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 September 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 November 2, 2023 was 6,993,406.

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

This Quarterly Report on Form 10-Q contains forward-looking statements. These forward-looking statements reflect our plans, estimates and beliefs. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "would" and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Because of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not transpire. These risks and uncertainties include, but are not limited to, the risks included in this Quarterly Report on Form 10-Q under Part II, Item IA, "Risk Factors" and in our Annual Report on Form 10-K for the year ended December 31, 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)

	September 30, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 46,903,960	$ 36,093,606
Restricted cash	100,000	100,000
Refundable regulatory fee	—	3,117,218
Prepaid expenses and other current assets	1,221,220	848,117
Total current assets	48,225,180	40,158,941
Equipment, net	12,245	16,326
Capitalized software, net	23,412	42,567
Goodwill	14,869,399	14,869,399
Total assets	**$ 63,130,236**	**$ 55,087,233**
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities		
Accounts payable	$ 1,395,070	$ 969,667
Accrued expenses and other current liabilities	1,954,590	407,909
Total current liabilities	3,349,660	1,377,576
Liability related to the sale of future royalties	79,826,671	73,733,876
Total liabilities	83,176,331	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 September 30, 2023 and December 31, 2022, respectively	—	—
Common stock; $0.0001 par value; 125,000,000 shares authorized; 6,993,406 and 5,340,193 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	699	534
Additional paid-in capital	367,746,175	346,785,322
Accumulated deficit	(387,792,969)	(366,810,075)
Total stockholders' (deficit) equity	(20,046,095)	(20,024,219)
Total liabilities and stockholders' (deficit) equity	**$ 63,130,236**	**$ 55,087,233**

See accompanying notes to condensed consolidated financial statements

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Expenses				
Research and development	$ 3,443,537	$ 2,367,364	$ 7,984,566	$ 11,459,205
General and administrative	2,635,583	2,839,784	7,963,067	8,702,390
Total expenses	6,079,120	5,207,148	15,947,633	20,161,595
Loss from operations	(6,079,120)	(5,207,148)	(15,947,633)	(20,161,595)
Foreign exchange (losses) gains	(5,096)	2,063	(20,988)	(135)
Investment income	348,681	180,091	1,078,522	259,886
Non-cash interest expense for the sale of future royalties	(2,084,911)	(1,875,482)	(6,092,795)	(5,480,775)
Net loss	$ (7,820,446)	$ (6,900,476)	$ (20,982,894)	$ (25,382,619)
Net loss per share, basic and diluted	$ (1.03)	$ (1.29)	$ (3.41)	$ (4.75)
Weighted average shares outstanding, basic and diluted	7,568,981	5,340,193	6,148,276	5,340,195

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)**
Stock-based compensation	—	—	1,036,874	—	1,036,874
Net loss	—	—	—	(6,900,476)	(6,900,476)
Balances at September 30, 2022	**5,340,193**	**$ 534**	**$ 345,837,638**	**$ (360,084,018)**	**$ (14,245,846)**
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)**
Stock-based compensation	—	—	371,943	—	371,943
Costs related to issuance of common stock and warrants	—	—	(86,691)	—	(86,691)
Net loss	—	—	—	(7,820,446)	(7,820,446)
Balances at September 30, 2023	**6,993,406**	**$ 699**	**$ 367,746,175**	**$ (387,792,969)**	**$ (20,046,095)**

See accompanying notes to condensed consolidated financial statements.

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (20,982,894)	$ (25,382,619)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4,081	—
Amortization of capitalized software	19,155	2,128
Stock-based compensation expense	1,357,317	3,161,135
Non-cash interest expense associated with the sale of future royalties	6,092,795	5,480,775
Changes in operating assets and liabilities		
Refundable regulatory fee	3,117,218	(3,117,218)
Prepaid expenses and other current assets	(373,103)	(57,173)
Accounts payable	425,403	(1,320,327)
Accrued expenses and other current liabilities	1,546,681	698,232
Net cash used in operating activities	(8,793,347)	(20,535,067)
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	(396,293)	—
Fees paid in connection with the reverse stock split fractional shares	—	(5)
Net cash provided by (used in) financing activities	19,603,701	(5)
Net increase (decrease) in cash, cash equivalents and restricted cash	10,810,354	(20,535,072)
Cash, cash equivalents and restricted cash		
Beginning of period	36,193,606	60,855,080
End of period	$ 47,003,960	$ 40,320,008
Reconciliation of the Condensed Consolidated Statements of Cash Flows to the Condensed Consolidated Balance Sheets		
Cash and cash equivalents	$ 46,903,960	$ 40,220,008
Restricted cash	100,000	100,000
Total cash, cash equivalents and restricted cash	$ 47,003,960	$ 40,320,008

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 September 30, 2023, the Company had an accumulated deficit of approximately $387.8 million and net cash used in operating activities was approximately $8.8 million during the nine months ended September 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 September 30, 2023, the Company had cash, cash equivalents, and restricted cash of $47.0 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 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.

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 September 30, 2023, the results of operations for the three and nine months ended September 30, 2023 and 2022 and cash flows for the nine months ended September 30, 2023 and 2022. The results of operations for the three and nine months ended September 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 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 September 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:

	September 30, 2023	December 31, 2022
Research and development costs and other accrued expenses	$ 656,341	$ 279,434
Accrued bonus	1,089,783	14,832
Professional fees	128,225	113,643
Vacation pay	80,241	—
Accrued expenses and other current liabilities	$ 1,954,590	$ 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 September 30, 2023.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net loss	$ (7,820,446)	$ (6,900,476)	$ (20,982,894)	$ (25,382,619)
Weighted average shares of common stock outstanding	7,568,981	5,340,193	6,148,276	5,340,195
Net loss per share of common stock – basic and diluted	$ (1.03)	$ (1.29)	$ (3.41)	$ (4.75)

The following securities outstanding at September 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Common stock options	735,929	467,429	735,929	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 September 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 September 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 September 30, 2023:

	September 30, 2023
Upfront payment from the sale of future royalties	$ 60,000,000
Non-cash interest expense associated with the sale of future royalties	19,826,671
Liability related to the sale of future royalties	$ 79,826,671

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 nine months ended September 30, 2023. The Company incurred approximately $0.4 million in offering expenses as of September 30, 2023, which have been included as a component of additional paid-in capital, resulting in net proceeds of $19.6 million as of September 30, 2023.

Pursuant to the Securities Purchase Agreement, the Company filed a registration statement on Form S-3 (File No. 333-273686), which was declared effective by the SEC on August 9, 2023, covering the resale of the Registrable Securities (as such term is defined in the Securities Purchase Agreement). 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).

Pursuant to the Securities Purchase Agreement, in connection with the Private Placement, Boehringer Ingelheim International GmbH ("BI"), 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). BI designated a board observer on August 29, 2023.

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 nine months ended September 30, 2023, no shares of the Company's common stock were issued or sold under the Sales Agreement. As of September 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 term loans were repaid in August 2018, all related warrants were outstanding and exercisable as of September 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 nine months ended September 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	62,500	$ 7.30		
Exercised	—	$ —		
Forfeited	(27,500)	$ 36.60		
Outstanding September 30, 2023	735,929	$ 14.19	8.1	$ 1,037
Exercisable September 30, 2023	301,197	$ 27.33	6.7	$ 85
Available for future grant	783,666			

The weighted average grant-date fair value of stock options outstanding on September 30, 2023 was $9.88 per share. Total unrecognized compensation costs related to non-vested stock options at September 30, 2023 were approximately $1.6 million and are expected to be recognized within future operating results over a weighted-average period of 2.1 years. The total intrinsic value of the options exercised during the nine months ended September 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 volatility of the Company and volatilities for industry peer companies. 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 nine months ended September 30, 2023 and 2022, the Company utilized the following assumptions:

	Nine Months Ended	
	September 30, 2023	September 30, 2022
Expected term (years)	5.50	5.50 - 6.25
Risk free interest rate	4.68%	1.96% - 3.25%
Volatility	119%	76% - 97%
Dividend yield	0%	0%
Weighted average grant date fair value per share of common stock	$6.26	$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 used 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 cost related to non-vested stock options at September 30, 2023 was approximately $0.2 million and is expected to be recognized within future operating results over a weighted-average period of 0.3 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 September 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 September 30, 2023, representing 50% of the incremental cost of the PRSUs granted under the Exchange Program. 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 following table presents stock-based compensation expense included in the Company's consolidated statements of operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	$ 185,075	$ 518,920	$ 667,558	$ 1,534,899
General and administrative	186,868	517,954	689,759	1,626,236
Total	$ 371,943	$ 1,036,874	$ 1,357,317	$ 3,161,135

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 September 30, 2023 and December 31, 2022, we had an accumulated deficit of $387.8 million and $366.8 million, respectively. For the nine months ended September 30, 2023 and 2022, we recorded net losses of $21.0 million and $25.4 million, respectively.

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 September 30, 2023 versus September 30, 2022

Research and Development Expenses

Research and development expenses were $3.4 million and $2.4 million for the three months ended September 30, 2023 and 2022, respectively, an increase of approximately $1.0 million. The increase in research and development expenses was primarily due to higher costs associated with the FDA's review of our NDA for roluperidone during 2023. Non-cash stock compensation costs included in research and development expenses were $0.2 million and $0.5 million for the three months ended September 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 September 30, 2023 and 2022, respectively, a decrease of approximately $0.2 million. The decrease in general and administrative expenses was primarily due to lower non-cash stock compensation costs. Non-cash stock compensation costs included in general and administrative expenses were $0.2 million and $0.5 million for the three months ended September 30, 2023 and 2022, respectively.

Foreign Exchange (Losses) Gains

Foreign exchange losses were $5 thousand and foreign exchange gains were $2 thousand for the three months ended September 30, 2023 and 2022, respectively, a decrease of $7 thousand, primarily due to currency movements.

