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, 2023

OR

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

For the transition period from _____ to _____

Commission File No. 001-36517

Minerva Neurosciences, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**26-0784194**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
1500 District Avenue Burlington, MA	**01803**
(Address of Principal Executive Offices)	**(Zip Code)**

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	NERV	The Nasdaq Capital 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

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

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

The number of shares of Registrant's Common Stock, $0.0001 par value per share, outstanding as of July 27, 2023 was 6,993,406.

INDEX TO FORM 10-Q

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

This Quarterly Report on Form 10-Q contains forward-looking statements. 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, 2022 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, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 51,796,711	$ 36,093,606
Restricted cash	100,000	100,000
Refundable regulatory fee	—	3,117,218
Prepaid expenses and other current assets	329,153	848,117
Total current assets	52,225,864	40,158,941
Equipment, net	13,605	16,326
Capitalized software, net	29,797	42,567
Goodwill	14,869,399	14,869,399
Total assets	**$ 67,138,665**	**$ 55,087,233**
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities		
Accounts payable	$ 298,251	$ 969,667
Accrued expenses and other current liabilities	1,609,555	407,909
Total current liabilities	1,907,806	1,377,576
Liability related to the sale of future royalties	77,741,760	73,733,876
Total liabilities	79,649,566	75,111,452
Commitments and contingencies (Note 8)		
Stockholders' (deficit) equity		
Preferred stock; $0.0001 par value; 100,000,000 shares authorized; none issued or outstanding as of June 30, 2023 and December 31, 2022, respectively	—	—
Common stock; $0.0001 par value; 125,000,000 shares authorized; 6,993,406 and 5,340,193 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	699	534
Additional paid-in capital	367,460,923	346,785,322
Accumulated deficit	(379,972,523)	(366,810,075)
Total stockholders' (deficit) equity	(12,510,901)	(20,024,219)
Total liabilities and stockholders' (deficit) equity	**$ 67,138,665**	**$ 55,087,233**

See accompanying notes to condensed consolidated financial statements

Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Expenses				
Research and development	$ 1,887,476	$ 4,131,978	$ 4,541,029	$ 9,091,841
General and administrative	2,632,519	2,833,211	5,327,484	5,862,606
Total expenses	4,519,995	6,965,189	9,868,513	14,954,447
Loss from operations	(4,519,995)	(6,965,189)	(9,868,513)	(14,954,447)
Foreign exchange (losses) gains	(7,206)	1,596	(15,892)	(2,198)
Investment income	365,623	72,378	729,841	79,795
Non-cash interest expense for the sale of future royalties	(2,030,458)	(1,826,499)	(4,007,884)	(3,605,293)
Net loss	$ (6,192,036)	$ (8,717,714)	$ (13,162,448)	$ (18,482,143)
Net loss per share, basic and diluted	$ (1.12)	$ (1.63)	$ (2.43)	$ (3.46)
Weighted average shares outstanding, basic and diluted	5,511,163	5,340,196	5,426,150	5,340,196

See accompanying notes to condensed consolidated financial statements.

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

	Common Stock		Additional	Accumulated	
	Shares	Amount	Paid-In Capital	Deficit	Total
Balances at January 1, 2022	**5,340,196**	**$ 534**	**$ 342,676,508**	**$ (334,701,399)**	**$ 7,975,643**
Stock-based compensation	—	—	1,052,656	—	1,052,656
Net loss	—	—	—	(9,764,429)	(9,764,429)
Balances at March 31, 2022	**5,340,196**	**$ 534**	**$ 343,729,164**	**$ (344,465,828)**	**$ (736,130)**
Stock-based compensation	—	—	1,071,605	—	1,071,605
Adjustments due to the rounding impact from the reverse stock split for fractional shares	(3)	—	(5)	—	(5)
Net loss	—	—	—	(8,717,714)	(8,717,714)
Balances at June 30, 2022	**5,340,193**	**$ 534**	**$ 344,800,764**	**$ (353,183,542)**	**$ (8,382,244)**
Balances at January 1, 2023	**5,340,193**	**$ 534**	**$ 346,785,322**	**$ (366,810,075)**	**$ (20,024,219)**
Stock-based compensation	—	—	376,459	—	376,459
Net loss	—	—	—	(6,970,412)	(6,970,412)
Balances at March 31, 2023	**5,340,193**	**$ 534**	**$ 347,161,781**	**$ (373,780,487)**	**$ (26,618,172)**
Issuance of common stock and warrants pursuant to a private placement	1,425,000	142	19,999,852	—	19,999,994
Costs related to issuance of common stock and warrants	—	—	(309,602)	—	(309,602)
Vesting of performance-based restricted stock units	228,213	23	(23)	—	—
Stock-based compensation	—	—	608,915	—	608,915
Net loss	—	—	—	(6,192,036)	(6,192,036)
Balances at June 30, 2023	**6,993,406**	**$ 699**	**$ 367,460,923**	**$ (379,972,523)**	**$ (12,510,901)**

See accompanying notes to condensed consolidated financial statements.

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Six Months Ended June 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (13,162,448)	$ (18,482,143)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,721	—
Amortization of capitalized software	12,770	—
Stock-based compensation expense	985,374	2,124,261
Non-cash interest expense associated with the sale of future royalties	4,007,884	3,605,293
Changes in operating assets and liabilities		
Refundable regulatory fee	3,117,218	—
Prepaid expenses and other current assets	518,964	1,161,538
Accounts payable	(671,416)	(333,486)
Accrued expenses and other current liabilities	1,201,646	923,460
Net cash used in operating activities	(3,987,287)	(11,001,077)
Cash flows from investing activities:		
Net cash provided by investing activities	—	—
Cash flows from financing activities:		
Proceeds from sales of common stock and warrants in private placement	19,999,994	—
Costs paid in connection with private placements	(309,602)	—
Fees paid in connection with the reverse stock split fractional shares	—	(5)
Net cash provided by (used in) financing activities	19,690,392	(5)
Net increase (decrease) in cash, cash equivalents and restricted cash	15,703,105	(11,001,082)
Cash, cash equivalents and restricted cash		
Beginning of period	36,193,606	60,855,080
End of period	$ 51,896,711	$ 49,853,998
Reconciliation of the Condensed Consolidated Statements of Cash Flows to the Condensed Consolidated Balance Sheets		
Cash and cash equivalents	$ 51,796,711	$ 49,753,998
Restricted cash	100,000	100,000
Total cash, cash equivalents and restricted cash	$ 51,896,711	$ 49,853,998

See accompanying notes to condensed consolidated financial statements.

NOTE 1 — NATURE OF OPERATIONS AND LIQUIDITY

Nature of Operations

Minerva Neurosciences, Inc. ("Minerva" or the "Company") is a clinical-stage biopharmaceutical company focused on the development and commercialization of product candidates to treat patients suffering from central nervous system diseases. 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. 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. In August 2022, the Company submitted a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") for its lead product candidate, roluperidone, for the treatment of negative symptoms in schizophrenia. In October 2022, the Company received a refusal to file letter ("RTF") from the FDA for the NDA for roluperidone. Subsequently, the Company requested a formal dispute resolution and appealed the RTF, following which, on April 27, 2023, the FDA filed the Company's NDA for roluperidone. In May 2023, the FDA confirmed that the NDA for roluperidone was assigned a standard review classification and a Prescription Drug User Fee Act goal date of February 26, 2024. The FDA advised that it identified potential review issues that had been previously cited in the RTF decision letter, which included those discussed at the Type C meeting in March 2022. See the section titled "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—Clinical and Regulatory Updates—Type C Meeting" for more information.

The Company has exclusive rights to develop and commercialize MIN-301, a compound 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 was 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 plc ("Royalty Pharma") for a $60 million up front payment and up to $95 million in potential future milestone payments.

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, 2023, the Company had an accumulated deficit of approximately $380.0 million and net cash used in operating activities was approximately $4.0 million during the six months ended June 30, 2023. 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, 2023, the Company had cash, cash equivalents, and restricted cash of $51.9 million, which it believes will be sufficient to meet the Company's operating commitments for the next 12 months from the date its 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 many 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, and the level of financial resources available. The Company can adjust its operating plan spending levels based on the timing of future clinical trials, which are predicated upon adequate funding to complete the trials. The Company routinely evaluates the status of its clinical development programs as well as potential strategic options.

The Company will need to raise additional capital in order to continue to fund operations and fully fund any potential 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.

Further, if the Company does not satisfy The Nasdaq Capital Market continued listing requirements, its common stock may be subject to delisting, which could impact the Company's ability to complete additional equity financings on terms acceptable to the Company. On June 16, 2023, the Company received written notice from The Nasdaq Stock Market LLC ("Nasdaq") informing the Company that it has regained compliance with Nasdaq Listing Rule 5550(b)(2), which requires that companies listed on The Nasdaq Capital Market maintain a minimum Market Value of Listed Securities, as defined by Nasdaq, of $35 million or greater.

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, 2023, the results of operations for the three and six months ended June 30, 2023 and 2022 and cash flows for the six months ended June 30, 2023 and 2022. The results of operations for the three and six months ended June 30, 2023 are not necessarily indicative of the results to be expected for the full year. The consolidated balance sheet as of December 31, 2022 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, 2022 included in the Company's Annual Report on Form 10-K filed with the SEC on March 8, 2023.

