

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

FORM 10-Q

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

For the quarterly period ended June 30, 2021

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
(State or Other Jurisdiction of
Incorporation or Organization)

1601 Trapelo Road, Suite 286
Waltham, MA
(Address of Principal Executive Offices)

26-0784194
(I.R.S. Employer
Identification No.)

02451
(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

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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

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

The number of shares of Registrant's Common Stock, \$0.0001 par value per share, outstanding as of July 28, 2021 was 42,721,566.

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

This Quarterly Report on Form 10-Q contains forward-looking statements. 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” and in our Annual Report on Form 10-K for the year ended December 31, 2020 under Part I, Item IA, “Risk Factors.”

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

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

PART I – Financial Information
Item 1 – Financial Statements

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Balance Sheets
(Unaudited)

	June 30, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	\$ 74,214,767	\$ 25,356,952
Restricted cash	100,000	100,000
Prepaid expenses and other current assets	910,577	1,983,264
Total current assets	75,225,344	27,440,216
Other noncurrent assets		
Operating lease right-of-use assets	14,808	14,808
In-process research and development	14,939	101,786
Goodwill	15,200,000	15,200,000
	14,869,399	14,869,399
Total assets	\$ 105,324,490	\$ 57,626,209
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 1,593,697	\$ 995,614
Accrued expenses and other current liabilities	2,834,425	2,053,409
Operating leases	16,288	111,229
Total current liabilities	4,444,410	3,160,252
Deferred taxes	1,803,356	1,803,356
Liability related to the sale of future royalties	62,907,895	—
Total liabilities	69,155,661	4,963,608
Commitments and contingencies (Note 9)		
Stockholders' equity		
Preferred stock; \$0.0001 par value; 100,000,000 shares authorized; none issued or outstanding as of June 30, 2021 and December 31, 2020, respectively	—	—
Common stock; \$0.0001 par value; 125,000,000 shares authorized; 42,721,566 shares issued and outstanding as of June 30, 2021 and December 31, 2020	4,272	4,272
Additional paid-in capital	340,353,900	337,453,776
Accumulated deficit	(304,189,343)	(284,795,447)
Total stockholders' equity	36,168,829	52,662,601
Total liabilities and stockholders' equity	\$ 105,324,490	\$ 57,626,209

See accompanying notes to condensed consolidated financial statements.

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenues				
Collaborative revenue	\$ —	\$ 41,175,600	\$ —	\$ 41,175,600
Total revenues	—	41,175,600	—	41,175,600
Expenses				
Research and development	\$ 5,520,928	\$ 5,766,984	\$ 8,779,635	\$ 13,849,494
General and administrative	3,442,365	5,900,518	7,691,179	10,089,586
Total expenses	8,963,293	11,667,502	16,470,814	23,939,080
(Loss) gain from operations	(8,963,293)	29,508,098	(16,470,814)	17,236,520
Foreign exchange losses	(18,997)	(3,661)	(23,853)	(13,053)
Investment income	4,566	24,939	8,666	154,744
Non-cash interest expense for the sale of future royalties	(1,611,439)	—	(2,907,895)	—
Net (loss) income	\$ (10,589,163)	\$ 29,529,376	\$ (19,393,896)	\$ 17,378,211
Net (loss) income per share, basic	\$ (0.25)	\$ 0.75	\$ (0.45)	\$ 0.44
Weighted average shares outstanding, basic	42,721,566	39,483,187	42,721,566	39,330,389
Net (loss) income per share, diluted	\$ (0.25)	\$ 0.73	\$ (0.45)	\$ 0.43
Weighted average shares outstanding, diluted	42,721,566	40,278,071	42,721,566	40,144,996

See accompanying notes to condensed consolidated financial statements.

MINERVA NEUROSCIENCES, INC.

**Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)**

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount			
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
Issuance of common stock in a public offering	1,361,956	136	5,178,324	—	5,178,460
Costs related to issuance of common stock	—	—	(219,517)	—	(219,517)
Exercise of stock options	63,749	7	346,019	—	346,026
Stock-based compensation	—	—	3,485,482	—	3,485,482
Net income	—	—	—	29,529,376	29,529,376
Balances at June 30, 2020	\$ 40,644,839	\$ 4,065	\$ 326,297,963	\$ (269,358,007)	\$ 56,944,021
Balances at January 1, 2021	42,721,566	\$ 4,272	\$ 337,453,776	\$ (284,795,447)	\$ 52,662,601
Stock-based compensation	—	—	1,516,064	—	1,516,064
Net loss	—	—	—	(8,804,733)	(8,804,733)
Balances at March 31, 2021	42,721,566	\$ 4,272	\$ 338,969,840	\$ (293,600,180)	\$ 45,373,932
Stock-based compensation	—	—	1,384,060	—	1,384,060
Net loss	—	—	—	(10,589,163)	(10,589,163)
Balances at June 30, 2021	\$ 42,721,566	\$ 4,272	\$ 340,353,900	\$ (304,189,343)	\$ 36,168,829

See accompanying notes to condensed consolidated financial statements.

MINERVA NEUROSCIENCES, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Six Months Ended June 30,	
	2021	2020
Cash flows from operating activities:		
Net (loss) income	\$ (19,393,896)	\$ 17,378,211
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation and amortization	—	8,733
Accretion of marketable securities premium	—	(83,098)
Amortization of right-of-use assets	86,847	77,932
Stock-based compensation expense	2,900,124	5,683,669
Non-cash interest expense associated with the sale of future royalties	2,907,895	—
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	1,072,687	639,737
Accounts payable	598,083	821,555
Accrued expenses and other current liabilities	781,016	(59,514)
Operating lease liabilities, current	(94,941)	11,876
Deferred revenue	—	(41,175,600)
Operating lease liabilities, noncurrent	—	(94,941)
Net cash used in operating activities	<u>(11,142,185)</u>	<u>(16,791,440)</u>
Cash flows from investing activities:		
Proceeds from the maturity and redemption of marketable securities	—	25,400,000
Purchase of marketable securities	—	(3,871,706)
Net cash provided by investing activities	<u>—</u>	<u>21,528,294</u>
Cash flows from financing activities:		
Proceeds from the sale of future royalties	60,000,000	—
Proceeds from sales of common stock in public offering	—	5,178,460
Fees paid in connection with public offering	—	(219,517)
Proceeds from exercise of stock options	—	1,143,655
Net cash provided by financing activities	<u>60,000,000</u>	<u>6,102,598</u>
Net increase in cash, cash equivalents and restricted cash	<u>48,857,815</u>	<u>10,839,452</u>
Cash, cash equivalents and restricted cash		
Beginning of period	25,456,952	21,512,623
End of period	<u>\$ 74,314,767</u>	<u>\$ 32,352,075</u>
Reconciliation of the Condensed Consolidated Statements of Cash Flows to the Condensed Consolidated Balance Sheets		
Cash and cash equivalents	\$ 74,214,767	\$ 32,252,075
Restricted cash	100,000	100,000
Total cash, cash equivalents and restricted cash	<u>\$ 74,314,767</u>	<u>\$ 32,352,075</u>

See accompanying notes to condensed consolidated financial statements.

