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 March 31, 2020

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 April 29, 2020 was 39,219,134.

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 ☒

INDEX TO FORM 10-Q

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)

	March 31, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 30,036,149	$ 21,412,623
Marketable securities	7,478,185	24,441,520
Restricted cash	100,000	100,000
Prepaid expenses and other current assets	851,864	1,182,483
Total current assets	38,466,198	47,136,626
Equipment, net	11,644	16,011
Other noncurrent assets	14,808	14,808
Operating lease right-of-use assets	223,503	261,952
In-process research and development	15,200,000	15,200,000
Goodwill	14,869,399	14,869,399
Total assets	**$ 68,785,552**	**$ 77,498,796**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 3,003,054	$ 2,317,004
Accrued expenses and other current liabilities	3,936,233	4,139,163
Operating leases	178,765	172,901
Total current liabilities	7,118,052	6,629,068
Deferred taxes	1,803,356	1,803,356
Deferred revenue	41,175,600	41,175,600
Noncurrent operating leases	64,350	111,229
Total liabilities	50,161,358	49,719,253
Commitments and contingencies (Note 8)		
Stockholders' equity		
Preferred stock; $0.0001 par value; 100,000,000 shares authorized; none issued or outstanding as of March 31, 2020 and December 31, 2019, respectively	—	—
Common stock; $0.0001 par value; 125,000,000 shares authorized; 39,219,134 and 39,084,121 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	3,922	3,908
Additional paid-in capital	317,507,655	314,511,853
Accumulated deficit	(298,887,383)	(286,736,218)
Total stockholders' equity	18,624,194	27,779,543
Total liabilities and stockholders' equity	**$ 68,785,552**	**$ 77,498,796**

See accompanying notes to condensed consolidated financial statements.

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Expenses		
Research and development	$ 8,082,510	$ 11,606,197
General and administrative	4,189,068	4,705,674
Total expenses	12,271,578	16,311,871
Loss from operations	(12,271,578)	(16,311,871)
Foreign exchange losses	(9,392)	(6,313)
Investment income	129,805	490,984
Net loss	$ (12,151,165)	$ (15,827,200)
Net loss per share, basic and diluted	$ (0.31)	$ (0.41)
Weighted average shares outstanding, basic and diluted	39,177,592	38,968,110

See accompanying notes to condensed consolidated financial statements.

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)

	Common Stock		Additional	Accumulated	
	Shares	Amount	Paid-In Capital	Deficit	Total
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**
Balances at January 1, 2020	**39,084,121**	**$ 3,908**	**$ 314,511,853**	**$ (286,736,218)**	**$ 27,779,543**
Exercise of stock options	135,013	14	797,615	—	797,629
Stock-based compensation	—	—	2,198,187	—	2,198,187
Net loss	—	—	—	(12,151,165)	(12,151,165)
Balances at March 31, 2020	**39,219,134**	**$ 3,922**	**$ 317,507,655**	**$ (298,887,383)**	**$ 18,624,194**

See accompanying notes to condensed consolidated financial statements.

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (12,151,165)	$ (15,827,200)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4,367	4,367
Accretion of marketable securities premium	(64,959)	(242,708)
Amortization of right-of-use assets	38,449	34,622
Stock-based compensation expense	2,198,187	2,461,699
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	330,619	851,715
Accounts payable	686,050	1,225,897
Accrued expenses and other current liabilities	(202,930)	1,911,423
Operating lease liabilities, current	5,864	20,609
Operating lease liabilities, noncurrent	(46,879)	(41,016)
Net cash used in operating activities	(9,202,397)	(9,600,592)
Cash flows from investing activities:		
Proceeds from the maturity and redemption of marketable securities	20,900,000	9,000,000
Purchase of marketable securities	(3,871,706)	(19,551,411)
Net cash provided (used in) by investing activities	17,028,294	(10,551,411)
Cash flows from financing activities:		
Proceeds from exercise of stock options	797,629	525,000
Net cash provided by financing activities	797,629	525,000
Net increase (decrease) in cash, cash equivalents and restricted cash	8,623,526	(19,627,003)
Cash, cash equivalents and restricted cash		
Beginning of period	21,512,623	50,334,871
End of period	$ 30,136,149	$ 30,707,868
Reconciliation of the Condensed Consolidated Statements of Cash Flows to the Condensed Consolidated Balance Sheets		
Cash and cash equivalents	$ 30,036,149	$ 30,607,868
Restricted cash	100,000	100,000
Total cash, cash equivalents and restricted cash	$ 30,136,149	$ 30,707,868