Investment Income

Investment income was $0.3 million and $0.2 million for the three months ended September 30, 2023 and 2022, respectively, an increase of approximately $0.1 million, 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 $2.1 million and $1.9 million for the three months ended September 30, 2023 and 2022, respectively, an increase of $0.2 million. We amortize non-cash interest expense for the difference between the balance of the liability related to the sale of future royalties and the estimated amount of future royalties to be received over the royalty period.

Comparison of Nine Months Ended September 30, 2023 versus September 30, 2022

Research and Development Expenses

Research and development expenses were $8.0 million and $11.5 million for the nine months ended September 30, 2023 and 2022, respectively, a decrease of approximately $3.5 million. The decrease in research and development expenses was primarily due to lower costs related to the preparation of our NDA for roluperidone, which was submitted during 2022. Non-cash stock compensation costs included in research and development expenses were $0.7 million and $1.5 million for the nine months ended September 30, 2023 and 2022, respectively.

General and Administrative Expenses

General and administrative expenses were $8.0 million and $8.7 million for the nine months ended September 30, 2023 and 2022, respectively, a decrease of approximately $0.7 million. The decrease in general and administrative expenses was primarily due to lower non-cash stock compensation costs. Non-cash stock compensation costs included in general and administrative expenses were $0.7 million and $1.6 million for the nine months ended September 30, 2023 and 2022, respectively.

Foreign Exchange Losses

Foreign exchange losses were $21 thousand and zero for the nine months ended September 30, 2023 and 2022, respectively, an increase of $21 thousand, primarily due to currency movements.

Investment Income

Investment income was $1.1 million and $0.3 million for the nine months ended September 30, 2023 and 2022, respectively, an increase of approximately $0.8 million, 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 $6.1 million and $5.5 million for the nine months ended September 30, 2023 and 2022, respectively, an increase of $0.6 million. We amortize non-cash interest expense for the difference between the balance of the liability related to the sale of future royalties and the estimated amount of future royalties to be received over the royalty period.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2023, we had an accumulated deficit of approximately $387.8 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 September 30, 2023, we had approximately $47.0 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 $0.4 million in offering expenses as of September 30, 2023, which have been included as a component of additional paid-in capital, resulting in net proceeds of $19.6 million as of September 30, 2023.

Pursuant to the Securities Purchase Agreement, we filed a registration statement on Form S-3 (File No. 333-273686), which was declared effective by the SEC on August 9, 2023, covering the resale of the Registrable Securities (as such term is defined in the Securities Purchase Agreement). 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).

Pursuant to the Securities Purchase Agreement, in connection with the Private Placement, Boehringer Ingelheim International GmbH ("BI"), 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). BI designated a board observer on August 29, 2023.

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 nine months ended September 30, 2023, no shares of our common stock were issued or sold under the Sales Agreement. As of September 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, geopolitical conflicts 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.

	Nine Months Ended September 30,	
	2023	2022
	(dollars in millions)	
Net cash (used in) provided by:		
Operating activities	$ (8.8)	$ (20.5)
Investing activities	—	—
Financing activities	19.6	—
Net increase (decrease) in cash	$ 10.8	$ (20.5)

Net Cash Used in Operating Activities

Net cash used in operating activities of approximately $8.8 million during the nine months ended September 30, 2023 was primarily due to our net loss of $21.0 million and a $0.4 million increase in prepaid expenses, partially offset by non-cash interest expense for the sale of future royalties of $6.1 million, a $3.1 million decrease in refundable regulatory fees, a $1.5 million increase in accrued expenses, stock-based compensation expense of $1.4 million, and an approximately $0.5 million increase in accounts payable.

Net cash used in operating activities of approximately $20.5 million during the nine months ended September 30, 2022 was primarily due to our net loss of $25.4 million, a $3.1 million increase in refundable regulatory fees, a $1.3 million decrease in accounts payable, and a $0.1 million increase in prepaid expense, partially offset by non-cash interest expense for the sale of future royalties of $5.5 million, stock-based compensation expense of $3.2 million, and an increase in accrued expenses of $0.7 million.

Net Cash Provided by Investing Activities

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

Net Cash Provided by Financing Activities

Net cash provided by financing activities of approximately $19.6 million during the nine months ended September 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 nine months ended September 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 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 nine months ended September 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 September 30, 2023. Based on the evaluation of our disclosure controls and procedures as of September 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 September 30, 2023, we had an accumulated deficit of approximately $387.8 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 September 30, 2023, we had cash, cash equivalents, and restricted cash of $47.0 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, geopolitical conflicts 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.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could negatively impact our business.

The ability of the FDA to review and approve proposed clinical trials or new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities.

If a prolonged government shutdown occurs, or if global health concerns, such as the COVID-19 pandemic, prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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, additional safety monitoring, 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. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP, regulations and GCPs, for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products.

In addition, 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, marketing authorization application or comparable foreign application, post-implementation notification, application for a variation or an existing marketing authorization, or other reporting may be required or requested, which may require additional data or additional pre-clinical studies and clinical trials.

Clinical trials of our product candidates are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. 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 restrict or suspend marketing of such product or the manufacturing process for any component thereof, or withdraw, recall or seize, such product;
- regulatory authorities may withdraw, vary, or suspend 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 issue a conditional approval and we may fail to fulfill the requirements of the conditional approval;
- regulatory authorities may require that we conduct post-marketing studies or surveillance;
- initiation of regulatory investigations and government enforcement actions;
- 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 2017/1572 of October 15, 2017. Despite our efforts to audit and verify regulatory compliance, third-party manufacturing vendors may be found on regulatory inspection by the FDA or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations. This may result in shutdown of the third-party vendor or invalidation of drug product lots or processes. In some cases, a product recall may be warranted or required, which would materially affect our ability to supply and market our drug products. 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, vary or withdraw regulatory approval;
- suspend, vary or terminate any ongoing clinical studies;
- bar us from submitting or assisting in the submission of new regulatory applications;
- refuse to approve or delay approval of 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 a marketing authorization. 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, national or industry codes of conduct or practice, such as the Association of the British Pharmaceutical Industry (the United Kingdom innovative pharmaceutical industry trade association) code of practice, may established additional, stricter requirements 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 geopolitical conflicts, 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.

Our common stock may be delisted from The Nasdaq Capital Market which could negatively impact the price of our common stock, liquidity and our ability to access the capital markets.

Our common stock is currently listed on The Nasdaq Capital Market under the symbol "NERV." The listing standards of The Nasdaq Capital Market provide that a company, in order to qualify for continued listing, must maintain a minimum stock price of $1.00 and satisfy standards relative to minimum stockholders' equity, minimum market value of publicly held shares and various additional requirements. If Nasdaq delists our securities from trading on its exchange for failure to meet the listing standards, we and our stockholders could face significant negative consequences including:

- limited availability of market quotations for our securities;
- a determination that the common stock is a "penny stock" which would require brokers trading in the common stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for shares of common stock;
- a limited amount of analyst coverage, if any; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

Delisting from The Nasdaq Capital Market could also result in other negative consequences, including the potential loss of confidence by suppliers, customers and employees, the loss of institutional investor interest and fewer business development opportunities.

There can be no assurance that we will be able to maintain compliance and remain in compliance in the future. In particular, our share price may continue to decline for a number of reasons, including many that are beyond our control. See the risk factor captioned "*The market price of our stock may be volatile, and you could lose all or part of your investment*", described in our Annual Report on Form 10-K for the year ended December 31, 2022.

If we fail to comply with the continued listing standards of The Nasdaq Capital Market, we may seek to list our common stock on the NYSE American or on a regional stock exchange or, if one or more broker-dealer market makers comply with applicable requirements, the over-the-counter ("OTC") market. Listing on such other market or exchange could reduce the liquidity of our common stock. If our common stock were to trade in the OTC market, an investor would find it more difficult to dispose of, or to obtain accurate quotations for the price of, the common stock. Delisting of the common stock could depress our stock price, substantially limit liquidity of our common stock and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Further, delisting of the common stock would likely result in the common stock becoming a "penny stock" under the Exchange Act.

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. 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. The regime does not, however, extended to procedures such as batch release certification. 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. 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. Under the terms of the Northern Ireland Protocol, Northern Ireland continues to follow many aspects of the EU regulatory rules, particularly in relation to trade in goods. Northern Ireland continues, 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 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 Framework is intended to revise the Northern Ireland Protocol to address some of the perceived shortcomings in its operation. The agreement was adopted at the Withdrawal Agreement Joint Committee on March 24, 2023. If the changes are adopted in the form proposed, medicinal products to be placed on the market in the UK will be authorized solely in accordance with UK laws. Northern Ireland would be reintegrated back into a UK-only regulatory environment under the authority of the MHRA with respect to all medicinal products. The implementation of the Windsor Framework would occur in stages, with new arrangements relating to the supply of medicinal products into Northern Ireland anticipated to take effect in 2025.

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). 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. On 12 October 2023, the MHRA introduced a new Notification Scheme to enable a more streamlined and risk-proportionate approach to the processing of initial clinical trial applications for Phase 3 and Phase 4 clinical trials. This new scheme forms part of the review of the regulatory framework governing clinical trials in the UK. Further initiatives adopted by the UK Government with respect to the regulation of clinical trials following 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 take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, 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) and mass arbitration demands; 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, such as those noted below. 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 information maintained about California residents.

In addition, the CPRA expanded the CCPA's requirements 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. These state laws and the CCPA create certain rights for individuals concerning their personal information, including the right to access, correct, delete, and opt-out of certain processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. 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 and 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") and the United Kingdom's GDPR ("UK GDPR") (collectively, "GDPR"), which impose strict requirements for processing personal data. Violators of these laws face significant penalties. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under EU GDPR / 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, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in the Framework), 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 (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating 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) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. 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 deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, 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, attacks enhanced or facilitated by AI, 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, ability to provide our products or services, 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. 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 or our information technology systems, or those of the third parties upon whom we rely. 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. Unremediated high risk or critical 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 or disrupt our ability to develop and provide our products and services. 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. Additionally, our sensitive could be leaked, disclosed, or revealed as a result of or in connection with our employee's, personnel's, or vendor's use of generative AI technologies.

