
Section 1: 10-Q (FORM 10-Q)

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, 2018

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
(State of other jurisdiction of incorporation or organization)

30-0645032
(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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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
Non-accelerated filer (Do not check if a smaller reporting company)

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 1, 2018 was 50,643,429 shares.

DIFFUSION PHARMACEUTICALS INC.
FORM 10-Q
SEPTEMBER 30, 2018

INDEX

	<u>Page</u>
PART I – FINANCIAL INFORMATION	1
ITEM 1. FINANCIAL STATEMENTS	1
ITEM 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	16
ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	26
ITEM 4. CONTROLS AND PROCEDURES	26
PART II – OTHER INFORMATION	27
ITEM 1. LEGAL PROCEEDINGS	27
ITEM 1A. RISK FACTORS	27
ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS	27
ITEM 3. DEFAULTS UPON SENIOR SECURITIES	27
ITEM 4. MINE SAFETY DISCLOSURES	27
ITEM 5. OTHER INFORMATION	27
ITEM 6. EXHIBITS	27

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, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 11,018,441	\$ 8,896,468
Prepaid expenses, deposits and other current assets	551,337	769,946
Total current assets	11,569,778	9,666,414
Property and equipment, net	379,202	460,652
Intangible asset	8,639,000	8,639,000
Goodwill	2,743,208	6,929,258
Other assets	263,480	450,491
Total assets	<u>\$ 23,594,668</u>	<u>\$ 26,145,815</u>
Liabilities, Convertible Preferred Stock and Stockholders' Equity		
Current liabilities:		
Current portion of convertible debt	\$ —	\$ 550,000
Accounts payable	129,057	511,956
Accrued expenses and other current liabilities	816,620	1,628,851
Total current liabilities	945,677	2,690,807
Deferred income taxes	1,741,253	2,223,678
Other liabilities	—	1,386
Total liabilities	<u>2,686,930</u>	<u>4,915,871</u>
Commitments and Contingencies (Note 8)		
Convertible preferred stock, \$0.001 par value:		
Series A - No shares and 13,750,000 shares authorized at September 30, 2018 and December 31, 2017, respectively. No shares and 12,376,329 shares issued at September 30, 2018 and December 31, 2017, respectively. No shares and 8,306,278 shares outstanding at September 30, 2018 and December 31, 2017, respectively.	—	—
Total convertible preferred stock	<u>—</u>	<u>—</u>
Stockholders' Equity:		
Common stock, \$0.001 par value:		
1,000,000,000 shares authorized; 50,572,001 and 14,519,629 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively.	50,571	14,520
Additional paid-in capital	95,210,928	82,770,313
Accumulated deficit	(74,353,761)	(61,554,889)
Total stockholders' equity	<u>20,907,738</u>	<u>21,229,944</u>
Total liabilities, convertible preferred stock and stockholders' equity	<u>\$ 23,594,668</u>	<u>\$ 26,145,815</u>

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,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	\$ 1,169,810	\$ 1,759,305	\$ 4,386,491	\$ 3,946,420
General and administrative	1,589,621	1,559,399	4,748,090	4,908,424
Goodwill impairment	4,186,050	—	4,186,050	—
Depreciation	26,723	27,374	81,450	39,767
Loss from operations	<u>6,972,204</u>	<u>3,346,078</u>	<u>13,402,081</u>	<u>8,894,611</u>
Other expense (income):				
Interest (income) expense, net	(37,981)	(1,318)	(120,784)	73,290
Change in fair value of warrant liability	—	(8,441,616)	—	(18,909,792)
Warrant related expenses	—	—	—	10,225,846
Other financing expenses	—	—	—	2,870,226
(Loss) income from operations before income tax benefit	(6,934,223)	5,096,856	(13,281,297)	(3,154,181)
Income tax benefit	(214,493)	—	(482,425)	—
Net (loss) income	<u>\$ (6,719,730)</u>	<u>\$ 5,096,856</u>	<u>\$ (12,798,872)</u>	<u>\$ (3,154,181)</u>
Series A cumulative preferred dividends	—	(366,641)	(85,993)	(912,946)
Undistributed earnings to participating securities	—	(1,838,354)	—	—
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) income attributable to common stockholders	<u>\$ (6,719,730)</u>	<u>\$ 2,891,861</u>	<u>\$ (21,052,760)</u>	<u>\$ (4,067,127)</u>
Per share information:				
Net (loss) income per share of common stock, basic	\$ (0.13)	\$ 0.21	\$ (0.44)	\$ (0.35)
Net (loss) income per share of common stock, diluted	\$ (0.13)	\$ 0.20	\$ (0.44)	\$ (1.83)
Weighted average shares outstanding, basic	<u>50,572,001</u>	<u>13,937,869</u>	<u>47,777,757</u>	<u>11,709,128</u>
Weighted average shares outstanding, diluted	<u>50,572,001</u>	<u>14,714,853</u>	<u>47,777,757</u>	<u>12,525,707</u>

See accompanying notes to unaudited condensed consolidated financial statements.

Diffusion Pharmaceuticals Inc.
Condensed Consolidated Statement of Changes in Convertible Preferred Stock and Stockholders' Equity
Nine Months Ended September 30, 2018
(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	\$ —	14,519,629	\$ 14,520	\$82,770,313	\$ (61,554,889)	\$ 21,229,944
Conversion of Series A convertible preferred stock to common stock	(8,306,278)	—	8,306,278	8,306	(8,306)	—	—
Issuance of common stock to Series A convertible preferred stockholders under make-whole adjustment feature	—	—	11,668,421	11,668	(11,668)	—	—
Issuance of common stock related to accrued dividends	—	—	1,032,219	1,032	1,147,275	—	1,148,307
Series A cumulative preferred dividend	—	—	—	—	(85,993)	—	(85,993)
Issuance of common stock and warrants, net of issuance costs	—	—	15,000,000	15,000	10,402,520	—	10,417,520
Common stock issued for advisory services	—	—	45,454	45	24,955	—	25,000
Stock-based compensation expense	—	—	—	—	971,832	—	971,832
Net loss	—	—	—	—	—	(12,798,872)	(12,798,872)
Balance at September 30, 2018	—	\$ —	50,572,001	\$ 50,571	\$95,210,928	\$ (74,353,761)	\$ 20,907,738