Reverse Stock Split

On June 17, 2022, the Company filed a Certificate of Amendment to its Amended and Restated Certificate of Incorporation (the "Amendment") with the Secretary of State of the State of Delaware to effect a one-for-eight (1-for-8) reverse stock split of its outstanding common stock. The Amendment became effective at 5:00 p.m. Eastern Time on June 17, 2022. A series of alternate amendments to effect a reverse stock split was approved by the Company's stockholders at the Company's 2022 Annual Meeting of Stockholders held on June 10, 2022, and the specific one-for-eight (1-for-8) reverse stock split was subsequently approved by the Company's board of directors on June 10, 2022.

The Amendment provided that, at the effective time of the Amendment, every eight (8) shares of the Company's issued and outstanding common stock automatically combined into one issued and outstanding share of common stock, without any change in par value per share. The reverse stock split affected all shares of the Company's common stock outstanding immediately prior to the effective time of the Amendment. As a result of the reverse stock split, proportionate adjustments were made to the per share exercise price and/or the number of shares issuable upon the exercise or vesting of all stock options, restricted stock units and restricted stock awards issued by the Company and outstanding immediately prior to the effective time of the Amendment, which resulted in a proportionate decrease in the number of shares of the Company's common stock reserved for issuance upon exercise or vesting of such stock options, restricted stock units and restricted stock awards, and, in the case of stock options, a proportionate increase in the exercise price of all such stock options. In addition, the number of shares reserved for issuance under the Company's equity compensation plans immediately prior to the effective time of the Amendment was reduced proportionately. The reverse stock split did not affect the number of shares of common stock authorized for issuance under the Company's Amended and Restated Certificate of Incorporation, which remained at 125,000,000 shares.

No fractional shares were issued as a result of the reverse stock split. Stockholders of record who would otherwise have been entitled to receive a fractional share received a cash payment in lieu thereof. The reverse stock split affected all stockholders proportionately and did not affect any stockholder's percentage ownership of the Company's common stock (except to the extent that the reverse stock split results in any stockholder owning only a fractional share). As a result of the reverse stock split, the number of the Company's outstanding shares of common stock as of June 17, 2022 decreased from 42,721,566 (pre-split) shares to 5,340,193 (post-split) shares.

All share and per share amounts in the accompanying financial statements, related footnotes, and management's discussion and analysis have been adjusted retroactively to reflect the reverse stock split as if it had occurred at the beginning of the earliest period presented. The Company's common stock began trading on The Nasdaq Global Market on a split-adjusted basis when the market opened on June 21, 2022. Effective September 12, 2022, the Company transferred the listing of its common stock from The Nasdaq Global Market to The Nasdaq Capital Market.

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, 2023 and December 31, 2022.

Refundable regulatory fee

On August 12, 2022, the Company paid $3,117,218 to the FDA for the NDA user fee related to roluperidone. The Company met the conditions of the Federal Food, Drug, and Cosmetic Act, as amended, for the small business waiver of the user fees and its request for a waiver of an application user fee was granted by the FDA on November 2, 2022. On January 26, 2023, the refund was received from the FDA.

Recent accounting pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") and are adopted by the Company as of the specified effective date. The Company believes that the impact of recently issued, but not yet adopted, accounting pronouncements will not have a material impact on the condensed consolidated financial statements or do not apply to the Company.

NOTE 3 — ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities consist of the following:

	June 30, 2023	December 31, 2022
Research and development costs and other accrued expenses	$ 413,749	$ 279,434
Accrued bonus	806,156	14,832
Professional fees	305,848	113,643
Vacation pay	83,802	—
Accrued expenses and other current liabilities	$ 1,609,555	$ 407,909

NOTE 4 — NET LOSS PER SHARE OF COMMON STOCK

Diluted loss per share is the same as basic loss per share for all periods presented as the effects of potentially dilutive items were anti-dilutive given the Company's net loss. Basic loss per share is computed by dividing net loss by the weighted average number of 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.

In June 2023, in connection with the Private Placement (as defined and described in Note 6, Stockholders' Equity), the Company issued and sold pre-funded warrants exercisable for an aggregate of 575,575 shares of common stock. The purchase price of the pre-funded warrants is $9.99 per share, which was paid to the Company upon issuance of the pre-funded warrants. The exercise price of the pre-funded warrants is $0.01 per share. The pre-funded warrants are exercisable by the holders at any time and do not expire. As the remaining shares underlying the pre-funded warrants are issuable for nominal consideration of $0.01 per share, 575,575 shares of common stock underlying the unexercised pre-funded warrants were considered outstanding for purposes of the calculation of loss per share as of June 30, 2023.

The following table sets forth the computation of basic and diluted loss per share for common stockholders:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net loss	$ (6,192,036)	$ (8,717,714)	$ (13,162,448)	$ (18,482,143)
Weighted average shares of common stock outstanding	5,511,163	5,340,196	5,426,150	5,340,196
Net loss per share of common stock – basic and diluted	$ (1.12)	$ (1.63)	$ (2.43)	$ (3.46)

The following securities outstanding at June 30, 2023 and 2022 have been excluded from the calculation of weighted average shares outstanding as their effect on the calculation of loss per share is antidilutive:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Common stock options	700,929	467,429	700,929	467,429
Performance-based restricted stock units ("PRSUs")	228,209	456,422	228,209	456,422
Common stock warrants	5,099	5,099	5,099	5,099

In April 2023, the Compensation Committee of the Company's board of directors certified the achievement of a performance condition occurring upon FDA acceptance of the NDA for roluperidone. As a result, 50% of the shares of common stock underlying the PRSUs vested. As of June 30, 2023, 228,213 PRSUs have vested, 20,218 have been cancelled and 228,209 remain outstanding.

NOTE 5 — SALE OF FUTURE ROYALTIES

The Company had previously co-developed seltorexant with Janssen for the treatment of insomnia disorder and adjunctive treatment of MDD. During 2020, the Company exercised its right to opt out of the joint development agreement with Janssen for the future development of seltorexant and, as a result, the Company was 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, the Company entered into an agreement with Royalty Pharma under which Royalty Pharma acquired the Company's royalty interest in seltorexant for an upfront payment of $60 million and up to an additional $95 million in potential 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 as 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. Under the terms of the agreement, all payments from Royalty Pharma to the Company, including the initial upfront payment of $60 million as well as amortized interest expense and potential milestone payments, are not repayable to Royalty Pharma in the event that Janssen discontinues the clinical development of seltorexant or ceases to pursue its commercialization at a future date for any reason. 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 from Janssen to 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 potential milestone payments will also be recorded as a liability related to the sale of future royalties and amortized as interest expense 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%. As of June 30, 2023, the Company estimated the effective annual interest rate to be approximately 10.7%. This estimate contains significant assumptions, which are considered Level 3 fair value inputs, regarding the timing and amount of expected royalty and milestone payments that impact 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 regulatory 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. Janssen is currently conducting two Phase 3 studies with seltorexant, a third Phase 3 study was discontinued during 2022.

The following table shows the activity of the Royalty Obligation since the transaction inception through June 30, 2023:

	June 30, 2023
Upfront payment from the sale of future royalties	$ 60,000,000
Non-cash interest expense associated with the sale of future royalties	17,741,760
Liability related to the sale of future royalties	$ 77,741,760

NOTE 6 — STOCKHOLDERS' EQUITY

Private Placement of Common Stock and Warrants

On June 27, 2023, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with certain institutional accredited investors (the "Investors"), pursuant to which the Company agreed to issue and sell to the Investors in a private placement (the "Private Placement") (i) an aggregate of 1,425,000 shares (the "Shares") of the Company's common stock at a purchase price of $10.00 per Share, and (ii) in lieu of additional shares of common stock, pre-funded warrants to purchase an aggregate of 575,575 shares of common stock at a purchase price of $9.99 per pre-funded warrant. The price per pre-funded warrant represents the price of $10.00 per Share sold in the Private Placement, minus the $0.01 per share exercise price of each such pre-funded warrant. The pre-funded warrants are exercisable at any time after their original issuance and will not expire until exercised in full.

The pre-funded warrants issued in the Private Placement provide that a holder of the pre-funded warrants will not have the right to exercise any portion of its pre-funded warrants to the extent such holder, together with its affiliates, after giving effect to such exercise, would beneficially own in excess of the beneficial ownership limitation, as elected by such Investor, immediately after giving effect to such exercise (the "Beneficial Ownership Limitation"); provided, however, that each pre-funded warrant holder may increase or decrease the Beneficial Ownership Limitation by giving 61 days' notice to the Company, but not to any percentage in excess of 19.99%.

On June 30, 2023, the Private Placement closed and the Company received aggregate gross proceeds from the Private Placement of $20.0 million, and, therefore, will be reflected on the condensed consolidated financial statements for the three and six month period ended June 30, 2023. The Company incurred approximately $0.3 million in offering expenses as of June 30, 2023, which have been included as a component of additional paid-in capital, resulting in net proceeds of $19.7 million as of June 30, 2023.

Pursuant to the Securities Purchase Agreement, the Company has agreed to file a registration statement covering the resale of the Registrable Securities (as such term is defined in the Securities Purchase Agreement) on or before the date that is 45 days after the date of the closing of the Private Placement. The Company has agreed to use its commercially reasonable efforts to keep such registration statement effective until the earlier of (i) the third anniversary of the effective date of the initial registration statement covering the Registrable Securities; (ii) the date all Shares and all shares of common stock underlying the pre-funded warrants may be sold under Rule 144 of the Securities Act of 1933, as amended, without being subject to any volume, manner of sale or publicly available information requirements; or (iii) immediately prior to the closing of a Change of Control (as such term is defined in the Securities Purchase Agreement). The Company has agreed to be responsible for all expenses incurred in connection with the registration of the Registrable Securities.