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).
10.1*†	Amended and Restated Non-Employee Director Compensation Plan.
10.2*†	Amended and Restated 2013 Equity Incentive Plan.
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)

* Filed herewith.
† Indicates management contract or compensatory plan or arrangement.
+ 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: November 7, 2023

EXHIBIT 10.1

AMENDED AND RESTATED NON-EMPLOYEE DIRECTOR COMPENSATION PLAN

Approved: March 7, 2018
Effective: April 1, 2018
As amended as of July 30, 2023 (the "Effective Date")

Effective as of the Effective Date, each non-employee member of the board of directors (the "Board") of Minerva Neurosciences, Inc. (the "Company") will receive an annual cash retainer of $35,000, the Lead Independent Director will receive an additional cash retainer of $10,000, and the Non-Employee Chairman of the Board will receive an additional annual cash retainer of $50,000. The chairpersons of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee will receive additional annual cash retainers of $15,000, $12,000 and $8,000, respectively. Other members of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee will receive additional annual cash retainers of $7,500, $6,000 and $4,000, respectively.

Effective as of the Effective Date, each newly elected non-employee director, on the date thereof (or, if such date is not a market trading day, the first market trading day thereafter), will be automatically (and without further action by the Board or the Compensation Committee thereof) granted an option to purchase 5,000 shares of the Company's common stock (the "Director Welcome Options"). The Director Welcome Options will vest monthly over three years, provided that the applicable non-employee director is, as of each such vesting date, then a non-employee director of the Company.

In addition, on the date of each annual stockholder meeting of the Company held after the Effective Date, each non-employee director who continues to serve as a non-employee director will be automatically (and without further action by the Board or the Compensation Committee thereof) granted an option to purchase 12,500 shares of the Company's common stock (the "Annual Grant"). The Annual Grant will vest in equal quarterly installments over one year following the grant date, provided that the applicable non-employee director is, as of each such vesting date, then a non-employee director of the Company.

The equity compensation set forth above will be granted under the Minerva Neurosciences, Inc. Amended and Restated 2013 Equity Incentive Plan (as amended from time to time, the ***"Plan"***), and will be documented on the applicable form of stock option agreement most recently approved for use by the Board (or a duly authorized committee thereof) for non-employee directors. All stock options granted hereunder will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying common stock on the date of grant, and a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan).
Non-employee directors are also reimbursed for their reasonable out-of-pocket expenses incurred in attending meetings of the Board or of any committee thereof.

The following is a summary of the terms of this Non-Employee Director Compensation Plan:

Cash

- Annual retainer for Non-employee Chairman of the Board – $85,000
- Annual retainer for Lead Independent Director – $45,000
- Committee chair annual retainers:
    - $15,000 Audit
    - $12,000 Compensation
    - $ 8,000 Nominating and Governance
- Committee member annual retainers:
    - $7,500 Audit
    - $6,000 Compensation
    - $4,000 Nominating and Governance
- Retainers are paid on a quarterly basis.

Stock Options

- Initial grant per Board member – 5,000 options vesting monthly over 3 years, provided that the applicable non-employee director is, as of each such vesting date, then a non-employee director of the Company

- Annual grant per Board member – 12,500 options vesting quarterly over 1 year, provided that the applicable non-employee director is, as of each such vesting date, then a non-employee director of the Company

MINERVA NEUROSCIENCES, INC.
AMENDED AND RESTATED 2013 EQUITY INCENTIVE PLAN

ADOPTED BY BOARD OF DIRECTORS ON: DECEMBER 19, 2013
APPROVED BY THE STOCKHOLDERS ON: DECEMBER 19, 2013
AMENDED AND RESTATED BY THE BOARD OF DIRECTORS ON: APRIL 29, 2014
AMENDMENT AND RESTATEMENT APPROVED BY THE STOCKHOLDERS ON: JUNE 2, 2014
AMENDED AND RESTATED BY THE BOARD OF DIRECTORS ON: APRIL 21, 2018
AMENDMENT AND RESTATEMENT APPROVED BY THE STOCKHOLDERS ON: JUNE 7, 2018
AMENDED AND RESTATED BY THE BOARD OF DIRECTORS ON: APRIL 17, 2020
AMENDMENT AND RESTATEMENT APPROVED BY THE STOCKHOLDERS ON: JUNE 19, 2020
AMENDED AND RESTATED BY THE BOARD OF DIRECTORS ON: JULY 30, 2023
AMENDMENT AND RESTATEMENT APPROVED BY THE STOCKHOLDERS ON: SEPTEMBER 27, 2023

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1. GENERAL.

(a) Successor to and Continuation of Prior Plan. The Plan is the successor to and continuation of the Prior Plan. As of the Effective Date, (i) no additional awards may be granted under the Prior Plan; (ii) the Prior Plan's Available Reserve plus any Returning Shares will become available for issuance pursuant to Awards granted under this Plan; and (iii) all outstanding Awards granted under the Prior Plan will remain subject to the terms of the Prior Plan (except to the extent such outstanding awards result in Returning Shares that become available for issuance pursuant to Awards granted under this Plan). All Awards granted under this Plan will be subject to the terms of this Plan.

(b) Plan Purpose. The Company, by means of the Plan, seeks to secure and retain the services of Employees, Directors and Consultants, to provide incentives for such persons to exert maximum efforts for the success of the Company and any Affiliate and to provide a means by which such persons may be given an opportunity to benefit from increases in value of the Common Stock through the granting of Awards.

(c) Available Awards. The Plan provides for the grant of the following Awards: (i) Incentive Stock Options; (ii) Nonstatutory Stock Options; (iii) SARs; (iv) Restricted Stock Awards; (v) RSU Awards; (vi) Performance Awards; and (vii) Other Awards.

(d) Effective Date. The Plan will come into existence on the Effective Date.

2. SHARES SUBJECT TO THE PLAN.

(a) Share Reserve. Subject to any adjustments as necessary to implement any Capitalization Adjustments, the aggregate number of shares of Common Stock that may be issued pursuant to Awards will not exceed the sum of (i) 700,000 shares that were approved at the Company's 2023 Annual Meeting of Stockholders, plus (ii) 2,000,000 shares that were approved at the Company's 2020 Annual Meeting of Stockholders, plus (iii) the Prior Plan's Available Reserve; plus, (iv) the number of Returning Shares, if any, as such shares become available from time to time.

(b) Aggregate Incentive Stock Option Limit. Notwithstanding anything to the contrary in Section 2(a) and subject to any adjustments as necessary to implement any Capitalization Adjustments, the aggregate maximum number of shares of Common Stock that may be issued pursuant to the exercise of Incentive Stock Options is 27,100,000 shares.

(c) Share Reserve Operation.

(i) Limit Applies to Common Stock Issued Pursuant to Awards. For clarity, the Share Reserve is a limit on the number of shares of Common Stock that may be issued pursuant to Awards and does not limit the granting of Awards, except that the Company will keep available at all times the number of shares of Common Stock reasonably required to satisfy its obligations to issue shares pursuant to such Awards. Shares may be issued in connection with a merger or acquisition as permitted by, as applicable, Nasdaq Listing Rule 5635(c), NYSE Listed Company Manual Section 303A.08, NYSE American Company Guide Section 711 or other

applicable rule, and such issuance will not reduce the number of shares available for issuance under the Plan.

(ii) Actions that Do Not Constitute Issuance of Common Stock and Do Not Reduce Share Reserve. The following actions do not result in an issuance of shares under the Plan and accordingly do not reduce the number of shares subject to the Share Reserve and available for issuance under the Plan: (1) the expiration or termination of any portion of an Award without the shares covered by such portion of the Award having been issued, or (2) the settlement of any portion of an Award in cash (*i.e.*, the Participant receives cash rather than Common Stock).

(iii) Reversion of Previously Issued Shares of Common Stock to Share Reserve. Any shares of Common Stock previously issued pursuant to an Award that are forfeited back to or repurchased by the Company because of a failure to meet a contingency or condition required for the vesting of such shares will be added back to the Share Reserve and again become available for issuance under the Plan.

(iv) Shares Not Available For Subsequent Issuance. Any shares of Common Stock reacquired or withheld (or not issued) by the Company to satisfy the exercise or purchase price of an Award will no longer be available for issuance under the Plan, including any shares subject to an Award that are not delivered to a Participant because such Award is settled through a reduction of shares subject to such Award. In addition, any shares reacquired or withheld (or not issued) by the Company to satisfy a tax withholding obligation in connection with an Award, or any shares repurchased by the Company on the open market with the proceeds from the exercise or purchase price of an Award will no longer be available for issuance under the Plan.

3. Eligibility and Limitations.

(a) Eligible Award Recipients. Subject to the terms of the Plan, Employees, Directors and Consultants are eligible to receive Awards.

(b) Specific Award Limitations.

(i) Limitations on Incentive Stock Option Recipients. Incentive Stock Options may be granted only to Employees of the Company or a "parent corporation" or "subsidiary corporation" thereof (as such terms are defined in Sections 424(e) and (f) of the Code).

(ii) Incentive Stock Option $100,000 Limitation. To the extent that the aggregate Fair Market Value (determined at the time of grant) of Common Stock with respect to which Incentive Stock Options are exercisable for the first time by any Optionholder during any calendar year (under all plans of the Company and any Affiliates) exceeds $100,000 (or such other limit established in the Code) or otherwise does not comply with the rules governing Incentive Stock Options, the Options or portions thereof that exceed such limit (according to the order in which they were granted) or otherwise do not comply with such rules will be treated as Nonstatutory Stock Options, notwithstanding any contrary provision of the applicable Option Agreement(s).