MINERVA NEUROSCIENCES, INC.
Notes to Condensed Consolidated Financial Statements
As of June 30, 2021 and for the Six Months Ended June 30, 2021 and 2020
(Unaudited)

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 product candidates to treat patients suffering from central nervous system diseases (“CNS”). The Company’s lead product candidate is roluperidone (f/k/a MIN-101), a compound the Company is developing for the treatment of negative symptoms in patients with schizophrenia, and MIN-301, a compound the Company is developing for the treatment of Parkinson’s disease. In addition, Minerva previously co-developed seltorexant (f/k/a MIN-202 or JNJ-42847922) with Janssen Pharmaceutica NV (“Janssen”) for the treatment of insomnia disorder and adjunctive treatment of Major Depressive Disorder (“MDD”). During 2020 Minerva exercised its right to opt out of the joint development agreement with Janssen for the future development of seltorexant. As a result, the Company will be entitled to collect royalties in the mid-single digits on potential future worldwide sales of seltorexant in certain indications, with no further financial obligations to Janssen. In January 2021, the Company sold its rights to these potential royalties to Royalty Pharma (see Notes 5 and 6).

The Company holds the license to roluperidone from Mitsubishi Tanabe Pharma Corporation (“MTPC”) with the rights to develop, sell and import roluperidone globally, excluding most of Asia. The Company also has exclusive rights to develop and commercialize MIN-301.

Liquidity

The accompanying interim 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 June 30, 2021, the Company has an accumulated deficit of approximately \$304.2 million and net cash used in operating activities was approximately \$11.1 million during the six months ended June 30, 2021. Management expects to continue to incur operating losses and negative cash flows from operations in the future. The Company has financed its operations to date from proceeds from the sale of common stock, warrants, loans, convertible promissory notes, collaboration agreements and royalty sales.

As of June 30, 2021, the Company had cash, cash equivalents, and restricted cash of \$74.3 million. The Company believes that its existing cash, cash equivalents, and restricted cash will be sufficient to meet its cash commitments for at least the next 12 months after the date that the interim 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 infrastructure to support a commercial enterprise, the cost of a commercial product launch, and the level of financial resources available. The Company has the ability to adjust its operating plan spending levels based on the timing of future clinical trials, which will be predicated upon adequate funding to complete the trials.

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

Significant Risks and Uncertainties

Litigation

On December 8, 2020 and January 11, 2021, purported stockholders of the Company filed two putative securities class action complaints in the United States District Court for the District of Massachusetts, entitled *McCoy v. Minerva Neurosciences, Inc., et al., No. 1:20-cv-12176* and *Ao v. Minerva Neurosciences, Inc. et al., No. 1:21-cv-10051*, respectively, against the Company and the Company's Chairman and Chief Executive Officer (collectively, the "Defendants"). The complaints are nearly identical and allege that the Defendants made material false and/or misleading statements regarding the development of the Company's drug candidate roluperidone purportedly causing losses to investors who acquired the Company's common stock between May 15, 2017 and November 30, 2020. The complaints do not quantify any alleged damages but, in addition to attorneys' fees and costs, plaintiffs seek to recover damages on behalf of themselves and others who acquired the Company's stock during the putative class period at allegedly inflated prices and purportedly suffered financial harm as a result. On March 5, 2021, the Court entered an order consolidating the actions into a case captioned *In re Minerva Neurosciences, Inc. Securities Litigation, No. 1:20-cv-12176* and appointing lead plaintiffs and their counsel. On March 19, 2021, the parties filed a stipulated proposed order with the Court staying the Defendants' response to the complaint until after plaintiffs file an amended complaint. On May 5, 2021, the parties filed a stipulation and proposed order voluntarily dismissing the lawsuit on behalf of the appointed lead plaintiffs. Also on May 5, 2021, a second plaintiff filed a motion for appointment as lead plaintiff, which the Court granted on May 21, 2021. On June 9, 2021, before the lead plaintiff's deadline to amend the complaint and before defendants filed any response to the complaint, the parties stipulated to voluntary dismissal of the lawsuit on behalf of the appointed lead plaintiff. The Court entered the parties' stipulation of dismissal on July 9, 2021 and closed the case.

COVID-19 Pandemic

The Company's business could be adversely affected by the effects of the ongoing COVID-19 pandemic, which continues to have a negative impact on the local, regional, national and global scale. In response to the pandemic, a number of jurisdictions in which the Company or its service providers operate implemented shelter-in-place or similar type restrictions, which limited on-site activity to certain service providers. To support the health and well-being of its employees, partners and communities, the Company implemented work-from-home policies for its employees, which continue to be in effect. While certain jurisdictions, including Massachusetts, have begun a phased re-opening of businesses and governmental agencies, there remain limitations on the physical operations of businesses and prohibitions on certain non-essential gatherings, and it is unclear if such phased re-openings will continue or be rolled back, and there is uncertainty about when, if, or how the Company's workforce may return. The effects of the state executive order, local shelter-in-place orders, government-imposed quarantines and the Company's work-from-home policies, including the uncertainty about their duration, may negatively impact productivity, disrupt our business and delay the clinical programs and timelines.

While the COVID-19 pandemic has not had a material adverse impact on the Company's operations to date, this disruption, if sustained or recurrent, could have a material adverse effect on the Company's operating results, its ability to raise capital needed to develop and commercialize products and the Company's overall financial condition. In addition, a recession or market correction resulting from the spread of the coronavirus could materially affect the value of the Company's common stock. The impact of the COVID-19 pandemic may also exacerbate other risks discussed in this Quarterly Report on Form 10-Q. Refer to Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q for a complete description of the material risks that the Company currently faces.