Pursuant to the Securities Purchase Agreement, in connection with the Private Placement, Boehringer Ingelheim International GmbH, an Investor in the Private Placement, has the right to designate an observer to attend, subject to certain exceptions, meetings of the Company's board of directors and its committees, until the earlier of (i) the occurrence of a Change of Control and (ii) the date that it and its affiliates collectively hold less than 10% of the Company's common stock (which shall be calculated by including in the amount of common stock held by such Investor and its affiliates any shares of common stock issuable upon exercise of any portion of the pre-funded warrant issued to such Investor and not yet exercised).

At-the-Market Equity Offering Program

In September 2022, the Company entered into an Open Market Sale Agreement (the "Sales Agreement") with Jefferies LLC ("Jefferies") pursuant to which the Company may offer and sell, from time to time, through Jefferies 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 six months ended June 30, 2023, no shares of the Company's common stock were issued or sold under the Sales Agreement. As of June 30, 2023, an aggregate of $22.6 million was eligible for sale pursuant to the Sales Agreement under the Company's effective registration statement on Form S-3 (File No. 333-267424).

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 5,099 shares of common stock at a per share exercise price of $44.13. The warrants were 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, 2023.

NOTE 7 — STOCK AWARD PLAN AND STOCK-BASED COMPENSATION

In December 2013, the Company adopted the 2013 Equity Incentive Plan (as subsequently amended and restated, the "Plan"), which provides for the issuance of options, stock appreciation rights, stock awards and stock units.

Stock Option Awards

Stock option activity for employees and non-employees for the six months ended June 30, 2023 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, 2023	700,929	$ 15.69	8.6	$ —
Granted	—	$ —		
Exercised	—	$ —		
Forfeited	—	$ —		
Outstanding June 30, 2023	700,929	$ 15.69	8.1	$ 2,022
Exercisable June 30, 2023	314,128	$ 29.04	6.8	$ 252
Available for future grant	118,666			

The weighted average grant-date fair value of stock options outstanding on June 30, 2023 was $10.75 per share. Total unrecognized compensation costs related to non-vested stock options at June 30, 2023 were approximately $1.3 million and are expected to be recognized within future operating results over a weighted-average period of 2.5 years. The total intrinsic value of the options exercised during the six months ended June 30, 2023 and 2022 was zero.

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 the 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, 2023 and 2022, the Company utilized the following assumptions:

	Six Months Ended	
	June 30, 2023	June 30, 2022
Expected term (years)	—	5.50-6.25
Risk free interest rate	—	1.96%-3.25%
Volatility	—	76%-97%
Dividend yield	—	0%
Weighted average grant date fair value per share of common stock	—	$4.78

Performance-Based Restricted Stock Units

On August 6, 2021, options to purchase 953,980 shares of the Company’s common stock were exchanged for 476,640 PRSUs. Options surrendered in the one-time stock option exchange program (the “Exchange Program”) were cancelled and shares subject to the cancelled options again became available for issuance under the Plan. The Exchange Program was treated as a Type II modification (Probable-to improbable) under ASC 718.

The Company will recognize the unrecognized grant-date fair value of the pre-modification stock options as well as any incremental non-cash compensation cost of the PRSUs granted in the Exchange Program, if the vesting conditions of the PRSUs are achieved or if they become probable. The incremental cost was measured as the excess of the fair value of each new PRSU, measured as of the date the new PRSUs were granted, over the fair value of the stock options surrendered in exchange for the new PRSU, measured immediately prior to the cancellation.

The Company is using the pre-modification stock options for determining the compensation cost related to the PRSUs as the vesting conditions remain uncertain for the outstanding PRSUs. The total unrecognized compensation costs related to non-vested stock options at June 30, 2023 were approximately $0.5 million and are expected to be recognized within future operating results over a weighted-average period of 0.5 year.

On April 28, 2023, the Compensation Committee of the Company's board of directors certified the achievement of a performance condition occurring upon FDA acceptance of the NDA for roluperidone. As a result, 50% of the shares of common stock underlying the Company's PRSUs vested. The remaining PRSUs vest upon roluperidone receiving FDA marketing approval, provided that such approval occurs within five years after the August 6, 2021 grant date. As of June 30, 2023, 228,213 PRSUs have vested, 20,218 have been cancelled, and 228,209 remain outstanding. As a result of the PRSUs vesting, the Company recognized approximately $0.2 million in non-cash compensation expense for the period ending June 30, 2023, representing 50% of the incremental cost of the PRSUs granted under the Exchange Program.

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,	
	2023	2022	2023	2022
Research and development	$ 297,756	$ 514,806	$ 482,483	$ 1,015,979
General and administrative	311,159	556,799	502,891	1,108,282
Total	$ 608,915	$ 1,071,605	$ 985,374	$ 2,124,261

NOTE 8 — COMMITMENTS AND CONTINGENCIES

Legal Proceedings

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

Leases

On October 11, 2022, the Company entered into an office lease agreement with Regus to lease approximately 491 rentable square feet of office space located at 1500 District Avenue, Burlington, MA 01803. The lease is on a month-to-month basis commencing on February 1, 2023, with a monthly payment of $8,290. The Company has elected to not recognize the lease agreement on the balance sheet as the term of the agreement is 12 months or less.

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, 2022 as filed with the Securities and Exchange Commission on March 8, 2023. This discussion and analysis contains forward-looking statements that involve significant risks and uncertainties. Our actual results, performance or experience could differ materially from what is indicated by any forward-looking statement due to various important factors, risks and uncertainties, including, but not limited to, those set forth under "Risk Factors" included elsewhere in this Quarterly Report on Form 10-Q.

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 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 have exclusive rights to develop and commercialize 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, one of the Janssen Pharmaceutical Companies of Johnson & Johnson ("Janssen"), for the treatment of insomnia disorder and adjunctive treatment of Major Depressive Disorder ("MDD"). 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 were 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 plc ("Royalty Pharma") for a $60 million cash payment and up to an additional $95 million in potential milestone payments, subject to completion of Phase 3 trials by Janssen and regulatory approvals. Janssen is currently conducting two Phase 3 studies with seltorexant, a third Phase 3 study was discontinued during 2022.

In August 2022, we submitted a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") for our lead product candidate, roluperidone, for the treatment of negative symptoms in schizophrenia. The FDA initially notified us that they would not accept the file for review, issuing a refusal to file letter ("RTF") in October 2022. Subsequently, we requested a formal dispute resolution and appealed the RTF, following which, on April 27, 2023, the FDA filed our NDA for roluperidone. In May 2023, the FDA confirmed that the NDA for roluperidone was assigned a standard review classification and a Prescription Drug User Fee Act ("PDUFA") goal date of February 26, 2024. The FDA advised that it identified potential review issues that had been previously cited in the RTF decision letter, which included those discussed at the Type C meeting in March 2022. See "—Clinical and Regulatory Updates" below for more information.

We have not received any 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 routinely evaluate the status of our drug development programs as well as potential strategic options. We have incurred significant operating losses since inception and expect to continue to incur net losses and negative cash flows from operating activities for the foreseeable future in connection with the clinical and regulatory activities associated with advancing our product candidates. As of June 30, 2023 and December 31, 2022, we had an accumulated deficit of $380.0 million and $366.8 million, respectively. For six months ended June 30, 2023 and 2022, we recorded net losses of $13.2 million and $18.5 million, respectively.

Recent Developments

Nasdaq Listing Requirement Compliance Notice

As previously reported, on June 16, 2023, we received written notice from The Nasdaq Stock Market LLC ("Nasdaq") informing us that we have regained compliance with Nasdaq Listing Rule 5550(b)(2) which requires that companies listed on The Nasdaq Capital Market maintain a minimum Market Value of Listed Securities, as defined by Nasdaq, of $35 million or greater. Our securities will continue to be listed and traded on The Nasdaq Capita Market.

Private Placement

On June 27, 2023, we entered into a securities purchase agreement with certain institutional accredited investors, pursuant to which we agreed to issue and sell in a private placement (i) an aggregate of 1,425,000 shares of the Company's common stock at a purchase price of $10.00 per share, and (ii) in lieu of additional shares of common stock, pre-funded warrants to purchase an aggregate of 575,575 shares of common stock at a purchase price of $9.99 per pre-funded warrant. On June 30, 2023, the private placement closed and we received aggregate gross proceeds from the private placement of $20.0 million. For more information, see the section titled "Liquidity and Capital Resources—Sources of Liquidity—Private Placement of Common Stock and Warrants" below.

Clinical and Regulatory Updates

New Drug Application Filed

On April 27, 2023, the FDA filed our NDA for roluperidone for the treatment of negative symptoms in patients with schizophrenia. The decision to file the NDA followed our request for formal dispute resolution and appeal of the RTF. The issues cited in the RTF decision included those discussed at the Type C meeting in March 2022. In granting the appeal, the FDA deciding official agreed with us that the issues cited in the RTF decision should be considered during the FDA's review of the NDA.

On May 8, 2023, we received confirmation from the FDA that the NDA for roluperidone has been filed in accordance with the Appeal Granted letter dated April 27, 2023 and assigned a standard review classification and a PDUFA goal date of February 26, 2024. The FDA advised that it identified potential review issues that had been previously cited in the RTF decision letter, which included those discussed at a Type C meeting in March 2022, described further below.

NDA Fee Refund

In January 2023, we received a refund of our NDA filing fee of approximately $3.1 million from the FDA. This refund was made in accordance with the Federal Food Drug and Cosmetic Act, which allows a fee waiver for a small business submitting its first human drug application.

