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

FORM 10-Q

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

For the quarterly period ended June 30, 2019

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File No. 001-36517

Minerva Neurosciences, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**26-0784194**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
1601 Trapelo Road, Suite 286 Waltham, MA	**02451**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 600-7373

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	NERV	The NASDAQ Global Market

The number of shares of Registrant's Common Stock, $0.0001 par value per share, outstanding as of July 31, 2019 was 39,025,471.

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, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
Emerging growth company	☒		

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). YES ☐ NO ☒

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Unless the context suggests otherwise, references in this Quarterly Report on Form 10-Q, or Quarterly Report, to "Minerva," "the Company," "we," "us," and "our" refer to Minerva Neurosciences, Inc. and, where appropriate, its subsidiaries.

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These forward-looking statements reflect our plans, estimates and beliefs. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "would" and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Because of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not transpire. These risks and uncertainties include, but are not limited to, the risks included in this Quarterly Report on Form 10-Q under Part II, Item IA, "Risk Factors."

Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our estimates and assumptions only as of the date of this document. You should read this document with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we do not undertake any obligation to publicly update or revise any forward-looking statements contained in this report, whether as a result of new information, future events or otherwise.

All trademarks, trade names and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

PART I – Financial Information
Item 1 – Financial Statements

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Balance Sheets
(Unaudited)

	June 30, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 27,844,692	$ 50,234,871
Marketable securities	41,448,613	37,762,439
Restricted cash	100,000	100,000
Prepaid expenses and other current assets	1,453,233	1,921,050
Total current assets	70,846,538	90,018,360
Equipment, net	24,744	33,478
Other noncurrent assets	14,808	14,808
Operating lease right-of-use assets	335,849	—
In-process research and development	34,200,000	34,200,000
Goodwill	14,869,399	14,869,399
Total assets	**$ 120,291,338**	**$ 139,136,045**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	2,941,788	1,799,666
Accrued expenses and other current liabilities	4,485,605	1,809,532
Operating leases	161,602	—
Total current liabilities	7,588,995	3,609,198
Deferred taxes	4,057,488	4,057,488
Deferred revenue	41,175,600	41,175,600
Noncurrent operating leases	201,066	—
Other noncurrent liabilities	—	28,990
Total liabilities	53,023,149	48,871,276
Commitments and contingencies (Note 9)		
Stockholders' equity		
Preferred stock; $0.0001 par value; 100,000,000 shares authorized; none issued or outstanding as of June 30, 2019 and December 31, 2018, respectively	—	—
Common stock; $0.0001 par value; 125,000,000 shares authorized; 39,025,471 and 38,937,971 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	3,903	3,894
Additional paid-in capital	310,120,685	304,813,603
Accumulated deficit	(242,856,399)	(214,552,728)
Total stockholders' equity	67,268,189	90,264,769
Total liabilities and stockholders' equity	**$ 120,291,338**	**$ 139,136,045**

See accompanying notes to condensed consolidated financial statements

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Expenses				
Research and development	$ 8,319,612	$ 9,062,234	$ 19,925,809	$ 17,511,501
General and administrative	4,584,361	3,872,309	9,290,035	8,166,854
Total expenses	12,903,973	12,934,543	29,215,844	25,678,355
Loss from operations	(12,903,973)	(12,934,543)	(29,215,844)	(25,678,355)
Foreign exchange (losses) gains	(6,718)	29,274	(13,031)	11,165
Investment income	434,220	411,542	925,204	825,849
Interest expense	—	(35,781)	—	(106,430)
Net loss	$ (12,476,471)	$ (12,529,508)	$ (28,303,671)	$ (24,947,771)
Net loss per share, basic and diluted	$ (0.32)	$ (0.32)	$ (0.73)	$ (0.64)
Weighted average shares outstanding, basic and diluted	39,025,471	38,749,343	38,996,949	38,749,343

See accompanying notes to condensed consolidated financial statements

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statement of Stockholders' Equity
(Unaudited)

	Common Stock		Additional	Accumulated	
	Shares	Amount	Paid-In Capital	Deficit	Total
Balances at January 1, 2018	**38,749,343**	**$ 3,875**	**$ 295,975,010**	**$ (164,381,441)**	**$ 131,597,444**
Stock-based compensation	—	—	2,113,936	—	2,113,936
Net loss	—	—	—	(12,418,263)	(12,418,263)
Balances at March 31, 2018	38,749,343	3,875	298,088,946	(176,799,704)	121,293,117
Stock-based compensation	—	—	1,897,873	—	1,897,873
Net loss	—	—	—	(12,529,508)	(12,529,508)
Balances at June 30, 2018	**38,749,343**	**$ 3,875**	**$ 299,986,819**	**$ (189,329,212)**	**$ 110,661,482**
Balances at January 1, 2019	**38,937,971**	**$ 3,894**	**$ 304,813,603**	**$ (214,552,728)**	**$ 90,264,769**
Exercise of stock options	87,500	9	524,991	—	525,000
Stock-based compensation	—	—	2,461,699	—	2,461,699
Net loss	—	—	—	(15,827,200)	(15,827,200)
Balances at March 31, 2019	39,025,471	3,903	307,800,293	(230,379,928)	77,424,268
Stock-based compensation	—	—	2,320,392	—	2,320,392
Net loss	—	—	—	(12,476,471)	(12,476,471)
Balances at June 30, 2019	**39,025,471**	**$ 3,903**	**$ 310,120,685**	**$ (242,856,399)**	**$ 67,268,189**

See accompanying notes to condensed consolidated financial statements

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Six Months Ended June 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (28,303,671)	$ (24,947,771)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	8,734	8,734
Amortization of debt discount recorded as interest expense	—	36,638
Accretion of marketable securities premium	(501,227)	(82,869)
Amortization of right-of-use assets	70,143	—
Stock-based compensation expense	4,782,091	4,011,809
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	452,516	(1,930,254)
Accounts payable	1,142,122	(125,793)
Accrued expenses and other current liabilities	2,676,073	871,614
Operating lease liabilities, current	26,052	—
Other noncurrent liabilities	—	790
Operating lease liabilities, noncurrent	(83,065)	—
Net cash used in operating activities	(19,730,232)	(22,157,102)
Cash flows from investing activities:		
Proceeds from the maturity and redemption of marketable securities	30,000,000	75,351,000
Purchase of marketable securities	(33,184,947)	(7,934,482)
Net cash (used in) provided by investing activities	(3,184,947)	67,416,518
Cash flows from financing activities:		
Proceeds from exercise of stock options	525,000	—
Repayments of notes payable	—	(2,602,632)
Net cash provided by (used in) financing activities	525,000	(2,602,632)
Net (decrease) increase in cash, cash equivalents, and restricted cash	(22,390,179)	42,656,784
Cash, cash equivalents and restricted cash		
Beginning of period	50,334,871	26,131,821
End of period	$ 27,944,692	$ 68,788,605
Supplemental disclosure of cash flow information		
Cash paid for interest	$ —	$ 85,082
Reconciliation of the Condensed Consolidated Statements of Cash Flows to the Condensed Consolidated Balance Sheets		
Cash and cash equivalents	$ 27,844,692	$ 68,688,605
Restricted cash	100,000	100,000
Total cash, cash equivalents and restricted cash	$ 27,944,692	$ 68,788,605

See accompanying notes to condensed consolidated financial statements

NOTE 1 — NATURE OF OPERATIONS AND LIQUIDITY

Nature of Operations

Minerva Neurosciences, Inc. ("Minerva" or the "Company") is a clinical-stage biopharmaceutical company focused on the development and commercialization of a portfolio of product candidates to treat patients suffering from central nervous system diseases. The Company has acquired or in-licensed four development-stage proprietary compounds that it believes have innovative mechanisms of action and therapeutic profiles that may potentially address the unmet needs of patients with these diseases. The Company's lead product candidate is roluperidone (also known as MIN-101), a compound the Company is developing for the treatment of schizophrenia. In addition, the Company's portfolio includes seltorexant (also known as MIN-202 or JNJ-42847922), a compound the Company is co-developing with Janssen Pharmaceutica NV ("Janssen") for the treatment of insomnia disorder and major depressive disorder ("MDD"); MIN-117, a compound the Company is developing for the treatment of MDD; and MIN-301, a compound the Company is developing for the treatment of Parkinson's disease.

In November 2013, the Company merged with Sonkei Pharmaceuticals Inc. ("Sonkei"), a clinical-stage biopharmaceutical company and, in February 2014, the Company acquired Mind-NRG, a pre-clinical-stage biopharmaceutical company. The Company refers to these transactions as the Sonkei Merger and Mind-NRG Acquisition, respectively. The Company holds licenses to roluperidone and MIN-117 from Mitsubishi Tanabe Pharma Corporation ("MTPC") with the rights to develop, sell and import roluperidone and MIN-117 globally, excluding most of Asia. With the acquisition of Mind-NRG, the Company obtained exclusive rights to develop and commercialize MIN-301. The Company has also entered into a co-development and license agreement with Janssen, for the exclusive right to commercialize, and the co-exclusive right (with Janssen and its affiliates) to use and develop, seltorexant in the European Union, Switzerland, Liechtenstein, Iceland and Norway (the "Minerva Territory"), subject to certain royalty payments to Janssen, and royalty rights for any sales outside the Minerva Territory.

Liquidity

The accompanying financial statements have been prepared as though the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has limited capital resources and has incurred recurring operating losses and negative cash flows from operations since inception. As of June 30, 2019, the Company has an accumulated deficit of approximately $242.9 million and net cash used in operating activities was approximately $19.7 million during the six months ended June 30, 2019. Management expects to continue to incur operating losses and negative cash flows from operations. The Company has financed its operations to date from proceeds from the sale of common stock, warrants, loans and convertible promissory notes.