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 June 30, 2021, the results of operations for the three and six months ended June 30, 2021 and 2020 and cash flows for the six months ended June 30, 2021 and 2020. The results of operations for the three and six months ended June 30, 2021 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, 2020 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, 2020 included in the Company's Annual Report on Form 10-K filed with the SEC on March 8, 2021.

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 June 30, 2021 and December 31, 2020.

Marketable securities

Marketable securities consisted of corporate and U.S. government debt securities. Based on the Company's intentions regarding its marketable securities, all marketable securities were classified as held-to-maturity and were carried under the amortized cost approach. The Company's investments in marketable securities were classified as Level 2 within the fair value hierarchy. As of June 30, 2021, all marketable securities have matured.

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 values of the research projects are recorded as intangible assets on the balance sheet, rather than expensed, regardless of whether these assets have an alternative future use.

The amounts capitalized are being accounted for as indefinite-lived intangible assets, subject to impairment testing, until completion or abandonment of research and development efforts associated with the project. An IPR&D asset is considered abandoned when it ceases to be used (that is, research and development efforts associated with the asset have ceased, and there are no plans to sell or license the asset or derive defensive value from the asset). At that point, the asset is considered to be disposed of and is written off. Upon successful completion of each project, the Company will make a determination about the then remaining useful life of the intangible asset and begin amortization. The Company tests its indefinite-lived intangibles, IPR&D assets, for impairment annually on November 30 and more frequently if events or changes in circumstances indicate that it is more likely than not that the asset is impaired. When testing indefinite-lived intangibles for impairment, the Company may assess qualitative factors for its indefinite-lived intangibles to determine whether it is more likely than not (that is, a likelihood of more than 50 percent) that the asset is impaired. Alternatively, the Company may bypass this qualitative assessment for some or all of its indefinite-lived intangibles and perform the quantitative impairment test that compares the fair value of the indefinite-lived intangible asset with the asset’s carrying amount. There was no impairment of IPR&D for the three and six months ended June 30, 2021 or 2020.

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) Income per share

Basic (loss) income per share is computed by dividing net (loss) income by the weighted-average number of shares of common stock outstanding for the period. Diluted (loss) income 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.

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 June 30, 2021 and 2020.

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 tested its goodwill for impairment as of November 30, 2020. There was no impairment of goodwill for the six months ended June 30, 2021 and 2020.

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. During the year ended December 31, 2020, the Company recognized \$41.2 million in collaborative revenue as a result of opting out of its agreement with Janssen (see Note 5).

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.

Liability related to the sale of future royalties

The Company treats the sale of future royalties to Royalty Pharma as a debt financing, as the Company has significant continuing involvement in facilitating the transfer of royalties to Royalty Pharma and Royalty Pharma has recourse against the Company relating to the payments due from Janssen. As a result, the Company recorded the upfront payment of \$60 million from this transaction as a liability related to the sale of future royalties to be amortized to interest expense using the effective interest rate method over the life of the arrangement.

The liability related to sale of future royalties and the related interest expense are based on our current estimates of future royalties expected to be paid over the life of the arrangement. The Company will periodically assess the expected royalty payments using a combination of internal projections and forecasts from external sources. To the extent the Company's future estimates of royalty payments are greater or less than previous estimates or the estimated timing of such payments is materially different than its previous estimates, the Company will prospectively recognize related non-cash interest expense.

For further discussion of the sale of future royalties, please refer to Note 6, Sale of Future Royalties.

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:

	<u>June 30, 2021</u>	<u>December 31, 2020</u>
Research and development costs and other accrued expenses	\$ 1,631,882	\$ 1,880,552
Accrued bonus	766,522	—
Professional fees	349,922	140,981
Vacation pay	86,099	—
Accrued severance	—	31,876
	<u>\$ 2,834,425</u>	<u>\$ 2,053,409</u>

NOTE 4 — NET (LOSS) INCOME PER SHARE OF COMMON STOCK

Basic (loss) income per share is calculated by dividing the net (loss) income by the weighted average number of shares of common stock outstanding. Diluted (loss) income per share is computed by dividing the net (loss) income by the weighted average number of shares of common stock outstanding, plus potential outstanding common stock for the period. Potential outstanding common stock includes stock options and shares underlying RSUs, but only to the extent that their inclusion is dilutive. The following table sets forth the computation of basic and diluted (loss) income per share for common stockholders:

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Net (loss) income	<u>\$(10,589,163)</u>	<u>\$29,529,376</u>	<u>\$(19,393,896)</u>	<u>\$17,378,211</u>
Weighted average shares of common stock				
outstanding - basic	42,721,566	39,483,187	42,721,566	39,330,389
Dilutive effect	—	794,884	—	814,607
Weighted average shares of common stock				
outstanding - diluted	<u>42,721,566</u>	<u>40,278,071</u>	<u>42,721,566</u>	<u>40,144,996</u>
Net (loss) income per ordinary share:				
Basic	<u>\$ (0.25)</u>	<u>\$ 0.75</u>	<u>\$ (0.45)</u>	<u>\$ 0.44</u>
Diluted	<u>\$ (0.25)</u>	<u>\$ 0.73</u>	<u>\$ (0.45)</u>	<u>\$ 0.43</u>

The following securities outstanding at June 30, 2021 and 2020 have been excluded from the calculation of weighted average shares outstanding as their effect on the calculation of (loss) income per share is antidilutive:

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Common stock options	9,724,748	6,528,386	9,724,748	6,528,386
Restricted stock units	—	48,650	—	48,650
Common stock warrants	40,790	40,790	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 granted the Company an exclusive license to certain patent and patent applications to sell products containing any orexin 2 compound, controlled by Janssen and to seltorexant for any use in humans.

The Company accounted for the Agreement as a joint risk-sharing collaboration in accordance with ASC 808, *Collaborative Arrangements*.

During 2017, the Company entered into an amendment (the “Amendment”) to the Agreement whereby Janssen waived its right to royalties on seltorexant insomnia sales in the Minerva Territory, made an upfront payment to the Company of \$30 million and agreed to waive development payments from the Company until completion of the Phase 2b development milestone, referred to as “Decision Point 4”.

Subsequent to the results reported from three Phase 2b trials of seltorexant, in June 2020 the Company exercised its right to opt out of the Agreement with Janssen under a Settlement Agreement pursuant to which the Company and Janssen resolved certain disputes under the Agreement. As a result of the exercise of its right to opt out of the Agreement with Janssen, the Company will be entitled to collect a royalty on potential worldwide sales of seltorexant in certain indications in the mid-single digits, with no further financial obligations to Janssen.