New Drug Application Submission

In August 2022, we submitted an NDA to the FDA for roluperidone for the treatment of negative symptoms in patients with schizophrenia. The NDA submission is supported by results from two late-stage, well-controlled studies in patients with moderate to severe negative symptoms and stable positive symptoms of schizophrenia, referred to as Study MIN-101C03 (the Phase 2b trial) and Study MIN-101C07 (the Phase 3 trial). Both studies were planned to constitute the bulk of evidence of roluperidone's effectiveness for the indication of treating negative symptoms of schizophrenia. This plan relied on both studies having the same overall study design: both were multicenter, multinational, randomized, double-blind, placebo-controlled, parallel-group studies in which patients received either 32 mg or 64 mg doses of roluperidone. In both studies, if patients were taking antipsychotic treatments, they were discontinued and a washout period of two days was implemented before beginning the assigned study treatment. Both studies capture comparative placebo-controlled data through their 12-week double-blind period. Both studies also provide long-term exposure data regarding the safety and tolerability of roluperidone, as well as efficacy based on blinded doses of roluperidone, specifically intended to demonstrate the maintenance of improvement in negative symptoms and the low rate of worsening of positive symptoms following 24-week (Study MIN-101C03) and 40-week (Study MIN-101C07) Open Label ("OL") periods. With the exception of the duration of the OL period, these two studies were nearly identical with respect to patient population and main assessment tools (namely, Positive and Negative Syndrome Scale ("PANSS"), Personal and Social Performance Scale ("PSP"), and Clinical Global Impression ("CGI")). As such, the data from these studies are the basis for the decision to submit the application at this stage of development as we believe they provide data to support the long-term safety and efficacy in adults in an area of high unmet medical need.

We are seeking approval for the 64 mg dose of roluperidone, and results described hereafter are for the 64 mg dose only.

Results of Study MIN-101C03 supported the primary hypothesis that after 12 weeks of treatment, roluperidone is superior to placebo in reducing negative symptoms of schizophrenia. In the primary efficacy analysis, 64 mg roluperidone resulted in a statistically significant reduction of negative symptoms of schizophrenia as measured by PANSS Pentagonal Structured Model Negative score ("PSM") ($p \leq 0.0036$). A post hoc analysis of the change from Baseline to Week 12 in the PANSS Marder's Negative Symptoms Factor Score ("NSFS") also demonstrated a statistically significant difference for 64 mg roluperidone compared with placebo ($p \leq 0.001$). Statistically significant improvements with 64 mg roluperidone compared with placebo after 12 weeks of the Double Blind ("DB") period were also seen for multiple secondary/exploratory efficacy analyses. Further improvements in the NSFS were also seen during the 24-week OL period.

The superiority of roluperidone over placebo was also demonstrated in Study MIN-101C07. Although the primary analysis (intent-to-treat ("ITT")) of change from Baseline in the NSFS to Week 12 for roluperidone compared to placebo marginally missed statistical significance ($p \leq 0.064$), the results were quantitatively superior for 64 mg roluperidone treatment. Furthermore, the analysis of the modified intent-to-treat ("mITT") population (mITT data set excludes data from one clinical site with implausible results for the 17 patients recruited at this site) demonstrated a nominal statistically significant improvement in the NSFS for 64 mg roluperidone compared to placebo ($p \leq 0.044$). In addition, statistically significant improvements (unadjusted) in the NSFS from Baseline were seen as early as Weeks 4 and 8 for 64 mg roluperidone compared to placebo for both the ITT and the mITT populations. PSP Total score (key secondary endpoint measuring vocational and social skills) reached statistical significance for both ITT and mITT populations ($p \leq 0.022$ and $p \leq 0.017$, respectively). Further improvements in the NSFS and PSP Total score were also seen during the 40-week OL period.

Type C Meeting

In April 2022, we received the official meeting minutes from the Type C meeting with the FDA held on March 2, 2022, in which the development of roluperidone for the treatment of negative symptoms in schizophrenia was discussed. Four main topics (listed below) were highlighted by the FDA for which they requested input and further clarification from us. Following the meeting, Minerva provided additional data to address:

1. The potential impact of roluperidone administration on the efficacy and safety of antipsychotic drugs. More specifically, the psychiatric division (the "Division") wanted reassurance that those patients administered roluperidone who manifest worsening of schizophrenia symptoms and in the opinion of the clinician/investigators need treatment with antipsychotics, do not experience a diminished benefit of the antipsychotic treatment or unexpected adverse effects.
2. The comparability of US and non-US schizophrenia patients. More specifically, the Division wanted to be reassured that data collected in MIN-101C03 in non-US patients is applicable to US patients.
3. Supporting statistical evidence of efficacy of roluperidone on negative symptoms.
4. The ability of clinicians to identify patients who might benefit from roluperidone.

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.

Research and Development Expenses

Research and development costs are expensed as they are incurred and consist principally of costs incurred in connection with the development of our product candidates including: fees paid to consultants and clinical research organizations ("CROs"), investigator grants, patient screening, laboratory work, database management, material management, statistical analysis, license fees, regulatory compliance, and costs related to salaries, benefits, bonuses and stock-based compensation granted to employees in research and development functions.

Completion dates and costs can vary significantly by product candidate and are difficult to predict. We anticipate making determinations as to which programs to pursue and the level of 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 of each product candidate's commercial potential. We will need to raise additional capital or may seek additional product collaborations in the future to complete the development and commercialization of our product candidates.

General and Administrative Expenses

General and administrative costs are expensed as they are incurred and consist principally of costs for facility and information systems, professional fees for auditing, consulting and legal services and costs related to salaries, benefits, bonuses and stock-based compensation granted to employees in administrative functions. General and administrative costs also include costs for maintaining a publicly listed company including increased audit and legal fees, compliance with securities laws, corporate governance and investor relations.

Foreign Exchange (Losses) Gains

Foreign exchange (losses) gains are comprised primarily of (losses) and gains on foreign currency transactions primarily related to research and development expenses. We incur certain expenses, primarily 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 that an expense is recorded and the payment date is recorded as a foreign currency (loss) or gain.

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 non-cash interest expense associated with the Royalty Pharma agreement.

Results of Operations

Comparison of Three Months Ended June 30, 2023 versus June 30, 2022

Research and Development Expenses

Research and development expenses were $1.9 million and $4.1 million for the three months ended June 30, 2023 and 2022, respectively, a decrease of approximately $2.2 million, or 54%. The decrease in research and development expenses was primarily due to lower non-cash stock compensation costs and lower consultant fees related to the preparation of our NDA for roluperidone, which was submitted during 2022, partially offset by higher professional service fees and staffing related expenses during 2023. Non-cash stock compensation expense included in research and development expenses was $0.3 million and $0.5 million for the three months ended June 30, 2023 and 2022, respectively.

General and Administrative Expenses

General and administrative expenses were $2.6 million and $2.8 million for the three months ended June 30, 2023 and 2022, respectively, a decrease of approximately $0.2 million, or 7%. The decrease in general and administrative expenses was primarily due to lower non-cash stock compensation expense and insurance costs, partially offset by higher staffing related expenses during 2023. Non-cash stock compensation expense included in general and administrative expenses was $0.3 million and $0.6 million for the three months ended June 30, 2023 and 2022, respectively.

Foreign Exchange (Losses) Gains

Foreign exchange losses were $7 thousand and foreign exchange gains were $2 thousand for the three months ended June 30, 2023 and 2022, respectively, a decrease of $9 thousand. The increase in foreign exchange losses was primarily due to currency movements.

Investment Income

Investment income was $366 thousand and $72 thousand for the three months ended June 30, 2023 and 2022, respectively, an increase of $294 thousand. The increase in investment income was primarily due to higher interest rates.

Non-cash interest expense for the sale of future royalties

Non-cash interest expense for the sale of future royalties was $2.0 million and $1.8 million for the three months ended June 30, 2023 and 2022, respectively, an increase of $0.2 million. The increase was primarily due to an increase in the carrying value of the liability related to the sale of future royalties for seltorexant to Royalty Pharma.

Liquidity and Capital Resources

Comparison of Six Months Ended June 30,2023 versus June 30, 2022

Research and Development Expenses

Research and development expenses were $4.5 million and $9.1 million for the six months ended June 30, 2023 and 2022, respectively, a decrease of approximately $4.6 million, or 51%. The decrease in research and development expenses was primarily due to lower non-cash stock compensation costs and lower consultant fees related to the preparation of our NDA for roluperidone, which was submitted during 2022, partially offset by higher professional service fees and staffing related expenses during 2023. Non-cash stock compensation expense included in research and development expenses was $0.5 million and $1.0 million for the six months ended June 30, 2023 and 2022, respectively.

General and Administrative Expenses

General and administrative expenses were $5.3 million and $5.9 million for the six months ended June 30, 2023 and 2022, respectively, a decrease of approximately $0.6 million, or 10%. The decrease in general and administrative expenses was primarily due to lower non-cash stock compensation expense and insurance costs, partially offset by higher staffing related expenses during 2023. Non-cash stock compensation expense included in general and administrative expenses was $0.5 million and $1.1 million for the six months ended June 30, 2023 and 2022, respectively.

Foreign Exchange Losses

Foreign exchange losses were $16 thousand and $2 thousand for the six months ended June 30, 2023 and 2022, respectively, an increase of $14 thousand. The increase in foreign exchange losses was primarily due to currency movements.