(iii) Limitations on Incentive Stock Options Granted to Ten Percent Stockholders. A Ten Percent Stockholder may not be granted an Incentive Stock Option unless (i) the exercise price of such Option is at least 110% of the Fair Market Value on the date of grant of such Option and (ii) the Option is not exercisable after the expiration of five years from the date of grant of such Option.

(iv) Limitations on Nonstatutory Stock Options and SARs. Nonstatutory Stock Options and SARs may not be granted to Employees, Directors and Consultants who are providing Continuous Service only to any "parent" of the Company (as such term is defined in Rule 405) unless the stock underlying such Awards is treated as "service recipient stock" under Section 409A because the Awards are granted pursuant to a corporate transaction (such as a spin off transaction) or unless such Awards otherwise comply with the distribution requirements of Section 409A.

(v) Dividends and Dividend Equivalents. Dividends or dividend equivalents may be paid or credited, as applicable, with respect to any shares of Common Stock subject to an Award, as determined by the Board and contained in the applicable Award Agreement; *provided*, *however*, that (i) no dividends or dividend equivalents may be paid with respect to any such shares before the date such shares have vested under the terms of such Award Agreement, (ii) any dividends or dividend equivalents that are credited with respect to any such shares will be subject to all of the terms and conditions applicable to such shares under the terms of such Award Agreement (including, but not limited to, any vesting conditions), and (iii) any dividends or dividend equivalents that are credited with respect to any such shares will be forfeited to the Company on the date, if any, such shares are forfeited to or repurchased by the Company due to a failure to meet any vesting conditions under the terms of such Award Agreement.

(vi) Minimum Vesting Requirements. The vesting period for each Award granted following the Effective Date, other than an Excepted Award (as defined below), must be at least equal to twelve months; provided, however, nothing in this Section 3(b)(vi) shall limit the Administrator's authority to accelerate the vesting of Awards as set forth in Section 6 or Section 7; and, provided further, notwithstanding the foregoing, (i) up to 5% of the shares of Common Stock authorized for issuance under the Plan may be utilized for Awards with a vesting period that is less than twelve months, (ii) Awards may granted as substitute Awards in replacement of other Awards (or awards previously granted by an entity being acquired (or assets of which are being acquired)) that were scheduled to vest within the twelve month period following the grant date or (iii) Awards may be granted in connection with an elective deferral of cash compensation that, absent a deferral election, otherwise would have been paid to the grantee within the twelve month period following the grant date (each such Award, an "***Excepted Award***").

(c) Aggregate Incentive Stock Option Limit. The aggregate maximum number of shares of Common Stock that may be issued pursuant to the exercise of Incentive Stock Options is the number of shares specified in Section 2(b).

(d) Non-Employee Director Compensation Limit. The aggregate value of all compensation granted or paid, as applicable, to any individual for service as a Non-Employee Director with respect to any calendar year, including Awards granted and cash fees paid by the Company to such Non-Employee Director, will not exceed (i) $500,000 in total value or (ii) in the

event such Non-Employee Director is first appointed or elected to the Board during such calendar year, $750,000 in total value, in each case calculating the value of any equity awards based on the grant date fair value of such equity awards for financial reporting purposes.

4. Options and Stock Appreciation Rights.

Each Option and SAR will have such terms and conditions as determined by the Board. Each Option will be designated in writing as an Incentive Stock Option or Nonstatutory Stock Option at the time of grant; provided, however, that if an Option is not so designated, then such Option will be a Nonstatutory Stock Option, and the shares purchased upon exercise of each type of Option will be separately accounted for. Each SAR will be denominated in shares of Common Stock equivalents. The terms and conditions of separate Options and SARs need not be identical; provided, however, that each Option Agreement and SAR Agreement will conform (through incorporation of provisions hereof by reference in the Award Agreement or otherwise) to the substance of each of the following provisions:

(a) Term. Subject to Section 3(b)(iii) regarding Ten Percent Stockholders, no Option or SAR will be exercisable after the expiration of ten years from the date of grant of such Award or such shorter period specified in the Award Agreement.

(b) Exercise or Strike Price. Subject to Section 3(b)(iii) regarding Ten Percent Stockholders, the exercise or strike price of each Option or SAR will not be less than 100% of the Fair Market Value on the date of grant of such Award. Notwithstanding the foregoing, an Option or SAR may be granted with an exercise or strike price lower than 100% of the Fair Market Value on the date of grant of such Award if such Award is granted pursuant to an assumption of or substitution for another option or stock appreciation right pursuant to a Change in Control and in a manner consistent with the provisions of Sections 409A and, if applicable, 424(a) of the Code.

(c) Exercise Procedure and Payment of Exercise Price for Options. In order to exercise an Option, the Participant must provide notice of exercise to the Plan Administrator in accordance with the procedures specified in the Option Agreement or otherwise provided by the Company. The Board has the authority to grant Options that do not permit all of the following methods of payment (or otherwise restrict the ability to use certain methods) and to grant Options that require the consent of the Company to utilize a particular method of payment. The exercise price of an Option may be paid, to the extent permitted by Applicable Law and as determined by the Board, by one or more of the following methods of payment to the extent set forth in the Option Agreement:

(i) by cash or check, bank draft or money order payable to the Company;

(ii) pursuant to a "cashless exercise" program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of the Common Stock subject to the Option, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the exercise price to the Company from the sales proceeds;

(iii) by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock that are already owned by the Participant free and clear of any liens, claims, encumbrances or security interests, with a Fair Market Value on the date of exercise that does not

exceed the exercise price, provided that (1) at the time of exercise the Common Stock is publicly traded, (2) any remaining balance of the exercise price not satisfied by such delivery is paid by the Participant in cash or other permitted form of payment, (3) such delivery would not violate any Applicable Law or agreement restricting the redemption of the Common Stock, (4) any certificated shares are endorsed or accompanied by an executed assignment separate from certificate, and (5) such shares have been held by the Participant for any minimum period necessary to avoid adverse accounting treatment as a result of such delivery;

(iv) if the Option is a Nonstatutory Stock Option, by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value on the date of exercise that does not exceed the exercise price, provided that (1) such shares used to pay the exercise price will not be exercisable thereafter and (2) any remaining balance of the exercise price not satisfied by such net exercise is paid by the Participant in cash or other permitted form of payment; or

(v) in any other form of consideration that may be acceptable to the Board and permissible under Applicable Law.

(d) Exercise Procedure and Payment of Appreciation Distribution for SARs. In order to exercise any SAR, the Participant must provide notice of exercise to the Plan Administrator in accordance with the SAR Agreement. The appreciation distribution payable to a Participant upon the exercise of a SAR will not be greater than an amount equal to the excess of (i) the aggregate Fair Market Value on the date of exercise of a number of shares of Common Stock equal to the number of Common Stock equivalents that are vested and being exercised under such SAR, over (ii) the strike price of such SAR. Such appreciation distribution may be paid to the Participant in the form of Common Stock or cash (or any combination of Common Stock and cash) or in any other form of payment, as determined by the Board and specified in the SAR Agreement.

(e) Transferability. Options and SARs may not be transferred to third party financial institutions for value. The Board may impose such additional limitations on the transferability of an Option or SAR as it determines. In the absence of any such determination by the Board, the following restrictions on the transferability of Options and SARs will apply, provided that except as explicitly provided herein, neither an Option nor a SAR may be transferred for consideration and *provided, further*, that if an Option is an Incentive Stock Option, such Option may be deemed to be a Nonstatutory Stock Option as a result of such transfer:

(i) Restrictions on Transfer. An Option or SAR will not be transferable, except by will or by the laws of descent and distribution, and will be exercisable during the lifetime of the Participant only by the Participant; provided, however, that the Board may permit transfer of an Option or SAR in a manner that is not prohibited by applicable tax and securities laws upon the Participant's request, including to a trust if the Participant is considered to be the sole beneficial owner of such trust (as determined under Section 671 of the Code and applicable state law) while such Option or SAR is held in such trust, provided that the Participant and the trustee enter into a transfer and other agreements required by the Company.

(ii) Domestic Relations Orders. Notwithstanding the foregoing, subject to the execution of transfer documentation in a format acceptable to the Company and subject to the approval of the Board or a duly authorized Officer, an Option or SAR may be transferred pursuant to a domestic relations order.

(f) Vesting. Subject to Section 3(b)(vi), the Board may impose such restrictions on or conditions to the vesting and/or exercisability of an Option or SAR as determined by the Board. Except as otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, vesting of Options and SARs will cease upon termination of the Participant's Continuous Service.

(g) Termination of Continuous Service for Cause. Except as explicitly otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, if a Participant's Continuous Service is terminated for Cause, the Participant's Options and SARs will terminate and be forfeited immediately upon such termination of Continuous Service, and the Participant will be prohibited from exercising any portion (including any vested portion) of such Awards on and after the date of such termination of Continuous Service and the Participant will have no further right, title or interest in such forfeited Award, the shares of Common Stock subject to the forfeited Award, or any consideration in respect of the forfeited Award.

(h) Post-Termination Exercise Period Following Termination of Continuous Service for Reasons Other than Cause. Subject to Section 4(i), if a Participant's Continuous Service terminates for any reason other than for Cause, the Participant may exercise his or her Option or SAR to the extent vested, but only within the following period of time or, if applicable, such other period of time provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate; provided, however, that in no event may such Award be exercised after the expiration of its maximum term (as set forth in Section 4(a)):

(i) three months following the date of such termination if such termination is a termination without Cause (other than any termination due to the Participant's Disability or death);

(ii) 12 months following the date of such termination if such termination is due to the Participant's Disability;

(iii) 18 months following the date of such termination if such termination is due to the Participant's death; or

(iv) 18 months following the date of the Participant's death if such death occurs following the date of such termination but during the period such Award is otherwise exercisable (as provided in (i) or (ii) above).

Following the date of such termination, to the extent the Participant does not exercise such Award within the applicable Post-Termination Exercise Period (or, if earlier, prior to the expiration of the maximum term of such Award), such unexercised portion of the Award will terminate, and the Participant will have no further right, title or interest in the terminated Award, the shares of

Common Stock subject to the terminated Award, or any consideration in respect of the terminated Award.