As a result of opting out of the Agreement with Janssen, the Company recognized \$41.2 million in collaborative revenue during the second quarter of 2020 which had previously been included on the balance sheet under deferred revenue. The \$41.2 million in collaborative revenue represents the \$30 million payment made by Janssen and \$11.2 million in previously accrued collaborative expenses forgiven by Janssen upon the effective date of the Amendment. The Company does not have any future performance obligations under the agreement and would recognize any future royalty revenues in the periods of the sale of the related products. In

January 2021, the Company sold its rights to these potential royalties to Royalty Pharma. Please refer to Note 6 further discussion of the sale of future royalties.

NOTE 6 — SALE OF FUTURE ROYALTIES

On January 19, 2021, the Company entered into an agreement with Royalty Pharma under which Royalty Pharma acquired Minerva's royalty interest in seltorexant for an upfront payment of \$60 million and up to an additional \$95 million in additional milestone payments. These milestone payments are contingent upon the achievement of certain clinical, regulatory and commercial milestones for seltorexant by Janssen or any other party in the event that Janssen sells seltorexant. Under the terms of the agreement, the Company has significant continuing involvement in facilitating the transfer of royalties to Royalty Pharma and Royalty Pharma has recourse against the Company relating to the payments due from Janssen. As such, the Company applied the debt recognition guidance under ASC 470, *Debt*, and recorded the upfront payment of \$60 million as a liability related to the sale of future royalties ("Royalty Obligation"), which will be amortized under the interest method over the estimated life of the agreement. In addition, in accordance with ASC 470, *Debt*, the Company will account for any royalties received in the future as non-cash royalty revenue.

As royalties are remitted to the Company from Janssen and subsequently passed onto Royalty Pharma, the balance of the Royalty Obligation will be effectively repaid over the life of the co-development and license agreement (the "Agreement") with Janssen. In order to determine the amortization of the Royalty Obligation, the Company is required to estimate the total amount of future royalty payments to Royalty Pharma over the life of the Agreement. In addition to the \$60 million upfront payment, up to an additional \$95 million in additional milestone payments will also be recorded as a liability related to the sale of future royalties when they are received and amortized under the interest method over the estimated remaining life of the agreement. At execution, the Company's estimate of this total interest expense resulted in an effective annual interest rate of approximately 10.5%. This estimate contains significant assumptions that impact both the amount recorded at execution and the interest expense that will be recognized over the royalty period. The Company will periodically assess the estimated royalty payments to Royalty Payments from Janssen and to the extent the amount or timing of such payments is materially different than the original estimates, an adjustment will be recorded prospectively to increase or decrease interest expense. There are a number of factors that could materially affect the amount and timing of royalty payments to Royalty Pharma from Janssen, and correspondingly, the amount of interest expense recorded by the Company, most of which are not within the Company's control. Such factors include, but are not limited to, delays or discontinuation of development of seltorexant, regulatory approval, changing standards of care, the introduction of competing products, manufacturing or other delays, generic competition, intellectual property matters, adverse events that result in governmental health authority imposed restrictions on the use of the drug products, significant changes in foreign exchange rates as the royalties remitted to Royalty Pharma are made in U.S. dollars ("USD") while the underlying sales of seltorexant will be made in currencies other than USD, the ongoing COVID-19 pandemic, and other events or circumstances that are not currently foreseen. Changes to any of these factors could result in increases or decreases to both royalty revenues and interest expense.

The following table shows the activity of the Royalty Obligation since the transaction inception through June 30, 2021:

	June 30, 2021
Upfront payment from the sale of future royalties	\$ 60,000,000
Non-cash interest expense associated with the sale of future royalties	2,907,895
Liability related to the sale of future royalties	\$ 62,907,895

NOTE 7 — STOCKHOLDERS' EQUITY

At-the-Market Equity Offering Program

On August 10, 2018, the Company entered into the Sales Agreement with Jefferies pursuant to which the Company may offer and sell, from time to time, through Jefferies, up to \$50.0 million in shares of the Company's common stock, by any method permitted by law deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. During the year ended December 31, 2020, the Company issued and sold 3,381,608 shares of the Company's common stock under the Sales Agreement. The shares were sold at an average price of \$3.7113 per share for aggregate net proceeds to the Company of approximately \$12.1 million, after deducting sales commissions and offering costs payable by the Company.

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 June 30, 2021.

NOTE 8 — STOCK AWARD PLAN AND STOCK-BASED COMPENSATION

In December 2013, the Company adopted the 2013 Equity Incentive Plan (as subsequently amended and restated, the "Plan"), which provides for the issuance of options, stock appreciation rights, stock awards and stock units. 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. As of September 30, 2020, all remaining inducement awards have been canceled or expired. In June 2020, the Company increased the aggregate number of shares of common stock authorized for issuance under the Plan by 2,000,000 shares. Stock option activity for employees and non-employees for the six months ended June 30, 2021 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, 2021	10,050,523	\$ 6.60	7.0	\$ —
Granted	140,000	\$ 2.90		
Exercised	—	\$ —		
Forfeited	(465,775)	\$ 6.53		
Outstanding June 30, 2021	9,724,748	\$ 6.55	6.5	\$ —
Exercisable June 30, 2021	6,943,670	\$ 6.80	5.7	\$ —
Available for future grant	483,391			

The weighted average grant-date fair value of stock options outstanding on June 30, 2021 was \$4.13 per share. Total unrecognized compensation costs related to non-vested stock options at June 30, 2021 were approximately \$7.6 million and are expected to be recognized within future operating results over a weighted-average period of 1.64 years. The total intrinsic value of the options exercised during the six months ended June 30, 2021, and 2020 was zero and approximately \$0.9 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. For stock options granted during the six months ended June 30, 2021 and 2020, the Company utilized the following assumptions:

	Six Months Ended June 30,	
	2021	2020
Expected term (years)	5.50	5.50-5.88
Risk free interest rate	0.86%	0.37%-0.42%
Volatility	75%	68%-69%
Dividend yield	0%	0%
Weighted average grant date fair value per share of common stock	\$ 1.83	\$ 1.61

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. The total unrecognized compensation costs related to non-vested RSUs at June 30, 2021 was zero. There were no unvested RSUs as of June 30, 2021 and December 31, 2020, respectively.