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2018	2017
Operating activities:		
Net loss	\$ (12,798,872)	\$ (3,154,181)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	81,450	39,767
Stock-based compensation expense	971,832	973,950
Common stock issued for advisory services	25,000	50,000
Warrant related expense, change in fair value, and other financing expenses	—	(5,813,720)
Change in deferred income taxes	(482,425)	—
Goodwill impairment	4,186,050	—
Non-cash interest expense	—	11,967
Changes in operating assets and liabilities:		
Prepaid expenses, deposits and other assets	405,620	(661,675)
Accounts payable, accrued expenses and other liabilities	(134,202)	(1,496,150)
Net cash used in operating activities	(7,745,547)	(10,050,042)
Cash flows used in investing activities:		
Purchases of property and equipment	—	(438,604)
Purchase of certificate of deposit	—	(10,000,000)
Net cash used in investing activities	—	(10,438,604)
Cash flows provided by financing activities:		
Repayment of convertible debt principal	(550,000)	(1,880,000)
Proceeds from the sale of common stock	10,846,062	—
Proceeds from the sale of Series A convertible preferred stock, net	—	22,129,774
Payment of offering costs	(428,542)	(97,980)
Net cash provided by financing activities	9,867,520	20,151,794
Net increase (decrease) in cash and cash equivalents	2,121,973	(336,852)
Cash and cash equivalents at beginning of period	8,896,468	1,552,852
Cash and cash equivalents at end of period	<u>\$ 11,018,441</u>	<u>\$ 1,216,000</u>
Supplemental disclosure of cash flow information		
Cash paid for interest	<u>\$ 40,142</u>	<u>\$ 112,800</u>
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 stock holders	<u>\$ 1,148,307</u>	<u>\$ —</u>
Series A cumulative preferred dividends	<u>\$ (85,993)</u>	<u>\$ (912,946)</u>
Conversion of accrued dividends related to Series A convertible preferred stock	<u>\$ —</u>	<u>\$ 187,172</u>

See accompanying notes to unaudited condensed consolidated financial statements.

DIFFUSION PHARMACEUTICALS INC.

NOTES TO UNAUDITED 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 focused on extending the life expectancy of cancer patients by improving the effectiveness of current standard-of-care treatments, including radiation therapy and chemotherapy. The Company is developing its lead product candidate, trans sodium crocetinate ("TSC") for use in many cancer types in which tumor oxygen deprivation ("hypoxia") is known to diminish the effectiveness of current treatments. TSC is designed to target the cancer's hypoxic micro-environment, re-oxygenating treatment-resistant tissue and making the cancer cells more susceptible to the therapeutic effects of standard-of-care radiation therapy and chemotherapy. Other possible uses of TSC include the treatment of hypoxic conditions such as stroke, cardiovascular disease, neurodegenerative disease and emergency medicine.

2. Liquidity

The Company has not generated any revenues from product sales and has funded operations primarily from the proceeds of public offerings, 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. On January 22, 2018, the Company closed an underwritten public offering of 15,000,000 shares of the Company's common stock, par value \$0.001 per share ("Common Stock") and warrants to purchase 15,000,000 shares of Common Stock. At the closing, the Company also issued warrants to purchase an additional 1,970,625 shares of Common Stock pursuant to the underwriter's partial exercise of its overallotment option. The shares of Common Stock and warrants were sold at a combined public offering price of \$0.80 per share and warrant for total proceeds of approximately \$10.8 million. The warrants have an exercise price of \$0.80 per share and a term of five years from the date of issuance. In addition, at the closing, the Company issued to designees of the underwriter of the offering warrants to purchase up to 750,000 shares of Common Stock. The underwriter's warrants have an exercise price of \$1.00, a term of five years from the date of issuance and otherwise substantially similar terms to the form of investor warrant. As a result of the offering, all outstanding shares of the Company's Series A convertible preferred stock converted into 21,006,918 shares of Common Stock (including accrued dividends paid-in-kind and issuance of shares in respect of the "make-whole" adjustment feature thereof).

The Company currently does not have any commitments to obtain additional funds and may be unable to obtain sufficient funding in the future on acceptable terms, if at all. On March 2, 2018, the Company received a written notice from the staff of the Listing Qualifications Department of the Nasdaq Stock Market LLC (the "Staff") indicating the Company was not in compliance with Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Rule") because the bid price for the Company's common stock had closed below \$1.00 per share for the previous 30 consecutive business days. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company had 180 calendar days from the date of such notice, or until August 29, 2018, to regain compliance with the minimum bid price requirement. To regain compliance, the bid price for the Company's Common Stock must close at \$1.00 per share or more for a minimum of 10 consecutive business days. On August 30, 2018, the Company received a written notice from the Staff providing that, although the Company had not regained compliance with the Minimum Bid Price Rule by August 29, 2018, in accordance with Nasdaq Listing Rule 5810(c)(3)(F), the Staff had determined that the Company is eligible for an additional 180 calendar days from the date of such notice, or until February 25, 2019, to regain compliance with the Minimum Bid Price Rule.

DIFFUSION PHARMACEUTICALS INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

In the event the Company is unable to regain compliance, it could adversely affect the Company's ability to obtain future funding. 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. At the Company's 2018 Annual Meeting of Stockholders on June 14, 2018, the Company's stockholders approved an amendment to the Company's certificate of incorporation to effect a reverse stock split of the shares of the Company's common stock at a ratio of not less than 1-to-2 and not greater than 1-to-15, with the exact ratio and effective time of the reverse stock split to be determined by the Company's Board of Directors, if at all.

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.

Operations of the Company are subject to certain risks and uncertainties including various internal and external factors that will affect whether and when the Company's product candidates become approved drugs and how significant their market share will be, some of which are outside of the Company's control. The length of time and cost of developing and commercializing these product candidates and/or failure of them at any stage of the drug approval process will materially affect the Company's financial condition and future operations. The Company believes its cash and cash equivalents at September 30, 2018 are sufficient to fund operations in to September 2019.

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, 2017, filed with the Securities and Exchange Commission on April 2, 2018 have not materially changed, except as set forth below.

DIFFUSION PHARMACEUTICALS INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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, 2018, its results of operations for the three and nine months ended September 30, 2018 and 2017 and cash flows for the nine months ended September 30, 2018 and 2017. Operating results for the nine months ended September 30, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018. 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, 2017 filed with the SEC on Form 10-K on April 2, 2018.

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. As of December 31, 2017, the fair value of the Company’s outstanding Series B convertible debt was approximately \$0.6 million. The fair value of the convertible debt was determined using a binomial lattice model that utilizes certain unobservable inputs that fall within Level 3 of the fair value hierarchy.

Convertible Debt

Upon maturity of the Series B convertible debt during the second quarter of 2018, the Company repaid the outstanding principal and interest of approximately \$0.6 million and \$40,000, respectively. As such, the Company does not have any debt outstanding as of September 30, 2018.

DIFFUSION PHARMACEUTICALS INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Intangible Asset and Goodwill

Goodwill and intangible assets deemed to have indefinite lives are not amortized but rather are tested at least annually for impairment, or when circumstances indicate that the carrying amount of the asset may not be recoverable. If the carrying value of the reporting unit exceeds fair value, goodwill is considered impaired. In January 2017, the FASB issued revised guidance that simplifies the test for goodwill impairment, effective for fiscal years beginning after December 15, 2019, with early adoption permitted. Under the revised guidance, if a reporting unit's carrying value exceeds its fair value, an impairment charge will be recorded to reduce the reporting unit to fair value. Prior to the revised guidance, the amount of the impairment was the difference between the carrying value of the goodwill and the "implied" fair value, which was calculated as if the reporting unit had just been acquired and accounted for as a business combination. The Company has a single reporting unit and all goodwill relates to that reporting unit. The Company's RES-529 intangible asset and goodwill are 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 three or nine months ended September 30, 2018 and 2017. During the three months ended September 30, 2018, the Company recorded a non-cash goodwill impairment of \$4.2 million (see Note 5).

