Neuralstem, Inc.
Form 10-Q
November 14, 2018

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

**(Mark one)**

**Quarterly Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934**

**For the Quarterly Period Ended September 30, 2018**

**Or**

**Transition Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Commission File Number 001-33672**

**NEURALSTEM, INC.**

(Exact name of registrant as specified in its charter)

| | |
|---|---|
| **Delaware** | **52-2007292** |
| State or other jurisdiction of incorporation or organization | (I.R.S. Employer Identification No.) |

**20271 Goldenrod Lane**
**Germantown, Maryland** **20876**
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code **(301)-366-4841**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company

Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act) Yes No

As of October 31, 2018, there were 18,205,060 shares of common stock, $.01 par value, issued and outstanding.

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**Neuralstem, Inc.**

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**PART I**

**FINANCIAL INFORMATION**

**ITEM 1. UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

Neuralstem, Inc.

Unaudited Condensed Consolidated Balance Sheets

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| ASSETS | | |
| CURRENT ASSETS | | |
| Cash and cash equivalents | $5,736,929 | $6,674,940 |
| Short-term investments | - | 5,000,000 |
| Trade and other receivables | 161,979 | 312,802 |
| Current portion of related party receivable, net of discount | 62,248 | 58,784 |
| Prepaid expenses | 545,187 | 402,273 |
| Total current assets | 6,506,343 | 12,448,799 |
| | | |
| Property and equipment, net | 107,154 | 172,886 |
| Patents, net | 788,733 | 883,462 |
| Related party receivable, net of discount and current portion | 290,354 | 365,456 |
| Other assets | 28,475 | 13,853 |
| Total assets | $7,721,059 | $13,884,456 |
| | | |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| CURRENT LIABILITIES | | |
| Accounts payable and accrued expenses | $835,749 | $875,065 |
| Accrued bonuses | - | 418,625 |
| Other current liabilities | 348,928 | 220,879 |
| Total current liabilities | 1,184,677 | 1,514,569 |
| | | |
| Warrant liabilities, at fair value | 2,047,563 | 3,852,882 |
| Other long term liabilities | 9,715 | 1,876 |
| Total liabilities | 3,241,955 | 5,369,327 |
| | | |
| Commitments and contingencies (Note 5) | | |

| | | |
|---|---|---|
| STOCKHOLDERS' EQUITY | | |
| Preferred stock, 7,000,000 shares authorized, $0.01 par value; 1,000,000 shares issued and outstanding at both September 30, 2018 and December 31, 2017 | 10,000 | 10,000 |
| Common stock, $0.01 par value; 300,000,000 shares authorized, 15,205,060 and 15,160,014 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively | 152,051 | 151,600 |
| Additional paid-in capital | 217,619,996 | 217,050,174 |
| Accumulated other comprehensive income | 630 | 2,631 |
| Accumulated deficit | (213,303,573) | (208,699,276) |
| Total stockholders' equity | 4,479,104 | 8,515,129 |
| Total liabilities and stockholders' equity | $7,721,059 | $13,884,456 |

See accompanying notes to unaudited condensed consolidated financial statements.

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**Neuralstem, Inc.**

Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Revenues | $2,500 | $2,500 | $257,500 | $7,500 |
| Operating expenses: | | | | |
| Research and development expenses | 897,098 | 1,383,863 | 3,081,319 | 6,871,028 |
| General and administrative expenses | 1,188,076 | 1,206,510 | 3,630,822 | 4,174,583 |
| Total operating expenses | 2,085,174 | 2,590,373 | 6,712,141 | 11,045,611 |
| Operating loss | (2,082,674) | (2,587,873) | (6,454,641) | (11,038,111) |
| Other income (expense): | | | | |
| Interest income | 17,619 | 18,099 | 54,882 | 52,995 |
| Interest expense | (1,498) | (1,383) | (4,190) | (155,843) |
| Change in fair value of derivative instruments | 236,270 | 2,679,770 | 1,805,319 | (403,155) |
| Fees related to issuance of indcuement warrants and other expenses | - | (242,396) | (5,667) | (806,115) |
| Total other income (expense) | 252,391 | 2,454,090 | 1,850,344 | (1,312,118) |
| Net loss | $(1,830,283) | $(133,783) | $(4,604,297) | $(12,350,229) |
| Net loss per share - basic | $(0.12) | $(0.01) | $(0.30) | $(1.00) |
| Net loss per share - diluted | $(0.12) | $(0.18) | $(0.30) | $(1.00) |
| Weighted average common shares outstanding - basic | 15,171,495 | 14,060,844 | 15,144,425 | 12,380,054 |
| Weighted average common shares outstanding - diluted | 15,171,495 | 14,163,072 | 15,144,425 | 12,380,054 |
| Comprehensive loss: | | | | |
| Net loss | $(1,830,283) | $(133,783) | $(4,604,297) | $(12,350,229) |
| Foreign currency translation adjustment | (512) | (1,005) | (2,001) | (1,560) |
| Comprehensive loss | $(1,830,795) | $(134,788) | $(4,606,298) | $(12,351,789) |

See accompanying notes to unaudited condensed consolidated financial statements.