As of June 30, 2019, the Company had cash, cash equivalents, marketable securities, and restricted cash of $69.4 million. The Company believes that its existing cash, cash equivalents, restricted cash and marketable securities will be sufficient to meet its cash commitments for at least the next 12 months after the date that the interim condensed financial statements are issued. The process of drug development can be costly and the timing and outcomes of clinical trials is uncertain. The assumptions upon which the Company has based its estimates are routinely evaluated and may be subject to change. The actual amount of the Company's expenditures will vary depending upon a number of factors including but not limited to the design, timing and duration of future clinical trials, the progress of the Company's research and development programs, the infrastructure to support a commercial enterprise, the cost of a commercial product launch and the level of financial resources available. The Company has the ability to adjust its operating plan spending levels based on the timing of future clinical trials which will be predicated upon adequate funding to complete the trials.

The Company will need to raise additional capital in order to continue to fund operations and fully fund later stage clinical development programs. The Company believes that it will be able to obtain additional working capital through equity financings or other arrangements to fund future operations; however, there can be no assurance that such additional financing, if available, can be obtained on terms acceptable to the Company. If the Company is unable to obtain such additional financing, future operations would need to be scaled back or discontinued.

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation

The interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim reporting and the requirements of the Securities and Exchange Commission ("SEC") in accordance with Regulation S-X, Rule 10-01. Under those rules, certain notes and financial information that are normally required for annual financial statements can be condensed or omitted. In the opinion of the Company's management, the accompanying financial statements contain all adjustments (consisting of items of a normal and recurring nature) necessary to present fairly the financial position as of June 30, 2019, the results of operations for the three and six months ended June 30, 2019 and 2018 and cash flows for the six months ended June 30, 2019 and 2018. The results of operations for the three and six months ended June 30, 2019 are not necessarily indicative of the results to be expected for the full year. When preparing financial statements in conformity with GAAP, management must make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates. The consolidated balance sheet as of December 31, 2018 was derived from the audited annual financial statements. The accompanying unaudited condensed consolidated financial statements and notes thereto should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2018 included in the Company's Annual Report on Form 10-K filed with the SEC on March 12, 2019.

Consolidation

The accompanying consolidated financial statements include the results of the Company and its wholly-owned subsidiaries, Mind-NRG Sarl and Minerva Neurosciences Securities Corporation. Intercompany transactions have been eliminated.

Significant risks and uncertainties

The Company's operations are subject to a number of factors that can affect its operating results and financial condition. Such factors include, but are not limited to: the results of clinical testing and trial activities of the Company's products, the Company's ability to obtain regulatory approval to market its products, competition from products manufactured and sold or being developed by other companies, the price of, and demand for, Company products, the Company's ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products, and the Company's ability to raise capital.

The Company currently has no commercially approved products and there can be no assurance that the Company's research and development will be successfully commercialized. Developing and commercializing a product requires significant time and capital and is subject to regulatory review and approval as well as competition from other biotechnology and pharmaceutical companies. The Company operates in an environment of rapid change and is dependent upon the continued services of its employees and consultants and obtaining and protecting intellectual property.

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Cash and cash equivalents

Cash equivalents include short-term, highly-liquid instruments, consisting of money market accounts and short-term investments with maturities from the date of purchase of 90 days or less. The majority of cash and cash equivalents are maintained with major financial institutions in North America. Deposits with these financial institutions may exceed the amount of insurance provided on such deposits. These deposits may be redeemed upon demand which reduces counterparty performance risk.

Marketable securities

Marketable securities consists of corporate and U.S. government debt securities maturing in 5.50 months or less. Based on the Company's intentions regarding its marketable securities, all marketable securities are classified as held-to-maturity and are carried under the amortized cost approach. The Company's investments in marketable securities are classified as Level 2 within the fair value hierarchy. As of June 30, 2019, remaining final maturities of marketable securities ranged from July 2019 to December 2019, with a weighted average remaining maturity of approximately 2 months. The following table provides the amortized cost basis, aggregate fair value, unrealized gains/losses, and the net carrying value of investments in held-to-maturity securities as of June 30, 2019:

	June 30, 2019				
	Amortized Cost	Aggregate Fair Value	Unrealized Gains	Unrealized Losses	Net Carrying Value
Marketable securities:					
Corporate bonds/notes	$ 5,836,239	$ 5,843,128	$ —	$ (6,889)	$ 5,836,239
Commercial paper	21,903,104	21,903,104	—	—	$ 21,903,104
U.S. government agency securities	11,978,768	11,981,760	—	(2,992)	$ 11,978,768
Foreign bonds	1,730,502	1,732,058	—	(1,556)	$ 1,730,502
Marketable securities current total	$ 41,448,613	$ 41,460,050	$ —	$ (11,437)	$ 41,448,613

	December 31, 2018				
	Amortized Cost	Aggregate Fair Value	Unrealized Gains	Unrealized Losses	Net Carrying Value
Marketable securities:					
Corporate bonds/notes	$ 16,054,071	$ 16,050,462	$ 3,609	$ —	$ 16,054,071
Commercial paper	17,756,394	17,756,394	—	—	17,756,394
U.S. government agency securities	3,951,974	3,951,040	934	—	3,951,974
Marketable securities current total	$ 37,762,439	$ 37,757,896	$ 4,543	$ —	$ 37,762,439

Restricted cash

Cash accounts with any type of restriction are classified as restricted. The Company maintained restricted cash balances as collateral for corporate credit cards in the amount of $0.1 million at June 30, 2019 and December 31, 2018.

Research and development costs

Costs incurred in connection with research and development activities are expensed as incurred. These costs include licensing fees to use certain technology in the Company's research and development projects as well as fees paid to consultants and various entities that perform certain research and testing on behalf of the Company and costs related to salaries, benefits, bonuses and stock-based compensation granted to employees in research and development functions. The Company determines expenses related to clinical studies based on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that conduct and manage clinical studies on its behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the accrual is adjusted accordingly. The expenses for some trials may be recognized on a straight-line basis if the anticipated costs are expected to be incurred ratably during the period. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued expenses.

In-process research and development

In-process research and development ("IPR&D") assets represent capitalized incomplete research projects that the Company acquired through business combinations. Such assets are initially measured at their acquisition date fair values. The initial fair value of the research projects are recorded as intangible assets on the balance sheet, rather than expensed, regardless of whether these assets have an alternative future use.

The amounts capitalized are being accounted for as indefinite-lived intangible assets, subject to impairment testing, until completion or abandonment of research and development efforts associated with the project. An IPR&D asset is considered abandoned when it ceases to be used (that is, research and development efforts associated with the asset have ceased, and there are no plans to sell or license the asset or derive defensive value from the asset). At that point, the asset is considered to be disposed of and is written off. Upon successful completion of each project, the Company will make a determination about the then remaining useful life of the intangible asset and begin amortization. The Company tests its indefinite-lived intangibles, IPR&D assets, for impairment annually on November 30 and more frequently if events or changes in circumstances indicate that it is more likely than not that the asset is impaired. When testing indefinite-lived intangibles for impairment, the Company may assess qualitative factors for its indefinite-lived intangibles to determine whether it is more likely than not (that is, a likelihood of more than 50 percent) that the asset is impaired. Alternatively, the Company may bypass this qualitative assessment for some or all of its indefinite-lived intangibles and perform the quantitative impairment test that compares the fair value of the indefinite-lived intangible asset with the asset's carrying amount. There was no impairment of IPR&D for the three and six months ended June 30, 2019 or 2018.

Stock-based compensation

The Company recognizes compensation cost relating to stock-based payment transactions using a fair-value measurement method, which requires all stock-based payments to employees, including grants of employee stock options, to be recognized in operating results as compensation expense based on fair value over the requisite service period of the awards. The Company determines the fair value of stock-based awards using the Black-Scholes option-pricing model which uses both historical and current market data to estimate fair value. The method incorporates various assumptions such as the risk-free interest rate, expected volatility, expected dividend yield, actual forfeiture rate and expected life of the options. The fair value of restricted stock units ("RSUs") is equal to the closing price of the Company's common stock on the date of grant.

The date of expense recognition for grants to non-employees is the earlier of the date at which a commitment for performance by the counterparty to earn the equity instrument is reached or the date at which the counterparty's performance is complete. The Company determines the fair value of stock-based awards granted to non-employees similar to the way fair value of awards are determined for employees except that certain assumptions used in the Black-Scholes option-pricing model, such as expected life of the option, may be different.

Foreign currency transactions

The Company's functional currency is the U.S. Dollar. The Company pays certain vendor invoices in the respective foreign currency. The Company records an expense in U.S. Dollars at the time the liability is incurred. Changes in the applicable foreign currency rate between the date an expense is recorded and the payment date is recorded as a foreign currency gain or loss.

Loss per share

Basic loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding for the period. Diluted loss per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that shared in the earnings of the entity. The treasury stock method is used to determine the dilutive effect of the Company's stock options and warrants. The Company had a net loss in all periods presented, thus the inclusion of stock options and warrants would be anti-dilutive to net loss per share.

Concentration of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash, cash equivalents and marketable securities. The Company maintains its cash and cash equivalent balances in the form of business checking accounts and money market accounts, the balances of which, at times, may exceed federally insured limits. Exposure to cash and cash equivalents credit risk is reduced by placing such deposits with major financial institutions and monitoring their credit ratings. Marketable securities consist primarily of corporate bonds, with fixed interest rates. Exposure to credit risk of marketable securities is reduced by maintaining a diverse portfolio and monitoring their credit ratings.

Equipment

Equipment is stated at cost less accumulated depreciation. Equipment is depreciated on the straight-line basis over their estimated useful lives of three years. Expenditures for maintenance and repairs are charged to expense as incurred.