(i) Restrictions on Exercise; Extension of Exercisability. A Participant may not exercise an Option or SAR at any time that the issuance of shares of Common Stock upon such exercise would violate Applicable Law. Except as otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, if a Participant's Continuous Service terminates for any reason other than for Cause and, at any time during the last thirty days of the applicable Post-Termination Exercise Period: (i) the exercise of the Participant's Option or SAR would be prohibited solely because the issuance of shares of Common Stock upon such exercise would violate Applicable Law, or (ii) the immediate sale of any shares of Common Stock issued upon such exercise would violate the Company's Trading Policy, then the applicable Post-Termination Exercise Period will be extended to the last day of the calendar month that commences following the date the Award would otherwise expire, with an additional extension of the exercise period to the last day of the next calendar month to apply if any of the foregoing restrictions apply at any time during such extended exercise period, generally without limitation as to the maximum permitted number of extensions); provided, however, that in no event may such Award be exercised after the expiration of its maximum term (as set forth in Section 4(a)).

(j) Non-Exempt Employees. No Option or SAR, whether or not vested, granted to an Employee who is a non-exempt employee for purposes of the Fair Labor Standards Act of 1938, as amended, will be first exercisable for any shares of Common Stock until at least six months following the date of grant of such Award. Notwithstanding the foregoing, in accordance with the provisions of the Worker Economic Opportunity Act, any vested portion of such Award may be exercised earlier than six months following the date of grant of such Award in the event of (i) such Participant's death or Disability, (ii) a Change in Control in which such Award is not assumed, continued or substituted, or (iii) such Participant's retirement (as such term may be defined in the Award Agreement or another applicable agreement or, in the absence of any such definition, in accordance with the Company's then current employment policies and guidelines). This Section 4(j) is intended to operate so that any income derived by a non-exempt employee in connection with the exercise or vesting of an Option or SAR will be exempt from his or her regular rate of pay.

(k) Whole Shares. Options and SARs may be exercised only with respect to whole shares of Common Stock or their equivalents.

5. Awards Other Than Options and Stock Appreciation Rights.

(a) Restricted Stock Awards and RSU Awards. Each Restricted Stock Award and RSU Award will have such terms and conditions as determined by the Board; provided, however, that each Restricted Stock Award Agreement and RSU Award Agreement will conform (through incorporation of the provisions hereof by reference in the Award Agreement or otherwise) to the substance of each of the following provisions:

(i) Form of Award.

(1) RSAs: To the extent consistent with the Company's Bylaws, at the Board's election, shares of Common Stock subject to a Restricted Stock Award may be (i) held in book entry form subject to the Company's instructions until such shares become vested or any other restrictions lapse, or (ii) evidenced by a certificate, which certificate will be held in such form and manner as determined by the Board. Unless otherwise determined by the Board, a Participant will have voting and other rights as a stockholder of the Company with respect to any shares subject to a Restricted Stock Award.

(2) RSUs: A RSU Award represents a Participant's right to be issued on a future date the number of shares of Common Stock that is equal to the number of restricted stock units subject to the RSU Award. As a holder of a RSU Award, a Participant is an unsecured creditor of the Company with respect to the Company's unfunded obligation, if any, to issue shares of Common Stock in settlement of such Award and nothing contained in the Plan or any RSU Agreement, and no action taken pursuant to its provisions, will create or be construed to create a trust of any kind or a fiduciary relationship between a Participant and the Company or an Affiliate or any other person. A Participant will not have voting or any other rights as a stockholder of the Company with respect to any RSU Award (unless and until shares are actually issued in settlement of a vested RSU Award).

(ii) Consideration.

(1) RSA: A Restricted Stock Award may be granted in consideration for (A) cash or check, bank draft or money order payable to the Company, (B) past services to the Company or an Affiliate, or (C) any other form of consideration (including future services) as the Board may determine and permissible under Applicable Law.

(2) RSU: Unless otherwise determined by the Board at the time of grant, a RSU Award will be granted in consideration for the Participant's services to the Company or an Affiliate, such that the Participant will not be required to make any payment to the Company (other than such services) with respect to the grant or vesting of the RSU Award, or the issuance of any shares of Common Stock pursuant to the RSU Award. If, at the time of grant, the Board determines that any consideration must be paid by the Participant (in a form other than the Participant's services to the Company or an Affiliate) upon the issuance of any shares of Common Stock in settlement of the RSU Award, such consideration may be paid in any form of consideration as the Board may determine and permissible under Applicable Law.

(iii) Vesting. Subject to Section 3(b)(vi), the Board may impose such restrictions on or conditions to the vesting of a Restricted Stock Award or RSU Award as determined by the Board. Except as otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, vesting of Restricted Stock Awards and RSU Awards will cease upon termination of the Participant's Continuous Service.

(iv) Termination of Continuous Service. Except as otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, if a Participant's Continuous Service terminates for any reason, (i) the Company may receive through a forfeiture condition or a repurchase right any or all of the shares of Common Stock held by the Participant under his or her Restricted Stock Award that have not vested as of

the date of such termination as set forth in the Restricted Stock Award Agreement and (ii) any portion of his or her RSU Award that has not vested will be forfeited upon such termination and the Participant will have no further right, title or interest in the RSU Award, the shares of Common Stock issuable pursuant to the RSU Award, or any consideration in respect of the RSU Award.

(v) Dividends and Dividend Equivalents. Subject to Section 3(b)(v), dividends or dividend equivalents may be paid or credited, as applicable, with respect to any shares of Common Stock subject to a Restricted Stock Award or RSU Award, as determined by the Board and specified in the Award Agreement.

(vi) Settlement of RSU Awards. A RSU Award may be settled by the issuance of shares of Common Stock or cash (or any combination thereof) or in any other form of payment, as determined by the Board and specified in the RSU Award Agreement. At the time of grant, the Board may determine to impose such restrictions or conditions that delay such delivery to a date following the vesting of the RSU Award.

(b) Performance Awards. With respect to any Performance Award and subject to Section 3(b)(vi), the length of any Performance Period, the Performance Goals to be achieved during the Performance Period, the other terms and conditions of such Award, and the measure of whether and to what degree such Performance Goals have been attained will be determined by the Board.

(c) Other Awards. Other forms of Awards valued in whole or in part by reference to, or otherwise based on, Common Stock, including the appreciation in value thereof (e.g., options or stock rights with an exercise price or strike price less than 100% of the Fair Market Value at the time of grant) may be granted either alone or in addition to Awards provided for under Section 4 and the preceding provisions of this Section 5. Subject to the provisions of the Plan (including, but not limited to, Section 3(b)(vi)), the Board will have sole and complete discretion to determine the persons to whom and the time or times at which such Other Awards will be granted, the number of shares of Common Stock (or the cash equivalent thereof) to be granted pursuant to such Other Awards and all other terms and conditions of such Other Awards.

6. Adjustments upon Changes in Common Stock; Other Corporate Events.

(a) Capitalization Adjustments. In the event of a Capitalization Adjustment, the Board shall appropriately and proportionately adjust: (i) the class(es) and maximum number of shares of Common Stock subject to the Plan pursuant to Section 2(a), (ii) the class(es) and maximum number of shares that may be issued pursuant to the exercise of Incentive Stock Options pursuant to Section 2(a), and (iii) the class(es) and number of securities and exercise price, strike price or purchase price of Common Stock subject to outstanding Awards. The Board shall make such adjustments, and its determination shall be final, binding and conclusive. Notwithstanding the foregoing, no fractional shares or rights for fractional shares of Common Stock shall be created in order to implement any Capitalization Adjustment. The Board shall determine an appropriate equivalent benefit, if any, for any fractional shares or rights to fractional shares that might be created by the adjustments referred to in the preceding provisions of this Section.

(b) Dissolution or Liquidation. Except as otherwise provided in the Award Agreement, in the event of a dissolution or liquidation of the Company, all outstanding Awards (other than Awards consisting of vested and outstanding shares of Common Stock not subject to a forfeiture condition or the Company's right of repurchase) will terminate immediately prior to the completion of such dissolution or liquidation, and the shares of Common Stock subject to the Company's repurchase rights or subject to a forfeiture condition may be repurchased or reacquired by the Company notwithstanding the fact that the holder of such Award is providing Continuous Service, provided, however, that the Board may determine to cause some or all Awards to become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent such Awards have not previously expired or terminated) before the dissolution or liquidation is completed but contingent on its completion.

(c) Change in Control. The following provisions will apply to Awards in the event of a Change in Control unless otherwise provided in the instrument evidencing the Award or any other written agreement between the Company or any Affiliate and the Participant or unless otherwise expressly provided by the Board at the time of grant of an Award.

(i) Awards May Be Assumed. In the event of a Change in Control, any surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) may assume or continue any or all Awards outstanding under the Plan or may substitute similar awards for Awards outstanding under the Plan (including but not limited to, awards to acquire the same consideration paid to the stockholders of the Company pursuant to the Change in Control), and any reacquisition or repurchase rights held by the Company in respect of Common Stock issued pursuant to Awards may be assigned by the Company to the successor of the Company (or the successor's parent company, if any), in connection with such Change in Control. A surviving corporation or acquiring corporation (or its parent) may choose to assume or continue only a portion of an Award or substitute a similar award for only a portion of an Award, or may choose to assume or continue the Awards held by some, but not all Participants. The terms of any assumption, continuation or substitution will be set by the Board.