Income Taxes

On December 22, 2017 the President of the United States signed into law the Tax Cuts and Jobs Act ("The 2017 Tax Act"), which resulted in significant changes from previous tax law. Among other things, the 2017 Tax Act reduced the federal corporate income tax rate to 21% from 34% effective January 1, 2018 and also changed the net operating loss carryforwards' period such that all net operating losses generated in 2018 and into the future now have an indefinite life. As a result of the change in net operating loss carryforward period, during the three and nine months ended September 30, 2018, the Company recognized an income tax benefit of \$0.2 million and \$0.5 million, respectively, 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 the Company's deferred tax assets.

Net (Loss) Income Per Common Share

For the three and nine months ended September 30, 2017, the Company used the two-class method to compute net income per common share because the Company had issued securities (Series A convertible preferred stock) that entitled the holder to participate in dividends and earnings of the Company. Under this method, net income is reduced by any dividends earned during the period. The remaining earnings (undistributed earnings) were allocated to common stock and the Series A convertible preferred stock to the extent that the Series A convertible preferred stock was entitled to share in earnings as if all of the earnings for the period had been distributed. The total earnings allocated to common stock is then divided by the number of outstanding shares to which the earnings are allocated to determine the earnings per share. The two-class method is not applicable during periods with a net loss, as the holders of the convertible preferred stock would have no obligation to fund losses.

Diluted net (loss) income per common share is computed under the two-class method by using the weighted-average number of shares of common stock outstanding, plus, for periods with net income attributable to common stockholders, the potential dilutive effects of stock options, unvested restricted stock, warrants, and convertible debt. In addition, the Company analyzed the potential dilutive effect of the previously outstanding Series A convertible preferred stock under the "if-converted" method when calculating diluted earnings per share, in which it was assumed that the previously outstanding convertible preferred stock converted into common stock at the beginning of the period or when issued, if later. The Company would report the more dilutive of the approaches (two class or "if-converted") as its diluted net (loss) income per share during the period.

For the periods in which the Company reported a net loss, there was no dilutive effect under either the two-class or "if-converted" method. For the three months ended September 30, 2017, the Company presented diluted net income per common share using the two-class method, which was more dilutive than the "if-converted" method.

For purposes of calculating diluted loss per common share, the denominator includes both the weighted average common shares outstanding and the number of common stock equivalents if the inclusion of such common stock equivalents would be dilutive. Dilutive common stock equivalents potentially include stock options, unvested restricted stock awards and warrants using the treasury stock method. The diluted loss per common share calculation is further affected by an add-back of change in fair value of warrant liability to the numerator under the assumption that the change in fair value of warrant liability would not have been incurred if the warrants had been converted into common stock. In addition, the Company considers the potential dilutive impact of its convertible debt instruments using the "if-converted" method.

DIFFUSION PHARMACEUTICALS INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The following table sets forth the computation of basic and diluted earnings per share:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Basic net (loss) income per common share calculation:				
Net (loss) income	\$ (6,719,730)	\$ 5,096,856	\$ (12,798,872)	\$ (3,154,181)
Accretion of Series A cumulative preferred dividends	—	(366,641)	(85,993)	(912,946)
Undistributed earnings allocated to participating securities	—	(1,838,354)		
Deemed dividend related to the make-whole provision for the conversion of Series A preferred stock into common	—	—	(8,167,895)	—
Net (loss) income attributable to common	(6,719,730)	2,891,861	(21,052,760)	(4,067,127)
Weighted average common shares outstanding, basic	50,572,001	13,937,869	47,777,757	11,709,128
Net (loss) income per share of common, basic	\$ (0.13)	\$ 0.21	\$ (0.44)	\$ (0.35)
Diluted net income (loss) per common share calculation:				
Net income (loss) attributable to common	(6,719,730)	2,891,861	(21,052,760)	(4,067,127)
Change in fair value of warrant liability	—	—	—	(18,909,792)
Interest on convertible debt	—	28,891	—	—
Diluted net loss	(6,719,730)	2,920,752	(21,052,760)	(22,976,919)
Weighted average common shares outstanding, basic	50,572,001	13,937,869	47,777,757	11,709,128
Common stock equivalents arising from stock options	—	20,608	—	—
Common stock equivalents arising from warrants	—	—	—	816,579
Common stock equivalents arising from convertible debt	—	756,376	—	—
Common stock equivalents	50,572,001	14,714,853	47,777,757	12,525,707
Diluted net loss per share of common	\$ (0.13)	\$ 0.20	\$ (0.44)	\$ (1.83)

The following potentially dilutive securities outstanding as of September 30, 2018 and 2017 have been excluded from the computation of diluted weighted average shares outstanding, as they would be anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Convertible debt	—	—	—	213,879
Common stock warrants	31,303,012	14,003,608	31,303,012	447,721
Stock options	3,213,797	2,521,605	3,213,797	2,545,989
Unvested restricted stock awards	—	4,599	—	4,599
	34,516,809	16,529,812	34,516,809	3,212,188

DIFFUSION PHARMACEUTICALS INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Amounts in the table reflect the common stock equivalents of the noted instruments.

As a result of the offering of its common stock consummated in January 2018, all outstanding shares of the Company's Series A convertible preferred stock converted into shares common stock. See Note 6 of these unaudited interim condensed consolidated statements for further details.

Recent 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.

In June 2018, the FASB issued ASU 2018-07, *Improvements to Nonemployee Share-Based Accounting*, which simplifies the accounting for share-based payments granted to nonemployees for goods and services. The ASU supersedes ASC 505-50 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. As a result, most of the guidance in ASC 718 associated with employee share-based payments, including most of its requirements related to classification and measurement, applies to nonemployee share-based payment arrangements. ASU 2018-07 generally requires an entity to use a modified retrospective transition approach, with a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year of adoption, for all (1) liability-classified nonemployee awards that have not been settled as of the adoption date and (2) equity-classified nonemployee awards for which a measurement date has not been established. 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 consolidated results of operations, financial position and cash flows and related disclosures.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. The first part of this update addresses the complexity of accounting for certain financial instruments with down round features and the second part addresses the complexity of distinguishing liabilities from equity. The guidance is applicable to public business entities for fiscal years beginning after December 15, 2018 and interim periods within those years. The Company is currently evaluating the potential impact of the adoption of this standard on its consolidated results of operations, financial position and cash flows and related disclosures.

In January 2017, the FASB issued ASU 2017-04, *Intangibles-Goodwill and Other (Topic 350)* which simplifies the accounting for goodwill impairments by eliminating step 2 from the goodwill impairment test. Instead, if the carrying amount of a reporting unit exceeds its fair value, an impairment loss shall be recognized in an amount equal to that excess, limited to the total amount of goodwill allocated to that reporting unit. The standard will be effective for fiscal years beginning after December 15, 2019, including interim periods within such fiscal years. Early adoption is allowed for all entities as of January 1, 2017, for annual and any interim impairment tests occurring on or after January 1, 2017. The Company early adopted this standard in the third quarter of 2018. See Note 5 for further discussion of the Company's intangible assets, including goodwill.