Leases

Effective January 1, 2019, the Company adopted Accounting Standards Codification ("ASC") Topic 842, *Leases* ("ASC 842"), using the required modified retrospective approach and utilizing the effective date as its date of initial application, for which prior periods are presented in accordance with the previous guidance in ASC 840, *Leases* ("ASC 840").

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Most leases with a term greater than one year are recognized on the balance sheet as right-of-use assets and short-term and long-term lease liabilities, as applicable. The Company has elected not to recognize on the balance sheet leases with terms of 12 months or less. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew. The Company monitors its plans to renew its material leases on a quarterly basis.

Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as incentives received. The interest rate implicit in the Company's leases is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term and in a similar economic environment. In transition to ASC 842, the Company utilized the remaining lease term of its leases in determining the appropriate incremental borrowing rates.

In accordance with ASC 842, components of a lease should be allocated between lease components (e.g., land, building, etc.) and non-lease components (e.g., common area maintenance, consumables, etc.). The fixed and in-substance fixed contract consideration (including any consideration related to non-components) must be allocated based on the respective relative fair values to the lease components and non-lease components.

Although separation of lease and non-lease components is required, certain expedients are available. Entities may elect the practical expedient to not separate lease and non-lease components by class of underlying asset where entities would account for each lease component and the related non-lease component together as a single component. For new and amended leases beginning in 2019 and after, the Company has elected to account for the lease and non-lease components for leases for classes of all underlying assets and allocate all of the contract consideration to the lease component only.

Long-lived assets

The Company reviews the recoverability of all long-lived assets, including the related useful lives, whenever events or changes in circumstances indicate that the carrying amount of a long-lived asset might not be recoverable. If required, the Company compares the estimated undiscounted future net cash flows to the related asset's carrying value to determine whether there has been an impairment. If an asset is considered impaired, the asset is written down to fair value, which is based either on discounted cash flows or appraised values in the period the impairment becomes known. The Company believes that all long-lived assets are recoverable, and no impairment was deemed necessary at June 30, 2019 and 2018.

Goodwill

The Company tests its goodwill for impairment annually, or whenever events or changes in circumstances indicate an impairment may have occurred, by comparing its reporting unit's carrying value to its fair value. Impairment may result from, among other things, deterioration in the performance of the acquired business, adverse market conditions, adverse changes in applicable laws or regulations and a variety of other circumstances. If the Company determines that an impairment has occurred, it is required to record a write-down of the carrying value and charge the impairment as an operating expense in the period the determination is made. In evaluating the recoverability of the carrying value of goodwill, the Company must make assumptions regarding estimated future cash flows and other factors to determine the fair value of the acquired assets. Changes in strategy or market conditions could significantly impact those judgments in the future and require an adjustment to the recorded balances. The Company tests its goodwill for impairment as of November 30. There was no impairment of goodwill for the six months ended June 30, 2019 and 2018.

Revenue recognition

The Company applies the revenue recognition guidance in accordance with Financial Accounting Standards Board ("FASB") ASC 606, *Revenue from Contracts with Customers*. Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred and title has passed, the price is fixed or determinable, and collectability is reasonably assured. The Company is a development stage company and has had no revenues from product sales to date.

When the Company enters into an arrangement that meets the definition of a collaboration under ASC 808, *Collaborative Arrangements*, the Company recognizes revenue as research and development is performed and its respective share of the expenses are incurred. The Company assesses whether the arrangement contains multiple elements or deliverables, which may include (1) licenses to the Company's technology, (2) research and development activities performed for the collaboration partner, and (3) participation on Joint Steering Committees. Payments may include non-refundable, upfront payments, milestone payments upon achieving significant development events, and royalties on future sales. Each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting based on whether the deliverable has "stand-alone value" to the customer. The arrangement's consideration is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The estimated selling price of each deliverable is determined using the following hierarchy of values: (i) vendor-specific objective evidence of fair value, (ii) third-party evidence of selling price, and (iii) best estimate of selling price. The best estimate of selling price reflects the Company's best estimate of what the selling price would be if the deliverable was regularly sold by the Company on a stand-alone basis. The consideration allocated to each unit of accounting is then recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables. Supply or service transactions may involve the charge of a nonrefundable initial fee with subsequent periodic payments for future products or services. The up-front fees, even if nonrefundable, are recognized as revenue as the products and/or services are delivered and performed over the term of the arrangement.

Deferred revenue

The Company applies the revenue recognition guidance in accordance with ASC 606. Using ASC 606, revenue that is unearned is deferred. Deferred revenue that is expected to be recognized as revenue more than one year subsequent to the balance sheet date is classified as long-term deferred revenue.

Segment information

Operating segments are defined as components of an enterprise (business activity from which it earns revenue and incurs expenses) about which discrete financial information is available and regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company's chief decision maker, who is the Chief Executive Officer, reviews operating results to make decisions about allocating resources and assessing performance for the entire Company. The Company views its operations and manages its business as one operating segment.

Comprehensive loss

The Company had no items of comprehensive loss other than its net loss for each period presented.

Recent accounting pronouncements

From time to time, new accounting pronouncements are issued by the FASB and are adopted by the Company as of the specified effective date.

Recently adopted accounting pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard was effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available.

The Company adopted ASC 842 on January 1, 2019 using a cumulative-effect adjustment on the effective date of the standard, for which comparative periods are presented in accordance with the previous guidance in ASC 840.

In adopting ASC 842, the Company elected to utilize the available package of practical expedients permitted under the transition guidance within the new standard, which did not require the reassessment of the following: (i) whether existing or expired arrangements are or contain a lease, (ii) the lease classification of existing or expired leases, and (iii) whether previous initial direct costs would qualify for capitalization under the new lease standard. Additionally, the Company made an accounting policy election to exclude leases with a term of 12 months or less from its balance sheet.

The adoption of this standard resulted in the recognition of operating lease liabilities and right-of-use assets of $0.4 million and $0.4 million, respectively, on the Company's balance sheet relating to its leases for its corporate headquarters at 1601 Trapelo Road, Suite 286, Waltham, MA 02451. The adoption of the standard did not have a material effect on the Company's condensed consolidated statements of operation and comprehensive loss or condensed consolidated statements of cash flows.

Refer to Note 10 – Leases, for the Company's current lease commitments.

In March 2017, the FASB issued ASU No. 2017-08, *Receivables—Nonrefundable Fees and Other Costs (Subtopic 310-20) Premium Amortization on Purchased Callable Debt Securities.* The new standard is intended to enhance the accounting for the amortization of premiums for purchased callable debt securities. This update is effective for annual periods beginning after December 15, 2018, and interim periods within those fiscal years, with early adoption permitted, including adoption in an interim period. The Company adopted the new standard on January 1, 2019. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. The new standard is intended to reduce the cost and complexity and to improve financial reporting for nonemployee share-based payments. This update expands the scope of *Topic 718, Compensation-Stock Compensation* (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. The new standard supersedes *Subtopic 505-50, Equity-Equity-Based payments to Non-Employees*. The update is effective for the Company for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than a company's adoption date of *Topic 606, Revenue from Contracts with Customers*. The Company adopted the new standard on January 1, 2019. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

Accounting pronouncements not yet adopted

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles — Goodwill and Other (Topic 350).* The new standard simplifies the test for goodwill impairment. This update is effective for annual periods beginning after December 15, 2019, and interim periods within those fiscal years, with early adoption permitted, including adoption in an interim period. The Company is currently evaluating the impact of the pending adoption of the new standard on the Company's consolidated financial statements.

NOTE 3 — ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities consist of the following:

	June 30, 2019	December 31, 2018
Research and development costs and other accrued expenses	$ 2,879,894	$ 1,353,987
Accrued bonus	935,697	—
Professional fees	586,850	455,545
Vacation pay	83,164	—
	$ 4,485,605	$ 1,809,532

NOTE 4 — NET LOSS PER SHARE OF COMMON STOCK

Diluted loss per share is the same as basic loss per share for all periods presented as the effects of potentially dilutive items were anti-dilutive given the Company's net loss. Basic loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding. The following table sets forth the computation of basic and diluted loss per share for common stockholders:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Net loss	$(12,476,471)	$(12,529,508)	$(28,303,671)	$(24,947,771)
Weighted average shares of common stock outstanding	39,025,471	38,749,343	38,996,949	38,749,343
Net loss per share of common stock – basic and diluted	$ (0.32)	$ (0.32)	$ (0.73)	$ (0.64)

The following securities outstanding at June 30, 2019 and 2018 have been excluded from the calculation of weighted average shares outstanding as their effect on the calculation of loss per share is antidilutive:

	June 30,	
	2019	2018
Common stock options	8,508,672	6,655,150
Restricted stock units	127,300	185,950
Common stock warrants	40,790	40,790

NOTE 5 — DEBT

Loan and security agreement

On January 16, 2015, the Company entered into a Loan and Security Agreement (as amended, the "Loan Agreement") with Oxford Finance LLC ("Oxford") and Silicon Valley Bank ("SVB" and, together with Oxford, the "Lenders"), providing for term loans to the Company in an aggregate principal amount of up to $15 million, in two tranches (the "Term Loans").

The Company drew down the initial Term Loans in the aggregate principal amount of $10 million (the "Term A Loans"), on January 16, 2015. The Term A Loans bore interest at a fixed rate of 7.05% per annum. The Company believes that the Company's debt obligations accrued interest at rates which approximated prevailing market rates for instruments with similar characteristics and, accordingly, the carrying values for these instruments approximated fair value.

The Company paid a facility fee at the time of borrowing of $75 thousand for access to the Term Loans and paid a final payment of $510 thousand in August 2018, representing 5.1% of the total amount borrowed, which has been included as a component of the debt discount and was amortized to interest expense over the term of the loans. The Term Loans matured on August 1, 2018 and the Company made a final repayment in the amount of $510 thousand on such date. As of June 30, 2019, the Company had no borrowings outstanding under the Term Loans.