Investment Income

Investment income was $730 thousand and $80 thousand for the six months ended June 30, 2023 and 2022, respectively, an increase of $650 thousand. The increase in investment income was primarily due to higher interest rates.

Non-cash interest expense for the sale of future royalties

Non-cash interest expense for the sale of future royalties was $4.0 million and $3.6 million for the six months ended June 30, 2023 and 2022, respectively, an increase of $0.4 million. The increase was primarily due to an increase in the carrying value of the liability related to the sale of future royalties for seltorexant to Royalty Pharma.

Sources of Liquidity

As of June 30, 2023, we had an accumulated deficit of approximately $380.0 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. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we may never generate product revenue or achieve profitability. As of June 30, 2023, we had approximately $51.9 million in cash, cash equivalents, and restricted cash, which we believe will be sufficient to meet our operating commitments for the next 12 months from the date our financial statements are issued. Our cash requirements primarily relate to expenditures to support the development of roluperidone, which includes advancing the program through the regulatory process.

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 many 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 and the level of financial resources available. We can adjust our operating plan spending levels based on the timing of future clinical trials which are predicated upon adequate funding to complete the trials. We routinely evaluate the status of our clinical development programs as well as potential strategic options.

Private Placement of Common Stock and Warrants

On June 27, 2023, we entered into a securities purchase agreement (the "Securities Purchase Agreement") with certain institutional accredited investors (the "Investors"), pursuant to which we agreed to issue and sell to the Investors in a private placement (the "Private Placement") (i) an aggregate of 1,425,000 shares (the "Shares") of our common stock at a purchase price of $10.00 per Share, and (ii) in lieu of additional shares of common stock, pre-funded warrants to purchase an aggregate of 575,575 shares of common stock at a purchase price of $9.99 per pre-funded warrant. The price per pre-funded warrant represents the price of $10.00 per Share to be sold in the Private Placement, minus the $0.01 per share exercise price of each such pre-funded warrant. The pre-funded warrants are exercisable at any time after their original issuance and will not expire until exercised in full.

The pre-funded warrants issued in the Private Placement will provide that a holder of the pre-funded warrants will not have the right to exercise any portion of its pre-funded warrants to the extent such holder, together with its affiliates, after giving effect to such exercise, would beneficially own in excess of the beneficial ownership limitation, as elected by such Investor, immediately after giving effect to such exercise (the "Beneficial Ownership Limitation"); provided, however, that each pre-funded warrant holder may increase or decrease the Beneficial Ownership Limitation by giving 61 days' notice to us, but not to any percentage in excess of 19.99%.

On June 30, 2023, the Private Placement closed and we received aggregate gross proceeds from the Private Placement of $20.0 million. We incurred approximately $0.3 million in offering expenses as of June 30, 2023, which have been included as a component of additional paid-in capital, resulting in net proceeds of $19.7 million as of June 30, 2023.

Pursuant to the Securities Purchase Agreement, we have agreed to file a registration statement covering the resale of the Registrable Securities (as such term is defined in the Securities Purchase Agreement) on or before the date that is 45 days after the date of the closing of the Private Placement. We have agreed to use our commercially reasonable efforts to keep such registration statement effective until the earlier of (i) the third anniversary of the effective date of the initial registration statement covering the Registrable Securities; (ii) the date all Shares and all shares of common stock underlying the pre-funded warrants may be sold under Rule 144 of the Securities Act of 1933, as amended, without being subject to any volume, manner of sale or publicly available information requirements; or (iii) immediately prior to the closing of a Change of Control (as such term is defined in the Securities Purchase Agreement). We have agreed to be responsible for all expenses incurred in connection with the registration of the Registrable Securities.

Pursuant to the Securities Purchase Agreement, in connection with the Private Placement, Boehringer Ingelheim International GmbH, an Investor in the Private Placement, has the right to designate an observer to attend, subject to certain exceptions, meetings of our board of directors and our committees, until the earlier of (i) the occurrence of a Change of Control and (ii) the date that it and its affiliates collectively hold less than 10% of our Common Stock (which shall be calculated by including in the amount of common stock held by such Investor and its affiliates any shares of common stock issuable upon exercise of any portion of the pre-funded warrant issued to such Investor and not yet exercised).

At-the-Market Equity Offering Program

In September 2022, we entered into an Open Market Sale Agreement (the "Sales Agreement") with Jefferies LLC ("Jefferies") pursuant to which we may offer and sell, from time to time, through Jefferies, 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 six months ended June 30, 2023, no shares of our common stock were issued or sold under the Sales Agreement. As of June 30, 2023, an aggregate of $22.6 million was eligible for sale pursuant to the Sales Agreement under our effective registration statement on Form S-3 (File No. 333-267424).

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 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.

On January 19, 2021, we entered into an agreement under which Royalty Pharma acquired our royalty interest in seltorexant for an upfront payment of $60 million and up to an additional $95 million in potential milestone payments, contingent upon the achievement of certain clinical, regulatory and commercial milestones for seltorexant by Janssen. Janssen is currently conducting two Phase 3 studies with seltorexant, a third Phase 3 study was discontinued during 2022.

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. Furthermore, the $60 million payment received from Royalty Pharma for the sale of our royalty interests in seltorexant has been included on our balance sheet under Liability related to the sale of future royalties. We do not know when, or if, we will generate any revenue from sales of our products, or from the potential future non-cash royalty revenue 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 our ability to raise additional capital may be adversely impacted by global economic conditions, including the recent disruptions to and volatility in the credit and financial markets in the U.S. and worldwide resulting from the COVID-19 pandemic, the war in Ukraine and other factors. 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 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.

	Six Months Ended June 30,	
	2023	2022
	(dollars in millions)	
Net cash (used in) provided by:		
Operating activities	$ (4.0)	$ (11.0)
Investing activities	—	—
Financing activities	19.7	—
Net increase (decrease) in cash	$ 15.7	$ (11.0)

Net Cash Used in Operating Activities

Net cash used in operating activities of approximately $4.0 million during the six months ended June 30, 2023 was primarily due to our net loss of $13.2 million and an approximately $0.6 million decrease in accounts payable, partially offset by non-cash interest expense for the sale of future royalties of $4.0 million, a $3.1 million decrease in refundable regulatory fees, a $1.2 million increase in accrued expenses, stock-based compensation expense of $1.0 million, and a $0.5 million decrease in prepaid expenses.

Net cash used in operating activities of approximately $11.0 million during the six months ended June 30, 2022 was primarily due to our net loss of $18.5 million and a $0.3 million decrease in accounts payable, partially offset by non-cash interest expense for the sale of future royalties of $3.6 million, stock-based compensation expense of $2.1 million, a $1.2 million decrease in prepaid expense, and an increase in accrued expenses of $0.9 million.

Net Cash Provided by Investing Activities

Net cash provided by investing activities was zero during the six months ended June 30, 2023 and 2022.

Net Cash Provided by Financing Activities

Net cash provided by financing activities of approximately $19.7 million during the six months ended June 30, 2023 was primarily due to the net proceeds from the Private Placement closed in June 2023.

Net cash provided by financing activities was zero during the six months ended June 30, 2022.

Reverse Stock Split

On June 17, 2022, we filed a Certificate of Amendment to our Amended and Restated Certificate of Incorporation (the "Amendment") with the Secretary of State of the State of Delaware to effect a one-for-eight (1-for-8) reverse stock split of our outstanding common stock. The Amendment became effective at 5:00 p.m. Eastern Time on June 17, 2022. A series of alternate amendments to effect a reverse stock split was approved by our stockholders at our 2022 Annual Meeting of Stockholders held on June 10, 2022, and the specific one-for-eight (1-for-8) reverse stock split was subsequently approved by our board of directors on June 10, 2022.

The Amendment provided that, at the effective time of the Amendment, every eight (8) shares of our issued and outstanding common stock automatically combined into one issued and outstanding share of common stock, without any change in par value per share. The reverse stock split affected all shares of our common stock outstanding immediately prior to the effective time of the Amendment. As a result of the reverse stock split, proportionate adjustments were made to the per share exercise price and/or the number of shares issuable upon the exercise or vesting of all stock options, restricted stock units and restricted stock awards issued by us and outstanding immediately prior to the effective time of the Amendment, which resulted in a proportionate decrease in the number of shares of our common stock reserved for issuance upon exercise or vesting of such stock options, restricted stock units and restricted stock awards, and, in the case of stock options, a proportionate increase in the exercise price of all such stock options. In addition, the number of shares reserved for issuance under our equity compensation plans immediately prior to the effective time of the Amendment was reduced proportionately. The reverse stock split did not affect the number of shares of common stock authorized for issuance under our Amended and Restated Certificate of Incorporation, which remained at 125,000,000 shares.

No fractional shares were issued as a result of the reverse stock split. Stockholders of record who would otherwise have been entitled to receive a fractional share received a cash payment in lieu thereof. The reverse stock split affected all stockholders proportionately and did not affect any stockholder's percentage ownership of our common stock (except to the extent that the reverse stock split results in any stockholder owning only a fractional share). As a result of the reverse stock split, the number of our outstanding shares of common stock as of June 17, 2022 decreased from 42,721,566 (pre-split) shares to 5,340,193 (post-split) shares.

All share and per share amounts in the accompanying financial statements, related footnotes, and management's discussion and analysis have been adjusted retroactively to reflect the reverse stock split as if it had occurred at the beginning of the earliest period presented. Our common stock began trading on The Nasdaq Global Market on a split-adjusted basis when the market opened on June 21, 2022. Effective September 12, 2022, we transferred the listing of our common stock from The Nasdaq Global Market to The Nasdaq Capital Market.