(ii) Awards Held by Current Participants. In the event of a Change in Control in which the surviving corporation or acquiring corporation (or its parent company) does not assume or continue such outstanding Awards or substitute similar awards for such outstanding Awards, then with respect to Awards that have not been assumed, continued or substituted and that are held by Participants whose Continuous Service has not terminated prior to the effective time of the Change in Control (referred to as the "***Current Participants***"), the vesting of such Awards (and, with respect to Options and Stock Appreciation Rights, the time when such Awards may be exercised) will be accelerated in full to a date prior to the effective time of such Change in Control (contingent upon the effectiveness of the Change in Control) as the Board determines (or, if the Board does not determine such a date, to the date that is five (5) days prior to the effective time of the Change in Control), and such Awards will terminate if not exercised (if applicable) at or prior to the effective time of the Change in Control, and any reacquisition or repurchase rights held by the Company with respect to such Awards will lapse (contingent upon the effectiveness of the Change in Control). With respect to the vesting of Performance Awards that will accelerate upon the occurrence of a Change in Control pursuant to this subsection (ii) and that have multiple vesting levels depending on the level of performance, unless otherwise provided in the Award Agreement, the vesting of such Performance Awards will accelerate at

100% of the target level upon the occurrence of the Change in Control. With respect to the vesting of Awards that will accelerate upon the occurrence of a Change in Control pursuant to this subsection (ii) and are settled in the form of a cash payment, such cash payment will be made no later than 30 days following the occurrence of the Change in Control.

(iii) Awards Held by Persons other than Current Participants. In the event of a Change in Control in which the surviving corporation or acquiring corporation (or its parent company) does not assume or continue such outstanding Awards or substitute similar awards for such outstanding Awards, then with respect to Awards that have not been assumed, continued or substituted and that are held by persons other than Current Participants, such Awards will terminate if not exercised (if applicable) prior to the occurrence of the Change in Control; provided, however, that any reacquisition or repurchase rights held by the Company with respect to such Awards will not terminate and may continue to be exercised notwithstanding the Change in Control.

(iv) Payment for Awards in Lieu of Exercise. Notwithstanding the foregoing, in the event an Award will terminate if not exercised prior to the effective time of a Change in Control, the Board may provide, in its sole discretion, that the holder of such Award may not exercise such Award but will receive a payment, in such form as may be determined by the Board, equal in value, at the effective time, to the excess, if any, of (1) the value of the property the Participant would have received upon the exercise of the Award (including, at the discretion of the Board, any unvested portion of such Award), over (2) any exercise price payable by such holder in connection with such exercise.

(d) Appointment of Stockholder Representative. As a condition to the receipt of an Award under this Plan, a Participant will be deemed to have agreed that the Award will be subject to the terms of any agreement governing a Change in Control involving the Company, including, without limitation, a provision for the appointment of a stockholder representative that is authorized to act on the Participant's behalf with respect to any escrow, indemnities and any contingent consideration.

(e) No Restriction on Right to Undertake Transactions. The grant of any Award under the Plan and the issuance of shares pursuant to any Award does not affect or restrict in any way the right or power of the Company or the stockholders of the Company to make or authorize any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, any merger or consolidation of the Company, any issue of stock or of options, rights or options to purchase stock or of bonds, debentures, preferred or prior preference stocks whose rights are superior to or affect the Common Stock or the rights thereof or which are convertible into or exchangeable for Common Stock, or the dissolution or liquidation of the Company, or any sale or transfer of all or any part of its assets or business, or any other corporate act or proceeding, whether of a similar character or otherwise.

7. ADMINISTRATION.

(a) Administration by Board. The Board will administer the Plan unless and until the Board delegates administration of the Plan to a Committee or Committees, as provided in subsection (c) below.

(b) Powers of Board. The Board will have the power, subject to, and within the limitations of, the express provisions of the Plan:

(i) To determine from time to time (1) which of the persons eligible under the Plan will be granted Awards; (2) when and how each Award will be granted; (3) what type or combination of types of Award will be granted; (4) the provisions of each Award granted (which need not be identical), including the time or times when a person will be permitted to receive an issuance of Common Stock or other payment pursuant to an Award; (5) the number of shares of Common Stock or cash equivalent with respect to which an Award will be granted to each such person; and (6) the Fair Market Value applicable to an Award.

(ii) To construe and interpret the Plan and Awards granted under it, and to establish, amend and revoke rules and regulations for its administration. The Board, in the exercise of this power, may correct any defect, omission or inconsistency in the Plan or in any Award Agreement, in a manner and to the extent it deems necessary or expedient to make the Plan or Award fully effective.

(iii) To settle all controversies regarding the Plan and Awards granted under it.

(iv) To accelerate the time at which an Award may first be exercised or the time during which an Award or any part thereof will vest, notwithstanding the provisions in the Award Agreement stating the time at which it may first be exercised or the time during which it will vest.

(v) To prohibit the exercise of any Option, SAR or other exercisable Award during a period of up to 30 days prior to the consummation of any pending stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other change affecting the shares of Common Stock or the share price of the Common Stock including any Change in Control, for reasons of administrative convenience.

(vi) To suspend or terminate the Plan at any time. Suspension or termination of the Plan will not Materially Impair rights and obligations under any Award granted while the Plan is in effect except with the written consent of the affected Participant.

(vii) To amend the Plan in any respect the Board deems necessary or advisable; provided, however, that stockholder approval will be required for any amendment to the extent required by Applicable Law. Except as provided above, rights under any Award granted before amendment of the Plan will not be Materially Impaired by any amendment of the Plan unless (1) the Company requests the consent of the affected Participant, and (2) such Participant consents in writing.

(viii) To submit any amendment to the Plan for stockholder approval.

(ix) To approve forms of Award Agreements for use under the Plan and to amend the terms of any one or more Awards, including, but not limited to, amendments to provide terms more favorable to the Participant than previously provided in the Award Agreement, subject to any specified limits in the Plan that are not subject to Board discretion; *provided however*, that, a Participant's rights under any Award will not be Materially Impaired by any such amendment

unless (1) the Company requests the consent of the affected Participant, and (2) such Participant consents in writing.

(x) Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan or Awards.

(xi) To adopt such procedures and sub-plans as are necessary or appropriate to permit and facilitate participation in the Plan by, or take advantage of specific tax treatment for Awards granted to, Employees, Directors or Consultants who are foreign nationals or employed outside the United States (provided that Board approval will not be necessary for immaterial modifications to the Plan or any Award Agreement to ensure or facilitate compliance with the laws of the relevant foreign jurisdiction).

(c) Delegation to Committee.

(i) General. The Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration of the Plan is delegated to a Committee, the Committee will have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to another Committee or a subcommittee of the Committee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board will thereafter be to the Committee or subcommittee), subject, however, to such resolutions, not inconsistent with the provisions of the Plan, as may be adopted from time to time by the Board. Each Committee may retain the authority to concurrently administer the Plan with Committee or subcommittee to which it has delegated its authority hereunder and may, at any time, revest in such Committee some or all of the powers previously delegated. The Board may retain the authority to concurrently administer the Plan with any Committee and may, at any time, revest in the Board some or all of the powers previously delegated.

(ii) Rule 16b-3 Compliance. To the extent an Award is intended to qualify for the exemption from Section 16(b) of the Exchange Act that is available under Rule 16b-3 of the Exchange Act, the Award will be granted by the Board or a Committee that consists solely of two or more Non-Employee Directors, as determined under Rule 16b-3(b)(3) of the Exchange Act and thereafter any action establishing or modifying the terms of the Award will be approved by the Board or a Committee meeting such requirements to the extent necessary for such exemption to remain available.

(d) Effect of Board's Decision. All determinations, interpretations and constructions made by the Board or any Committee in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

(e) Cancellation and Re-Grant of Awards. Neither the Board nor any Committee will have the authority to: (i) reduce the exercise price or strike price of any outstanding Options or SARs under the Plan, or (ii) cancel any outstanding Options or SARs that have an exercise price or strike price greater than the current Fair Market Value in exchange for cash or other Awards

under the Plan, unless the stockholders of the Company have approved such an action within twelve months prior to such an event.

(f) Delegation to an Officer. The Board or any Committee may delegate to one or more Officers the authority to do one or both of the following (i) designate Employees who are not Officers to be recipients of Options and SARs (and, to the extent permitted by Applicable Law, other types of Awards) and, to the extent permitted by Applicable Law, the terms thereof, and (ii) determine the number of shares of Common Stock to be subject to such Awards granted to such Employees; provided, however, that the resolutions or charter adopted by the Board or any Committee evidencing such delegation will specify the total number of shares of Common Stock that may be subject to the Awards granted by such Officer and that such Officer may not grant an Award to himself or herself. Any such Awards will be granted on the applicable form of Award Agreement most recently approved for use by the Board or the Committee, unless otherwise provided in the resolutions approving the delegation authority. Notwithstanding anything to the contrary herein, neither the Board nor any Committee may delegate to an Officer who is acting solely in the capacity of an Officer (and not also as a Director) the authority to determine the Fair Market Value.

8. Tax Withholding

(a) Withholding Authorization. As a condition to acceptance of any Award under the Plan, a Participant authorizes withholding from payroll and any other amounts payable to such Participant, and otherwise agrees to make adequate provision for (including), any sums required to satisfy any U.S. federal, state, local and/or foreign tax or social insurance contribution withholding obligations of the Company or an Affiliate, if any, which arise in connection with the grant, exercise, vesting or settlement of such Award, as applicable. Accordingly, a Participant may not be able to exercise an Award even though the Award is vested, and the Company shall have no obligation to issue shares of Common Stock subject to an Award, unless and until such obligations are satisfied.

(b) Satisfaction of Withholding Obligation. To the extent permitted by the terms of an Award Agreement, the Company may, in its sole discretion, satisfy any U.S. federal, state, local and/or foreign tax or social insurance withholding obligation relating to an Award by any of the following means or by a combination of such means: (i) causing the Participant to tender a cash payment; (ii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to the Participant in connection with the Award; (iii) withholding cash from an Award settled in cash; (iv) withholding payment from any amounts otherwise payable to the Participant; (v) by allowing a Participant to effectuate a “cashless exercise” pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board, or (vi) by such other method as may be set forth in the Award Agreement.