For the three months ended June 30, 2019 and 2018, the Company recognized interest expense of zero and $43 thousand, respectively, including zero and $12 thousand, respectively, related to the debt discount. For the six months ended June 30, 2019 and 2018, the Company recognized interest expense of zero and $0.1 million respectively, including zero and $37 thousand, respectively, related to the debt discount.

NOTE 6 — CO-DEVELOPMENT AND LICENSE AGREEMENT

On February 13, 2014, the Company signed a co-development and license agreement (the "Agreement") with Janssen, which became effective upon completion of the Company's initial public offering and provided for the payment of a $22.0 million license fee by the Company. Under the Agreement, Janssen, the licensor, granted the Company an exclusive license, with the right to sublicense, in the Minerva Territory, under (i) certain patent and patent applications to sell products containing any orexin 2 compound, controlled by the licensor and claimed in a licensor patent right as an active ingredient, and (ii) seltorexant for any use in humans. In addition, upon regulatory approval in the Minerva Territory (and earlier if certain default events occur), the Company will have rights to manufacture seltorexant, also known as JNJ-42847922. The Company has granted to the licensor an exclusive license, with the right to sublicense, under all patent rights and know-how controlled by the Company covering selective antagonists of orexin-2 receptors, including seltorexant, to sell those compounds outside the Minerva Territory. In consideration of the licenses granted on July 7, 2014, the Company made a license fee payment of $22.0 million, which was included as a component of research and development expense in 2014.

The Company accounts for the Agreement as a joint risk-sharing collaboration in accordance with ASC 808, *Collaborative Arrangements*. Payments between the Company and the licensor with respect to each party's share of seltorexant development costs that have been incurred pursuant to the joint development plan are recorded within research and development expenses or general and administrative expenses, as applicable, in the accompanying consolidated statements of operations due to the joint risk-sharing nature of the activities.

On July 6, 2016, the Company and Janssen agreed that "Decision Point 2" had been reached as defined under the Agreement. As neither party exercised their right to withdraw from the Agreement, the Company paid Janssen $3.5 million and has incurred direct expenses of $0.3 million related to development activities under the current phase of development. During the three and six months ended June 30, 2019 and 2018, the Company recorded an expense of zero for certain development activities in accordance with the terms of the Agreement.

In June 2017, the Company entered into an amendment ("the Amendment") to the Agreement. The effectiveness of the Amendment was contingent upon approval of its terms by the European Commission and the closing of the acquisition of Actelion Ltd. by affiliates of Janssen. These conditions were subsequently met, and the Amendment became effective on August 29, 2017. Under the Amendment, Janssen has waived its right to royalties on seltorexant insomnia sales in the Minerva Territory. The Company retains all of its rights to seltorexant, including commercialization of the molecule for the treatment of insomnia and as an adjunctive therapy for MDD, which include an exclusive license in the Minerva Territory, with royalties payable by the Company to Janssen on seltorexant sales outside of the insomnia indication. Royalties on sales outside of the Minerva Territory are payable by Janssen to the Company. Janssen made an upfront payment to the Company of $30 million upon the effectiveness of the Amendment and agreed to make a $20 million payment at the start of a Phase 3 insomnia trial for seltorexant and a $20 million payment when 50% of the patients are enrolled in this trial. Janssen further agreed to waive development payments from the Company until completion of the Phase 2b development milestone. This milestone is referred to as "Decision Point 4". Completion of the current Phase 2b studies is expected to occur in the second half of 2019. The $30 million payment and $11.2 million in previously accrued collaborative expenses, which were forgiven upon the effective date of the Amendment, are earned and recognized as revenue as the services are performed from the commencement of Phase 3 development to the completion of the development activities using the proportional performance method. The $30 million payment along with the $11.2 million in previously accrued collaborative expenses have been included under deferred revenue on the Company's balance sheet at June 30, 2019 and December 31, 2018. In connection with the Amendment, the Company repurchased all of the approximately 3.9 million shares of its common stock previously owned by Johnson & Johnson Innovation-JJDC Inc. at a per share price of $0.0001, for an aggregate purchase price of approximately $389.

As a result of the Amendment, the Company assumed strategic control of matters relating to the clinical development of seltorexant for insomnia and has no further financial obligations until after Decision Point 4. After Decision Point 4, both the Company and Janssen have the right to opt-out of the Agreement.

If the Company opts-out, it collects a royalty on worldwide sales of seltorexant in the single digits with no further obligations to Janssen. If Janssen opts-out, the Minerva Territory would be expanded to include North America and the Company would pay Janssen single digit royalties on sales of seltorexant outside of the insomnia indication.

If both parties elect to continue past Decision Point 4 into Phase 3, the Company would be obligated to fund the clinical trials related to insomnia, receive up to $40 million in milestone payments from Janssen, and be responsible for 40% of all costs incurred in the Phase 3 MDD program.

The Company determined that the license under the Amendment is not considered to be a separate deliverable as it contains no value without the development activities performed under the Agreement. The participation in the joint steering committee under the Amendment is considered to be not separable from the development activities and therefore the two deliverables are combined into a single unit of account. The Company concluded that the milestone payments are related to future performance obligations and will be recognized as those performance obligations are performed by the Company. Similarly, the Company will recognize royalty revenues in the periods of the sale of the related products, provided that no future performance obligations exist and revenue recognition is limited to amounts for which it is probable that a significant reversal will not occur.

NOTE 7 — STOCKHOLDERS' EQUITY

Term loan warrants

In connection with the Loan Agreement, the Company issued the Lenders warrants to purchase shares of its common stock upon its draw of each tranche of the Term Loans (see Note 5). The aggregate number of shares of common stock issuable upon exercise of the warrants is equal to 2.25% of the amount drawn of such tranche, divided by the average closing price per share of the Company's common stock reported on the Nasdaq Global Market for the 10 consecutive trading days prior to the applicable draw. Upon the draw of the Term A Loans, the Company issued the Lenders warrants to purchase 40,790 shares of common stock at a per share exercise price of $5.516. The warrants are immediately exercisable upon issuance, and other than in connection with certain mergers or acquisitions, will expire on the ten-year anniversary of the date of issuance. The fair value of the warrants was estimated at $0.2 million using a Black-Scholes model and assuming: (i) expected volatility of 100.8%, (ii) risk free interest rate of 1.83%, (iii) an expected life of 10 years and (iv) no dividend payments. The fair value of the warrants was included as a discount to the Term A Loans and also as a component of additional paid-in capital and will be amortized to interest expense over the term of the loan. All such warrants were outstanding as of June 30, 2019.

NOTE 8 — STOCK AWARD PLAN AND STOCK-BASED COMPENSATION

In December 2013, the Company adopted the 2013 Equity Incentive Plan (as subsequently amended and restated, the "Plan"), which provides for the issuance of options, stock appreciation rights, stock awards and stock units. On January 1, 2018, in accordance with the terms of the Plan**,** the total shares authorized for issuance under the plan increased by 750,000 to 6,531,333. This increase represents the lesser of 750,000 shares or 4% of the total shares outstanding calculated as of the end of the most recent fiscal year. The exercise price per share shall not be less than the fair value of the Company's underlying common stock on the grant date and no option may have a term in excess of ten years. Further, pursuant to Nasdaq listing rules, the Company issued inducement awards in December 2017 outside of the Plan in the form of an option to purchase 775,000 shares of the Company's common stock and a restricted stock unit award to purchase 40,000 shares of the Company's common stock. In June 2018, the Company increased the aggregate number of shares of common stock authorized for issuance under the Plan by 2,500,000 shares. Stock option activity for employees and non-employees for the six months ended June 30, 2019 is as follows:

	Shares Issuable Pursuant to Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Total Intrinsic Value (in thousands)
Outstanding January 1, 2019	8,498,047	$ 6.99	8.1	$ 5,214
Granted	140,000	$ 5.11		
Exercised	(87,500)	$ 6.00		
Forfeited	(41,875)	$ 6.49		
Outstanding June 30, 2019	8,508,672	$ 6.97	7.6	$ 945
Exercisable June 30, 2019	4,397,446	$ 6.48	6.4	$ 793
Available for future grant	671,654			

The weighted average grant-date fair value of stock options outstanding on June 30, 2019 was $5.14 per share. Total unrecognized compensation costs related to non-vested stock options at June 30, 2019 was approximately $19.5 million and is expected to be recognized within future operating results over a weighted-average period of 2.79 years. The total intrinsic value of the options exercised during the six months ended June 30, 2019 was approximately $0.2 million. No options were exercised during the six months ended June 30, 2018.

The expected term of the employee-related options was estimated using the "simplified" method as defined by the SEC's Staff Accounting Bulletin No. 107, *Share-Based Payment*. The volatility assumption was determined by examining the historical volatilities

for industry peer companies, as the Company did not have sufficient trading history for its common stock. The risk-free interest rate assumption is based on the U.S. Treasury instruments whose term was consistent with the expected term of the options. The dividend assumption is based on the Company's history and expectation of dividend payouts. The Company has never paid dividends on its common stock and does not anticipate paying dividends on its common stock in the foreseeable future. Accordingly, the Company has assumed no dividend yield for purposes of estimating the fair value of the options.

The Company uses the Black-Scholes model to estimate the fair value of stock options granted. For stock options granted to employees during the six months ended June 30, 2019 and 2018, the Company utilized the following assumptions:

	June 30,	
	2019	2018
Expected term (years)	5.5	5.5-6.25
Risk free interest rate	1.91-1.96%	2.33-2.80%
Volatility	74-77%	76-83%
Dividend yield	0%	0%
Weighted average grant date fair value per share of common stock	$ 3.26	$ 4.66

The Company from time to time grants options to purchase common stock to non-employees for services rendered and records expense ratably over the vesting period of each award. The Company estimates the fair value of the stock options using the Black-Scholes valuation model at each reporting date. The Company granted zero stock options to non-employees and recorded stock-based compensation expense of $0.3 million during the six months ended June 30, 2019. The Company granted 40,000 stock options to non-employees and recorded stock-based compensation expense of $0.5 million during the six months ended June 30, 2018.