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"); 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 condensed consolidated 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 March 31, 2020, the Company has an accumulated deficit of approximately $298.9 million and net cash used in operating activities was approximately $9.2 million during the three months ended March 31, 2020. The Company's management team 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 March 31, 2020, the Company had cash, cash equivalents, restricted cash, and marketable securities of $37.6 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 condensed consolidated 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 resolution of the Company's dispute with Janssen as described in Notes 5 and 8, the infrastructure to support a commercial enterprise, the cost of a commercial product launch, and the level of financial resources available. If it is determined that the Company is required to make a significant payment to Janssen, it may not have sufficient cash to make such payment and may be required to incur additional indebtedness or to raise additional funds via an equity financing in order to make such payment to Janssen. 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 8-03. 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 March 31, 2020, the results of operations for the three months ended March 31, 2020 and 2019 and cash flows for the three months ended March 31, 2020 and 2019. The results of operations for the three months ended March 31, 2020 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, 2019 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, 2019 included in the Company's Annual Report on Form 10-K filed with the SEC on March 9, 2020.

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.

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 each of March 31, 2020 and December 31, 2019.

Marketable securities

Marketable securities consist of corporate and U.S. government debt securities maturing in five 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 March 31, 2020, remaining final maturities of marketable securities ranged from April 2020 to August 2020, with a weighted average remaining maturity of approximately 2.1 months. The following tables provide the amortized cost basis, aggregate fair value, unrealized gains/losses, and the net carrying value of investments in held-to-maturity securities as of March 31, 2020 and December 31, 2019:

	March 31, 2020				
	Amortized Cost	Aggregate Fair Value	Unrealized Gains	Unrealized Losses	Net Carrying Value
Marketable securities:					
Commercial paper	$ 7,478,185	$ 7,478,185	$ —	$ —	$ 7,478,185
Marketable securities total	$ 7,478,185	$ 7,478,185	$ —	$ —	$ 7,478,185

	December 31, 2019				
	Amortized Cost	Aggregate Fair Value	Unrealized Gains	Unrealized Losses	Net Carrying Value
Marketable securities:					
Corporate bonds/notes	$ 2,701,114	$ 2,700,678	$ 436	$ —	$ 2,701,114
Commercial paper	19,245,921	19,245,921	—	—	19,245,921
U.S. government agency securities	2,494,485	2,495,675	—	(1,190)	2,494,485
Marketable securities total	$ 24,441,520	$ 24,442,274	$ 436	$ (1,190)	$ 24,441,520

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 ("CROs") 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 months ended March 31, 2020 or 2019.

Impairment of MIN-117 In-process Research and Development Asset.

As a result of the Company's Phase 2b trial of MIN-117 in adult patients suffering from moderate to severe MDD not meeting its primary and key secondary endpoints and the Company's decision not to further the clinical development of MIN-117 in MDD, the Company determined that the MIN-117 IPR&D is fully impaired and recognized a $19.0 million expense, which was included as a component of research and development expense, during the year ended December 31, 2019.

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, and expected life of the options. Forfeitures are recorded as they occur instead of estimating forfeitures that are expected to occur. 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.

An accounting policy change was made by the Company related to the accounting for non-employee awards on January 1, 2019 as a result of the adoption of ASU No. 2018-07, *Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* for which the Company now accounts for non-employee awards in the same manner as employee awards.

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 Financial Accounting Standards Board ("FASB") 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 March 31, 2020 and 2019.

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 three months ended March 31, 2020 and 2019.

Revenue recognition

The Company applies the revenue recognition guidance in accordance with 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 November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*. This update is intended to clarify that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606. The Company adopted the new standard on January 1, 2020.