DIFFUSION PHARMACEUTICALS INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which supersedes the guidance in ASC 840, *Leases*. ASC 842 will be effective for the Company on January 1, 2019, and the Company expects to apply the practical expedients allowed by the standard. See Note 8 for details of the Company's current lease arrangement. While the Company continues to evaluate the provisions of ASC 842 to determine how it will be impacted, the primary effect of adopting the new standard will be to record assets and obligations for current operating leases. The adoption of ASC 842 is not expected to have a material impact on the Company's results of operations or cash flows.

4. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	September 30, 2018	December 31, 2017
Accrued interest payable	\$ —	\$ 37,415
Accrued Series A dividends	—	1,062,314
Accrued payroll and payroll related expenses	618,131	312,221
Accrued professional fees	80,051	122,711
Accrued clinical studies expenses	47,688	63,350
Other accrued expenses	70,750	30,840
Total	\$ 816,620	\$ 1,628,851

5. Goodwill and Intangible Assets

Goodwill is the excess of the cost of an acquired entity over the net amounts assigned to tangible and intangible assets acquired and liabilities assumed. The Company applies ASC 350 "*Goodwill and Other Intangible Assets*," which requires testing goodwill for impairment on an annual basis. The Company evaluates goodwill on a consolidated basis as the Company is organized as a single reporting unit. The Company completes its annual impairment test on October 1 each year, or more frequently if triggering events indicate a possible impairment. The Company considers certain triggering events when evaluating whether an interim goodwill impairment analysis is warranted. Among these would be a significant long-term decrease in the market capitalization of the Company. The Company's market capitalization was below the carrying value of equity throughout the third quarter and as a result, management concluded that the carrying value of goodwill may not be recoverable and that a triggering event requiring an interim assessment of goodwill impairment had occurred during the three months ended September 30, 2018.

Management performed the goodwill impairment assessment using a market approach to estimate the fair value of the Company using the Company's market capitalization. This fair value was derived by multiplying the Company's shares outstanding by the average daily close prices of the Company's stock during the third quarter. The carrying value of the Company's net equity exceeded its fair value, and accordingly, the Company recognized a \$4.2 million non-cash impairment charge to goodwill that reduced the carrying value to fair value. The following table shows the changes in the carrying value of goodwill during the nine months ended September 30, 2018:

Carrying value of goodwill at December 31, 2017:	\$ 6,929,258
Impairment of goodwill	(4,186,050)
Carrying value of goodwill at September 30, 2018:	<u>\$ 2,743,208</u>

DIFFUSION PHARMACEUTICALS INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS^c

The Company has an indefinite-lived In-Process Research and Development Asset (IPR&D) called RES-529, which has a balance of \$8.6 million at both September 30, 2018 and December 31, 2017. RES-529 is a PI3K/Akt/mTOR pathway inhibitor in preclinical development for oncology. There was no impairment to the Company's RES-529 intangible asset recognized during the three or nine months ended September 30, 2018 or 2017.

6. Convertible Preferred Stock, Common Stock 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 15,000,000 shares of Common Stock and warrants to purchase 15,000,000 shares of Common Stock with an initial exercise price of \$0.80 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, 2,250,000 shares of Common Stock (the "Option Shares") and warrants to purchase up to 2,250,000 shares of Common Stock (the "Option Warrants"). The underwriter exercised its right to purchase a portion of the Option Warrants and received an additional 1,970,625 warrants to purchase Common Stock with an initial exercise price \$0.80 per share.

In addition, at the closing, the Company issued to designees of the underwriter warrants to purchase up to 750,000 shares of Common Stock. The underwriter's warrants have an exercise price of \$1.00 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 21,006,918 shares of Common Stock of which (i) 8,306,278 shares were issued for the automatic conversion of Series A convertible preferred stock (ii) 1,032,219 shares were issued upon settlement of accrued dividends and (iii) 11,668,421 shares were issued for the settlement of the "make-whole" adjustment feature. A deemed dividend of \$8.2 million was recognized for the value of the common shares issued for the settlement of the make-whole adjustment feature.

DIFFUSION PHARMACEUTICALS INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Common Stock Warrants

As of September 30, 2018, 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	26,500	\$37.50 - \$49.00	2018 through 2019
Common stock warrants issued related to Series A convertible preferred stock offering	13,555,887	\$2.22	March 2022
Common stock warrants issued in 2018 related to the common stock offering	17,720,625	\$0.80 - \$1.00	January 2023
	<u>31,303,012</u>		

During the nine months ended September 30, 2018, 421,221 warrants expired and no warrants were exercised.

7. 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, 580,785 shares were added to the reserve as of January 1, 2018, 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, 2018, there were 27,268 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,	
	2018	2017	2018	2017
Research and development	\$ 16,202	\$ 14,333	\$ 48,848	\$ 81,737
General and administrative	311,194	278,168	922,984	892,213
Total stock-based compensation expense	<u>\$ 327,396</u>	<u>\$ 292,501</u>	<u>\$ 971,832</u>	<u>\$ 973,950</u>

DIFFUSION PHARMACEUTICALS INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The following table summarizes the activity related to all stock option grants to employees and non-employees for the nine months ended September 30, 2018:

	Number of Options	Weighted average exercise price per share	Weighted average remaining contractual life (in years)
Balance at January 1, 2018	2,555,989	\$ 7.32	
Granted	660,000	1.02	
Expired	(2,192)	17.10	
Outstanding at September 30, 2018	<u>3,213,797</u>	<u>\$ 6.02</u>	7.01
Exercisable at September 30, 2018	<u>2,361,007</u>	<u>\$ 7.09</u>	6.35

Non-employee Stock Options

Non-employee stock options are remeasured to fair value each period using a Black-Scholes option-pricing model until the options vest. The Company did not grant any stock options to non-employees during the nine months ended September 30, 2018. The total fair value of non-employee stock options vested during the three months ended September 30, 2018 and 2017 was approximately \$1,000 and \$7,000, respectively. The total fair value of non-employee stock options vested during the nine months ended September 30, 2018 and 2017 was approximately \$3,000 and \$83,000, respectively. At September 30, 2018, there were 5,166 unvested options subject to remeasurement and approximately \$2,000 of unrecognized compensation expense that will be recognized over a weighted-average period of 1.26 years.

Employee Stock Options

During the nine months ended September 30, 2018, the Company granted 660,000 stock options to employees. The weighted average grant date fair value of stock option awards granted to employees was \$0.86 during the nine months ended September 30, 2018. During the three months ended September 30, 2018 and 2017 the Company recognized stock-based compensation expense of \$0.3 million and \$0.3 million, respectively. During the nine months ended September 30, 2018 and 2017, the Company recognized stock-based compensation expense of \$1.0 million and \$0.9 million, respectively. No options were exercised during any of the periods presented. At September 30, 2018, there was \$2.1 million of unrecognized compensation expense that will be recognized over a weighted-average period of 5.2 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, 2018 and 2017 were as follows:

	<u>2018</u>	<u>2017</u>
Expected term (in years)	5.57	6.03
Risk-free interest rate	2.4%	2.0%
Expected volatility	114.7%	114.9%
Dividend yield	—%	—%

DIFFUSION PHARMACEUTICALS INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Restricted Stock Awards

As of September 30, 2018, there were no unvested shares of restricted stock. During the nine months ended September 30, 2018 and 2017, there were 3,066 and 4,599 shares that vested, respectively and the Company recognized stock-based compensation expense of approximately \$6,000 and \$9,000, respectively.