For stock options granted to non-employees, the Company utilized the following assumptions:

	June 30,	
	2019(1)	2018
Expected term (years)	—	8.2-9.6
Risk free interest rate	—	2.46-2.84%
Volatility	—	83-110%
Dividend yield	—	0%
Weighted average reporting date fair value per share of common stock	—	$ 7.35

(1) There were no stock options granted to non-employees during the six months ended June 30, 2019.

RSU activity under the Plan for the six months ended June 30, 2019 is as follows:

	RSUs	Weighted-Average Grant Date Fair Value
Unvested January 1, 2019	127,300	$ 11.71
Granted	—	$ —
Vested	—	$ —
Forfeited	—	$ —
Unvested June 30, 2019	127,300	$ 11.71

RSUs awarded to employees generally vest one-fourth per year over four years from the anniversary of the date of grant, provided the employee remains continuously employed with the Company. Shares of the Company's stock are delivered to the employee upon vesting, subject to payment of applicable withholding taxes. The fair value of RSUs is equal to the closing price of the Company's common stock on the date of grant. Total unrecognized compensation costs related to non-vested RSUs at June 30, 2019 was approximately $1.1 million and is expected to be recognized within future operating results over a period of 1.59 years. The following table presents stock-based compensation expense included in the Company's consolidated statements of operations:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Research and development	$ 653,718	$ 584,719	$ 1,353,981	$ 1,108,865
General and administrative	1,666,674	1,313,154	3,428,110	2,902,944
Total	$ 2,320,392	$ 1,897,873	$ 4,782,091	$ 4,011,809

NOTE 9 — COMMITMENTS AND CONTINGENCIES

From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of the Company's business activities. At this time, the Company is not aware of any such legal proceedings or claims. The Company is not aware of any claim or litigation, the outcome of which, if determined adversely to the Company, would have a material effect on the Company's financial position or results of operations

Refer to Note 10 – Leases, for the Company's current lease commitments.

NOTE 10 — LEASES

Operating leases

On October 2, 2017, the Company entered into an office sublease agreement (the "Sublease") with Profitect, Inc. (the "Sublandlord") to sublease approximately 5,923 rentable square feet of office space located at 1601 Trapelo Road, Waltham, MA 02451 (the "Premises"). The term of the Sublease began on November 1, 2017 and will expire on July 31, 2021 (the "Term"), with a monthly rental rate starting at $14,808 and escalating to a maximum monthly rental rate of $16,288 in the final 12 months of the Term. The Sublandlord provided the Premises to the Company free of charge for the first two months of the Term. The Company will recognize the remaining expense on a straight-line basis over the remaining Term.

Throughout the Term, the Company is responsible for paying certain costs and expenses, in addition to the rent, as specified in the Sublease, including a proportionate share of applicable taxes, operating expenses and utilities. In applying the ASC 842 transition guidance, the Company retained the classification of this Sublease as operating and recorded a lease liability and a right-of-use asset on the ASC 842 effective date.

The following table contains a summary of the Sublease costs recognized under ASC 842 and other information pertaining to the Company's operating Sublease for the six months ended June 30, 2019:

	Six Months Ended June 30, 2019
Sublease cost	
Operating Sublease cost	$ 89,635
Total Sublease cost	$ 89,635
Other information	
Operating cash flows used for operating Sublease	$ 76,505
Weighted average remaining Sublease term	2.1 years
Weighted average discount rate	10%

Future minimum Sublease payments under the Company's non-cancelable operating Sublease as of June 30, 2019, are as follows:

Future Operating Sublease Payments		Waltham
2019 (excluding the six months ended June 30, 2019)	$	94,274
2020		192,004
2021		114,018
Thereafter		—
Total Sublease payments	$	400,296
Less: imputed interest		(37,629)
Total operating Sublease liabilities at June 30, 2019	$	362,667

NOTE 11 — RELATED PARTY TRANSACTIONS

In January 2016, the Company entered into a services agreement with V-Watch SA ("V-Watch"), for approximately $105 thousand for the use of V-Watch's SomnoArt device for monitoring sleep in the roluperidone Phase 2b and MIN-117 Phase 2a trials. The Company's Chief Executive Officer is the chairman of the board of directors of V-Watch. Funds affiliated with Index Ventures, a stockholder of the Company, hold greater than 10% of the outstanding capital stock of V-Watch.

Also refer to Note 6 – Co-Development and License Agreement and Note 7 – Stockholders' Equity for additional related party transactions.

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 in conjunction with our condensed consolidated financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q and with our annual audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2018 as filed with the Securities and Exchange Commission on March 12, 2019.

Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of a portfolio of product candidates to treat patients suffering from central nervous system ("CNS") diseases. Leveraging our scientific insights and clinical experience, we have acquired or in-licensed four development-stage proprietary compounds that we believe have innovative mechanisms of action and therapeutic profiles that potentially address the unmet needs of patients with these diseases.

Our product portfolio and potential indications include: roluperidone (also known as MIN-101) for the treatment of negative symptoms in patients with schizophrenia; seltorexant (also known as MIN-202 or JNJ-42847922), which we are co-developing with Janssen Pharmaceutica NV ("Janssen") for the treatment of insomnia disorder and adjunctive treatment of Major Depressive Disorder ("MDD"); MIN-117 for the treatment of MDD; and MIN-301 for the treatment of Parkinson's disease. We believe our product candidates have significant potential to improve the lives of a large number of affected patients and their families who are currently not well-served by available therapies.

We have not received regulatory approvals to commercialize any of our product candidates, and we have not generated any revenue from the sales or license of our product candidates. We have incurred significant operating losses since inception. We expect to incur net losses and negative cash flow from operating activities for the foreseeable future in connection with the clinical development and the potential regulatory approval, infrastructure development and commercialization of our product candidates.

Clinical Updates

Roluperidone (MIN-101)

Phase 3 Clinical Trial

In December 2017, the first patient was screened in the pivotal Phase 3 clinical trial of roluperidone (Study "MIN-101C07") as monotherapy for negative symptoms in patients diagnosed with schizophrenia. The trial is a multicenter, randomized, double-blind, parallel-group, placebo-controlled, 12-week study to evaluate the efficacy and safety of 32 milligrams ("mg"), and 64 mg of roluperidone in adult patients with negative symptoms of schizophrenia. The 12-week study will be followed by a 40-week, open-label extension period during which patients on the drug will continue receiving their original dose and patients on placebo will receive either 32 mg or 64 mg of roluperidone.

The approximately 500 patients we expect to enroll in this trial at clinical sites in the U.S. and Europe will be initially randomized equally to receive one of the two doses of roluperidone or placebo for 12 weeks. Thereafter, all patients will continue treatment with roluperidone for the 40-week extension period if they elect to enter that period.

We expect to complete enrollment in this trial during the second half of 2019, with top line results from the 12-week, double-blind portion of the study to be available in the fourth quarter of 2019.

The primary endpoint of this trial will be improvement in negative symptoms in patients treated with roluperidone compared to placebo as measured by the change in the Positive and Negative Syndrome Scale, or PANSS, Marder negative symptoms factor score ("NSFS"), over the 12-week double-blind treatment period. To support the use of the Marder NSFS as the primary endpoint in the Phase 3 study, it was applied to the Phase 2b PANSS data, and the resulting analysis confirmed the robustness of the effect of roluperidone for the two tested doses. The key secondary endpoint will be the effect of roluperidone compared to placebo as measured by the Personal and Social Performance, or PSP, total score over the same period. Additional secondary endpoints will be the effect of roluperidone compared to placebo on the Clinical Global Impression of Severity ("CGI-S") score and safety and tolerability.

Patients admitted into the trial must have a documented diagnosis of schizophrenia for at least one year and be symptomatically stable for at least 6 months with moderate to severe negative symptoms (>20 on the PANSS negative symptom subscale) and stable positive symptoms. Patients without moderate to severe symptoms of excitement/hyperactivity, suspiciousness/persecution, hostility, uncooperativeness, or poor impulse control will be recruited. We believe these eligibility criteria represent the real-world patient population who may benefit when the drug is used in clinical practice. In addition, patients treated with psychotropic agents will need to undergo a wash-out period of a few days before receiving study drug. These parameters were applied in screening the population treated in the Phase 2b trial.

Chemistry, Manufacturing and Controls program

The chemistry, manufacturing and controls ("CMC") scale-up program for roluperidone is ongoing to ensure consistency between the drug batches to be used during Phase 3 testing and those that will be available for potential marketing and commercialization pending the completion of our Phase 3 trial and subsequent regulatory submission and review of a New Drug Application ("NDA") for roluperidone. The CMC program requires validation of all aspects of the manufacturing processes required to result in a drug product that consistently meets approved quality standards.

Drug-Drug Interaction Studies

We have recently completed certain pharmacology trials that include a Drug-Drug Interaction ("DDI") study, which comprise a standard part of the NDA. We have studied interactions separately with molecules inhibiting two subtypes of the cytochrome P450 (CYP2D6 and CYP3A4). The data from this study are currently being analyzed and preliminary data show minimal interaction.

Brain-Derived Neurotrophic Factor Findings

We have completed a non-clinical study that provides evidence of the effect of roluperidone on Brain-Derived Neurotrophic Factor ("BDNF") and on Glial Cell-Derived Neurotrophic Factor ("GDNF"). BDNF is the most widely distributed member of neurotrophins in the brain and has been associated with neurogenesis, neuroplasticity, neuroprotection, synaptic regulation, and learning and memory. Its involvement in schizophrenia has also been described. GDNF is another neurotrophin known to promote the survival of different types of brain cells and has been shown to be essential for the maintenance and survival of dopamine neurons.