The following table presents stock-based compensation expense included in the Company's consolidated statements of operations:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development	\$ 641,373	\$ 694,540	\$ 1,285,549	\$ 1,376,153
General and administrative	742,687	2,790,942	1,614,575	4,307,516
Total	\$ 1,384,060	\$ 3,485,482	\$ 2,900,124	\$ 5,683,669

NOTE 9 — COMMITMENTS AND CONTINGENCIES

Legal Proceedings

Please refer to Note 1 for the Company's significant risks and uncertainties in regards to litigation.

Leases

Please refer to Note 10 for the Company's current lease commitments.

NOTE 10 — LEASES

Operating leases

On October 2, 2017, the Company entered into an office sublease agreement (the "Sublease") with Profitect, Inc. (the "Sublandlord") to sublease approximately 5,923 rentable square feet of office space located at 1601 Trapelo Road, Waltham, MA 02451 (the "Premises"). The term of the Sublease began on November 1, 2017 and will expire on July 31, 2021 (the "Term"), with a monthly rental rate starting at \$14,808 and escalating to a maximum monthly rental rate of \$16,288 in the final 12 months of the Term. The Sublandlord provided the Premises to the Company free of charge for the first two months of the Term. The Company will recognize the remaining expense in accordance with ASC 842.

On May 5, 2021, the Company entered into an office license agreement with BP Reservoir Place to license approximately 5,923 rentable square feet of office space located at 1601 Trapelo Road, Waltham, MA 02451. The term of the license agreement is scheduled to begin on August 1, 2021 and will expire on July 31, 2022, with an annual rate of \$239,881.50 payable in equal monthly installments. The Company has elected to not recognize the license agreement on the balance sheet as the term of the agreement is 12 months or less. Please refer to Note 2 for additional information on ASC 842, *Leases*.

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

The following table contains a summary of the Sublease costs recognized under ASC 842 and other information pertaining to the Company's operating Sublease for the six months ended June 30, 2021:

	Six Months Ended June 30, 2021
Sublease cost	
Operating Sublease cost	\$ 89,635
Total Sublease cost	\$ 89,635
Other information	
Operating cash flows used for operating Sublease	\$ 97,730
Weighted average remaining Sublease term	0.1 years
Weighted average discount rate	10%

Future minimum Sublease payments under the Company's non-cancelable operating Sublease as of June 30, 2021 and December 31, 2020 are as follows:

	Six Months Ended June 30, 2021
Future Operating Sublease Payments	
2021 (excluding the six months ended June 30, 2021)	\$ 16,288
Thereafter	—
Total Sublease payments	\$ 16,288
Less: imputed interest	—
Total operating Sublease liabilities at June 30, 2021	\$ 16,288
	Year Ended December 31, 2020
Future Operating Sublease Payments	
2021	114,018
Thereafter	—
Total Sublease payments	\$ 114,018
Less: imputed interest	(2,789)
Total operating Sublease liabilities at December 31, 2020	\$ 111,229

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, 2020 as filed with the Securities and Exchange Commission on March 8, 2021.

Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of proprietary 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 compounds that we believe have innovative mechanisms of actions and therapeutic profiles that potentially address the unmet needs of patients with these diseases.

We are developing roluperidone (f/k/a MIN-101) for the treatment of negative symptoms in patients with schizophrenia and MIN-301 for the treatment of Parkinson's disease. In addition, we previously co-developed seltorexant (f/k/a MIN-202 or JNJ-42847922) with Janssen Pharmaceutica NV ("Janssen") for the treatment of insomnia disorder and adjunctive treatment of Major Depressive Disorder ("MDD"). During 2020, we exercised our right to opt out of a joint development agreement with Janssen for the future development of seltorexant. As a result, we were entitled to collect royalties in the mid-single digits on potential future sales of seltorexant worldwide in certain indications, with no further financial obligations to Janssen. In January 2021, we sold our rights to these potential royalties to Royalty Pharma plc ("Royalty Pharma").

On November 30, 2020 we received official meeting minutes from our November 10, 2020 Type C meeting with the U.S. Food and Drug Administration ("FDA") regarding the development of roluperidone for treatment of negative symptoms of schizophrenia. The objective of this meeting was to obtain FDA input regarding the roluperidone data package and its readiness to support a New Drug Application ("NDA"). We summarized FDA's comments in our 10-K filed on March 8, 2021, and we plan to continue to communicate with FDA regarding their comments and continue to move forward with the clinical pharmacology, non-clinical, and chemistry, manufacturing and controls work needed to support an NDA submission in the first half of 2022.

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 every year 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 and Regulatory Update

Roluperidone

Open Label Extension

On May 11, 2021, we announced results from the 40-week open-label extension (OLE) of the Company's phase 3 trial of roluperidone for the treatment of negative symptoms (NS) of schizophrenia. The OLE followed the 12-week double-blind, placebo-controlled portion of this trial. During the 40-week OLE, both investigators and patients were blinded to the roluperidone dose received. The OLE was designed to evaluate the safety of roluperidone after long-term exposure. Efficacy endpoints were also assessed during the OLE period. As such, efficacy data collected during the OLE are not placebo-controlled and therefore their interpretation is limited.

Over the 40-week OLE period, 333 patients participated, of whom 166 patients received the 32 mg dose and 167 patients received the 64 mg dose. A total of 202 of the 333 patients completed the 40-week OLE period.

The mean improvement in negative symptoms was 6.8 points in the 32 mg arm and 7.5 points in the 64 mg arm. PSP total score improved by a mean of 12.3 points in the 32 mg arm and 14.5 points in the 64 mg arm, suggesting functional improvement.

The mean improvement in positive symptoms, as measured by the PANSS positive symptom subscore, was 1.9 points in the 32 mg arm and 1.8 points in the 64 mg arm.

Reduced emotional experience, as measured by a sub-factor of the NSFS that assesses a patient's motivation to take part in everyday life activities, had a mean improvement of 2.8 points in the 32 mg group and 3.0 points in the 64 mg group.

The relapse rate during the OLE, defined as patients being withdrawn from the trial due to worsening of symptoms of psychosis, was 15 patients out of 166 patients (9%) in the 32 mg arm and 10 patients out of 167 patients (6%) in the 64 mg arm. Over the one-year duration the relapse rate was 11.7% overall.