Critical Accounting Policies and Estimates

In our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, 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; income taxes; and the liability related to the sale of future royalties. We reviewed our policies and determined that those policies were our most critical accounting policies for the six months ended June 30, 2023.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") and are adopted by us as of the specified effective date. See Note 2 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and Note 2 in our condensed consolidated financial statements appearing elsewhere in this Form 10-Q for a description of recent accounting pronouncements applicable to our financial statements. We believe that the impact of recently issued, but not yet adopted, accounting pronouncements will not have a material impact on the condensed consolidated financial statements 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 ("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, 2023. Based on the evaluation of our disclosure controls and procedures as of June 30, 2023, 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***

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

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

We operate in a rapidly changing environment that involves a number of risks which could materially affect our business, financial condition or future results, some of which are beyond our control. In addition to the other information set forth in this Quarterly Report on Form 10-Q, the risks and uncertainties that we believe are most important for you to consider are discussed in Part I-Item 1A under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission ("SEC") on March 8, 2023. 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, 2022, 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 Sarl ("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. In August 2022, we submitted a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") for our lead product candidate, roluperidone. The FDA subsequently notified us that they would not accept the file for review, issuing a refusal to file letter ("RTF") in October 2022. In December 2022, following a Type A meeting held on November 30, 2022, the FDA confirmed the RTF remained in effect with respect to our NDA for roluperidone. On May 1, 2023, we announced that the FDA filed our NDA for roluperidone on April 27, 2023. The decision to file the NDA followed our request for formal dispute resolution and appeal of the October 2022 RTF. On May 8, 2023, we received confirmation from the FDA that the NDA for roluperidone has been assigned a standard review classification, and that the FDA has assigned a Prescription Drug User Fee Act ("PDUFA") goal date of February 26, 2024. The FDA advised that it identified potential review issues that had been previously cited in the RTF decision letter, which included those discussed at the Type C meeting in March 2022, namely: (i) the potential impact of roluperidone administration on the efficacy and safety of antipsychotic drugs, or more specifically, the psychiatric division (the "Division") wanted reassurance that those patients administered roluperidone who manifest worsening of schizophrenia symptoms and in the opinion of the clinician/investigators need treatment with antipsychotics, do not experience a diminished benefit of the antipsychotic treatment or unexpected adverse effects; (ii) the comparability of US and non-US schizophrenia patients, or more specifically, the Division wanted to be reassured that data collected in MIN-101C03 in non-US patients is applicable to US patients; (iii) supporting statistical evidence of efficacy of roluperidone on negative symptoms; and (iv) the ability of clinicians to identify patients who might benefit from roluperidone. See also the section titled "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—Clinical and Regulatory Updates—Type C Meeting" for more information. While the FDA filed the NDA for roluperidone, we may never succeed in any or all these activities and, even if we do, we may never generate sufficient revenue to achieve profitability.

We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we may never generate product revenue or achieve profitability. As of June 30, 2023, we had an accumulated deficit of approximately $380.0 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/or seek regulatory approvals for, roluperidone and other potential product candidates. If any of our product candidates fail in clinical trials or do not obtain 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. Failure to become and remain profitable may adversely affect the market price of shares of our common stock and our ability to raise capital and continue operations. 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 results of operations, financial position 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. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

Our operations and the historic operations of Sonkei and Mind-NRG have consumed substantial amounts of cash since inception. As of June 30, 2023, we had cash, cash equivalents, and restricted cash of $51.9 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 are 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 will require additional capital to continue advancing the development, regulatory approval process and potential commercialization of roluperidone and other potential product candidates that we may develop in the future. Because the length of time and activities associated with successful development of product candidates are highly uncertain, we are unable to estimate with certainty the actual funds we will require for development and any approved marketing and commercialization activities. Additional capital may not be available in sufficient amounts or on reasonable terms, if at all, and our ability to raise additional capital may be adversely impacted by global economic conditions, including the recent disruptions to and volatility in the credit and financial markets in the U.S. and worldwide resulting from the COVID-19 pandemic, the war in Ukraine and other factors. 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 European Commission, 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.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to delay, limit or terminate the development or commercialization of one or more of our product candidates or other operations, including potentially discontinue operations altogether. In addition, 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. Any of these events could significantly harm our business, financial condition and prospects, and our stockholders could lose all or part of their investment in our company.

We cannot give any assurance that any of our product candidates will receive regulatory approval in a timely manner or at all, which is necessary before they can be commercialized.

The regulatory approval process is expensive and the time required to obtain approval from the European Commission (following the opinion of the Committee of Medicinal Products for Human Use of the European Medicines Agency (“EMA”)), FDA or other comparable regulatory authorities in other jurisdictions to sell any product is uncertain and may take years.

Whether regulatory approval will be granted is unpredictable and depends upon numerous factors, including the substantial discretion of the regulatory authorities. Moreover, the filing of an application for regulatory approval, including NDA, or Biologics License Application ("BLA"), a Marketing Authorization Application ("MAA") in the EEA, or comparable foreign regulatory applications for approval, requires a payment of a significant user fee upon submission. The filing of applications for regulatory approval of our product candidates may be delayed due to our lack of financial resources to pay such user fee.

If, following submission, our application is not accepted for substantive review or approved, the EMA, FDA or other comparable foreign regulatory authorities may require that we conduct additional clinical or pre-clinical trials, provide additional data, manufacture additional validation batches or develop additional analytical tests methods before they will reconsider our application. On October 14, 2022, we received a refusal-to-file communication from the FDA for our NDA submission for roluperidone, our lead product candidate, which decision was confirmed by the FDA in a subsequent Type A meeting. On April 27, 2023, the FDA filed our NDA for roluperidone following our request for formal dispute resolution and appeal of the refusal-to-file letter. On May 8, 2023, we received confirmation from the FDA that our NDA for roluperidone had been assigned a standard review classification and a Prescription Drug User Fee Act ("PDUFA") goal date of February 26, 2024. The FDA also advised that it identified potential review issues that had been previously cited in the RTF decision letter, which included those discussed at the Type C meeting in March 2022, namely: (i) the potential impact of roluperidone administration on the efficacy and safety of antipsychotic drugs, or more specifically, the Division wanted reassurance that those patients administered roluperidone who manifest worsening of schizophrenia symptoms and in the opinion of the clinician/investigators need treatment with antipsychotics, do not experience a diminished benefit of the antipsychotic treatment or unexpected adverse effects; (ii) the comparability of US and non-US schizophrenia patients, or more specifically, the Division wanted to be reassured that data collected in MIN-101C03 in non-US patients is applicable to US patients; (iii) supporting statistical evidence of efficacy of roluperidone on negative symptoms; and (iv) the ability of clinicians to identify patients who might benefit from roluperidone. See also the section titled "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—Clinical and Regulatory Updates—Type C Meeting" for more information. Even though the NDA has been filed by the FDA, the review issues may prevent approval and result in a Complete Response Letter, potentially requiring additional studies. Additional studies and data would impose increased costs and delays in the regulatory approval process, which may require us to expend more resources than we have available. In addition, the EMA, FDA or other comparable foreign regulatory authorities may not consider any additional required trials, data or information that we perform or provide to be sufficient, or we may decide, or be required, to abandon the program.

Moreover, policies, regulations, or the type and amount of pre-clinical and clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. It is possible that none of our existing product candidates or any of our future product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- The EMA, FDA or other regulatory authorities may disagree with the design or implementation of our clinical trials.
- We may be unable to demonstrate to the satisfaction of the EMA, the European Commission, the FDA or other comparable regulatory authorities that a product candidate is safe and effective for its proposed indication.
- The results of clinical trials may not meet the level of statistical significance required by the EMA, the European Commission, FDA or other regulatory authorities for approval.
- We may be unable to demonstrate that a product candidate's clinical and other benefits outweigh any safety risks.
- The EMA, the European Commission, the FDA or other regulatory authorities may disagree with our interpretation of data from pre-clinical studies or clinical trials.
- The data collected from clinical trials of our product candidates may not be sufficient to support an NDA or other submission or to obtain regulatory approval in the United States or elsewhere.
- The national competent authorities of EU Member States, FDA or other regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies.
- The approval policies or regulations of the European Commission, FDA or other regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Even if we obtain approval for a particular product, regulatory authorities may approve that product for fewer or more limited indications, including more limited patient populations, than we request, may require that contraindications, warnings, or precautions be included in the product labeling, including a boxed warning, may grant approval contingent on the performance of costly post-marketing clinical trials or other post-market requirements, including risk evaluation and mitigation strategies ("REMS") or comparable foreign strategies, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product. Any of the foregoing could materially harm the commercial prospects for our product candidates.

Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties, including ongoing regulatory obligations and continued regulatory review. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to administrative sanctions or penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Even if we obtain regulatory approval for a product candidate, product candidates may be approved for fewer or more limited indications, including more limited subject populations, than we request, and regulatory authorities may require that contraindications, warnings, or precautions be included in the product labeling, including a black box warning, may grant approval contingent on the performance of costly post-marketing clinical trials or other post-market requirements, such as REMS or comparable foreign strategies, may require post-marketing surveillance, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. For instance, in 2007, the FDA requested that makers of all antidepressant medications update existing black box warnings about increased risk of suicidal thoughts and behavior in young adults, ages 18 to 24, during initial treatment. If approved for marketing, our drugs may be required to carry warnings similar to this and other class-wide warnings.

