 2019 will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2020. 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.

Goodwill Impairment Expense

Goodwill impairment expense relates to a non-cash impairment charge recognized to write-down goodwill due to the fact the Company's carrying value of equity exceeded its fair value throughout the third quarter of 2018.

Interest Income

Interest income consists of 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 September 30, 2019 Compared to Three Months Ended September 30, 2018

The following table sets forth our results of operations for the three months ended September 30, 2019 and 2018.

	Three Months Ended September 30, 2019		
	2019	2018	Change
Operating expenses:			
Research and development	$ 1,743,494	$ 1,169,810	$ 573,684
General and administrative	1,290,371	1,589,621	(299,250)
Goodwill impairment	—	4,186,050	(4,186,050)
Depreciation	18,178	26,723	(8,545)
Loss from operations	3,052,043	6,972,204	(3,920,161)
Other income:			
Interest income	(21,991)	(37,981)	15,990
Loss from operations before income tax benefit	(3,030,052)	(6,934,223)	3,904,171
Income tax benefit	(225,960)	(214,493)	(11,467)
Net loss	$ (2,804,092)	$ (6,719,730)	$ 3,915,638

We recognized $1.7 million in research and development expenses during the three months ended September 30, 2019 compared to $1.2 million during the three months ended September 30, 2018. The increase in research and development expense was attributable to a $0.6 million increase in expense related to the commencement of our Phase 2 stroke trial and an increase in manufacturing expense of $0.2 million, offset by a decrease of $0.2 million in expense related to our Phase 3 GBM trial and a $0.1 million decrease in salary and other expenses.

General and administrative expenses were $1.3 million during the three months ended September 30, 2019 compared to $1.6 million during the three months ended September 30, 2018. Salaries and wages decreased by $0.2 million and stock compensation expense decreased by $0.2 million. These amounts were partially offset by an increase in insurance and other costs of $0.1 million.

We recognized a non-cash goodwill impairment charge of $4.2 million during the three months ended September 30, 2018 as a result of a sustained decrease in our market capitalization during the third quarter of 2018.

As a result of the change in net operating loss carryforward period associated with the 2017 Tax Act, the Company recognized an income tax benefit of $0.2 million to reflect the utilization of indefinite deferred tax liabilities as a source of income against indefinite-lived portions of our deferred tax assets.

Results of Operations for Nine Months Ended September 30, 2019 Compared to Nine Months Ended September 30, 2018

The following table sets forth our results of operations for the nine months ended September 30, 2019 and 2018.

	Nine Months Ended September 30,		
	2019	2018	Change
Operating expenses:			
Research and development	$ 4,961,720	$ 4,386,491	$ 575,229
General and administrative	3,559,551	4,748,090	(1,188,539)
Goodwill impairment	—	4,186,050	(4,186,050)
Depreciation	70,840	81,450	(10,610)
Loss from operations	8,592,111	13,402,081	(4,809,970)
Other income:			
Interest income	(59,596)	(120,784)	61,188
Loss from operations before income tax benefit	(8,532,515)	(13,281,297)	4,748,782
Income tax benefit	(485,216)	(482,425)	(2,791)
Net loss	$ (8,047,299)	$ (12,798,872)	$ 4,751,573

We recognized $5.0 million in research and development expenses during the nine months ended September 30, 2019 compared to $4.4 million during the nine months ended September 30, 2018. The increase in research and development expense was attributable to a $1.6 million increase in expense related to the commencement of our Phase 2 stroke trial and an increase in manufacturing expense of $0.2 million, offset by a decrease of $1.2 million in expense related to our Phase 3 GBM trial.

General and administrative expenses were $3.6 million during the nine months ended September 30, 2019 compared to $4.7 million during the nine months ended September 30, 2018. The decrease in general and administrative expense was primarily due to a $0.6 million decrease in stock-based compensation expense, a $0.4 million decrease in salaries and wages and a $0.1 million decrease in professional fees and other expense.

We recognized a non-cash goodwill impairment charge of $4.2 million during the nine months ended September 30, 2018 as a result of a sustained decrease in our market capitalization during the third quarter of 2018.