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. The Company adopted the new standard on January 1, 2020.

NOTE 3 — ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities consist of the following:

	March 31, 2020	December 31, 2019
Research and development costs and other accrued expenses	$ 3,090,336	$ 3,824,950
Accrued bonus	504,600	—
Professional fees	281,050	314,213
Vacation pay	60,247	—
	$ 3,936,233	$ 4,139,163

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 March 31,	
	2020	2019
Net loss	$ (12,151,165)	$ (15,827,200)
Weighted average shares of common stock outstanding	39,177,592	38,968,110
Net loss per share of common stock – basic and diluted	$ (0.31)	$ (0.41)

The following securities outstanding at March 31, 2020 and 2019 have been excluded from the calculation of weighted average shares outstanding as their effect on the calculation of loss per share is antidilutive:

	Three Months Ended March 31,	
	2020	2019
Common stock options	8,799,959	8,378,672
Restricted stock units	68,650	127,300
Common stock warrants	40,790	40,790

NOTE 5 — 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 months ended March 31, 2020 and 2019 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, which is referred to as "Decision Point 4". Top-line results have been reported from three Phase 2b trials and

one Phase 1b trial with seltorexant. 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 March 31, 2020 and December 31, 2019. If the Company opts out of the program, then any remaining deferred revenue would be recognized at the time of the opt out. 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 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 MDD program.

After reviewing the data from the Phase 2b trials already conducted, the Company is not in agreement with Janssen that Decision Point 4 under the Agreement has been reached. Under the Agreement, the Company's cost-sharing obligations do not begin until Decision Point 4 has been reached. The Company has the right to opt-out of the Agreement at any time after Decision Point 4, and if it opts-out, the Company will collect a royalty on worldwide sales of seltorexant in the mid-single digits with no further obligations to Janssen. If Janssen opts-out, the Minerva Territory would expand to include North America and the Company would pay Janssen single digit royalties on sales of seltorexant outside of the insomnia indication. In January 2020, Janssen invoiced the Company $3.4 million, representing the Company's 40% portion of the Phase 3 development costs through December 31, 2019. In April 2020, Janssen invoiced the Company an additional $3.1 million, for a cumulative total through March 31, 2020 of $6.5 million. Janssen has previously indicated they may incur approximately $100 million in Phase 3 development costs in 2020. The Company has been conducting discussions with Janssen regarding this disagreement and the Company has not accrued any Phase 3 development costs incurred by Janssen (See Note 8).

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 6 — STOCKHOLDERS' EQUITY

Term Loan Warrants

In connection with the Company's former Loan and Security Agreement with Oxford Finance LLC and Silicon Valley Bank (the "Lenders"), which provided for term loans to the Company in an aggregate principal amount of up to $15 million in two tranches on January 15, 2016, 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 loans drawn at such time and also as a component of additional paid-in capital and were amortized to interest expense over the term of the loan. Although the term loans were repaid in August 2018, all related warrants were outstanding and exercisable as of March 31, 2020.

NOTE 7 — 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. Pursuant to Nasdaq listing rules, the Company issued inducement awards in December 2017 to the Company's President outside of the Plan in the form of an option to purchase 775,000 shares of the Company's common stock and a RSU 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 three months ended March 31, 2020 is as follows:

	Shares Issuable Pursuant to Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Terms (years)	Total Intrinsic Value (in thousands)
Outstanding January 1, 2020	9,040,328	$ 6.98	7.3	$ 7,420
Granted	—	$ —		
Exercised	(135,013)	$ 5.91		
Forfeited	(105,356)	$ 9.63		
Outstanding March 31, 2020	8,799,959	$ 6.96	7.1	$ 1,625
Exercisable March 31, 2020	5,614,559	$ 6.69	6.4	$ 1,586
Available for future grant	245,354			

The weighted average grant-date fair value of stock options outstanding on March 31, 2020 was $5.01 per share. Total unrecognized compensation costs related to non-vested stock options at March 31, 2020 were approximately $15.8 million and are expected to be recognized within future operating results over a weighted-average period of 2.29 years. The total intrinsic value of the options exercised during the three months ended March 31, 2020, and 2019 was approximately $0.3 million and $0.2 million, respectively.