Any approved products would further be subject to ongoing requirements imposed by the FDA, and other comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, marketing, recordkeeping and reporting of safety and other post-market information. If there are any modifications to the drug, including changes in indications, labeling, manufacturing processes or facilities, or if new safety issues arise, a new or supplemental NDA, post-implementation notification or other reporting may be required or requested, which may require additional data or additional pre-clinical studies and clinical trials.

The EMA, FDA and other comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the EMA, FDA or other comparable foreign regulatory authorities become aware of new adverse safety information after approval of any of our product candidates, a number of potentially significant negative consequences could result, including:

- we may suspend marketing of, or withdraw or recall, such product;
- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings or otherwise restrict the product's indicated use, label, or marketing;
- the FDA or other comparable foreign regulatory authorities may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- the FDA may require the establishment or modification of a REMS or the EMA or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, require us to issue a medication guide outlining the risks of such side effects for distribution to subjects or restrict distribution of our products and impose burdensome implementation requirements on us;
- regulatory authorities may require that we conduct post-marketing studies or surveillance;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

In addition, manufacturers of drug products and their facilities, including contracted facilities, are subject to continual review and periodic inspections by national competent authorities of EU Member States, the FDA and other comparable foreign regulatory authorities for compliance with current Good Manufacturing Practices ("cGMP"), regulations and standards. The European Union cGMP guidelines are as set forth in Commission Directive 2003/94/EC of October 8, 2003. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, the product's stability (changes in levels of impurities or dissolution profile) or problems with the facility where the product is manufactured, we may be

subject to reporting obligations, additional testing and additional sampling, and a regulatory authority may impose restrictions on that product, the manufacturing facility, our suppliers, or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates, the manufacturing facilities for our product candidates, our CROs, or other persons or entities working on our behalf fail to comply with applicable regulatory requirements either before or after regulatory approval, a regulatory authority may, depending on the stage of product development and approval:

- issue adverse inspectional findings;
- issue Warning Letters or Untitled Letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- amend and update labels or package inserts;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil, criminal and/or administrative penalties, damages or monetary fines or imprisonment;
- suspend or withdraw regulatory approval;
- suspend or terminate any ongoing clinical studies;
- bar us from submitting or assisting in the submission of new regulatory applications;
- refuse to approve pending applications or supplements to applications filed by us;
- refuse to allow us to enter into government contracts;
- suspend or impose restrictions on operations, including restrictions on marketing or manufacturing of the product, or the imposition of costly new manufacturing requirements or use of alternative suppliers; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

Our product candidates and the activities associated with their development and commercialization in the United States, including, but not limited to, their advertising and promotion, will further be heavily scrutinized by the FDA, the United States Department of Justice, the United States Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress and the public. Violations of applicable law, including advertising, marketing and promotion of our products for unapproved (or off-label) uses, are subject to enforcement letters, inquiries and investigations, and civil, criminal and/or administrative sanctions by regulatory authorities. Additionally, comparable foreign regulatory authorities will heavily scrutinize advertising and promotion of any product candidate that obtains approval outside of the United States. In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Although general requirements for advertising and promotion of medicinal products are established under EU legislation, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities in connection with an MA. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. Direct-to-consumer advertising of prescription medicinal products is also prohibited in the EU. Enforcement of advertising and promotional requirements relating to medicinal products in the EU is carried out at the national level by the national competent authorities of EU Member States. Furthermore, in the United Kingdom the code of practice of the Association of the British Pharmaceutical Industry (the lead United Kingdom trade association) is considerably stricter than applicable legislative requirements.

In the United States, engaging in the impermissible promotion of products for off-label uses can also subject the entity engaging in such conduct to false claims litigation under federal and state statutes, which can lead to civil, criminal and/or administrative penalties, damages, monetary fines, disgorgement, exclusion from participation in Medicare, Medicaid and other federal healthcare programs, curtailment or restructuring of its operations and agreements that materially restrict the manner in which it promotes or distributes drug products. Accordingly, we are subject to the federal civil False Claims Act, which prohibits persons and entities from knowingly filing, or causing to be filed, a false claim, or the knowing use of false statements, to obtain payment from the federal government. Certain suits filed under the civil False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, commonly known as "whistleblowers," may share in certain amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the civil False Claims Act, it may be required to pay

up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Various states have also enacted laws modeled after the federal civil False Claims Act. We are also subject to the federal criminal False Claims Act, which imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing such claim to be false, fictitious, or fraudulent. Additionally, we may be subject to civil monetary penalties that may be imposed against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to substantial civil and criminal settlements regarding certain sales practices, including promoting off-label drug uses. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claims action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and/or be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our products, we may become subject to such litigation, which may have a material adverse effect on our business, financial condition and results of operations. Failure to comply with EU and EU Member State laws that apply to the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products and marketing of such products, both before and after grant of the marketing authorization, or with other applicable regulatory requirements may result in administrative, civil or criminal penalties.

These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

The policies of the FDA, the competent authorities of the EU Member States, the European Commission and other comparable regulatory authorities with respect to drugs or clinical trials may change and additional government regulations may be enacted. As an example, the regulatory landscape related to clinical trials in the EU has evolved. The EU Clinical Trials Regulation ("CTR"), which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR permits trial sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment of some elements of the application by all EU Member States in which the trial is to be conducted, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State's decision is communicated to the sponsor through a centralized EU portal. The CTR provides a three-year transition period. The extent to which ongoing clinical trials will be governed by the CTR varies. For clinical trials in relation to which application for approval was made on the basis of the Clinical Trials Directive before January 31, 2023, the Clinical Trials Directive will continue to apply on a transitional basis for three years until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. Our compliance with the CTR requirements and that of our third-party service providers, such as CROs, may impact our developments plans.

On April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation. If adopted in the form proposed, the recent European Commission proposals to revise the existing EU laws governing authorization of drugs may result in a decrease in data and market exclusivity for our product candidates in the EU.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

A variety of risks associated with international operations could materially adversely affect our business.

We own one Swiss subsidiary, expect to engage in significant cross-border activities, and we will be subject to risks related to international operations, including:

- different regulatory requirements for conduct of clinical trials of investigational drugs and obtaining and maintaining approval of drugs in foreign countries;
- reduced protection for contractual and intellectual property rights in certain countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, political instability in particular foreign economies and markets, such as the instability caused by Russia's invasion of Ukraine, or public health issues or pandemics, such as the COVID-19 pandemic;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

- compliance with tax laws of various jurisdictions, including with respect to intercompany transfer pricing arrangements and taxable nexus;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in North America;
- tighter restrictions on privacy and the collection and use of patient data; and
- business interruptions resulting from geopolitical actions, including political instability, hostilities, war and terrorism, such as the war in Ukraine, or natural disasters including pandemics, earthquakes, typhoons, floods and fires.

If any of these issues were to occur, our business could be materially harmed.

In addition, we publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

The United Kingdom's withdrawal from the EU may have a negative effect on global economic conditions, financial markets and our business, which could reduce the price of our common stock.

Following the result of a referendum in 2016, the United Kingdom ("UK") left the EU on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the EU, the UK, was subject to a transition period until December 31, 2020, or the Transition Period, during which EU rules continued to apply. The UK and the EU have signed a EU-UK Trade and Cooperation Agreement ("TCA"), which became provisionally applicable on January 1, 2021 and entered into force on May 1, 2021. This agreement provides details on how some aspects of the UK and EU's relationship will operate going forwards however there are still many uncertainties. The TCA primarily focuses on ensuring free trade between the EU and the UK in relation to goods, including drugs. Although the body of the TCA includes general terms which apply to drugs, greater detail on sector-specific issues is provided in an Annex to the TCA. The Annex provides a framework for the recognition of Good Manufacturing Practice (GMP), inspections and for the exchange and acceptance of official GMP documents. The regime does not, however, extended to procedures such as batch release certification. Among the changes that have occurred are that Great Britain (England, Scotland and Wales) is treated as a "third country," a country that is not a member of the EU and whose citizens do not enjoy the EU right to free movement. Northern Ireland continues to follow many aspects of the EU regulatory rules, particularly in relation to trade in goods. As part of the TCA, the EU and the UK recognize GMP inspections carried out by the other party and the acceptance of official GMP documents issued by the other party. The TCA also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release. The UK has unilaterally agreed to accept EU batch testing and batch release. However, the EU continues to apply EU laws that require batch testing and batch release to take place in the EU territory. This means that drugs that are tested and released in the UK must be retested and re-released when entering the EU market for commercial use. As it relates to marketing authorizations, Great Britain has a separate regulatory submission process, approval process and a separate national marketing authorization. Northern Ireland continues, however, to be covered by the marketing authorizations granted by the European Commission. For example, the scope of a marketing authorization for a drug granted by the European Commission or by the competent authorities of EU Member States will no longer encompass Great Britain (England, Scotland and Wales). In these circumstances, a separate marketing authorization granted by the UK competent authorities is required to place drugs on the market in Great Britain.

On February 27, 2023, the European Commission and the UK government reached a political agreement in principle, commonly referred to as the "Windsor Framework". The purpose of the agreement is to establish a set of joint solutions that would allow goods to be traded between Great Britain and Northern Ireland and between Northern Ireland and Ireland whilst ensuring the integrity of the EU Single Market. New legislation must be passed by the UK and the EU in order to implement the provisions of the Windsor Framework, including those that relate to drugs. The implementation of the framework is set to take place in stages with measures relating to drugs taking effect in January 2025. The Windsor Framework provides, however, that drugs to be placed on the market in Northern Ireland will be authorized solely in accordance with UK laws.