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Neuralstem, Inc.

Unaudited Condensed Consolidated Statements of Cash Flows

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2018 | 2017 |
| Cash flows from operating activities: | | |
| Net loss | $(4,604,297) | $(12,350,229) |
| Adjustments to reconcile net loss to cash used in operating activities: | | |
| Depreciation and amortization | 160,464 | 233,589 |
| Share-based compensation expense | 570,273 | 1,504,143 |
| Amortization of deferred financing fees and debt discount | - | 59,781 |
| Change in fair value of liability classified warrants | (1,805,319) | 403,155 |
| Warrant inducement expense | - | 563,744 |
| Expenses related to issuance of derivative instruments | - | 242,676 |
| Loss on disposal of fixed assets | - | 8,128 |
| Changes in operating assets and liabilities: | | |
| Trade and other receivables | 150,823 | (26,967) |
| Related party receivable | 71,638 | 63,856 |
| Prepaid expenses | (154,271) | 150,589 |
| Other assets | (4,000) | 1,971 |
| Accounts payable and accrued expenses | (25,487) | (920,624) |
| Accrued bonuses | (418,625) | (852,963) |
| Other current liabilities | 26,288 | (196,132) |
| Other long term liabilities | (1,876) | (14,809) |
| Net cash used in operating activities | (6,034,389) | (11,130,092) |
| Cash flows from investing activities: | | |
| Maturity of short-term investments | 5,000,000 | 5,000,000 |
| Purchase of short-term investments | - | (5,000,000) |
| Patent costs | - | (82,645) |
| Purchase of property and equipment | - | (10,993) |
| Net cash provided by (used in) investing activities | 5,000,000 | (93,638) |
| Cash flows from financing activities: | | |
| Proceeds from issuance of common stock from warrants exercised, net of issuance costs | - | 3,225,176 |
| Proceeds from sale of common stock and warrants, net | - | 5,510,840 |
| Payments of long-term debt | - | (3,765,568) |
| Proceeds from short-term note payable | 349,578 | 346,863 |
| Payments of short-term notes payable | (247,817) | (223,425) |
| Net cash (used in ) provided by financing activities | 101,761 | 5,093,886 |
| Effects of exchange rates on cash | (5,383) | (1,395) |

| | | |
|---|---|---|
| Net increase (decrease) in cash and cash equivalents | (938,011 ) | (6,131,239 ) |
| Cash and cash equivalents, beginning of period | 6,674,940 | 15,194,949 |
| Cash and cash equivalents, end of period | $5,736,929 | $9,063,710 |
| Supplemental disclosure of cash flows information: | | |
| Cash paid for interest | $4,190 | $115,034 |

See accompanying notes to unaudited condensed consolidated financial statements.

**NEURALSTEM, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**SEPTEMBER 30, 2018 AND 2017**

**Note 1. Organization, Business and Financial Condition**

Nature of business

Neuralstem, Inc. and its subsidiary are referred to as "Neuralstem," the "Company," "us," or "we" throughout this report. The operations of our wholly-owned and controlled subsidiary located in the People's Republic of China are consolidated in our unaudited condensed consolidated financial statements and all intercompany activity has been eliminated. The Company operates in one business segment.

Neuralstem is a clinical stage biopharmaceutical company that is utilizing its proprietary human neural stem cell technology to create a comprehensive platform of therapies for the treatment of central nervous system diseases. The Company has utilized this technology as a tool for small-molecule drug discovery and to create cell therapy biotherapeutics to treat central nervous system diseases. The Company was founded in 1997 and currently has laboratory and office space in Germantown, Maryland and laboratory facilities in the People's Republic of China. Our operations to date have primarily focused on developing business strategies, raising capital, research and development activities, and conducting pre-clinical testing and human clinical trials of our product candidates.

Liquidity and Going Concern

The Company has incurred losses since its inception and has not demonstrated an ability to generate significant revenues from the sales of its therapies or services and accordingly has not yet achieved profitable operations. There can be no assurance that profitable operations will ever be achieved, or if achieved, could be sustained. In addition, development activities, clinical and pre-clinical testing, and commercialization of our products will require significant additional financing. These factors create substantial doubt about the Company's ability to continue as a going concern beyond one year after the date that the consolidated financial statements are issued. In making this assessment the Company performed a comprehensive analysis of its current circumstances including: its financial position at September 30, 2018, its cash flow and cash usage forecasts for the period covering one-year from the issuance date of this Quarterly Report and its current capital structure including outstanding warrants and other equity-based instruments and its obligations and debts.

The consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern. Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

We expect that our existing cash and cash equivalents will be sufficient to enable us to fund our anticipated level of operations based on our current operating plans into the second quarter of 2019. Accordingly, we will require additional capital to further develop our product candidates, conduct our pre-clinical and clinical development programs and to fund our operations. We anticipate raising additional capital through the private and public sales of our equity or debt securities, collaborative arrangements, licensing agreements or a combination thereof. Although management believes that such capital sources will be available, there can be no assurance that any such collaborative or licensing arrangements will be entered into or that financing will be available to us when needed in order to allow us to continue our operations, or if available, on terms acceptable to us. If we do not raise sufficient capital in a timely manner, among other things, we may be forced to delay, scale back or eliminate some or all of our research and product development programs, planned clinical trials, and/or our capital expenditures or to license our potential products or technologies to third parties on unfavorable terms. We currently do not have any commitments for future funding from any source.

Our independent registered public accounting firm issued an emphasis of matter in their audit report regarding substantial doubt over our ability to continue as a going concern in our audited financial statements as of and for the year ended December 31, 2017.

We have spent and will continue to spend substantial funds in the research, development, pre-clinical and clinical testing of our small molecule and stem cell product candidates with the goal of ultimately obtaining approval from the United States Food and Drug Administration (the “FDA”) and its international equivalents regulatory agencies, to market and sell our products. No assurance can be given that (i) the FDA or any other regulatory agency will grant approval for us to market and sell our product candidates, or (ii) if regulatory approval is granted, that we will ever be able to sell our proposed products or be profitable.

**Note 2. Significant Accounting Policies and Basis of Presentation**

Basis of Presentation

In management’s opinion, the accompanying interim unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly our financial position, results of operations and cash flows. The unaudited condensed consolidated balance sheet at December 31, 2017, has been derived from audited financial statements as of that date. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in the financial statements prepared in accordance with generally accepted accounting principles in the United States of America (U.S. GAAP) have been condensed or omitted pursuant to instructions, rules and regulations prescribed by the U.S. Securities and Exchange Commission ("SEC"). We believe that the disclosures provided herein are adequate to make the information presented not misleading when these unaudited condensed consolidated financial statements are read in conjunction with the Financial Statements and Notes included in our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC, and as may be amended.

Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The unaudited condensed consolidated financial statements include significant estimates for the expected economic life and value of our licensed technology and related patents, our net operating loss and related valuation allowance for tax purposes, the fair value of our liability classified warrants and our share-based compensation related to employees and directors, consultants and advisors, among other things. Because of the use of estimates inherent in the financial reporting process, actual results could differ significantly from those estimates.

Fair Value Measurements

The carrying amounts of our short-term financial instruments, which primarily include cash and cash equivalents, short-term investments, accounts payable and accrued expenses, approximate their fair values due to their short maturities. The fair value of our long-term indebtedness was estimated based on the quoted prices for the same or similar issues or on the current rates offered to the Company for debt of the same remaining maturities and approximates the carrying value. The fair values of our liability classified warrants were estimated using Level 3 unobservable inputs. See Note 3 for further details.

Foreign Currency Translation

The functional currency of our wholly owned foreign subsidiary is its local currency. Assets and liabilities of our foreign subsidiary are translated into United States dollars based on exchange rates at the end of the reporting period; income and expense items are translated at the weighted average exchange rates prevailing during the reporting period. Translation adjustments for subsidiary are accumulated in other comprehensive income or loss, a component of stockholders' equity. Transaction gains or losses are included in the determination of net loss.

Cash, Cash Equivalents, Short-Term Investments and Credit Risk

Cash equivalents consist of investments in low risk, highly liquid money market accounts and certificates of deposit with original maturities of 90 days or less. Cash deposited with banks and other financial institutions may exceed the amount of insurance provided on such deposits. If the amount of a deposit at any time exceeds the federally insured amount at a bank, the uninsured portion of the deposit could be lost, in whole or in part, if the bank were to fail.

Short-term investments consist entirely of fixed income certificates of deposit (“CDs”) with original maturities of greater than 90 days but not more than one year.

Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash equivalents and short-term investments. Our investment policy, approved by our Board of Directors, limits the amount we may invest in any one type of investment issuer, thereby reducing credit risk concentrations. In addition, our certificates of deposit are typically invested through the Certificate of Deposit Account Registry Service (“CDARS”) program which reduces or eliminates our risk related to concentrations of investments above FDIC insurance levels. We attempt to limit our credit and liquidity risks through our investment policy and through regular reviews of our portfolio against our policy. To date, we have not experienced any loss or lack of access to cash in our operating accounts or to our cash equivalents and short-term investments.