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, the term of which 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. There were no stock options granted during the three months ended March 31, 2020, and 2019.

RSU activity under the Plan for the three months ended March 31, 2020 is as follows:

	RSUs	Weighted-Average Grant Date Fair Value
Unvested January 1, 2020	68,650	$ 11.29
Granted	—	$ —
Vested	—	$ —
Forfeited	—	$ —
Unvested March 31, 2020	68,650	$ 11.29

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 March 31, 2020 was approximately $0.6 million and is expected to be recognized within future operating results over a period of 0.9 years. The following table presents stock-based compensation expense included in the Company's consolidated statements of operations:

	Three Months Ended March 31,	
	2020	2019
Research and development	$ 681,613	$ 700,263
General and administrative	1,516,574	1,761,436
Total	$ 2,198,187	$ 2,461,699

NOTE 8 — 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. While the outcome of these claims cannot be predicted with certainty, management does not believe that the outcome of any of these other legal matters will have a material adverse effect on the Company's consolidated financial statements.

Disagreement with Janssen

After reviewing the data from the Phase 2b trials already conducted, the Company is not in agreement with Janssen that Decision Point 4 under the Agreement has been reached. Under the Agreement, the Company's cost-sharing obligations do not begin until Decision Point 4 has been reached. Following occurrence of Decision Point 4, Janssen is responsible for 60% of the cost of Phase 3 development in all indications except insomnia and the Company is responsible for 40%. The Company has the right to opt-out of the Agreement at any time after Decision Point 4, and if it opts-out, the Company will collect a royalty on worldwide sales of seltorexant in the mid-single digits with no further obligations to Janssen. In January 2020, Janssen invoiced the Company $3.4 million, representing the Company's 40% portion of the Phase 3 development costs through December 31, 2019. In April 2020, Janssen invoiced the Company an additional $3.1 million, for a cumulative total through March 31, 2020 of $6.5 million. Janssen has previously indicated they may incur approximately $100 million in Phase 3 development costs in 2020. The Company has been conducting discussions with Janssen regarding this disagreement and the Company has not accrued any Phase 3 development costs incurred by Janssen.

Refer to Note 9 – Leases, for the Company's current lease commitments.

NOTE 9 — 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 in accordance with ASC 842.

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 three months ended March 31, 2020:

	Three Months Ended March 31, 2020
Sublease cost	
Operating Sublease cost	$ 44,817
Total Sublease cost	$ 44,817
Other information	
Operating cash flows used for operating Sublease	$ 47,384
Weighted average remaining Sublease term	1.3 years
Weighted average discount rate	10%

Future minimum Sublease payments under the Company's non-cancelable operating Sublease as of March 31, 2020 and December 31, 2019 are as follows:

Future Operating Sublease Payments	Three Months Ended March 31, 2020
2020 (excluding the three months ended March 31, 2020)	144,620
2021	114,018
Thereafter	—
Total Sublease payments	$ 258,638
Less: imputed interest	(15,523)
Total operating Sublease liabilities at March 31, 2020	$ 243,115

Future Operating Sublease Payments	Year Ended December 31, 2019
2020	192,004
2021	114,018
Thereafter	—
Total Sublease payments	$ 306,022
Less: imputed interest	(21,892)
Total operating Sublease liabilities at December 31, 2019	$ 284,130

NOTE 10 — 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 5 – Co-Development and License Agreement 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, 2019 as filed with the Securities and Exchange Commission on March 9, 2020.

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 three proprietary compounds that are currently in development. We believe these compounds 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"); 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 as compared to placebo in adult patients with negative symptoms of schizophrenia. The 12-week study is being followed by a 40-week, open-label extension period during which patients on roluperidone will continue receiving their original dose and patients on placebo will receive either 32 mg or 64 mg doses of roluperidone.