(c) No Obligation to Notify or Minimize Taxes; No Liability to Claims. Except as required by Applicable Law the Company has no duty or obligation to any Participant to advise such holder as to the time or manner of exercising such Award. Furthermore, the Company has no duty or obligation to warn or otherwise advise such holder of a pending termination or expiration of an Award or a possible period in which the Award may not be exercised. The Company has no duty or obligation to minimize the tax consequences of an Award to the holder

of such Award and will not be liable to any holder of an Award for any adverse tax consequences to such holder in connection with an Award. As a condition to accepting an Award under the Plan, each Participant (i) agrees to not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates related to tax liabilities arising from such Award or other Company compensation and (ii) acknowledges that such Participant was advised to consult with his or her own personal tax, financial and other legal advisors regarding the tax consequences of the Award and has either done so or knowingly and voluntarily declined to do so. Additionally, each Participant acknowledges any Option or SAR granted under the Plan is exempt from Section 409A only if the exercise or strike price is at least equal to the "fair market value" of the Common Stock on the date of grant as determined by the Internal Revenue Service and there is no other impermissible deferral of compensation associated with the Award. Additionally, as a condition to accepting an Option or SAR granted under the Plan, each Participant agrees not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates in the event that the Internal Revenue Service asserts that such exercise price or strike price is less than the "fair market value" of the Common Stock on the date of grant as subsequently determined by the Internal Revenue Service.

(d) Withholding Indemnification. As a condition to accepting an Award under the Plan, in the event that the amount of the Company's and/or its Affiliate's withholding obligation in connection with such Award was greater than the amount actually withheld by the Company and/or its Affiliates, each Participant agrees to indemnify and hold the Company and/or its Affiliates harmless from any failure by the Company and/or its Affiliates to withhold the proper amount.

9. MISCELLANEOUS.

(a) Source of Shares. The stock issuable under the Plan will be shares of authorized but unissued or reacquired Common Stock, including shares repurchased by the Company on the open market or otherwise.

(b) Use of Proceeds from Sales of Common Stock. Proceeds from the sale of shares of Common Stock pursuant to Awards will constitute general funds of the Company.

(c) Corporate Action Constituting Grant of Awards. Corporate action constituting a grant by the Company of an Award to any Participant will be deemed completed as of the date of such corporate action, unless otherwise determined by the Board, regardless of when the instrument, certificate, or letter evidencing the Award is communicated to, or actually received or accepted by, the Participant. In the event that the corporate records (e.g., Board consents, resolutions or minutes) documenting the corporate action approving the grant contain terms (e.g., exercise price, vesting schedule or number of shares) that are inconsistent with those in the Award Agreement or related grant documents as a result of a clerical error in the Award Agreement or related grant documents, the corporate records will control and the Participant will have no legally binding right to the incorrect term in the Award Agreement or related grant documents.

(d) Stockholder Rights. No Participant will be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to such Award unless and until (i) such Participant has satisfied all requirements for exercise of the Award

pursuant to its terms, if applicable, and (ii) the issuance of the Common Stock subject to such Award is reflected in the records of the Company.

(e) No Employment or Other Service Rights. Nothing in the Plan, any Award Agreement or any other instrument executed thereunder or in connection with any Award granted pursuant thereto will confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Award was granted or affect the right of the Company or an Affiliate to terminate at will and without regard to any future vesting opportunity that a Participant may have with respect to any Award (i) the employment of an Employee with or without notice and with or without cause, (ii) the service of a Consultant pursuant to the terms of such Consultant's agreement with the Company or an Affiliate, or (iii) the service of a Director pursuant to the Bylaws of the Company or an Affiliate, and any applicable provisions of the corporate law of the state or foreign jurisdiction in which the Company or the Affiliate is incorporated, as the case may be. Further, nothing in the Plan, any Award Agreement or any other instrument executed thereunder or in connection with any Award will constitute any promise or commitment by the Company or an Affiliate regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of employment or service or confer any right or benefit under the Award or the Plan unless such right or benefit has specifically accrued under the terms of the Award Agreement and/or Plan.

(f) Change in Time Commitment. In the event a Participant's regular level of time commitment in the performance of his or her services for the Company and any Affiliates is reduced (for example, and without limitation, if the Participant is an Employee of the Company and the Employee has a change in status from a full-time Employee to a part-time Employee or takes an extended leave of absence) after the date of grant of any Award to the Participant, the Board may determine, to the extent permitted by Applicable Law, to (i) make a corresponding reduction in the number of shares or cash amount subject to any portion of such Award that is scheduled to vest or become payable after the date of such change in time commitment, and (ii) in lieu of or in combination with such a reduction, extend the vesting or payment schedule applicable to such Award. In the event of any such reduction, the Participant will have no right with respect to any portion of the Award that is so reduced or extended.

(g) Execution of Additional Documents. As a condition to accepting an Award under the Plan, the Participant agrees to execute any additional documents or instruments necessary or desirable, as determined in the Plan Administrator's sole discretion, to carry out the purposes or intent of the Award, or facilitate compliance with securities and/or other regulatory requirements, in each case at the Plan Administrator's request.

(h) Electronic Delivery and Participation. Any reference herein or in an Award Agreement to a "written" agreement or document will include any agreement or document delivered electronically, filed publicly at www.sec.gov (or any successor website thereto) or posted on the Company's intranet (or other shared electronic medium controlled by the Company to which the Participant has access). By accepting any Award the Participant consents to receive documents by electronic delivery and to participate in the Plan through any on-line electronic system established and maintained by the Plan Administrator or another third party selected by the Plan Administrator. The form of delivery of any Common Stock (e.g., a stock certificate or electronic entry evidencing such shares) shall be determined by the Company.

(i) Clawback/Recovery. All Awards granted under the Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other Applicable Law and any clawback policy that the Company otherwise adopts, to the extent applicable and permissible under Applicable Law. In addition, the Board may impose such other clawback, recovery or recoupment provisions in an Award Agreement as the Board determines necessary or appropriate, including but not limited to a reacquisition right in respect of previously acquired shares of Common Stock or other cash or property upon the occurrence of Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a Participant's right to voluntary terminate employment upon a "resignation for good reason," or for a "constructive termination" or any similar term under any plan of or agreement with the Company.

(j) Securities Law Compliance. A Participant will not be issued any shares in respect of an Award unless either (i) the shares are registered under the Securities Act; or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Each Award also must comply with other Applicable Law governing the Award, and a Participant will not receive such shares if the Company determines that such receipt would not be in material compliance with Applicable Law.

(k) Transfer or Assignment of Awards; Issued Shares. Except as expressly provided in the Plan or the form of Award Agreement, Awards granted under the Plan may not be transferred or assigned by the Participant. After the vested shares subject to an Award have been issued, or in the case of Restricted Stock and similar awards, after the issued shares have vested, the holder of such shares is free to assign, hypothecate, donate, encumber or otherwise dispose of any interest in such shares provided that any such actions are in compliance with the provisions herein, the terms of the Trading Policy and Applicable Law.

(l) Effect on Other Employee Benefit Plans. The value of any Award granted under the Plan, as determined upon grant, vesting or settlement, shall not be included as compensation, earnings, salaries, or other similar terms used when calculating any Participant's benefits under any employee benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company's or any Affiliate's employee benefit plans.

(m) Deferrals. To the extent permitted by Applicable Law, the Board, in its sole discretion, may determine that the delivery of Common Stock or the payment of cash, upon the exercise, vesting or settlement of all or a portion of any Award may be deferred and may also establish programs and procedures for deferral elections to be made by Participants. Deferrals by will be made in accordance with the requirements of Section 409A.

(n) Section 409A. Unless otherwise expressly provided for in an Award Agreement, the Plan and Award Agreements will be interpreted to the greatest extent possible in a manner that makes the Plan and the Awards granted hereunder exempt from Section 409A, and, to the extent not so exempt, in compliance with the requirements of Section 409A. If the Board determines that any Award granted hereunder is not exempt from and is therefore subject to Section 409A, the

Award Agreement evidencing such Award will incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code, and to the extent an Award Agreement is silent on terms necessary for compliance, such terms are hereby incorporated by reference into the Award Agreement. Notwithstanding anything to the contrary in this Plan (and unless the Award Agreement specifically provides otherwise), if the shares of Common Stock are publicly traded, and if a Participant holding an Award that constitutes "deferred compensation" under Section 409A is a "specified employee" for purposes of Section 409A, no distribution or payment of any amount that is due because of a "separation from service" (as defined in Section 409A without regard to alternative definitions thereunder) will be issued or paid before the date that is six months and one day following the date of such Participant's "separation from service" or, if earlier, the date of the Participant's death, unless such distribution or payment can be made in a manner that complies with Section 409A, and any amounts so deferred will be paid in a lump sum on the day after such six month period elapses, with the balance paid thereafter on the original schedule.

(o) Choice of Law. This Plan and any controversy arising out of or relating to this Plan shall be governed by, and construed in accordance with, the internal laws of the State of Delaware, without regard to conflict of law principles that would result in any application of any law other than the law of the State of Delaware.

10. Covenants of the Company.

(a) Compliance with Law. The Company will seek to obtain from each regulatory commission or agency, as may be deemed to be necessary, having jurisdiction over the Plan such authority as may be required to grant Awards and to issue and sell shares of Common Stock upon exercise or vesting of the Awards; provided, however, that this undertaking will not require the Company to register under the Securities Act the Plan, any Award or any Common Stock issued or issuable pursuant to any such Award. If, after reasonable efforts and at a reasonable cost, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary or advisable for the lawful issuance and sale of Common Stock under the Plan, the Company will be relieved from any liability for failure to issue and sell Common Stock upon exercise or vesting of such Awards unless and until such authority is obtained. A Participant is not eligible for the grant of an Award or the subsequent issuance of Common Stock pursuant to the Award if such grant or issuance would be in violation of any Applicable Law.