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 $0.5 million during both the nine months ended September 30, 2019 and 2018 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 issuance and sale of common stock and warrants, convertible debt and convertible preferred stock. In May 2019, we completed a registered direct public 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.

As of September 30, 2019, we had $6.1 million in cash and cash equivalents, working capital of $5.5 million and an accumulated deficit of $88.0 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 nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,	
Net cash (used in) provided by:	**2019**	**2018**
Operating activities	$ (7,420,352)	$ (7,745,547)
Financing activities	5,568,950	9,867,520
Net (decrease) increase in cash and cash equivalents	$ (1,851,402)	$ 2,121,973

Operating Activities

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

Net cash used in operating activities of $7.7 million during the nine months ended September 30, 2018 was primarily attributable to our net loss of $12.8 million and a change in deferred income taxes of $0.5 million. This amount was offset by the recognition of a $4.2 million non-cash impairment charge to goodwill, $1.0 million in stock-based compensation expense, our net change in operating assets and liabilities of $0.3 million and $0.1 million of depreciation expense. The net change in our operating assets and liabilities is primarily attributable to the decrease in our prepaid expenses, deposits and other current assets.

Financing Activities

Net cash provided by financing activities was $5.6 million during the nine months ended September 30, 2019, which was attributable to the $5.7 million in proceeds received upon the sale of our Common Stock and warrants, offset by approximately $0.2 million in payments for related offering costs.

Net cash provided by financing activities was $9.9 million during the nine months ended September 30, 2018, which was attributable to the $10.8 million in proceeds received upon the sale of our Common Stock, offset by approximately $0.4 million in payments for additional related offering costs. During the nine months ended September 30, 2018, we repaid the outstanding balance of our convertible debt in the amount of approximately $0.6 million.

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. 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. While we believe we have adequate cash resources to continue operations into the first quarter of 2020, 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 September 30, 2019, we did not have credit facilities under which we could borrow funds or any other sources of committed capital. We may seek to raise additional funds through various sources, such as equity and debt financings, or through strategic collaborations and license 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. If we raise additional funds through strategic collaborations in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses.

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.

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 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 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 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, future revenues, capital requirements and needs for additional financing;
- our ability to enroll subjects in our clinical trials at anticipated rates;
- 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 satisfy the continued listing requirements of the NASDAQ Capital Market or any other exchange on which our securities may trade in the future;
- the ability of the Company 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 September 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

For this item, please refer to Note 7, Commitments and Contingencies to the Notes to the Unaudited Interim 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 1A - "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.

The Bylaws of the Company include a forum selection clause, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Our Bylaws (the "Bylaws") require that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our Certificate of Incorporation or our Bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine, in each case subject to said Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein.

This exclusive forum provision will not apply to claims under the Exchange Act, but will apply to other state and federal law claims including actions arising under the Securities Act (although our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder). Section 22 of the Securities Act, however, creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Accordingly, there is uncertainty as to whether a court would enforce such a forum selection provision as written in connection with claims arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the foregoing provisions. This forum selection provision in our Bylaws may limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents, which may discourage lawsuits against us and such persons. It is also possible that, notwithstanding the forum selection clause included in our Bylaws, a court could rule that such a provision is inapplicable or unenforceable.

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
4.1	Form of May 2019 Warrant	Incorporated by reference to Exhibit 4.1 to the registrant's current report on Form 8-K filed on May 28, 2019
4.2	Form of May 2019 Placement Agent's Warrant	Incorporated by reference to Exhibit 4.2 to the registrant's current report on Form 8-K filed on May 28, 2019
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)	Filed herewith
31.2	Certification of principal financial officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)	Filed herewith
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
32.2	Certification of principal financial officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
101	The following materials from Diffusion's quarterly report on Form 10-Q for the quarter ended September 30, 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: November 8, 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 Officer and
Principal Accounting Officer)

Exhibit 31.1

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

I, 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: November 8, 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 Hornung, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 8, 2019

/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 September 30, 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
November 8, 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 September 30, 2019 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
November 8, 2019