We have completed enrollment and a total of 515 patients were randomized in this trial at clinical sites in the United States and Europe. We have taken precautionary measures to protect the health and safety of our employees and patients as well as to mitigate any business impact related to the coronavirus disease 2019 ("COVID-19") pandemic. Because the MIN-101C07 study is fully enrolled and there are sufficient clinical trial supplies to conduct the trial, we continue to anticipate top-line results from the 12-week, double-blind portion of the study to be available in the second quarter of 2020. We and our CROs have been in frequent contact with the clinical sites for this trial to identify and mitigate potential risks that may result from travel and other restrictions aimed at minimizing the spread of COVID-19. In March, the Company issued guidance to the clinical sites that were based on recent Food and Drug Administration ("FDA") and European Medicines Agency ("EMA") guidelines and which allow some protocol exceptions in order to help ensure the safety of patients and their access to study medication. It is possible that, despite these measures, we could face difficulties retaining patients in the 40-week, open-label extension period of the MIN-101C07 study if patients are affected by the COVID-19 virus, are unable to travel to the clinical trial sites or are unable to obtain study medication. To date, no such difficulties have occurred. In total, 362 patients have completed the double-blind phase, 333 patients from the double-blind phase have elected to transition into the open-label extension period, and 92 patients have completed the extension phase as of April 30, 2020.

The primary endpoint of this trial is improvement in negative symptoms in patients treated with roluperidone compared to placebo as measured by the change from baseline in the Positive and Negative Syndrome Scale, or PANSS, Marder negative symptoms factor score ("NSFS") over the 12-week double-blind treatment period. The key secondary endpoint is the effect of roluperidone compared to placebo as measured by the change from baseline in the Personal and Social Performance, or PSP, total score over the same period. Additional secondary endpoints include the effect of roluperidone compared to placebo on the Clinical Global Impression of Severity ("CGI-S") score, the PANSS total and subscale scores, the remaining Marder 4 factor scores, and safety and tolerability.

Patients admitted into the trial had a documented diagnosis of schizophrenia for at least one year and been 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 were 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 needed to undergo a wash-out period of a few days before receiving study drug. These parameters were applied in screening the population enrolled 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 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.

On September 23, 2019, we announced that we have entered into a long-term commercial supply agreement for roluperidone with Catalent, Inc. ("Catalent"), a leading global provider of advanced delivery technologies, development, and manufacturing solutions for drugs, biologics, gene therapies, and consumer health products. Under the terms of the agreement, Catalent will manufacture and package the finished dose form of roluperidone at its facility in Schorndorf, Germany. To date, Catalent has worked with us to enable the transfer from pilot to commercial-scale production. This has included analytical methods transfer and validation, process optimization, stability studies, and registration batch manufacturing, as well as packaging studies and the assessment of the influence of formulation factors on the product's critical quality attributes as required by Quality by Design process.

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 show minimal to no interaction with the strong CYP3A4 inhibitor, and some interaction (< 1.6 folds increase in exposure) with the moderate CYP2D6 inhibitor.

Brain-Derived Neurotrophic Factor ("BDNF") Findings

We have completed non-clinical studies 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 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 sigma2, serotoninergic 5-HT_{2A}, and possibly α1-adrenergic neurotransmitter pathways.

MIN-117

On December 18, 2019, we announced that our Phase 2b trial of MIN-117 in adult patients suffering from moderate to severe MDD and presenting with symptoms of anxious distress failed to meet its primary and key secondary endpoints. Neither the 5.0 mg nor the 2.5 mg dose of MIN-117 tested in this trial showed a statistically significant separation from placebo on the reduction in the symptoms of MDD over the 6-week treatment period as measured by the change in the Montgomery–Åsberg Depression Rating Scale ("MADRS"). In addition, neither dose showed a statistically significant separation from placebo on the key secondary endpoint, reduction of symptoms of anxiety as measured by Hamilton Anxiety Rating Scale ("HAM-A") over the 6-week treatment period. Patients treated with the 2.5 mg dose experienced an improvement of 1.6 points compared to placebo at Week 2 ($p \leq 0.029$). Additionally, the percentage of patients with remission, defined as an MADRS total score < 12, was significantly higher in the 2.5 mg MIN 117 (29%, $p \leq 0.044$) and 5.0 mg MIN 117 (31%, $p \leq 0.021$) groups when compared to placebo (19%). No other statistically significant separation from placebo on HAM-A was observed.