Revenue

On January 1, 2018, the Company adopted Topic 606, Revenue from Contracts with Customer using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018. The Company analyzes contracts to determine the appropriate revenue recognition using the following steps: (i) identification of contracts with customers; (ii) identification of distinct performance obligations in the contract; (iii) determination of contract transaction price; (iv) allocation of contract transaction price to the performance obligations; and (v) determination of revenue recognition based on timing of satisfaction of the performance obligation. The Company recognizes revenues upon the satisfaction of its performance obligation (upon transfer of control of promised goods or services to customers) in an amount that reflects the consideration to which it expects to be entitled to in exchange for those goods or services. Deferred revenue results from cash receipts from or amounts billed to customers in advance of the transfer of control of the promised services to the customer and is recognized as performance obligations are satisfied. When sales commissions or other costs to obtain contracts with customers are considered incremental and recoverable, those costs are deferred and then amortized as selling and marketing expenses on a straight-line basis over an estimated period of benefit.

Research and Development

Research and development costs are expensed as they are incurred. Research and development expenses consist primarily of costs associated with the pre-clinical development and clinical trials of our product candidates. We record cost reimbursements under our Small Business Innovation Research (SBIR) grants as an offset to research and development expenses. For the three- and nine-month periods ended September 30, 2018, we recorded approximately $143,000 and $318,000, respectively of such cost reimbursements as an offset to research and development expenses. No reimbursements were recorded in any of the periods of 2017.

Income (Loss) per Common Share

Basic income (loss) per common share is computed by dividing total net income (loss) available to common stockholders by the weighted average number of common shares outstanding during the period.

For periods of net income when the effects are dilutive, diluted earnings per share is computed by dividing net income available to common stockholders by the weighted average number of shares outstanding and the dilutive impact of all dilutive potential common shares. Dilutive potential common shares consist primarily of convertible preferred stock, stock options, restricted stock units and common stock purchase warrants. The dilutive impact of potential common shares resulting from common stock equivalents is determined by applying the treasury stock method. Our unvested restricted shares contain non-forfeitable rights to dividends, and therefore are considered to be participating securities; the calculation of basic and diluted income per share excludes net income attributable to the unvested restricted shares from the numerator and excludes the impact of the shares from the denominator.

Following is a reconciliation of diluted and basic earnings per share for all periods presented:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| Numerator: | 2018 | 2017 | 2018 | 2017 |
| Net loss | $(1,830,283) | $(133,783) | $(4,604,297) | $(12,350,229) |
| Numerator for basic earnings per share | $(1,830,283) | $(133,783) | $(4,604,297) | $(12,350,229) |
| Adjustment for gain related to mark-to-market adjustment for liability classified warrants | - | (2,398,453) | - | - |
| Numerator for diluted earnings per share | $(1,830,283) | $(2,532,236) | $(4,604,297) | $(12,350,229) |
| | | | | |
| Denominator: | | | | |
| Denominator for basic earnings per share - weighted-average shares | 15,171,495 | 14,060,844 | 15,144,425 | 12,380,054 |

| | | | | |
|---|---|---|---|---|
| Effect of dilutive securities: liability classified warrants | - | 102,228 | - | - |
| Denominator for diluted earnings per share - weighted-average shares and assumed exercises | 15,171,495 | 14,163,072 | 15,144,425 | 12,380,054 |

A total of approximately 9.7 million potential dilutive shares have been excluded in the calculation of diluted net income per share for both the three- and nine-month periods ended September 30, 2018, as their inclusion would be anti-dilutive. A total of approximately 10.0 and 9.2 million potential dilutive shares have been excluded in the calculation of diluted net income per share for the three- and nine-month periods ended September 30, 2017, respectively, as their inclusion would be anti-dilutive.

Share-Based Compensation

We account for share-based compensation at fair value. Share-based compensation cost for stock options and stock purchase warrants granted to employees and board members is generally determined at the grant date while awards granted to non-employee consultants are generally valued at the vesting date using an option pricing model that uses Level 3 unobservable inputs; share-based compensation cost for restricted stock and restricted stock units is determined at the grant date based on the closing price of our common stock on that date. The value of the award is recognized as expense on a straight-line basis over the requisite service period or based on probability of vesting for performance-based awards.

Intangible and Long-Lived Assets

We assess impairment of our long-lived assets using a "primary asset" approach to determine the cash flow estimation period for a group of assets and liabilities that represents the unit of accounting for a long-lived asset to be held and used. Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The carrying amount of a long-lived asset is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset. No significant impairment losses were recognized during the three- or nine-month periods ended September 30, 2018 or 2017.