8. Commitments and Contingencies

Office Space Rental

The Company leases office and laboratory facilities in Charlottesville, Virginia. Rent expense related to the Company's operating lease for the three months ended September 30, 2018 and 2017 was approximately \$28,000 and \$28,000, respectively. Rent expense for the nine months ended September 30, 2018 and 2017 was approximately \$84,000 and \$80,000, respectively. The Company will continue to recognize rent expense on a straight-line basis over the lease period and will accrue for rent expense incurred but not yet paid. Future minimum rental payments under the Company's non-cancelable operating lease at September 30, 2018 was as follows:

	Rental Commitments
2018	\$ 28,260
2019	114,409
2020	116,464
2021	118,519
2022	39,735
Total	<u>\$ 417,387</u>

Arrangement with Clinical Research Organization

On July 5, 2017, the Company entered into a Master Services Agreement ("MSA") with a contract research organization ("CRO") to provide clinical trial services for individual studies and projects by executing individual work orders. The MSA and associated work orders are designed such that payments are to be made in advance of the work to be performed. The Company recognized research and development expenses related to this MSA of \$0.4 million and \$1.6 million during the three and nine months ended September 30, 2018. As of September 30, 2018, there was \$0.3 million of prepaid research and development costs that are estimated to be recognized during 2018.

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. No arbitration hearing has yet been scheduled. A dismissal hearing is scheduled for November 19, 2018. 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, 2017. 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 focused on extending the life expectancy of cancer patients by improving the effectiveness of current standard-of-care treatments, including radiation therapy and chemotherapy. We are developing our lead product candidate, *transcrocinatate sodium*, also known as *trans sodium crocinatate* (“TSC”), for use in the many cancer types in which tumor oxygen deprivation (“hypoxia”) is known to diminish the effectiveness of current treatments. TSC is designed to target the cancer’s hypoxic micro-environment, re-oxygenating treatment-resistant tissue and making the cancer cells more susceptible to the therapeutic effects of standard-of-care radiation therapy and chemotherapy. Other possible uses of TSC include the treatment of hypoxic conditions such as stroke, cardiovascular disease, neurodegenerative disease and emergency medicine.

Our lead development programs target TSC against cancers known to be inherently treatment-resistant, with a focus on brain cancer. A Phase 2 clinical program, completed in the second quarter of 2015, evaluated 59 patients with newly diagnosed glioblastoma multiforme (“GBM”). This open label, historically controlled study demonstrated a favorable safety and efficacy profile for TSC combined with 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. 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. TSC with concomitant temozolomide is being assigned to the first 8 patients. During their temozolomide-only treatment period, these patients will be assigned TSC at ascending doses over two 28-day cycles, with the Data Safety Monitoring Board examining and reporting on the resultant data.

Using its novel mechanism of action, TSC has been shown to safely re-oxygenate a range of tumor types in our preclinical and clinical studies. Diffusion believes its therapeutic potential is not limited to one specific tumor type, thereby making it potentially useful to improve standard-of-care treatments of other life-threatening cancers. Given TSC’s safety profile and animal data, we can, with appropriate funding, move directly into Phase 2 studies in other cancers. We also believe that TSC has potential application in other indications involving hypoxia, such as stroke, cardiovascular disease, neurodegenerative diseases and emergency medicine. In September 2018, we received approval from the U.S. Food and Drug Administration to enroll patients in an ambulance-based Phase 2 clinical trial testing using TSC, for the treatment of acute stroke. The trial, named PHAST-TSC (Pre-Hospital Ambulance Stroke Trial-TSC), will involve 23 hospitals across urban, suburban, and rural areas in Los Angeles and Central Virginia, working closely with approximately 150 emergency medical transport groups. The decision on when to commence this trial will be based principally on two factors. The first is driven by timing on key contract negotiations which are expected to continue into early 2019. The second factor is availability of additional funding either through a financing or a collaboration partner.

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 is currently 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 can cross the blood brain barrier.

Financial Summary

In January 2018, we closed our underwritten public offering of 15,000,000 shares of our Common Stock, par value \$0.001 per share, and warrants to purchase 15,000,000 shares of Common Stock. At the closing, we also issued warrants to purchase an additional 1,970,625 shares of Common Stock pursuant to the underwriter's partial exercise of its over-allotment option. The shares of Common Stock and warrants were sold at a combined public offering price of \$0.80 per share and warrant for total gross proceeds of approximately \$12.0 million. The warrants have an exercise price of \$0.80 per share and a term of five years from the date of issuance. In addition, at the closing, the Company issued to designees of the underwriter of the offering warrants to purchase up to 750,000 shares of Common Stock. The underwriter's warrants have an exercise price of \$1.00, a term of five years from the date of issuance and otherwise substantially similar terms to the form of investor warrant.

At September 30, 2018, we had cash and cash equivalents of \$11.0 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 \$6.7 million and \$12.8 million for the three and nine months ended September 30, 2018, respectively. Our accumulated deficit as of September 30, 2018 was \$74.4 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:

- complete regulatory and manufacturing activities and commence our planned Phase II and III clinical trials for TSC;
- 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 for use in the treatment of GBM and other hypoxia related indications. We believe that our cash and cash equivalents as of September 30, 2018 will enable us to fund our operating expenses and capital expenditure requirements in to September 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. As we advance our product candidates, we expect the amount of research and development costs will continue to increase for the foreseeable future.

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) Expense, Net

Interest (income) expense, net consists principally of interest earned from our cash and cash equivalents offset by the interest expense recorded in connection with our convertible debt instruments.

Change in Fair Value of Warrant Liabilities, Warrant Related Expenses, and Other Financing Expenses

In connection with our Series A convertible preferred stock private placement in March 2017, we recorded warrant expense associated with the change in fair value of the common stock warrants from issuance, the excess fair value of the common stock warrants over the gross cash proceeds from such offering, and placement agent commissions and other offering costs. Until their reclassification into stockholders' equity in November 2017 in connection with the amendment of our certificate of incorporation, the warrants were liability classified and remeasured at each reporting period with changes in fair value recorded through earnings. As a result of the offering of our common stock consummated in January 2018, all outstanding shares of the Company's Series A convertible preferred stock converted into shares common stock.

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"), the Company recognized an 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 the Company's deferred tax assets.

Results of Operations for Three Months Ended September 30, 2018 Compared to Three Months Ended September 30, 2017

The following table sets forth our results of operations for the three months ended September 30, 2018 and 2017.