MIN-117 was generally well tolerated, and the incidence of patients who reported treatment emergent adverse events over the duration of 6 weeks of treatment and 2 weeks of follow-up were 37% for the 2.5 mg, 39% for the 5 mg, and 38% for placebo. Only headaches were reported at ≥5% in this study at 12% for both the 2.5 and 5 mg, and 7% for placebo. There were no deaths, and only 5 patients in total discontinued from the study due to TEAE (2 for 2.5 mg, 1 for 5 mg, and 2 for placebo).

As a result of these findings, we have no plans for the further clinical development of MIN-117 in MDD.

Seltorexant (MIN-202)

Two 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 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 ≥ 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. We believe these findings, if confirmed in Phase 3 studies, will 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.

On October 1, 2019, we announced top-line results from a Phase 2b clinical trial in which flexibly dosed seltorexant (20 mg or 40 mg) was compared to flexibly dosed quetiapine XR (150 mg or 300 mg) for adjunctive treatment of patients with MDD (the "MDD2002 Trial"). There were 102 patients enrolled, each with MDD not responding adequately to SSRIs and SNRIs. The primary endpoint was all cause discontinuation of therapy over 6 months. Mood improvement, measured using the MADRS, and safety and tolerability were evaluated. The primary intent of this exploratory trial was to generate data to assist with the planning of Phase 3 studies; it was not powered to detect statistical significance. Quetiapine XR was used as a comparator, because it is the only medication approved for the adjunctive treatment of MDD in both the United States and Europe.

Seltorexant showed a quantitative advantage in the number of discontinuations due to all causes, with 41% discontinuation in the seltorexant arm versus 47% in the quetiapine XR arm. As expected, there was not a statistical separation between the two treatment arms.

Mood improvement as measured by MADRS total score showed patients treated with seltorexant 20 mg dose experienced a greater improvement at week 24 (-22.7 points), compared to those treated with seltorexant 40 mg dose (-7.9 points), quetiapine 150 mg dose (-17.0 points) and quetiapine 300 mg dose (-14.8 points). As was shown in previous trials of seltorexant in MDD, a greater improvement in MADRS total score was observed in patients with sleep disturbance (ISI ≥15) who received the 20 mg seltorexant dose. In these patients with insomnia, the improvements observed were -26.5 for the 20 mg seltorexant dose, -7.0 for the 40 mg seltorexant dose, -18.2 for the 150 mg quetiapine dose and -13.8 for the 300 mg quetiapine dose.

The overall safety profile of the seltorexant groups was favorable compared to quetiapine, consistent with prior seltorexant studies, and extended to longer-term exposure over 6 months. Patients receiving seltorexant also experienced fewer potentially treatment-related discontinuations than did patients receiving quetiapine (29.4% vs 47.1%).

The results of this study, taken with the results of the two previous studies (MDD2001 in MDD patients and ISM2005 in patients with insomnia), will help to define a Phase 3 clinical development program for seltorexant that potentially will encompass both MDD and insomnia.

Phase 1b trial in MDD

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). The presence of subjective sleep disturbance (subjective sleep assessment, 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.

Phase 3 development

After reviewing the data from the Phase 2b trials already conducted, we are not in agreement with Janssen that Decision Point 4 under the Agreement has been reached. Under the Agreement, our cost-sharing obligations do not begin until Decision Point 4 has been reached. Following occurrence of Decision Point 4, Janssen is responsible for 60% of the cost of Phase 3 development in all indications except insomnia and Minerva is responsible for 40%. We have the right to opt-out of the Agreement at any time after Decision Point 4, and if we opt-out, we collect a royalty on worldwide sales of seltorexant in the mid-single digits with no further obligations to Janssen. In January 2020, Janssen invoiced the Company $3.4 million, representing the Company's 40% portion of the Phase 3 development costs through December 31, 2019. In April 2020, Janssen invoiced the Company an additional $3.1 million, for a cumulative total through March 31, 2020 of $6.5 million. Janssen has previously indicated they may incur approximately $100 million in Phase 3 development costs in 2020. We have been conducting discussions with Janssen regarding this disagreement and have not accrued any Phase 3 development costs incurred by Janssen.