Income Taxes

We account for income taxes using the asset and liability approach, which requires the recognition of future tax benefits or liabilities on the temporary differences between the financial reporting and tax bases of our assets and liabilities. A valuation allowance is established when necessary to reduce deferred tax assets to the amounts expected to be realized. We also recognize a tax benefit from uncertain tax positions only if it is “more likely than not” that the position is sustainable based on its technical merits. Our policy is to recognize interest and penalties on uncertain tax positions as a component of income tax expense.

Corporate tax rate changes resulting from the impacts of the Tax Cuts and Jobs Act of 2017 (the “Tax Act”) are reflected in deferred tax assets and liabilities as of December 31, 2017 and September 30, 2018.

Significant New Accounting Pronouncements

*Recently Adopted Guidance*

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standard Update (“ASU”), No. 2014-09, Revenue from Contracts with Customers. This ASU consists of a comprehensive revenue recognition standard that superseded nearly all existing revenue recognition guidance under U.S. GAAP. The guidance is effective for interim and annual periods beginning after December 15, 2017. Either full retrospective adoption or modified retrospective adoption is permitted. In addition to expanded disclosures regarding revenue, this pronouncement may impact timing of recognition in some arrangements with variable consideration or contracts for the sale of goods or services. We adopted this guidance effective January 1, 2018 on a modified retrospective basis and it did not have a material impact on the consolidated financial statements.

In May 2017, the FASB issued *ASU No. 2017-09, Compensation – Stock Compensation*. This ASU provides clarification regarding when changes to the terms or conditions of share-based payment awards should be accounted for as modifications. This guidance is effective for fiscal years beginning after December 15, 2017 and early adoption is permitted. This guidance must be applied prospectively to awards modified after the adoption date. We adopted this guidance effective January 1, 2018 and it did not have a material impact on the consolidated financial statements.

In July 2017, the FASB issued *ASU No. 2017-11, I. Accounting for Certain Financial Instrument with Down Round Features 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.* Part I of this guidance simplifies the accounting for certain equity-linked financial instruments and embedded features with down round features that reduce the exercise price when the pricing of a future round of financing is lower ("down round protection"). Current accounting guidance provides that instruments with down round protection be classified as derivative liabilities with changes in fair value recorded through earnings. The updated guidance provides that instruments with down round protection are no longer precluded from being classified as equity. This guidance is effective for fiscal years beginning after December 15, 2018 and early adoption is permitted. This guidance must be applied retrospectively. We adopted this guidance on January 1, 2018, and it did not have a material impact on the financial statements.

*Unadopted Guidance*

In February 2016, the FASB issued *ASU, No. 2016-02, Leases.* This ASU consists of a comprehensive lease accounting standard. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. The guidance is effective for reporting periods beginning after December 15, 2018 and early adoption is permitted. The guidance must be adopted on a modified retrospective basis and provides for certain practical expedients. We currently expect that the adoption of this guidance will likely change the way we account for our operating leases and will likely result in recording the future benefits of those leases and the related minimum lease payments on our consolidated balance sheets. We are currently in the process of evaluating the specific impacts of this guidance.

In June 2016, the FASB issued *ASU No. 2016-13, Financial Instrument's – Credit Losses*. This ASU relates to measuring credit losses on financial instruments, including trade receivables. The guidance eliminates the probable initial recognition threshold that was previously required prior to recognizing a credit loss on financial instruments. The credit loss estimate can now reflect an entity's current estimate of all future expected credit losses. Under the previous guidance, an entity only considered past events and current conditions. The guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The adoption of certain amendments of this guidance must be applied on a modified retrospective basis and the adoption of the remaining amendments must be applied on a prospective basis. We currently expect that the adoption of this guidance will likely change the way we assess the collectability of our receivables and recoverability of other financial instruments. We have not yet begun to evaluate the specific impacts of this guidance nor have we determined the manner in which we will adopt this guidance.

In June 2018, the FASB issued *ASU 2018-07, Compensation-Stock Compensation, Improvements to Nonemployee Share-Based Payment Accounting*. This ASU expands the scope of *ASC 718, Compensation – Stock Compensation* to include share-based payment transactions for acquiring goods and services from nonemployees. This guidance provides for the following changes: (1) awards to nonemployees will be measured at the grant date fair value of equity instruments that the entity is obligated to issue, (2) performance-based awards to nonemployees will be measured based on the probability of the performance condition being met and (3) eliminating the need to reassess the classification (equity or liability) of awards to nonemployees upon vesting. We expect the adoption of this guidance will change the way we measure awards to nonemployees. We have not yet determined the specific impacts of this guidance upon adoption.