	Three Months Ended September 30, 2018		Change
	2018	2017	
Operating expenses:			
Research and development	\$ 1,169,810	\$ 1,759,305	\$ (589,495)
General and administrative	1,589,621	1,559,399	30,222
Goodwill impairment	4,186,050	—	4,186,050
Depreciation	26,723	27,374	(651)
Loss from operations	6,972,204	3,346,078	3,626,126
Other expense (income):			
Interest income, net	(37,981)	(1,318)	(36,663)
Change in fair value of warrant liabilities	—	(8,441,616)	8,441,616
(Loss) income from operations before income tax benefit	(6,934,223)	5,096,856	(12,031,079)
Income tax benefit	(214,493)	—	(214,493)
Net (loss) income	<u>\$ (6,719,730)</u>	<u>\$ 5,096,856</u>	<u>\$ (11,816,586)</u>

We recognized \$1.2 million in research and development expenses during the three months ended September 30, 2018 compared to \$1.8 million during the three months ended September 30, 2017. The decrease in research and development expense was attributable to a \$0.3 million decrease in expense related to our Phase 3 GMB trial and a decrease in manufacturing expense of \$0.4 million, offset by a \$0.1 million increase in salary and wages expense. The decrease in GBM expense was attributable to the fact that the current 8 patient dose escalation phase of the trial is less costly than the startup and implementation costs that were incurred during the three months ended September 30, 2017.

General and administrative expenses were \$1.6 million during the three months ended September 30, 2018 compared to \$1.6 million during the three months ended September 30, 2017. Although overall general and administrative expenses remained flat, there was a \$0.2 million decrease in professional fees, offset by an increase in salary and wages expense of \$0.2 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. There was no such charge during the three months ended September 30, 2017.

The change in interest income, net for the three months ended September 30, 2018 compared to the three months ended September 30, 2017 is primarily attributable to having a larger cash and cash equivalents balance earning more interest during the three months ended September 30, 2018 compared to the three months ended September 30, 2017. During the three months ended September 30, 2017, we had a higher debt principal balance with a higher interest rate outstanding compared to having no debt outstanding during the same period in 2018.

In connection with the private placement of our Series A convertible preferred stock and common stock warrants in March 2017, we determined the warrants to be classified as liabilities and subject to remeasurement at each reporting period. As a result of the liability classification, during the three months ended September 30, 2017, we recorded a \$8.4 million gain for the change in fair value of our common stock warrant liabilities which was primarily attributable to the decrease in the market price for our common stock. There were no such charges in 2018 as the warrants were reclassified into equity in November of 2017.

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 adjustment allowed by the 2017 Tax Act to utilize indefinite deferred tax liabilities as a source of income against indefinite lived portions of the Company's deferred tax assets.

Results of Operations for Nine Months Ended September 30, 2018 Compared to Nine Months Ended September 30, 2017

The following table sets forth our results of operations for the nine months ended September 30, 2018 and 2017.

	Nine Months Ended September 30,		Change
	2018	2017	
Operating expenses:			
Research and development	\$ 4,386,491	\$ 3,946,420	\$ 440,071
General and administrative	4,748,090	4,908,424	(160,334)
Goodwill impairment	4,186,050	—	4,186,050
Depreciation	81,450	39,767	41,683
Loss from operations	13,402,081	8,894,611	4,507,470
Other expense (income):			
Interest (income) expense, net	(120,784)	73,290	(194,074)
Change in fair value of warrant liabilities	—	(18,909,792)	18,909,792
Warrant related expenses	—	10,225,846	(10,225,846)
Other financing expenses	—	2,870,226	(2,870,226)
Loss from operations before income tax benefit	(13,281,297)	(3,154,181)	(10,127,116)
Income tax benefit	(482,425)	—	(482,425)
Net loss	<u>\$ (12,798,872)</u>	<u>\$ (3,154,181)</u>	<u>\$ (9,644,691)</u>

We recognized \$4.4 million in research and development expenses during the nine months ended September 30, 2018 compared to \$3.9 million during the nine months ended September 30, 2017. The increase in research and development expense was mainly attributable to a \$1.6 million increase in expense related to our Phase 3 GBM trial and an increase in salary and wages expense of \$0.2 million, offset by a \$1.3 million decrease in manufacturing costs.

General and administrative expenses were \$4.7 million during the nine months ended September 30, 2018 compared to \$4.9 million during the nine months ended September 30, 2017. The decrease in general and administrative expense was primarily due to a \$0.8 million decrease in professional fees offset by an increase in salary and other expense of \$0.6 million.

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. There was no such charge during the nine months ended September 30, 2017.

The change in interest (income) expense, net for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017 is primarily attributable to having a larger cash and cash equivalents balance earning more interest during the nine months ended September 30, 2018 compared to the same period in 2017. During the nine months ended September 30, 2017, we had a larger debt principal balance with a higher interest rate outstanding compared to the same period in 2018.

For the nine months ended September 30, 2017, we recorded an \$18.9 million gain for the change in fair value of our common stock warrant liabilities which was primarily attributable to the decrease in the market price for our common stock. We also recognized \$10.2 million in excess fair value of the common stock warrants over the gross proceeds from our private placement and \$2.9 million in placement agent commissions and other offering costs. There were no such charges in 2018 as the warrants were reclassified into equity in November of 2017.

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 \$0.5 million 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 the Company's 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 debt. In January 2018, the Company closed an underwritten public offering of 15,000,000 shares of Common Stock and warrants to purchase 15,000,000 shares of Common Stock and received approximately \$10.6 million aggregate net proceeds. As of September 30, 2018, we had \$11.0 million in cash and cash equivalents, working capital of \$10.6 million and an accumulated deficit of \$74.4 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, 2018 and 2017:

	Nine Months Ended September 30,	
	2018	2017
Net cash (used in) provided by:		
Operating activities	\$ (7,745,547)	\$ (10,050,042)
Investing activities	—	(10,438,604)
Financing activities	9,867,520	20,151,794
Net increase (decrease) in cash and cash equivalents	<u>\$ 2,121,973</u>	<u>\$ (336,852)</u>

Operating Activities

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.

Net cash used in operating activities of \$10.1 million during the nine months ended September 30, 2017 was primarily attributable to our net loss of \$3.2 million \$5.8 million in non-cash warrant related and other financing expenses and our net change in operating assets and liabilities of \$2.2 million. This amount was offset by \$1.0 million in stock-based compensation expense. The net change in our operating assets and liabilities is primarily attributable to the decrease in our accounts payable due to the timing of payments to our vendors, offset by an increase in accrued expenses due to additional accrued interest and dividends as well as an increase in prepaid expenses, mainly related to prepaid research and development and insurance costs.

Investing Activities

During the nine months ended September 30, 2017, we purchased a certificate of deposit in the amount of \$10.0 million and had approximately \$439,000 in fixed asset purchases. We had no such purchases in 2018.

Financing Activities

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. Net cash provided by financing activities was \$20.2 million during the nine months ended September 30, 2017, which was attributable to the \$22.1 million in proceeds received upon the closing of our Series A private placement offset by approximately \$98,000 in payments for Series B offering costs. This amount was further offset by the repayment of our convertible note in the amount of \$1.9 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 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. While we believe we have adequate cash resources to continue operations in to September 2019, we will need to raise additional funds in order to complete this trial. 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.

As of September 30, 2018, 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.