Janssen has proposed a Phase 3 development program with a target indication of “adjunctive treatment of MDD (aMDD) in patients with insomnia symptoms” and clinical trials to support that target indication. We and Janssen are consulting with FDA and EMA/ Committee for Medicinal Products for Human Use (“CHMP”) about this target indication and these trials. We believe that under the terms of the Agreement we have the right to strategic control of the proposed development program, and this matter is part of the ongoing discussions that we are conducting with Janssen.

Because the Phase 3 development program for seltorexant is in its preliminary stage, the potential effect of the COVID-19 pandemic is uncertain and difficult to predict.

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 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 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, 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.

Results of Operations

Comparison of Three Months Ended March 31, 2020 versus March 31, 2019

Research and Development Expenses

Total research and development expenses were $8.1 million for the three months ended March 31, 2020 compared to $11.6 million for the same period in 2019, a decrease of approximately $3.5 million. The decrease in research and development expenses primarily reflects lower 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 decrease during 2020 as we have completed the MIN-117 clinical trial and expect to complete the 12-week, double-blind portion of Phase 3 clinical trial of roluperidone.

General and Administrative Expenses

Total general and administrative expenses were $4.2 million for the three months ended March 31, 2020 compared to $4.7 million for the same period in 2019, a decrease of approximately $0.5 million. The decrease in general and administrative expenses was primarily due to a decrease in non-cash stock-based compensation expenses and a decrease in professional fees.

Foreign Exchange Losses

Foreign exchange losses were $9 thousand for the three months ended March 31, 2020 compared to a loss of $6 thousand for the same period in 2019, an increased loss of $3 thousand. The loss was primarily due to clinical activities denominated in Euros.

Investment Income

Investment income was $0.1 million for the three months ended March 31, 2020 compared to $0.5 million for the same period in 2019, a decrease of $0.4 million. The decrease was due to investment income on cash equivalents and marketable securities.

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 March 31, 2020, we had an accumulated deficit of approximately $298.9 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 March 31, 2020, we had approximately $37.6 million in cash, cash equivalents, restricted cash, and marketable securities. 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 Securities and Exchange Commission. 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.

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.

If it is determined that we are required to make a significant payment to Janssen, we may not have sufficient cash to make such payment and may be required to incur additional indebtedness or to raise additional funds via an equity financing in order to make such payment to Janssen. We cannot be certain that we will be able to borrow or raise sufficient funds for this purpose under terms acceptable to us, if at all, and uncertainty and volatility in the capital markets caused by the COVID-19 pandemic may negatively impact the availability and cost of capital. While we are engaged in ongoing discussions with Janssen concerning the Agreement and our continued business relationship, there can be no assurance that we will be able to resolve this disagreement to our satisfaction, or at all.

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, and the uncertainty and volatility in the capital markets caused by the COVID-19 pandemic may negatively impact the availability and cost of capital. 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, 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 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.

Cash Flows

The tables below set forth our significant sources and uses of cash for the periods.

	Three Months Ended March 31,	
	2020	2019
	(dollars in millions)	
Net cash provided by (used in):		
Operating activities	$ (9.2)	$ (9.6)
Investing activities	17.0	(10.5)
Financing activities	0.8	0.5
Net increase (decrease) in cash	$ 8.6	$ (19.6)

Net Cash Used in Operating Activities

Net cash used in operating activities of approximately $9.2 million during the three months ended March 31, 2020 was primarily due to our net loss of $12.2 million, a $0.2 decrease in accrued expenses, and amortization of investments of $0.1 million, partially offset by stock-based compensation expense of $2.2 million, a $0.8 increase in accounts payable, and a decrease in prepaid expense of $0.3 million.