In relation to clinical trials, it is currently unclear to what extent the UK will seek to align its regulations with the EU in the future. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). However, the Retained EU Law (Revocation and Reform) Bill which received Royal Assent on 29 June 2023 and is intended to remove certain EU-derived legislation from the UK statute book by the end of 2023, may result in a divergence of approach between the EU and the UK. On January 17, 2022, the UK Medicines and Healthcare products Regulatory Agency, or MHRA, launched an eight-week consultation on reframing the UK legislation for clinical trials. The consultation closed on March 14, 2022. The outcome of the consultation will be closely watched and will determine whether the UK chooses to align with the regulation or diverge from it to maintain regulatory flexibility. A decision by the UK not to closely align its regulations with the new approach that will be adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries and/or make it harder to seek a marketing authorization in the EU for our product candidates on the basis of clinical trials conducted in the UK.

Since a significant proportion of the regulatory framework in the UK is derived from EU Directives and Regulations, Brexit, following the Transition Period, could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the UK or the EU, now that UK legislation has the potential to diverge from EU legislation. All of these changes could increase our costs and otherwise adversely affect our business. Any delay in obtaining, or an inability to obtain, any regulatory approvals for our product candidates, as a result of Brexit or otherwise, could prevent us from commercializing our product candidates in the UK or the EU and restrict our ability to generate revenue and achieve and sustain profitability. In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of our product candidates into the EU. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the UK or the EU for our product candidates, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the UK.

Even if we commercialize any of our product candidates, these products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

The laws that govern regulatory approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. In many countries, the pricing review period begins after marketing or product licensing approval is granted. Some countries require approval of the sale price of a drug before it can be marketed or soon thereafter. Additionally, in some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates even if our product candidates obtain regulatory approval.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In the European Union (“EU”), the pricing and reimbursement schemes of drugs is governed by the national legislation of each EU Member State and also vary widely from country to country. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of regulatory approval for a product. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval. This Health Technology Assessment (“HTA”) process, which is currently governed by the national laws of the individual EU Member States, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given drug in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific drugs will often influence the pricing and reimbursement status granted to these drugs by the competent authorities of individual EU Member States. In December 2021, a Regulation governing health technologies assessment was adopted. The Regulation is intended to boost cooperation among EU Member States in assessing health technologies, including new drugs, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The HTA Regulation will apply from January 12, 2025.

In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures in the current economic climate in the European Union. There is very limited harmonization between EU Member States regarding pricing and reimbursement practices.

Legislators, policymakers and healthcare insurance funds in the EU may continue to propose and implement cost-containing measures to keep healthcare costs down; particularly due to the financial strain that the COVID-19 pandemic has placed on national healthcare systems of the EU Member States. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of EU and other foreign countries use prices for drugs established in other countries as "reference prices" to help determine the price of the product in their own territory. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced EU Member States, can further reduce prices. In particular, Germany, Portugal and Spain have all introduced a number of short-term measures to lower healthcare spending, including mandatory discounts, clawbacks and price referencing rules, which could have a material adverse effect on our business. Consequently, a downward trend in prices of drugs in some countries could contribute to similar downward trends elsewhere.

There can be no assurance that our products will be considered cost-effective, that an adequate level of reimbursement will be available or that a foreign country's reimbursement policies will not adversely affect our ability to sell our products profitably.

If reimbursement of our drugs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

Our ability to commercialize any products successfully will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities and other third-party payors, such as private health insurers and health maintenance organizations. Government authorities and other third-party payors determine which medications they will cover and establish reimbursement levels. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

Government authorities and other third-party payors are developing increasingly sophisticated methods of controlling healthcare costs, such as by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices as a condition of coverage, are using restrictive formularies and preferred drug lists to leverage greater discounts in competitive classes, and are challenging the prices charged for medical products. In addition, in the United States, federal programs impose penalties on drug manufacturers in the form of mandatory additional rebates and/or discounts if commercial prices increase at a rate greater than the Consumer Price Index-Urban, and these rebates and/or discounts, which can be substantial, may impact our ability to raise commercial prices. Further, in the United States there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Additionally, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain regulatory approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain regulatory approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the European Commission, FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Prices paid for a drug also vary depending on the class of trade. Prices charged to government customers and certain customers that receive federal funds are subject to price controls, and private institutions may obtain discounts through group purchasing organizations or use formularies to leverage discounts. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Presidential executive orders, Congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, in July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at prescription drugs. In response to Biden’s executive order, on September 9, 2021, the U.S. Department of Health and Human Services (“HHS”) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (“IRA”) into law which, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. These provisions will take effect progressively starting in fiscal year 2023, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, in response to the Biden administration’s October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. At the state level, legislatures are passing increasing amounts of legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims); fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) personal data and other sensitive data, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, sensitive third-party data, and employee data. Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws (e.g. Section 5 of the Federal Trade Commission Act). For example, the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. In addition, the California Consumer Privacy Act of 2018 as amended by the California Privacy Rights Act of 2020 (“CPRA”) (collectively, “CCPA”) applies to personal information of consumers, business representatives, and employees who are California residents, requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for civil penalties of up to $7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages.

Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data maintained about California residents.

In addition, the CPRA expanded the CCPA's requirements, adds a new right for individuals to correct their personal information, and establishes a new regulatory agency to implement and enforce the law. Other states, such as Virginia, Colorado and Utah, have also passed comprehensive privacy laws, and similar laws are being considered in several other states. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts, and may increase legal risk and compliance costs for us, the third parties upon whom we rely. In addition, data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts.

Outside the United States, an increasing number of laws, regulations, and industry standards may apply to data privacy and security, including the European Union's General Data Protection Regulation ("EU GDPR"), the United Kingdom's GDPR ("UK GDPR"), imposes strict requirements for processing personal data, and violators of these laws face significant penalties. For example, under the EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros / 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data, as well as other adverse consequences. In particular we may be unable to import personal data to the United States, which could significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with parties that are subject to such cross-border data transfer or localization laws; or requiring us to increase our personal data processing capabilities and infrastructure in foreign countries at significant expense. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

In addition to data privacy and security laws, we may be contractually subject to data privacy and security obligations, including industry standards adopted by industry groups and may become subject to new data privacy and security obligations in the future. For example, certain privacy laws require our customers to impose specific contractual restrictions on their service providers. We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security are quickly changing, becoming increasingly stringent and, creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources. These obligations may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed in our efforts to comply with our data privacy and security obligations). Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including proceedings against us by governmental entities or others.

If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims); additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

In the ordinary course of our business, we or the third parties upon which we rely, may process proprietary, confidential, and sensitive data, including personal data (such as health-related data and data related to clinical trials), intellectual property, and trade secrets (collectively, sensitive information).

Cyberattacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats.

In particular, ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners’ supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third-party information technology systems that support us and our services. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities’ systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program. Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

We may rely upon third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email, content delivery to customers, and other functions. Our ability to monitor these third parties’ information security practices is limited, and these third parties may not have adequate information security measures in place. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties’ infrastructure in our supply chain or our third-party partners’ supply chains have not been compromised. We may also share or receive sensitive information with or from third parties.

Any of the previously identified or similar threats could cause a security incident or other interruption. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our services. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures, or those of a third party upon whom we rely, will be effective. For example, an external contractor experienced a cyberattack in 2019, which resulted in a disruption to patient recruitment in our Phase 3 clinical trial of roluperidone. We may be unable in the future to detect vulnerabilities in our information technology systems. We take steps to detect and remediate vulnerabilities, but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. Despite our efforts to identify and address vulnerabilities, if any, in our information technology systems, our efforts may not be successful. These vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may negatively impact our ability to grow and operate our business. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

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

None.

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 (File No. 333-195169) 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 quarterly report on Form 10-Q (File No. 001-36517) filed with the SEC on November 4, 2019)
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Minerva Neurosciences, Inc., effective June 17, 2022 (incorporated by reference to Exhibit 3.1 to the Registration's current report on Form 8-K (File No. 001-36517) filed with the SEC on June 17, 2022).
4.1	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's current report on Form 8-K (File No. 001-36517) filed with the SEC on June 28, 2023).
10.1	Securities Purchase Agreement, dated June 27, 2023, by and among Minerva Neurosciences, Inc. and the purchasers party thereto (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K (File No. 001-36517) filed with the SEC on June 28, 2023).
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	Cover Page Interactive Data file (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 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/ Frederick Ahlholm

Frederick Ahlholm
Chief Financial Officer
(Principal Financial Officer)
(On behalf of the Registrant)

Date: August 1, 2023

EXHIBIT 31.1

CERTIFICATION

I, Remy Luthringer, certify that:

1. I have reviewed this Form 10-Q of Minerva Neurosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

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

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

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

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

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

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

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

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

Date: August 1, 2023

/s/ Remy Luthringer Ph.D.

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

EXHIBIT 31.2

CERTIFICATION

I, Frederick Ahlholm, 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 1, 2023

/s/ Frederick Ahlholm

Frederick Ahlholm

Chief Financial Officer

(Principal Financial Officer)

EXHIBIT 32.1

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Remy Luthringer, Executive Chairman and Chief Executive Officer (Principal Executive Officer) of Minerva Neurosciences, Inc. (the "Company") and Frederick Ahlholm, 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, 2023, to which this Certification is attached as Exhibit 32.1 (the "Quarterly Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

/s/ Remy Luthringer, Ph.D.

Date: August 1, 2023

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

/s/ Frederick Ahlholm

Date: August 1, 2023

Frederick Ahlholm
Chief Financial Officer
(Principal Financial Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be 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.