Roluperidone at both doses was safe and well tolerated and treatment-emergent adverse events (TEAE) were generally mild to moderate in severity. The most frequently reported TEAE in the overall group of 333 patients that participated in the OLE were headaches in 26 patients (7.8%), followed by worsening of schizophrenia in 18 patients (5.4%) and insomnia in 15 patients (4.5%). No other TEAE was reported by more than 4% of the patients. There was one death that occurred after treatment discontinuation (45-year old male) in the 64 mg arm due to treatment-unrelated respiratory failure. Twenty patients (6%) experienced serious adverse events, with the majority of them associated with the disease characteristics, and only 5 were judged by the investigator to be related to roluperidone. In total, 37 patients (11%) did not complete the OLE due to TEAE, with 25 patients (7.5%) due to relapse-related events and the remaining 12 patients due to a variety of other TEAE reported in $\leq 1\%$ of the patients. Few QT prolongations were observed during the OLE, were generally transient in duration and only one in the 64 mg arm led to discontinuation from the study.

As previously announced on May 29, 2020, the double-blind, placebo-controlled portion of the Phase 3 trial enrolled a total of 515 patients that were randomized in a 1:1:1 ratio to 32 mg/day roluperidone, 64 mg/day roluperidone, or placebo for 12 weeks, and 513 patients received study drugs. The 12-week double-blind, placebo-controlled portion of the trial did not meet its primary or key secondary endpoints in the intent-to-treat population. The 32 mg and 64 mg doses were not statistically significantly different from placebo at week 12 on the primary endpoint of NSFS ($p \leq 0.259$ and $p \leq 0.064$, respectively), or on the key secondary endpoint, PSP total score ($p \leq 0.542$ and nominal $p \leq 0.021$, respectively). The subsequent analysis of the change in baseline in NSFS and PSP total score based on the modified ITT population treated with the 64 mg dose resulted in nominally statistically significant $p \leq 0.044$ and $p \leq 0.017$, respectively.

Bioequivalence Study

On April 23, 2021, we initiated subject screening in a pivotal bioequivalence study in healthy volunteers comparing the formulations employed in the Phase 2b and Phase 3 trials as well as at least one new formulation designed in conjunction with our commercial supplier to facilitate large scale manufacturing. On June 29, 2021, we completed the enrollment of 48 subjects in this study, and top line results are expected in the third quarter of 2021.

Seltorexant

In June 2020 we exercised our right to opt out of our agreement with Janssen for the future Phase 3 development and commercialization of seltorexant. Under the terms of the opt-out agreement, we are entitled to collect royalties in the mid-single digits on potential future worldwide sales of seltorexant in certain indications, with no further financial obligations to Janssen. In January 2021 we sold our rights to these potential royalties to Royalty Pharma for a \$60 million cash payment and up to an additional \$95 million in potential milestones, subject to completion of the Phase 3 program by Jansen and regulatory approvals.

Financial Overview

Revenue. None of our product candidates have been approved for commercialization and we have not received any revenue in connection with the sale or license of our product candidates.

Collaborative Revenue. During 2020 we exercised our right to opt out of the joint development agreement with Janssen for the future development of seltorexant. As a result, we have no future obligations under the agreement and recognized approximately \$41.2 million in collaborative revenue during 2020, which we had previously included on our balance sheet under deferred revenue.

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

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

will need to raise additional capital or may seek additional product collaborations in the future in order to complete the development and commercialization of our product candidates.

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

We expect to continue to incur general and administrative expenses related to operating as a publicly traded company, including increased audit and legal fees, costs of compliance with securities laws, corporate governance and other regulations, investor relations expenses and higher insurance premiums.

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 United States 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.

Non-cash interest expense for the sale of future royalties. Non-cash interest expense for the sale of future royalties consists of the interest expense associated with the Royalty Pharma agreement.

Results of Operations

Comparison of Three Months Ended June 30, 2021 versus June 30, 2020

Collaborative Revenue

Collaborative Revenue was zero and \$41.2 million for the three months ended June 30, 2021 and 2020, respectively, a decrease of \$41.2 million. The decrease in collaborative revenue was the result of opting out of our co-development and license agreement with Janssen and recognizing the revenue during the three months ended June 30, 2020 and no similar activity in the corresponding period in 2021.

Research and Development Expenses

Research and development expenses were \$5.5 million and \$5.8 million for the three months ended June 30, 2021 and 2020, respectively, a decrease of approximately \$0.3 million. The decrease in research and development expenses was primarily due to lower costs for the Phase 3 clinical trial of roluperidone as a result of the completion in May 2020 of the three-month core study portion of the trial. Non-cash stock compensation expense included in research and development expenses was \$0.6 million and \$0.7 million for the three months ended June 30, 2021 and 2020, respectively.

General and Administrative Expenses

General and administrative expenses were \$3.4 million and \$5.9 million for the three months ended June 30, 2021 and 2020, respectively, a decrease of approximately \$2.5 million. The decrease in general and administrative expenses was primarily due to a decrease in non-cash stock-based compensation expenses and severance benefits. Non-cash stock compensation expense included in general and administrative expenses was \$0.7 million and \$2.8 million for the three months ended June 30, 2021 and 2020, respectively. The decrease in stock compensation expense of \$2.1 million was due primarily to certain stock option awards approved in June 2020 as well as additional stock compensation expense incurred under a severance agreement.

Foreign Exchange Losses

Foreign exchange losses were \$19 thousand and \$4 thousand for the three months ended June 30, 2021 and 2020, respectively, an increase of \$15 thousand. The increase in foreign exchange losses was primarily due to a higher level of clinical activities in 2021 denominated in Euros.

Investment Income

Investment income was \$5 thousand and \$25 thousand for the three months ended June 30, 2021 and 2020, respectively, a decrease of \$20 thousand. The decrease was primarily due to lower average balances for cash equivalents and marketable securities during 2021.

Non-cash interest expense for the sale of future royalties

Non-cash interest expense for the sale of future royalties was \$1.6 million for the three months ended June 30, 2021 and zero for the prior year period. The increase was primarily due to the sale of our royalty interest in seltorexant to Royalty Pharma and the effective interest associated with the agreement, see Note 6 for the sale of future royalties.

Comparison of Six Months Ended June 30, 2021 versus June 30, 2020

Collaborative Revenue

Collaborative Revenue was zero and \$41.2 million for the six months ended June 30, 2021 and 2020, respectively, a decrease of \$41.2 million. The decrease in collaborative revenue was the result of opting out of our co-development and license agreement with Janssen and recognizing the revenue during the six months ended June 30, 2020 and no similar activity in the corresponding period in 2021.