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In August 2018, the FASB issued *ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*. This ASU addresses the disclosure requirements for fair value measurements. The guidance intends to improve the effectiveness of the disclosures relating to recurring and nonrecurring fair value measurements. The guidance is effective for fiscal years beginning after December 15, 2019. Portions of the guidance are to be adopted prospectively while other portions are to be adopted retroactively. Early adoption is permitted. The Company is currently evaluating the impact, if any, that this guidance will have on the consolidated financial statements. The Company is currently evaluating the impact, if any, that this guidance will have on the consolidated financial statements.

In August 2018, the FASB issued *ASU 2018-15, Intangibles – Goodwill and Other – Internal-Use Software*. This ASU addresses the accounting for implementation, setup and other upfront costs paid by a customer in a cloud computing or hosting arrangement. The guidance aligns the accounting treatment of these costs incurred in a hosting arrangement treated as a service contract with the requirements for capitalization and amortization costs to develop or obtain internal-use software. The guidance is effective for fiscal years beginning after December 15, 2019. The guidance can be adopted either retrospectively or prospectively. Early adoption is permitted. The Company is currently evaluating the impact, if any, that this guidance will have on the consolidated financial statements.

We have reviewed other recent accounting pronouncements and concluded that they are either not applicable to our business, or that no material effect is expected on the consolidated financial statements as a result of future adoption.

**Note 3. Fair Value Measurements**

Fair value is the price that would be received from the sale of an asset or paid to transfer a liability assuming an orderly transaction in the most advantageous market at the measurement date. U.S. GAAP establishes a hierarchical disclosure framework which prioritizes and ranks the level of observability of inputs used in measuring fair value. These levels are:

- *Level 1* – inputs are based upon unadjusted quoted prices for identical instruments traded in active markets.

- *Level 2* – inputs are based upon quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-based valuation techniques (e.g. the Black-Scholes model) for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs including interest rate curves, foreign exchange rates, and forward and spot prices for currencies and commodities.

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*Level 3* – inputs are generally unobservable and typically reflect management's estimates of assumptions that market participants would use in pricing the asset or liability. The fair values are therefore determined using model-based techniques, including option pricing models and discounted cash flow models.

Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis

We have segregated our financial assets and liabilities that are measured at fair value on a recurring into the most appropriate level within the fair value hierarchy based on the inputs used to determine the fair value at the measurement date.

At September 30, 2018 and December 31, 2017, we had certain common stock purchase warrants that were originally issued in connection with our May 2016 and August 2017 offerings (See Note 4) that are accounted for as liabilities whose fair value was determined using Level 3 inputs. The following table identifies the carrying amounts of such liabilities:

| | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| Liabilities | | | | |
| Liability classified stock purchase warrants | $ - | $ - | $3,852,882 | $3,852,882 |
| Balance at December 31, 2017 | $ - | $ - | $3,852,882 | $3,852,882 |
| | | | | |
| Liability classified stock purchase warrants | $ - | $ - | $2,047,563 | $2,047,563 |
| Balance at September 30, 2018 | $ - | $ - | $2,047,563 | $2,047,563 |

The following table presents the activity for those items measured at fair value on a recurring basis using Level 3 inputs for the nine months ended September 30, 2018:

| | Mark-to-market liabilities - stock purchase warrants |
|---|---|
| Balance at December 31, 2017 | $ 3,852,882 |
| Change in fair value - gain | (1,805,319) |
| Balance at September 30, 2018 | $ 2,047,563 |

The following table presents the activity for those items measured at fair value on a recurring basis using Level 3 inputs for the nine months ended September 30, 2017:

| | Mark-to-market liabilities - stock purchase warrants |
|---|---|
| Balance at December 31, 2016 | $ 3,921,917 |
| Issuance of warrants | 2,483,848 |
| Exercise of warrants | (4,023,057) |
| Change in fair value - loss | 403,155 |
| Balance at September 30, 2017 | $ 2,785,863 |

The (gains) losses resulting from the changes in the fair value of the liability classified warrants are classified as other income or expense in the accompanying unaudited condensed consolidated statements of operations. The fair value of the common stock purchase warrants is determined based on the Black-Scholes option pricing model or other option pricing models as appropriate and includes the use of unobservable inputs such as the expected term, anticipated volatility and expected dividends. Changes in any of the assumptions related to the unobservable inputs identified above may change the embedded conversion options' fair value; increases in expected term, anticipated volatility and expected dividends generally result in increases in fair value, while decreases in these unobservable inputs generally result in decreases in fair value.