Data from this study were presented at the 2019 Congress of the Schizophrenia International Research Society on April 11, 2019. These findings demonstrate that administration of roluperidone significantly increased BDNF release by astrocytes and hippocampal neurons obtained from the cerebral cortex of newborn rats, as well as the release of GDNF (Glial cell derived neurotrophic factor) in cultured astrocytes. Furthermore, data showed that roluperidone enhanced BDNF gene expression at drug concentrations comparable to those observed in humans at tested doses.

Based on these results, we believe that the effect of roluperidone on BDNF and GDNF may indicate its potential for disease modification and improved neuroplasticity, in addition to its observed effects on the sigma$_2$, serotoninergic 5-HT$_{2A}$, and possibly α1-adrenergic neurotransmitter pathways.

The Journal of Clinical Psychiatry Publication

The Journal of Clinical Psychiatry has published online results demonstrating cognitive improvements in patients with schizophrenia treated with roluperidone (Cognitive Effects on MIN-101 in Patients with Schizophrenia and Negative Symptoms: Results from a Randomized Controlled Trial). The results also demonstrated that cognitive improvements correlate with previously reported improvements in negative symptoms. This is the third peer-reviewed publication of Phase 2b data with roluperidone.

MIN-117

Phase 2b Trial

We initiated a Phase 2b trial in MDD in the U.S. and Europe on April 9, 2018. The primary objective of the trial is to evaluate the efficacy of two fixed doses of MIN-117, 5.0 mg and 2.5 mg daily, compared with placebo in reducing the symptoms of major depression as measured by the change in the Montgomery-Asberg Depression Rating Scale ("MADRS") total score over six weeks of treatment. Secondary objectives include: (1) assessment of the change from baseline in symptoms of anxiety using the Hamilton Anxiety Scale ("HAM-A"); (2) the change in severity of illness CGI-S and Clinical Global Impression of Improvement Scale ("CGI-I"); and (3) safety over six weeks of treatment.

The study is recruiting adults with a diagnosis of moderate or severe MDD with anxious distress and without psychotic features. Based upon previous clinical observations, we believe that patients with MDD who also have symptoms of anxiety may benefit from treatment with MIN-117.

Approximately 324 patients are expected to be enrolled in the U.S. and Europe. Patients will be randomized to one of three arms, placebo and the two dosage arms, in a 2:1:1 ratio, resulting in approximately 162 patients in the placebo group and 81 patients in each of the two MIN-117 treatment groups. The study design includes a screening phase of up to three weeks, a 6-week double-blind treatment phase and a 2-week post-study follow-up period. We expect to complete enrollment in this trial in the third quarter of 2019, with top line results to be available in the fourth quarter of 2019.

New Patent Application Related to Pain

We have filed a U.S. patent application for MIN-117 to treat pain. Pre-clinical rat models submitted in the patent application included peripheral motoneuropathy, inflammatory pain and chemotherapy-induced peripheral neuropathic pain. Findings in these models showed that MIN-117 restored approximately 60 percent of the nociceptive pain threshold after peripheral motoneuropathy or inflammatory pain and significantly reduced, in a dose-dependent manner, chemotherapy-induced peripheral neuropathic pain.

These results suggest that MIN-117 may be a candidate for study in the treatment of diseases with chronic pain symptoms and may have the potential to address the urgent need for non-opioid therapeutic options for the treatment of pain. Furthermore, the currently available treatments for chronic pain are often not satisfactory and may be associated with adverse reactions, tolerance, dependence and reductions in the quality of life for patients.

Seltorexant (MIN-202)

Phase 2b Trials in MDD

On May 13, 2019, we announced positive top line results from a Phase 2b trial of seltorexant (the "MDD2001 Trial") as adjunctive therapy to antidepressants in adult patients with MDD who have responded inadequately to antidepressant therapy, including selective serotonin reuptake inhibitors ("SSRIs") and/or serotonin-norepinephrine reuptake inhibitors ("SNRIs"). In this dose finding study, the 20 mg dose of seltorexant showed a statistically significant improvement in the MADRS (Montgomery-Asberg Depression Rating Scale) score compared to placebo. The least squares mean (LS mean) difference from placebo of the change in MADRS total score at the end of week 6 was 3.1 for the 20 mg dose of seltorexant, and the 2-sided p-value was 0.083, which is below the pre-specified 2-sided type I error level of 0.1.

After three weeks of treatment, seltorexant at the 20 mg dose also showed a statistically significant improvement over placebo, highlighting its short onset of action time. In addition, a key secondary outcome measure, which was based on patient stratification according to baseline insomnia severity index ("ISI"), showed an even greater difference from placebo for the seltorexant 20 mg arm in patients with clinically significant insomnia (ISI $\geq$ 15) with LS mean difference versus placebo of 4.9 on the MADRS total score and a 2-sided p-value of 0.050 compared to the overall patient population in this trial.

The 40 mg dose, to which further enrollment was stopped following the interim analysis, showed an improvement in the MADRS total score versus placebo at the end of week 6 but did not reach statistical significance. Results for the 10 mg dose were not interpretable due to the small sample size of patients receiving this dose.

Seltorexant was well tolerated, and observed adverse events were comparable to those seen in previous studies and similar to or lower than those observed in the placebo group.

We believe these results represent the first clinical observation in a large, late-stage study that a selective orexin molecule can achieve a positive effect as an adjunctive treatment in patients with MDD who have an inadequate response to SSRIs and SNRIs. These findings, if confirmed in Phase 3 studies, suggest a novel approach to treating MDD, with an improved safety profile compared to existing therapies. Approximately 60%-70% of patients diagnosed and treated with first-line therapies, including SSRIs and/or SNRIs, do not experience adequate treatment response, and seltorexant potentially represents a unique opportunity to improve treatment response rates safely in most of these patients.

A Phase 2b clinical trial comparing seltorexant versus quetiapine as adjunctive therapy in patients with MDD who have responded inadequately to antidepressant therapy (the "MDD2002 Trial") is ongoing. The primary objective of this multi-center, double-blind, randomized, flexible-dose, parallel-group study is to assess the efficacy of flexibly dosed seltorexant compared to flexibly dosed quetiapine as adjunctive therapy to a baseline antidepressant drug in delaying time to all-cause discontinuation of study drug over a 6-month treatment period. Time to all-cause discontinuation is defined as the number of days from administration of the first dose of study drug to administration of the last dose of study drug.

The trial consists of three phases: a screening phase lasting up to four weeks, a six-month double-blind treatment phase and a 2-week follow-up phase. Approximately 100 patients 18 to 64 years of age are planned to be randomized in the U.S. to receive either flexibly dosed seltorexant, 20 mg or 40 mg, or flexibly dosed quetiapine XR, 150 mg or 300 mg. Subjects will continue to take their baseline antidepressant therapy of either an SSRI or an SNRI at the same dose throughout the screening, double-blind and follow-up phases.

Enrollment has been completed in the MDD2002 Trial and we expect top line results from this trial to be available in the third quarter of 2019.

Phase 1b trial

We have recently analyzed data from an exploratory, biomarker, multicenter, placebo-controlled, randomized, double-blind Phase 1b trial of seltorexant (the "MDD1009 Trial"), administered at doses of 20 and 40 mg, as monotherapy in 128 subjects with moderate to severe MDD. The primary objective of this study was to analyze the treatment effect of seltorexant versus placebo on symptoms of depression as measured by the Hamilton Rating Scale for Depression ($HDRS_{17}$). The presence of subjective sleep disturbance (subjective sleep assessment, Insomnia Severity Index (ISI), and Ruminative Response Scale [RRS]) as a possible indicator of hyper-arousal was used as a stratification factor in patient randomization.

Results of the primary endpoint analysis showed a significant positive treatment effect at week 5 for seltorexant versus placebo. The efficacy signal for the 20 mg dose was statistically significant and more pronounced in the MDD population with sleep disorder, measured as having an ISI > 15 and subjective sleep onset latency >30 min during at least 3 nights over 7 recorded days, and in MDD patients with higher rumination, measured as a having RRS ≥ 50.

The seltorexant 40 mg dose did not show a statistically significant effect at week 5, although the efficacy signal was also more pronounced in the subgroups (MDD patients with presence of subjective sleep disorder, measured as having an ISI >15 or RRS ≥ 50).

We believe these data further characterize the mechanism of seltorexant as an antagonist of the orexin system, which is involved in the control of several key functions in the brain, including mood, metabolism and wakefulness.

Phase 2b Trial in Insomnia Disorder

On June 24, 2019, we announced positive top line results from a Phase 2b clinical trial of seltorexant in patients with insomnia disorder (the "ISM2005 Trial") that demonstrated highly statistically significant ($p \leq 0.001$) and clinically meaningful improvement on Latency to Persistent Sleep ("LPS") at Night 1, the primary endpoint of the study. The mean decrease from baseline at Night 1 in LPS was 15 minutes for placebo, 30 minutes for seltorexant 5 mg, 50 minutes for seltorexant 10 mg, and 48 minutes for seltorexant 20 mg.

The key secondary endpoint, defined as Wake After Sleep Onset over the first 6 hours ("WASO-6") at Night 1, showed improvement with a p-value ≤ 0.005 after treatment with 10 and 20 mg doses of seltorexant. The mean improvement from baseline at Night 1 was 15 minutes for placebo, 23 minutes for seltorexant 5 mg, 43 minutes for 10 mg, and 45 minutes for 20 mg of seltorexant. Furthermore, multiple secondary endpoints were also improved versus placebo and standard of care zolpidem, which is available under the brand name Ambien.