Net cash used in operating activities of approximately $9.6 million during the three months ended March 31, 2019 was primarily due to our net loss of $15.8 million and amortization of investments of $0.2 million, partially offset by stock-based compensation expense of $2.5 million, a $1.9 million increase in accrued expenses, a $1.2 increase in accounts payable and an increase in prepaid expense of $0.8 million.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities of approximately $17.0 million during the three months ended March 31, 2020 was primarily due to the maturity and redemption of marketable securities of $20.9 million, partially offset by the purchase of marketable securities of $3.9 million.

Net cash used in investing activities of approximately $10.5 million during the three months ended March 31, 2019 was primarily due to the purchase of marketable securities of $19.5 million, partially offset by the maturity and redemption of marketable securities of $9.0 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities of $0.8 million during the three months ended March 31, 2020 was due to the proceeds from the exercise of common stock options of $0.8 million.

Net cash provided by financing activities of $0.5 million during the three months ended March 31, 2019 was due to the proceeds from the exercise of common stock options of $0.5 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, 2019, 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; 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 three months ended March 31, 2020.

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 March 31, 2020. Based on the evaluation of our disclosure controls and procedures as of March 31, 2020, 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, 2019, as filed with the SEC on March 9, 2020. 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, 2019, 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 three months ended March 31, 2020, and 2019, we reported net losses of $12.2 million and $15.8 million, respectively. As of March 31, 2020, we had an accumulated deficit of $298.9 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 products.

As of March 31, 2020, we had cash, cash equivalents, restricted cash, and marketable securities of $37.6 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.

We are subject to risks and uncertainties as a result of the COVID-19 pandemic

Our business could be adversely affected by the effects of health pandemics or epidemics, including the recent COVID-19 outbreak, which was declared by the World Health Organization as a global pandemic, and is resulting in travel and other restrictions to reduce the spread of the disease, including a Massachusetts executive order and several other state and local orders across the country, which, among other things, direct individuals to shelter at their places of residence, direct businesses and governmental agencies to cease non-essential operations at physical locations, prohibit certain non-essential gatherings, and order cessation of non-essential travel. As a result of these recent developments, we have implemented work-from-home policies for our employees. The effects of the state executive order, local shelter-in-place orders, government-imposed quarantines and our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

In addition, our clinical trials may be affected by the COVID-19 pandemic. We may face difficulties retaining patients in the open-label extension period of the MIN-101C07 study of roluperidone and may have difficultly enrolling or retaining patients in future clinical trials if patients are affected by the COVID-19 virus or are unable to travel to the clinical trial sites or obtain study medication. Our clinical trials may further be delayed due to prioritization of hospital resources toward the COVID-19 pandemic, and some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to the COVID-19 virus, could be delayed or disrupted, which would adversely impact our clinical trial operations. As a result, we could experience delays in the completion of our trials, which could result in a material adverse impact on our clinical trial plans and timelines.

Furthermore, the COVID-19 pandemic has caused a broad negative impact globally on capital markets and economies worldwide, which could have a negative impact on us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic, may be difficult to assess or predict, it is currently resulting in significant disruption of global financial markets. This disruption, if sustained or recurrent, could have a material adverse effect on our operating results, our ability to raise capital needed to develop and commercialize products and our overall financial condition. In addition, a recession or market correction resulting from the spread of the coronavirus could materially affect the value of our common stock.

The extent of the impact of the COVID-19 pandemic on our business is uncertain and difficult to predict, as the pandemic continues to rapidly evolve. The ultimate impact of the COVID-19 pandemic or a similar health pandemic or epidemic is highly uncertain and subject to change. We do not yet know the extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. These effects could have a material impact on our operations, and we will continue to monitor the COVID-19 pandemic closely.

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 March 31, 2020.

Issuer Purchases of Equity Securities

We did not repurchase any securities during the three months ended March 31, 2020.

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 November 4, 2019)	001-36517
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: May 4, 2020

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

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

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

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

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

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

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

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

Date: May 4, 2020

/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: May 4, 2020

/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 March 31, 2020, 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: May 4, 2020

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

/s/ Geoffrey Race

Date: May 4, 2020

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 Act of 1933, as amended, or 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.