**Note 4. Stockholders' Equity**

We have granted share-based compensation awards to employees, board members and service providers. Awards may consist of common stock, restricted common stock, restricted common stock units, common stock purchase warrants, or common stock purchase options. Our common stock purchase options and stock purchase warrants have lives of up to ten years from the grant date. Awards vest either upon the grant date or over varying periods of time. The stock options provide for exercise prices equal to or greater than the fair value of the common stock at the date of the grant. Restricted stock units grant the holder the right to receive fully paid common shares with various restrictions on the holder's ability to transfer the shares. As of September 30, 2018, we have approximately 6.1 million shares of common stock reserved for issuance upon the exercise of share-based compensation awards.

We typically record share-based compensation expenses on a straight-line basis over the requisite service period. Share-based compensation expenses included in the statements of operations are as follows:

| | Three Months Ended September 30, | |
|---|---|---|
| | 2018 | 2017 |
| Research and development expenses | $22,917 | $185,492 |
| General and administrative expenses | 111,778 | 144,263 |
| Total | $134,695 | $329,755 |

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2018 | 2017 |
| Research and development expenses | $110,417 | $993,927 |
| General and administrative expenses | 459,856 | 510,216 |
| Total | $570,273 | $1,504,143 |

Stock Options

A summary of stock option activity and related information for the nine months ended September 30, 2018 follows:

| | Number of Options | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Life (in years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding at January 1, 2018 | 1,894,077 | $ 19.76 | 4.7 | $108,000 |
| Granted | 488,640 | $ 1.13 | | |
| Exercised | - | $ - | | $- |
| Forfeited | (550,215 ) | $ 34.52 | | |
| Outstanding at September 30, 2018 | 1,832,502 | $ 10.37 | 5.6 | $- |
| Exercisable at September 30, 2018 | 1,300,538 | $ 14.08 | 4.9 | $- |

| Range of Exercise Prices | Number of Options Outstanding | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Life (in years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| $1.00 - $3.50 | 638,640 | $ 1.15 | 7.7 | $ - |
| $3.51 - $13.00 | 682,076 | $ 9.59 | 5.2 | - |
| $13.01 - $26.00 | 343,782 | $ 14.79 | 3.3 | - |
| $26.01 - $39.00 | 65,504 | $ 30.85 | 2.7 | - |
| $39.01 - $56.00 | 102,500 | $ 45.03 | 4.8 | - |
| | 1,832,502 | $ 10.37 | 5.6 | $ - |

The Company uses the Black-Scholes option pricing model for “plain vanilla” options and other pricing models as appropriate to calculate the fair value of options. Significant assumptions used in these models include:

| | Nine Months Ended September 30, 2018 | 2017 |
|---|---|---|
| Annual dividend | - | - |
| Expected life (in years) | 2.5 - 5.3 | 0.3 - 5.5 |
| Risk free interest rate | 2.7% - 2.8% | 0.8% - 1.9% |
| Expected volatility | 97% - 117% | 62% - 83% |

Options granted in the nine months ended September 30, 2018 and 2017, had a weighted average grant date fair value of $0.77 and $3.19 per share, respectively.

Unrecognized compensation cost for unvested stock option awards outstanding at September 30, 2018 was approximately $363,000 to be recognized over approximately 1.3 years.

RSUs

We have granted restricted stock units (RSUs) to certain employees and board members that entitle the holders to receive shares of our common stock upon vesting and subject to certain restrictions regarding the exercise of the RSUs. The grant date fair value of RSUs is based upon the market price of the underlying common stock on the date of grant.

In the nine months ended September 30, 2018, we granted 45,046 RSU’s. RSUs granted in the nine months ended September 30, 2018 and 2017, had a weighted average grant date fair value of $1.11 and $5.37, respectively.

RSUs vesting in the nine months ended September 30, 2018 had a total value of approximately $25,000.

At September 30, 2018, we had 56,281 outstanding RSUs with a weighted average grant date fair value of $3.24 and a total intrinsic value of approximately $60,000. No RSUs were converted in the nine months ended September 30, 2018. Unrecognized compensation cost for unvested RSUs at September 30, 2018 was approximately $37,000 to be recognized over approximately 0.75 years.

Restricted Stock

We have granted restricted stock to certain board members that vest quarterly over the grant year. The grant date fair value of the restricted stock is based upon the market price of the common stock on the date of grant.

In the nine months ended September 30, 2018, we granted 45,046 shares of restricted stock. Restricted stock granted in the nine months ended September 30, 2018 and 2017, had a weighted average grant date fair value of $1.11 and $3.63, respectively.

Restricted stock vesting in the nine months ending September 30, 2018, had a weighted average grant date fair value of $2.65 and a total intrinsic value of approximately $81,000.

At September 30, 2018, we had 33,785 shares of restricted stock outstanding with an average grant date fair value of $1.11. Unrecognized compensation cost for unvested restricted stock awards at September 30, 2018 was approximately $38,000 to be recognized over approximately 0.75 years.