On March 2, 2018, we received a written notice from NASDAQ indicating we were not in compliance with Nasdaq Listing Rule 5550(a)(2) (the “Minimum Bid Price Rule”) because the bid price for the Common Stock had closed below \$1.00 per share for the previous 30 consecutive business days. On August 30, 2018, the Company received a written notice from NASDAQ providing that, although the Company had not regained compliance with the Minimum Bid Price Rule by August 29, 2018, in accordance with Nasdaq Listing Rule 5810(c)(3)(F), the Staff had determined that the Company is eligible for an additional 180 calendar days from the date of such notice, or until February 25, 2019, to regain compliance with the Minimum Bid Price Rule. See Note 2 of our unaudited interim condensed consolidated statements for further details. At the Company’s 2018 Annual Meeting of Stockholders on June 14, 2018, the Company’s stockholders approved an amendment to the Company’s certificate of incorporation to effect a reverse stock split of the shares of the Company’s common stock at a ratio of not less than 1-to-2 and not greater than 1-to-15, with the exact ratio and effective time of the reverse stock split to be determined by the Company’s Board of Directors, if at all.

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, 2017, filed with the SEC pursuant to Section 13 or 15(d) under the Securities Act on April 2, 2018, as amended to this date, 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;
- 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;
- the success of competing products that are or may become available;
- the performance of third parties, including contract research organizations and manufacturers; and
- the ability of the Company to continue as a going concern.

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 April 2, 2018, 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 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, 2018 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 8, 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 1A - “Risk Factors,” in our Annual Report on Form 10-K for the year ended December 31, 2017, 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, 2017, except as set forth below.

We have a history of operating losses and expect to continue to incur losses in the foreseeable future, which raises substantial doubt about our ability to continue as a going concern.

As discussed further in Note 2 to our unaudited consolidated financial statements included herein, we have a history of operating losses and expect to continue to incur losses in the foreseeable future, which raises substantial doubt regarding our ability to continue as a going concern. We currently have no sources of revenue and our ability to continue as a going concern is dependent on our ability to raise capital to fund our 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 our ability to continue as a going concern. The consolidated financial statements 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.

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

On November 8, 2018, Isaac Blech provided notice to the Company of his resignation from the board of directors of the Company (the “Board”) effective immediately. Mr. Blech was not serving as a member of any committee of the Board prior to his resignation. Mr. Blech indicated that his decision to resign was due to his desire to focus on other personal pursuits and was not the result of any disagreement with the Company, the Company’s management or the Board.

ITEM 6. EXHIBITS

See attached Exhibit Index.

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

Exhibit No.	Description	Method of Filing
3.1	<u>Certificate of Incorporation of Diffusion Pharmaceuticals, Inc., as amended</u>	Filed herewith
10.1	<u>Amended and Restated Employment Agreement, dated as of September 21, 2018, by and between William Hornung and Diffusion Pharmaceuticals Inc.</u>	Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 27, 2018.
10.2	<u>Separation Letter, effective as of September 26, 2018, by and between Ben L. Shealy and Diffusion Pharmaceuticals Inc.</u>	Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 27, 2018.
31.1	<u>Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)</u>	Filed herewith
31.2	<u>Certification of principal financial officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)</u>	Filed herewith
32.1	<u>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</u>	Furnished herewith
32.2	<u>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</u>	Furnished herewith
101	The following materials from Diffusion's quarterly report on Form 10-Q for the quarter ended September 30, 2018, 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 13, 2018

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)

29

[\(Back To Top\)](#)

Section 2: EX-3.1 (EXHIBIT 3.1)

EXHIBIT 3.1

CERTIFICATE OF INCORPORATION OF DIFFUSION PHARMACEUTICALS INC. (AS AMENDED)

ARTICLE I NAME

The name of the corporation is Diffusion Pharmaceuticals Inc. (the "Corporation").

ARTICLE II REGISTERED OFFICE AND AGENT

The address of the registered office of the Corporation in the State of Delaware is 615 South Dupont Hwy., in the City of Dover, Zip Code of 19901, County of Kent. The name of the registered agent of the Corporation at that address is National Corporate Research, Ltd.

ARTICLE III PURPOSE

The purpose of the Corporation is to engage in any lawful act or activity for which a corporation may be organized under the General Corporation Law of the State of Delaware ("DGCL").

ARTICLE IV CAPITAL STOCK

A. The total number of shares of common stock which the Corporation shall have authority to issue is 1,000,000,000, at a par value of \$0.001 per share ("Common Stock"), and the total number of shares of preferred stock which the Corporation shall have authority to issue is 30,000,000, at a par value of \$0.001 per share ("Preferred Stock").

1. Common Stock. All preferences, voting powers, relative, participating, optional or other special rights and privileges, and qualifications, limitations, or restrictions of the Common Stock are expressly made subject and subordinate to those that may be fixed with respect to any shares of the Preferred Stock. Except as otherwise required by law or this Certificate of Incorporation, each share of Common Stock shall entitle the holder thereof to one (1) vote, in person or by proxy, on each matter submitted to a vote of stockholders of the Corporation. Subject to the preferential rights of the Preferred Stock, the holders of shares of Common Stock shall be entitled to receive, when and if declared by the Board of Directors, out of the assets of the Corporation which are by law available therefor, dividends payable

either in cash, in property or in shares of capital stock. In the event of any dissolution, liquidation or winding up of the affairs of the Corporation, after distribution in full of the preferential amounts, if any, to be distributed to the holders of shares of the Preferred Stock, holders of Common Stock shall be entitled, unless otherwise provided by law or this Certificate of Incorporation, to receive all of the remaining assets of the Corporation of whatever kind available for distribution to stockholders ratably in proportion to the number of shares of Common Stock held by them respectively.

2. Preferred Stock. The Preferred Stock may be issued from time to time in one or more series, as determined by the Board of Directors of the Corporation (the "Board of Directors"). The Board of Directors is expressly authorized to provide for the issue, in one or more series, of all or any of the remaining shares of Preferred Stock and, in the resolution or resolutions providing for such issue, to establish for each such series the number of its shares, the voting powers, full or limited, of the shares of such series, or that such shares shall have no voting powers, and the designations, preferences and relative, participating, optional or other special rights, if any, of the shares of such series, and any qualifications, limitations or restrictions thereof. The powers, preferences and relative, participating, optional and other special rights of each series of preferred stock and the qualifications, limitations or restrictions thereof, if any, may differ from those of any and all other series at any time outstanding. The Board of Directors is further expressly authorized to increase or decrease (but not below the number of shares of any such series then outstanding) the number of shares of any series, the number of which was fixed by it, subsequent to the issuance of shares of such series then outstanding, subject to the powers, preferences and rights, and the qualifications, limitations and restrictions thereof stated in this Certificate of Incorporation or the resolution of the Board of Directors originally fixing the number of shares of such series. If the number of shares of any series is so decreased, then the shares constituting such decrease shall resume the status which they had prior to the adoption of the resolution originally fixing the number of shares of such series.