We believe these findings demonstrate that seltorexant significantly improves sleep induction and maintenance, while also showing a significantly greater improvement in these sleep parameters compared to zolpidem. In addition, the beneficial effects on LPS and WASO of seltorexant in elderly patients in the study, in conjunction with a favorable tolerability profile, suggest its potential benefit in the large and growing population of elderly patients whose prevalence of insomnia is higher than in younger patients, thus representing an important therapeutic option.

Based on the results from the ISM2005 Trial, observations of seltorexant include a clinically meaningful effect on insomnia in a wide age range of patients. We believe this demonstration of a significant benefit across a broad spectrum of patients who suffer with insomnia who have not responded adequately to existing therapies reflects a differentiated clinical profile and suggests a new potential way to address these unmet medical needs.

MIN-301

Results from a non-human primate study showed that treatment with an analog of MIN-301 resulted in improvements in a range of symptoms associated with a Parkinson's disease model in primates. The results confirmed the beneficial effects of MIN-301 in non-primate pre-clinical models. We believe these data provide support for advancing MIN-301 into clinical trials for the treatment of Parkinson's disease in humans. Building upon these data, we are continuing to conduct pre-clinical studies in preparation for an

Investigational New Drug ("IND") or Investigational Medicinal Product Dossier ("IMPD") filing, with a Phase 1 study expected to commence thereafter.

Financial Overview

Revenue. None of our product candidates have been approved for commercialization and we have not recognized any revenue in connection with the sale or license of our product candidates. As a result of the Amendment to our Co-Development and License Agreement with Janssen, we have Deferred Revenue that will be recognized in future periods, the timing of which is subject to certain future events that will be evaluated in conjunction with the relevant revenue recognition pronouncements.

Research and Development Expenses. Research and development expenses consists of costs incurred in connection with the development of our product candidates, including: fees paid to consultants and clinical research organizations ("CROs") including in connection with our non-clinical and clinical trials, and other related clinical trial fees, such as for investigator grants, patient screening, laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis; licensing fees; costs related to acquiring clinical trial materials; costs related to compliance with regulatory requirements; and costs related to salaries, benefits, bonuses and stock-based compensation granted to employees in research and development functions. We expense research and development costs as they are incurred.

In the future, we expect research and development expenses to be our largest category of operating expenses and to increase as we continue our planned pre-clinical and clinical trials for our product candidates and as we hire additional research and development staff.

Completion dates and completion costs can vary significantly for each product candidate and are difficult to predict. We anticipate we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success or failure of each product candidate, the estimated costs to continue the development program relative to our available resources, as well as an ongoing assessment as to each product candidate's commercial potential. We will need to raise additional capital or may seek additional product collaborations in the future in order to complete the development and commercialization of our product candidates.

General and Administrative Expenses. General and administrative expenses consist principally of costs for functions in executive, finance, legal, auditing and taxes. Our general and administrative expenses include salaries, bonuses, facility and information system costs and professional fees for auditing, accounting, consulting and legal services. General and administrative costs also include non-cash stock-based compensation expense as part of our compensation strategy to attract and retain qualified staff.

We expect to continue to incur general and administrative expenses related to operating as a publicly-traded company, including increased audit and legal fees, costs of compliance with securities, corporate governance and other regulations, investor relations expenses and higher insurance premiums. In addition, we expect to incur additional costs as we hire personnel and enhance our infrastructure to support the anticipated growth of our business.

Foreign Exchange (Losses) Gains. Foreign exchange (losses) gains are comprised primarily of losses and gains of foreign currency transactions related to clinical trial expenses denominated in Euros. Since our current clinical trials are conducted in Europe, we incur certain expenses in Euros and record these expenses in U.S. Dollars at the time the liability is incurred. Changes in the applicable foreign currency rate between the date an expense is recorded and the payment date is recorded as a foreign currency loss or gain. We expect to continue to incur future expenses denominated in Euros as certain of our planned clinical trials are expected to be conducted in Europe.

Investment Income. Investment income consists of income earned on our cash equivalents and marketable securities (current and non-current).

Interest Expense. Interest expense consists of interest incurred under our current outstanding loan with Oxford Finance LLC, or Oxford, and Silicon Valley Bank, or SVB.

Results of Operations

Comparison of Three Months Ended June 30, 2019 versus June 30, 2018

Research and Development Expenses

Total research and development expenses were $8.3 million for the three months ended June 30, 2019 compared to $9.1 million for the same period in 2018, a decrease in total expense of $0.8 million. The decrease in research and development expenses primarily

reflects decreased non-clinical and clinical pharmacology expenses, partially offset by increased costs for the Phase 3 clinical trial of roluperidone and the Phase 2b clinical trial of MIN-117. We expect research and development expenses to increase during 2019 as we increase patient enrollment and related support activities for the roluperidone and MIN-117 clinical trials.

General and Administrative Expenses

Total general and administrative expenses were $4.6 million for the three months ended June 30, 2019 compared to $3.9 million for the same period in 2018, an increase of approximately $0.7 million. This increase in general and administrative expenses was primarily due to an increase in non-cash stock-based compensation expenses and salary costs from increased staffing to support our pre-commercial activities. We expect general and administrative expenses to increase during 2019 as we begin to prepare for the transition from clinical development to commercialization.

Foreign Exchange (Losses) Gains

Foreign exchange losses were $7 thousand for the three months ended June 30, 2019 compared to gains of $29 thousand for the same period in 2018, a decrease of $36 thousand. The loss was primarily due to clinical activities denominated in Euros.

Investment Income

Investment income was $0.4 million in both three months ended June 30, 2019 and 2018.

Interest Expense

Interest expense was zero for the three months ended June 30, 2019 compared to $36 thousand for the same period in 2018, a decrease of $36 thousand. The decrease was due to the repayment of principal on our Term A loans in 2018.

Comparison of Six Months Ended June 30, 2019 versus June 30, 2018

Research and Development Expenses

Total research and development expenses were $19.9 million for the six months ended June 30, 2019 compared to $17.5 million for the same period in 2018, an increase in total expense of $2.4 million. The increase in research and development expenses primarily reflects higher development expenses for the Phase 3 clinical trial of roluperidone and the Phase 2b clinical trial of MIN-117. We expect research and development expenses to increase during 2019 as we increase patient enrollment and related support activities for the roluperidone and MIN-117 clinical trials.

General and Administrative Expenses

Total general and administrative expenses were $9.3 million for the six months ended June 30, 2019 compared to $8.2 million for the same period in 2018, an increase of approximately $1.1 million. This increase in general and administrative expenses was primarily due to an increase in non-cash stock-based compensation expenses and salary costs from increased staffing to support our pre-commercial activities. We expect general and administrative expenses to increase during 2019 as we begin to prepare for the transition from clinical development to commercialization.

Foreign Exchange (Losses) Gains

Foreign exchange losses were $13 thousand for the six months ended June 30, 2019 compared to gains of $11 thousand for the same period in 2018, an increase of $24 thousand. The loss was primarily due to clinical activities denominated in Euros.

Investment Income

Investment income was $0.9 million for the six months ended June 30, 2019 compared to $0.8 million for the same period in 2018, an increase of $0.1 million. The increase was due to investment income on cash equivalents and marketable securities.

Interest Expense

Interest expense was zero for the six months ended June 30, 2019 compared to $0.1 million for the same period in 2018, a decrease of $0.1 million. The decrease was due to the repayment of principal on our Term A loans in 2018.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred losses and cumulative negative cash flows from operations since our inception in April 2007 and, as of June 30, 2019, we had an accumulated deficit of approximately $242.9 million. We anticipate that we will continue to incur net losses for the foreseeable future as we continue the development and potential commercialization of our product candidates and to support our operations as a public company. At June 30, 2019, we had approximately $69.4 million in cash, cash equivalents, marketable securities, and restricted cash. We believe that our existing cash, cash equivalents, restricted cash, and marketable securities will be sufficient to meet our cash commitments for at least the next 12 months after the date that the interim condensed financial statements are issued. The process of drug development can be costly and the timing and outcomes of clinical trials is uncertain. The assumptions upon which we have based our estimates are routinely evaluated and may be subject to change. The actual amount of our expenditures will vary depending upon a number of factors including but not limited to the design, timing and duration of future clinical trials, the progress of our research and development programs, the infrastructure to support a commercial enterprise, the cost of a commercial product launch and the level of financial resources available. We have the ability to adjust our operating plan spending levels based on the timing of future clinical trials which will be predicated upon adequate funding to complete the trials.

Sources of Funds

Amendment to Co-Development and License Agreement with Janssen

On August 29, 2017, the European Commission approved the Amendment to our Co-Development and License Agreement with Janssen under which Janssen made an upfront payment to us of $30 million in August 2017 and agreed to make a $20 million payment at the start of a Phase 3 insomnia trial for seltorexant and a $20 million payment when 50% of the patients are enrolled in this trial. Janssen further agreed to waive the remaining payments due from us until the completion of certain Phase 2b trials, including $11.2 million in previously accrued collaborative expenses. In connection with the Amendment, we also repurchased all of the approximately 3.9 million shares of our stock previously owned by Johnson & Johnson Innovation-JJDC Inc. at a per share price of $0.0001, for an aggregate purchase price of approximately $389.

Public Offering of Common Stock

On July 5, 2017, we closed a public offering of common stock, in which we issued and sold 5,750,000 shares of our common stock, including 750,000 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares, at a public offering price of $7.75, for aggregate gross proceeds to us of $44.6 million. All of the shares issued and sold in this public offering were registered under the Securities Act pursuant to a registration statement on Form S-3 (File No. 333-205764) and a related prospectus and prospectus supplement, in each case filed with the SEC. We incurred $3.0 million in underwriting discounts and commissions and transaction costs, which will be included as a component of additional paid-in capital, resulting in net proceeds of approximately $41.6 million.

Exercise of Warrants

In March 2017, certain investors in our March 2015 private placement exercised their warrants and received an aggregate of 1,621,073 shares of our common stock. We received gross proceeds of approximately $9.4 million from the exercise of these warrants.