Stock Purchase Warrants.

We have issued warrants to purchase common stock to certain officers, directors, stockholders and service providers as well as in conjunction with debt and equity offerings and at various times replacement warrants were issued as an inducement for warrant exercises.

In May 2016 and August 2017, we issued a total of 1,746,173 and 2,250,000 common stock purchase warrants, respectively in conjunction with our offerings. Such warrants are classified as liabilities due to the existence of certain net cash settlement provisions contained in the warrants. At September 30, 2018, after giving effect to exercises, 2,982,709 of these common stock purchase warrants remain outstanding and are recorded at fair value as mark-to-market liabilities (see Note 3).

A summary of outstanding warrants at September 30, 2018 follows:

| Range of Exercise Prices | Number of Warrants Outstanding | Range of Expiration Dates |
|---|---|---|
| $1.11 - $5.79 | 3,017,326 | May 2021 - August 2024 |
| $12.80 - $12.90 | 39,296 | January 2022 |
| $16.20 - $16.30 | 174,544 | March 2020 |
| $22.10 - $27.90 | 153,755 | March 2019 - January 2021 |
| $34.50 - $39.00 | 5,784 | October 2019 |
| $39.10 - $39.20 | 230,772 | October 2020 - October 2021 |
| $47.30 - $52.20 | 275,897 | January 2019 - July 2019 |
| | 3,897,374 | |

Preferred and Common Stock

We have outstanding 1,000,000 shares of Series A 4.5% Convertible Preferred Stock issued in December 2016. Shares of the Series A 4.5% Convertible Preferred Stock are convertible into 3,887,387 shares of the Company's common stock subject to certain ownership restrictions.

**Note 5. Commitments and Contingencies**

We currently operate one facility located in the United States and one facility located in the People's Republic of China. Our corporate offices and primary research facilities are located in Germantown, Maryland, where we lease approximately 1,500 square feet. This lease provides for monthly payments of approximately $5,600 per month with the term expiring on December 31, 2018.

In 2015, we entered into a lease consisting of approximately 3,100 square feet of research space in San Diego, California. This lease provides for current monthly payments of approximately $11,600 and expires on August 31, 2019. In May 2017, we ceased-use of this property and recognized a loss of approximately $92,000 representing the present value of the expected remaining net payments due under such lease and the costs to vacate the property. In April 2018, we entered into an agreement for the sub-lease of the property and recognized an additional loss of approximately $50,000 reflecting the present value of the revised expected remaining net payments due.

We also lease a research facility in People's Republic of China. This lease expires on March 31, 2019 with lease payments of approximately $3,800 per month.

From time to time, we are parties to legal proceedings that we believe to be ordinary, routine litigation incidental to the business. We are currently not a party to any litigation or legal proceeding.

**Note 6. Related Party Receivable**

On August 10, 2016, we entered into a reimbursement agreement with a former executive officer. Pursuant to the reimbursement agreement, the former officer agreed to repay the Company, over a six-year period, approximately $658,000 in expenses that the Company determined to have been improperly paid under the Company's prior expense reimbursement policies. In addition to this reimbursement agreement, the Company has implemented and is continuing to implement enhanced policies and procedures for travel expense reimbursements and disbursements.

The $658,000 non-interest-bearing receivable was recorded net of a $199,000 discount to reflect the net present value of the future cash payments. The discount is being amortized through interest income using the effective interest method. The principal amount of $458,000 remains outstanding at September 30, 2018 and is payable in $100,000 annual installments with a final payment due July 2022.

**Note 7. Subsequent Events**

On October 29, 2018, we closed a registered direct offering and concurrent private placement with institutional investors. In connection with the offering we issued an aggregate of 3,000,000 shares of common stock in the registered direct offering and 3,000,000 common stock purchase warrants in the private offering. We issued the shares in the registered offering at a price of $0.70 per share. We also issued each investor an accompanying warrant for each share purchased. We received gross proceeds of $2.1 million from this offering. The warrants have an exercise price of $0.75 per share of common stock, will be exercisable commencing with the six-month anniversary of the issuance date and will expire five and one-half years from issuance. The common stock issued in this offering was sold pursuant to our shelf registration statement that was declared effective by the SEC on June 23, 2017 (Registration No. 333-218608). In connection with the offering we also issued our placement agent 180,000 common stock purchase warrants. The placement agent warrants are substantially similar to the investor warrants except that they have an exercise price of $0.875 per share and a term of 5 years.

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

*Statements in this Quarterly Report that are not strictly historical are forward-looking statements and include statements about products in development, results and analyses of pre-clinical studies, clinical trials and studies, research and development expenses, cash expenditures, and alliances and partnerships, among other matters. You can identify these forward-looking statements because they involve our expectatio*