Research and Development Expenses

Research and development expenses were \$8.8 million and \$13.8 million for the six months ended June 30, 2021 and 2020, respectively, a decrease of approximately \$5.0 million. The decrease in research and development expenses was primarily due to lower costs for the Phase 3 clinical trial of roluperidone as a result of the completion in May 2020 of the three-month core study portion of the trial. Non-cash stock compensation expense included in research and development expenses was \$1.3 million and \$1.4 million for the six months ended June 30, 2021 and 2020, respectively.

General and Administrative Expenses

General and administrative expenses were \$7.7 million and \$10.1 million for the six months ended June 30, 2021 and 2020, respectively, a decrease of approximately \$2.4 million. The decrease in general and administrative expenses was primarily due to a decrease in non-cash stock-based compensation expenses and severance benefits. Non-cash stock compensation expense included in general and administrative expenses was \$1.6 million and \$4.3 million for the six months ended June 30, 2021 and 2020, respectively. The decrease in stock compensation expense of \$2.7 million was due primarily to certain stock option awards approved in June 2020 as well as additional stock compensation expense incurred under a severance agreement.

Foreign Exchange Losses

Foreign exchange losses were \$24 thousand and \$13 thousand for the six months ended June 30, 2021 and 2020, respectively, an increase of \$11 thousand. The increase in foreign exchange losses was primarily due to a higher level of clinical activities in 2021 denominated in Euros.

Investment Income

Investment income was \$9 thousand and \$155 thousand for the six months ended June 30, 2021 and 2020, respectively, a decrease of \$146 thousand. The decrease was primarily due to lower average balances for cash equivalents and marketable securities during 2021.

Non-cash interest expense for the sale of future royalties

Non-cash interest expense for the sale of future royalties was \$2.9 million for the six months ended June 30, 2021 and zero for the prior year period. The increase was primarily due to the sale of our royalty interest in seltorexant to Royalty Pharma and the effective interest associated with the agreement, see Note 6 for the sale of future royalties.

Liquidity and Capital Resources

Sources of Liquidity

As of June 30, 2021, we had an accumulated deficit of approximately \$304.2 million. We anticipate that we will continue to incur net losses for the foreseeable future as we continue the development and potential commercialization of our product candidates and to support our operations as a public company. At June 30, 2021, we had approximately \$74.3 million in cash, cash equivalents, and restricted cash. In January 2021, Royalty Pharma acquired our royalty interest in seltorexant for an upfront payment of \$60 million

and up to \$95 million in additional milestone payments. The potential future milestone payments to us will be contingent on the achievement of certain clinical, regulatory and commercialization milestones for seltorexant by Janssen. Seltorexant is currently in Phase 3 development for the treatment of MDD with insomnia symptoms by Janssen. We believe that our existing cash, cash equivalents, and restricted cash will be sufficient to meet our cash commitments for at least the next 12 months after the date that the interim condensed financial statements are issued.

The 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

At-the-Market Equity Offering Program

In August 2018 we entered into the Sales Agreement with Jefferies LLC pursuant to which we may offer and sell, from time to time, through Jefferies, up to \$50.0 million in shares of our common stock, by any method permitted by law deemed to be an “at-the-market” offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. During the year ended December 31, 2020, we issued and sold 3,381,608 shares of our common stock under the Sales Agreement. The shares were sold at an average price of \$3.7113 per share for aggregate net proceeds to us of approximately \$12.1 million, after deducting sales commissions and offering costs payable by us.

Seltorexant Royalties

We previously co-developed seltorexant with Janssen for the treatment of insomnia disorder and adjunctive treatment of MDD. During 2020 we exercised our right to opt out of a joint development agreement with Janssen for the future development of seltorexant. As a result, we are entitled to collect royalties in the mid-single digits on potential future sales of seltorexant worldwide in certain indications, with no further financial obligations to Janssen.

On January 19, 2021, we entered into an agreement with Royalty Pharma under which Royalty Pharma has acquired our royalty interest in seltorexant for an upfront payment of \$60 million and up to \$95 million in future milestone payments, contingent upon the achievement of certain clinical, regulatory and commercial milestones for seltorexant by Janssen.

Uses of Funds

To date, we have not generated any revenue from sales of products. We have only generated collaborative revenue due to opting out of our license and co-development agreement with Janssen, and have only generated revenue from the one-time sale of our royalty interests in seltorexant to Royalty Pharma. We do not know when, or if, we will generate any revenue from sales of our products, or from the potential future royalty streams associated with the sale of our royalty interests in seltorexant to Royalty Pharma. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize any of our product candidates. At the same time, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our product candidates. We also expect to continue to incur costs associated with operating as a public company. In addition, subject to obtaining regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution.

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

Cash Flows

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

	<u>Six Months Ended June 30,</u>	
	<u>2021</u>	<u>2020</u>
	(dollars in millions)	
Net cash (used in) provided by:		
Operating activities	\$ (11.1)	\$ (16.8)
Investing activities	—	21.5
Financing activities	60.0	6.1
Net increase in cash	<u>\$ 48.9</u>	<u>\$ 10.8</u>

Net Cash Used in Operating Activities

Net cash used in operating activities of approximately \$11.1 million during the six months ended June 30, 2021 was primarily due our net loss of \$19.4 million, partially offset by stock-based compensation expense of \$2.9 million, non-cash interest expense for the sale of future royalties of \$2.9 million, a \$1.1 million decrease in prepaid expense, a \$0.6 million increase in accounts payable, and an increase in accrued expenses of \$0.8 million.

Net cash used in operating activities of approximately \$16.8 million during the six months ended June 30, 2020 was primarily due to our net income of \$17.4 million, stock-based compensation expense of \$5.7 million, a \$0.9 increase in accounts payable, and a decrease in prepaid expense of \$0.6 million, partially offset by a decrease in deferred revenue of \$41.2 million, a \$0.1 million decrease in accrued expenses, and amortization of investments of \$0.1 million.

Net Cash Provided by Investing Activities

Net cash provided by investing activities was zero during the three months ended June 30, 2021.

Net cash provided by investing activities of approximately \$21.5 million during the six months ended June 30, 2020 was primarily due to the maturity and redemption of marketable securities of \$25.4 million, partially offset by the purchase of marketable securities of \$3.9 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities of \$60 million during the six months ended June 30, 2021 was due to the proceeds from the sale of future royalties of \$60 million.