Uses of Funds

To date, we have not generated any revenue. We do not know when, or if, we will generate any revenue from sales of our products or royalty payments from our collaboration with Janssen. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize any of our product candidates. At the same time, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our product candidates. We also expect to continue to incur costs associated with operating as a public company. In addition, subject to obtaining regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third-party funding, commercialization, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. There can be no assurance that such additional funding, if available, can be obtained on terms acceptable to us. If we are unable to obtain additional financing, future operations would need to be scaled back or discontinued. We believe that our existing cash, cash equivalents, marketable securities, and restricted cash will be sufficient to meet our cash commitments for at least the next 12 months after the date that the interim condensed financial statements are issued. The timing of future capital requirements depends upon many factors including the size and timing of future clinical trials, the timing and scope of any strategic partnering activity and the progress of other research and development activities.

Under our $10.0 million Term A Loan, (See Note 5) we have made principal repayments of approximately $10 million and made a final repayment of all outstanding borrowings on August 1, 2018.

Cash Flows

The table below sets forth our significant sources and uses of cash for the periods.

	Six Months Ended June 30,	
	2019	2018
	(dollars in millions)	
Net cash provided by (used in):		
Operating activities	$ (19.7)	$ (22.2)
Investing activities	(3.2)	67.5
Financing activities	0.5	(2.6)
Net (decrease) increase in cash	$ (22.4)	$ 42.7

Net Cash Used in Operating Activities

Net cash used in operating activities of approximately $19.7 million during the six months ended June 30, 2019 was primarily due to our net loss of $28.3 million and amortization of investments of $0.5 million, partially offset by stock-based compensation expense of $4.8 million, a $2.7 million increase in accrued expenses, a $1.1 million increase in accounts payable, and a decrease in prepaid expense of $0.5 million.

Net cash used in operating activities of approximately $22.2 million during the six months ended June 30, 2018 was primarily due to our net loss of $24.9 million, an increase in prepaid expense of $2.0 million, amortization of investments of $0.1 million and $0.1 million decrease in accounts payable, partially offset by stock-based compensation expense of $4.0 million and a $0.9 million increase in accrued expenses.

Net Cash (Used in) Provided by Investing Activities

Net cash used in investing activities of approximately $3.2 million during the six months ended June 30, 2019 was primarily due to the purchase of marketable securities of $33.2 million, partially offset by the maturity and redemption of marketable securities of $30.0 million.

Net cash provided by investing activities of approximately $67.5 million during the six months ended June 30, 2018 was primarily due to the maturity and redemption of marketable securities of $75.4 million, partially offset by the purchase of marketable securities of $7.9 million.

Net Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities of $0.5 million during the six months ended June 30, 2019 was due to the proceeds from the exercise of common stock options of $0.5 million.

Net cash used in financing activities of $2.6 million during the six months ended June 30, 2018 was due to principal repayments under the Term A loans of $2.6 million.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements as defined under SEC rules.

Critical Accounting Policies and Estimates

In our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, our most critical accounting policies and estimates upon which our financial status depends were identified as those relating to stock-based compensation; research and development costs; in-process research and development; goodwill; income taxes; Jumpstart Our Business Startups Act; net operating losses and tax credit carryforwards; and impairment of long-lived assets. We reviewed our policies and determined that those policies remain our most critical accounting policies for the six months ended June 30, 2019.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, and are adopted by us as of the specified effective date. Our significant accounting policies are described in Note 2 to our condensed consolidated financial statements appearing elsewhere in this Form 10-Q. Except as described in Note 2, we believe that the impact of other recently issued accounting pronouncements will not have a material impact on consolidated financial position, results of operations, and cash flows, or do not apply to our operations.

Item 3. ***Quantitative and Qualitative Disclosures about Market Risk***

Not applicable.

Item 4. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act, that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer), evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2019. Based on the evaluation of our disclosure controls and procedures as of June 30, 2019, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in internal control over financial reporting during our latest fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

Item 1. ***Legal Proceedings***

From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, as of the date of this Quarterly Report on Form 10-Q, we do not believe we are party to any claim or litigation, the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. ***Risk Factors***

We operate in a rapidly changing environment that involves a number of risks which could materially affect our business, financial condition or future results, some of which are beyond our control. In addition to the other information set forth in this Quarterly Report on Form 10-Q, the risks and uncertainties that we believe are most important for you to consider are discussed in Part I-Item 1A under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the SEC on March 12, 2019. The risk factors set forth below are risk factors containing changes, which may be material, from the risk factors previously disclosed in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, as filed with the SEC.

We have incurred significant losses since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.

We are a clinical development-stage biopharmaceutical company. In November 2013, we merged with Sonkei Pharmaceuticals, Inc. ("Sonkei") and, in February 2014, we acquired Mind-NRG, which were also clinical development-stage biopharmaceutical companies. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval or become commercially viable. As an early stage company, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly the biopharmaceutical area. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations.

We are not profitable and have incurred losses in each period since our inception in 2007. For the six months ended June 30, 2019, and 2018, we reported net losses of $28.3 million and $24.9 million, respectively. As of June 30, 2019, we had an accumulated deficit of $242.9 million.

We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates. If any of our product candidates fail in clinical trials or do not gain regulatory approval, or if any of our product candidates, if approved, fail to achieve market acceptance, we may never generate revenue or become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will require additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. As a result, we may not complete the development and commercialization of our product candidates or develop new product candidates.

Our operations and the historic operations of Sonkei and Mind-NRG have consumed substantial amounts of cash since inception. We expect our research and development expenses to increase substantially in connection with our ongoing activities to develop and commercialize product candidates.

As of June 30, 2019, we had cash, cash equivalents, marketable securities, and restricted cash of $69.4 million. We believe that our existing cash, cash equivalents, restricted cash, and marketable securities will be sufficient to meet our cash commitments for at least the next 12 months after the date that our interim condensed financial statements are issued. The process of drug development can be costly and the timing and outcomes of clinical trials is uncertain. The assumptions upon which we have based our estimates are routinely evaluated and may be subject to change. The actual amount of our expenditures will vary depending upon a number of factors including but not limited to the design, timing and duration of future clinical trials, the progress of our research and development programs, the infrastructure to support a commercial enterprise, the cost of a commercial product launch and the level of financial resources available.

Our future funding requirements, both short and long-term, will depend on many factors, including:

- the initiation, progress, timing, costs and results of pre-clinical studies and clinical trials for our product candidates and future product candidates we may develop;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the EMA, FDA, and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more studies than those that we currently expect;
- the cost to establish, maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the effect of competing technological and market developments;
- market acceptance of any approved product candidates;
- the costs of acquiring, licensing or investing in additional businesses, products, product candidates and technologies; and
- the cost of establishing sales, marketing and distribution capabilities for our product candidates for which we may receive regulatory approval and that we determine to commercialize ourselves or in collaboration with our partners.

When we need to secure additional financing, such additional fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we raise additional equity financing, our stockholders may experience significant dilution of their ownership interests, and the per-share value of our common stock could decline. If we engage in debt financing, we may be required to accept terms that restrict our ability to incur additional indebtedness and force us to maintain specified liquidity or other ratios. Further, the evolving and volatile global economic climate and global financial market conditions could limit our ability to raise funding and otherwise adversely impact our business or those of our collaborators and providers. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. Any of these events could significantly harm our business, financial condition and prospects.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Recent Sales of Unregistered Securities

We did not sell any unregistered securities during the three months ended June 30, 2019.

Issuer Purchases of Equity Securities

We did not repurchase any securities during the three months ended June 30, 2019.

Item 3. Defaults upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

The following exhibits are incorporated by reference or filed as part of this report.

Exhibit Number	Description	SEC File No.
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's registration statement on Form S-1/A filed with the SEC on June 10, 2014)	333-195169
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's registration statement on Form S-1/A filed with the SEC on June 10, 2014)	333-195169
31.1	Certification of Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002	
31.2	Certification of Chief Financial Officer (Principal Financial Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002	
32.1+	Certification of Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer) pursuant to Section 906 of Sarbanes-Oxley Act of 2002	
101.INS	XBRL Instance Document	
101.SCH	XBRL Taxonomy Extension Schema Document	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	

+ These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURE

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MINERVA NEUROSCIENCES, INC.

By: /s/ Geoffrey Race
Geoffrey Race
Chief Financial Officer (Principal Financial Officer)
(On behalf of the Registrant)

Date: August 5, 2019

EXHIBIT 31.1

CERTIFICATION

I, Remy Luthringer, certify that:

1. I have reviewed this Form 10-Q of Minerva Neurosciences, 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 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 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: August 5, 2019

/s/ Remy Luthringer Ph.D.
Remy Luthringer Ph.D.
Chief Executive Officer and
Chairman of the Board of Directors
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Geoffrey Race, certify that:

1. I have reviewed this Form 10-Q of Minerva Neurosciences, 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 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 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: August 5, 2019

/s/ Geoffrey Race
Geoffrey Race
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

STATEMENT PURSUANT TO 18 U.S.C. § 1350

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Remy Luthringer, President and Chief Executive Officer (Principal Executive Officer) of Minerva Neurosciences, Inc. (the "Company") and Geoffrey Race, Chief Financial Officer (Principal Financial Officer) of the Company, each hereby certifies that, to the best of his knowledge:

(1) The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2019, to which this Certification is attached as Exhibit 32.1 (the "Quarterly Report") fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

(2) The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Remy Luthringer, Ph.D.

Date: August 5, 2019

Remy Luthringer, Ph.D.
Chief Executive Officer and
Chairman of the Board of Directors

/s/ Geoffrey Race

Date: August 5, 2019

Geoffrey Race
Chief Financial Officer
(Principal Financial Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not incorporated by reference into any filing of Minerva Neurosciences, Inc. under the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.