Effective upon the effective time of the Certificate of Amendment of the Certificate of Incorporation filed on August 17, 2016 with the Secretary of State of the State of Delaware (the "Effective Time"), each ten (10) shares of Common Stock issued and outstanding immediately prior to the Effective Time shall, automatically and without the necessity for any further action, be changed, reclassified and combined into one (10 share of Common Stock (the "Reverse Stock Split"). No fractional shares shall be issued in connection with the Reverse Stock Split. Stockholders who otherwise would be entitled to receive fractional shares of Common Stock shall have that rounded up to one additional whole share. Each certificate that immediately prior to the Effective Time represented shares of Common Stock ("Old Certificates") shall thereafter represent that number of shares of Common Stock into which the shares of Common Stock represented by the Old Certificate shall have been combined, subject to the elimination of fractional shares as described above.

ARTICLE V EXCULPATION AND INDEMNIFICATION

A. Limitation of Liability. A director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except to the extent such exemption from liability or limitation thereof is not permitted under the DGCL as it presently exists or may hereafter be amended. Any amendment, modification or repeal of the foregoing sentence shall not adversely affect any right arising prior to the time of such amendment, modification or repeal.

B. Right of Indemnification. The Corporation shall indemnify and hold harmless, to the fullest extent permitted by applicable law as it presently exists or may hereafter be amended, any person (a "Covered Person") who was or is made or is threatened to be made a party or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative (a "Proceeding"), by reason of the fact that he or she, or a person for whom he or she is the legal representative, is or was a director, officer, employee or agent of the Corporation or, while a director, officer, employee or agent of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys' fees) reasonably incurred by such Covered Person. Notwithstanding the preceding sentence, except as otherwise provided in section D of this Article V, the Corporation shall not be required to indemnify a Covered Person in connection with a Proceeding (or part thereof) commenced by such Covered Person unless the commencement of such Proceeding (or part thereof) by the Covered Person was authorized in the specific case by the Board of Directors.

C. Prepayment of Expenses. The Corporation shall to the fullest extent not prohibited by applicable law pay the expenses (including attorneys' fees) incurred by a Covered Person in defending any Proceeding in advance of its final disposition, provided, however, that, to the extent required by law, such payment of expenses in advance of the final disposition of the Proceeding shall be made only upon receipt of an undertaking by the Covered Person to repay all amounts advanced if it should be ultimately determined that the Covered Person is not entitled to be indemnified under this Article V or otherwise.

D. Claims. If a claim for indemnification (following the final disposition of the Proceeding with respect to which indemnification is sought, including any settlement of such Proceeding) or advancement of expenses under this Article V is not paid in full within thirty (30) days after a written claim therefor by the Covered Person has been received by the Corporation, the Covered Person may file suit to recover the unpaid amount of such claim and, if successful in whole or in part, shall be entitled to be paid the expense of prosecuting such claim to the fullest extent permitted by applicable law. In any such action the Corporation shall have the burden of proving that the Covered Person is not entitled to the requested indemnification or advancement of expenses under this Article V and applicable law.

E. Non-Exclusivity of Rights. The rights conferred on any Covered Person by this Article V shall not be exclusive of any other rights which such Covered Person may have or hereafter acquire under any statute, any other provision of this Certificate of Incorporation, the Bylaws of the Corporation, or any agreement, vote of stockholders or disinterested directors or otherwise.

F. Insurance. The Corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the Corporation would have the power to indemnify such person against such liability under this Article V, the DGCL or otherwise.

G. Amendment or Repeal. Any right to indemnification or to advancement of expenses of any Covered Person arising hereunder shall not be eliminated or impaired by an amendment to or repeal of this Article V after the occurrence of the act or omission that is the subject of the civil, criminal, administrative or investigative action, suit or proceeding for which indemnification or advancement of expenses is sought.

H. Other Indemnification and Advancement of Expenses. This Article V shall not limit the right of the Corporation, to the extent and in the manner permitted by law, to indemnify and to advance expenses to persons other than Covered Persons when and as authorized by appropriate corporate action.

ARTICLE VI MANAGEMENT

For the management of the business and for the conduct of the affairs of the Corporation, and in further definition, limitation and regulation of the powers of the Corporation, of its directors and of its stockholders or any class thereof, as the case may be, it is further provided that:

A. The management of the business and the conduct of the affairs of the Corporation shall be vested in the Board of Directors. The Board of Directors shall fix the number of directors that constitute the whole Board of Directors in the manner provided in the Bylaws of the Corporation, subject to any restrictions that may be set forth in this Certificate of Incorporation.

B. In furtherance and not in limitation of the powers conferred by statute, the Board of Directors is expressly empowered to adopt, amend or repeal the Bylaws of the Corporation or adopt new Bylaws of the Corporation without any action on the part of the stockholders. Any adoption, amendment or repeal of the Bylaws of the Corporation by the Board of Directors shall require the approval of a majority of the directors then in office. The stockholders of the Corporation shall also have the power to adopt, amend or repeal the Bylaws of the Corporation; provided, however, that, in addition to any vote of the holders of any class or series of stock of the Corporation required by law or by this Certificate of Incorporation, the affirmative vote of the holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting power of all of the then-outstanding shares of the capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required to adopt, amend or repeal any provision of the Bylaws of the Corporation.

C. The Corporation reserves the right to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by the DGCL, and all rights conferred upon stockholders herein are granted subject to this reservation.

ARTICLE VII STOCKHOLDER MEETINGS

Meetings of stockholders may be held within or without the State of Delaware, as the Bylaws of the Corporation may provide. Elections of directors need not be by written ballot unless and except to the extent that the Bylaws of the Corporation so provide. Any action required to or which may be taken at a meeting of stockholders of the corporation may be taken without a meeting if authorized by a writing signed by all of the holders of shares who would be entitled to vote upon the action at a meeting for such purpose.

**ARTICLE VIII
INCORPORATOR**

The name and mailing address of the incorporator of the Corporation are as follows:

Amy E. Culbert
Oppenheimer Wolff & Donnelly LLP
Campbell Mithun Tower, Suite 2000
222 South Ninth Street
Minneapolis, MN 55402

**ARTICLE IX
EFFECTIVE TIME**

This Certificate of Incorporation shall be effective as of 5:00 p.m. Eastern Time on June 18, 2015.

The undersigned, being the incorporator named above, for the purpose of forming a corporation pursuant to the DGCL, does hereby make this Certificate of Incorporation, hereby acknowledging, declaring and certifying that the foregoing Certificate of Incorporation is the undersigned's act and deed and the facts herein stated are true, and accordingly has hereunto set the undersigned's hand this 17th day of June, 2015.

INCORPORATOR:

By: /s/ Amy E. Culbert
Amy E. Culbert

Amended: January 8, 2016; August 17, 2016; January 23, 2017; March 13, 2017; August 13, 2018.

[\(Back To Top\)](#)

Section 3: EX-31.1 (EXHIBIT 31.1)

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 13, 2018

/s/ David G. Kalergis

David G. Kalergis
Chairman and Chief Executive Officer
(Principal Executive Officer)

[\(Back To Top\)](#)

Section 4: EX-31.2 (EXHIBIT 31.2)

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.

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

[\(Back To Top\)](#)

Section 5: EX-32.1 (EXHIBIT 32.1)

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, 2018 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 13, 2018

[\(Back To Top\)](#)

Section 6: EX-32.2 (EXHIBIT 32.2)

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, 2018 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 13, 2018

[\(Back To Top\)](#)