Net cash provided by financing activities of \$6.1 million during the six months ended June 30, 2020 was due to the gross proceeds from the June 2020 at the market stock offering of \$5.2 million less costs of \$0.2 million, and proceeds from the exercise of common stock options of \$1.1 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, 2020, our most critical accounting policies and estimates upon which our financial status depends were identified as those relating to research and development costs; in-process research and development; goodwill; and income taxes. We reviewed our policies and determined that those policies and the accounting policies and

estimates relating to the liability related to the sale of future royalties were our most critical accounting policies for the six months ended June 30, 2021.

Liability related to the sale of future royalties

The Company treats the sale of future royalties to Royalty Pharma as a debt financing, as the Company has significant continuing involvement in facilitating the transfer of royalties to Royalty Pharma and Royalty Pharma has recourse against the Company relating to the payments due from Janssen. As a result, the Company recorded the upfront payment of \$60 million from this transaction as a liability related to the sale of future royalties to be amortized to interest expense using the effective interest rate method over the life of the arrangement.

The liability related to sale of future royalties and the related interest expense are based on our current estimates of future royalties expected to be paid over the life of the arrangement. The Company will periodically assess the expected royalty payments using a combination of internal projections and forecasts from external sources. To the extent the Company's future estimates of royalty payments are greater or less than previous estimates or the estimated timing of such payments is materially different than its previous estimates, the Company will prospectively recognize related non-cash interest expense.

For further discussion of the sale of future royalties, please refer to Note 6, Sale of Future Royalties.

Recent Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Our management, with the participation of our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer), evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2021. Based on the evaluation of our disclosure controls and procedures as of June 30, 2021, 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 would have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

Item 1. *Legal Proceedings*

On December 8, 2020 and January 11, 2021, purported stockholders of the Company filed two putative securities class action complaints in the United States District Court for the District of Massachusetts, entitled *McCoy v. Minerva Neurosciences, Inc., et al., No. 1:20-cv-12176* and *Ao v. Minerva Neurosciences, Inc. et al., No. 1:21-cv-10051*, respectively, against the Company and the Company's Chairman and Chief Executive Officer (collectively, the "Defendants"). The complaints are nearly identical and allege that the Defendants made material false and/or misleading statements regarding the development of the Company's drug candidate roluperidone purportedly causing losses to investors who acquired the Company's common stock between May 15, 2017 and November 30, 2020. The complaints do not quantify any alleged damages but, in addition to attorneys' fees and costs, plaintiffs seek to recover damages on behalf of themselves and others who acquired the Company's stock during the putative class period at allegedly inflated prices and purportedly suffered financial harm as a result. On March 5, 2021, the Court entered an order consolidating the actions into a case captioned *In re Minerva Neurosciences, Inc. Securities Litigation, No. 1:20-cv-12176* and appointing lead plaintiffs and their counsel. On March 19, 2021, the parties filed a stipulated proposed order with the Court staying the Defendants' response to the complaint until after plaintiffs file an amended complaint. On May 5, 2021, the parties filed a stipulation and proposed order voluntarily dismissing the lawsuit on behalf of the appointed lead plaintiffs. Also on May 5, 2021, a second plaintiff filed a motion for appointment as lead plaintiff, which the Court granted on May 21, 2021. On June 9, 2021, before the lead plaintiff's deadline to amend the complaint and before defendants filed any response to the complaint, the parties stipulated to voluntary dismissal of the lawsuit on behalf of the appointed lead plaintiff. The Court entered the parties' stipulation of dismissal on July 9, 2021 and closed the case.

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, 2020, as filed with the SEC on March 8, 2021. 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, 2020, 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. Our recent collaborative revenue was due to the recognition of deferred revenue as a result of opting out of an agreement, and is not a recurring source of revenue.

As of June 30, 2021, we had an accumulated deficit of \$304.2 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. As of June 30, 2021, we had cash, cash equivalents, and restricted cash of \$74.3 million. We believe that our existing cash, cash equivalents, and restricted cash 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 ongoing COVID-19 pandemic, and could be subject to risks from further health pandemics or epidemics, as well as uncertainty regarding returning to work and phased re-openings.

Our business could be adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID-19 pandemic, which continues to have a negative impact on the local, regional, national and global scale. In response to the pandemic, a number of jurisdictions in which we or our service providers operate implemented shelter-in-place or similar type restrictions, which limited on-site activity to certain service providers. To support the health and well-being of our employees, partners and communities, we implemented work-from-home policies for our employees, which continue to be in effect. While certain jurisdictions, including Massachusetts, have begun a phased re-opening of businesses and governmental agencies, there remain limitations on the physical operations of businesses and prohibitions on certain non-essential gatherings, and it is unclear if such phased re-openings will continue or be rolled back, and there is uncertainty about when, if, or how our workforce may return. The effects of the state executive order, local shelter-in-place orders, government-imposed quarantines and our work-from-home policies, including the uncertainty about their duration, may negatively impact productivity, disrupt our business and delay our clinical programs and timelines. The magnitude of these negative effects 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, and our ability to respond with minimal disruptions to the evolving restrictions, reopenings, and any future curtailment. These and similar, and perhaps more severe, disruptions in our operations in response to the ongoing COVID-19 pandemic and any future health pandemics or epidemics 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 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 six months ended June 30, 2021.

Issuer Purchases of Equity Securities

We did not repurchase any securities during the six months ended June 30, 2021.

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
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)
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)
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	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	The cover page from Minerva Neuroscience's Quarterly Report on Form 10-Q for the three months ended June 30, 2021 is formatted in Inline XBRL and it is contained in Exhibit 101

⁺ 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 and
Chief Business Officer
(Principal Financial Officer)
(On behalf of the Registrant)

Date: August 2, 2021

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: August 2, 2021

/s/ Remy Luthringer Ph.D.

Remy Luthringer Ph.D.
Executive Chairman and
Chief Executive Office
(Principal Executive Officer)

CERTIFICATION

I, Geoffrey Race, certify that:

1. I have reviewed this Form 10-Q of Minerva Neurosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 2, 2021

/s/ Geoffrey Race

Geoffrey Race
Chief Financial Officer and
Chief Business Officer
(Principal Financial Officer)

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

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

- (1) The Company’s Quarterly Report on Form 10-Q for the period ended June 30, 2021, 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.

Date: August 2, 2021

/s/ Remy Luthringer, Ph.D.

Remy Luthringer, Ph.D.
Executive Chairman and
Chief Executive Officer

Date: August 2, 2021

/s/ Geoffrey Race

Geoffrey Race
Chief Financial Officer and
Chief Business 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.