11. Severability.

If all or any part of the Plan or any Award Agreement is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of the Plan or such Award Agreement not declared to be unlawful or invalid. Any Section of the Plan or any Award Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

12. TERMINATION OF THE PLAN.

The Board may suspend or terminate the Plan at any time. Unless sooner terminated by the Board, the Plan shall terminate upon the earliest to occur of (i) April 20, 2028, (ii) the date on which all shares available for issuance under the Plan shall have been issued as fully vested shares or (iii) the termination of all outstanding Awards in connection with a Change in Control. No Incentive Stock Options may be granted after the tenth anniversary of the earlier of: (i) the Adoption Date, or (ii) the Effective Date. No Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

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DEFINITIONS.

As used in the Plan, the following definitions apply to the capitalized terms indicated below:

(a) "***Acquiring Entity***" means the surviving or acquiring corporation (or its parent company) in connection with a Change in Control.

(b) "***Adoption Date***" means April 17, 2020.

(c) "***Affiliate***" means, at the time of determination, any "parent" or "subsidiary" of the Company as such terms are defined in Rule 405 promulgated under the Securities Act. The Board may determine the time or times at which "parent" or "subsidiary" status is determined within the foregoing definition.

(d) "***Applicable Law***" means shall mean any applicable securities, federal, state, foreign, material local or municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, edict, decree, rule, listing rule, regulation, judicial decision, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Body (including under the authority of any applicable self-regulating organization such as the Nasdaq Stock Market, New York Stock Exchange, or the Financial Industry Regulatory Authority).

(e) "***Award***" means any right to receive Common Stock, cash or other property granted under the Plan (including an Incentive Stock Option, a Nonstatutory Stock Option, a Restricted Stock Award, a RSU Award, a SAR, a Performance Award or any Other Award).

(f) "***Award Agreement***" means a written agreement between the Company and a Participant evidencing the terms and conditions of an Award. The Award Agreement generally consists of the Grant Notice and the agreement containing the written summary of the general terms and conditions applicable to the Award and which is provided to a Participant along with the Grant Notice.

(g) "***Board***" means the Board of Directors of the Company (or its designee). Any decision or determination made by the Board shall be a decision or determination that is made in the sole discretion of the Board (or its designee), and such decision or determination shall be final and binding on all Participants.

(h) "***Capitalization Adjustment***" means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or subject to any Award after the Effective Date without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, reverse stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or any similar equity restructuring transaction, as that term is used in Statement of Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto). Notwithstanding the foregoing, the conversion of any convertible securities of the Company will not be treated as a Capitalization Adjustment.

(i) "***Cause***" has the meaning ascribed to such term in any written agreement between the Participant and the Company defining such term and, in the absence of such agreement, such term means, with respect to a Participant, the occurrence of any of the following events: (i) such Participant's attempted commission of, or participation in, a fraud or act of dishonesty against the Company; (ii) such Participant's intentional, material violation of any contract or agreement between the Participant and the Company or of any statutory duty owed to the Company; (iii) such Participant's unauthorized use or disclosure of the Company's confidential information or trade secrets; or (iv) such Participant's gross misconduct. The determination that a termination of the Participant's Continuous Service is either for Cause or without Cause will be made by the Board with respect to Participants who are executive officers of the Company and by the Company's Chief Executive Officer with respect to Participants who are not executive officers of the Company. Any determination by the Company that the Continuous Service of a Participant was terminated with or without Cause for the purposes of outstanding Awards held by such Participant will have no effect upon any determination of the rights or obligations of the Company or such Participant for any other purpose.

(j) "***Change in Control***" or "***Change of Control***" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events; provided, however, to the extent necessary to avoid adverse personal income tax consequences to the Participant in connection with an Award, also constitutes a Section 409A Change in Control:

(i) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control shall not be deemed to occur (A) on account of the acquisition of securities of the Company directly from the Company, (B) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person that acquires the Company's securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities, or (C) solely because the level of Ownership held by any Exchange Act Person (the "*Subject Person*") exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control shall be deemed to occur;

(ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing more than 50% of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or (B) more than 50% of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar transaction,

in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction;

(iii) the stockholders of the Company approve or the Board approves a plan of complete dissolution or liquidation of the Company, or a complete dissolution or liquidation of the Company shall otherwise occur, except for a liquidation into a parent corporation;

(iv) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than 50% of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; or

(v) individuals who, on the date the Plan is adopted by the Board, are members of the Board (the "***Incumbent Board***") cease for any reason to constitute at least a majority of the members of the Board; provided, however, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member shall, for purposes of this Plan, be considered as a member of the Incumbent Board.

Notwithstanding the foregoing or any other provision of this Plan, the term Change in Control shall not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company.

(k) "***Code***" means the Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(l) "***Committee***" means the Compensation Committee and any other committee of Directors to whom authority has been delegated by the Board or Compensation Committee in accordance with the Plan.

(m) "***Common Stock***" means the common stock of the Company.

(n) "***Company***" means **Minerva Neurosciences, Inc.,** a Delaware corporation.

(o) "***Compensation Committee***" means the Compensation Committee of the Board.

(p) "***Consultant***" means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for such services. However, service solely as a Director, or payment of a fee for such service, will not cause a Director to be considered a "Consultant" for purposes of the Plan. Notwithstanding the foregoing, a person is treated as a Consultant under this Plan only if a Form S-8 Registration Statement under the Securities Act is available to register either the offer or the sale of the Company's securities to such person.

(q) "***Continuous Service***" means that the Participant's service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Director or Consultant or a change in the Entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant's service with the Company or an Affiliate, will not terminate a Participant's Continuous Service; provided, however, that if the Entity for which a Participant is rendering services ceases to qualify as an Affiliate, as determined by the Board, such Participant's Continuous Service will be considered to have terminated on the date such Entity ceases to qualify as an Affiliate. For example, a change in status from an Employee of the Company to a Consultant of an Affiliate or to a Director will not constitute an interruption of Continuous Service. To the extent permitted by law, the Board or the chief executive officer of the Company, in that party's sole discretion, may determine whether Continuous Service will be considered interrupted in the case of (i) any leave of absence approved by the Board or chief executive officer, including sick leave, military leave or any other personal leave, or (ii) transfers between the Company, an Affiliate, or their successors. Notwithstanding the foregoing, a leave of absence will be treated as Continuous Service for purposes of vesting in an Award only to such extent as may be provided in the Company's leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law. In addition, to the extent required for exemption from or compliance with Section 409A, the determination of whether there has been a termination of Continuous Service will be made, and such term will be construed, in a manner that is consistent with the definition of "separation from service" as defined under Treasury Regulation Section 1.409A-1(h) (without regard to any alternative definition thereunder).

(r) "***Director***" means a member of the Board.

(s) "***determine***" ***or*** "***determined***" means as determined by the Board or the Committee (or its designee) in its sole discretion.

(t) "***Disability***" means, with respect to a Participant, such Participant is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months, as provided in Section 22(e)(3) of the Code, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances.

(u) "***Effective Date***" means the date of the annual meeting of stockholders of the Company held in 2020 provided this Plan is approved by the Company's stockholders at such meeting.

(v) "***Employee***" means any person employed by the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, will not cause a Director to be considered an "Employee" for purposes of the Plan.

(w) "***Employer***" means the Company or the Affiliate of the Company that employs the Participant.

(x) "***Entity***" means a corporation, partnership, limited liability company or other entity.

(y) "***Exchange Act***" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

(z) "***Exchange Act Person***" means any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that "Exchange Act Person" will not include (i) the Company or any Subsidiary of the Company, (ii) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (iii) an underwriter temporarily holding securities pursuant to a registered public offering of such securities, (iv) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company; or (v) any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that, as of the Effective Date, is the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities.

(aa) "***Fair Market Value***" means, as of any date, unless otherwise determined by the Board, the value of the Common Stock (as determined on a per share or aggregate basis, as applicable) determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value will be the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the date of determination, as reported in a source the Board deems reliable.

(ii) If there is no closing sales price for the Common Stock on the date of determination, then the Fair Market Value will be the closing selling price on the last preceding date for which such quotation exists.

(iii) In the absence of such markets for the Common Stock, or if otherwise determined by the Board, the Fair Market Value will be determined by the Board in good faith and in a manner that complies with Sections 409A and 422 of the Code.

(bb) "***Governmental Body***" means any: (a) nation, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or regulatory body, or quasi-governmental body of any nature (including any governmental division, department, administrative agency or bureau, commission, authority, instrumentality, official, ministry, fund, foundation, center, organization, unit, body or Entity and any court or other tribunal, and for the avoidance of doubt, any Tax authority) or other body exercising similar powers or authority; or (d) self-regulatory organization (including the Nasdaq Stock Market, New York Stock Exchange, and the Financial Industry Regulatory Authority).

(cc) "***Grant Notice***" means the notice provided to a Participant that he or she has been granted an Award under the Plan and which includes the name of the Participant, the type of Award, the date of grant of the Award, number of shares of Common Stock subject to the Award or potential cash payment right, (if any), the vesting schedule for the Award (if any) and other key terms applicable to the Award.

(dd) "***Incentive Stock Option***" means an option granted pursuant to Section 4 of the Plan that is intended to be, and qualifies as, an "incentive stock option" within the meaning of Section 422 of the Code.

(ee) "***Materially Impair***" means any amendment to the terms of the Award that materially adversely affects the Participant's rights under the Award. A Participant's rights under an Award will not be deemed to have been Materially Impaired by any such amendment if the Board, in its sole discretion, determines that the amendment, taken as a whole, does not materially impair the Participant's rights. For example, the following types of amendments to the terms of an Award do not Materially Impair the Participant's rights under the Award: (i) imposition of reasonable restrictions on the minimum number of shares subject to an Option that may be exercised, (ii) to maintain the qualified status of the Award as an Incentive Stock Option under Section 422 of the Code; (iii) to change the terms of an Incentive Stock Option in a manner that disqualifies, impairs or otherwise affects the qualified status of the Award as an Incentive Stock Option under Section 422 of the Code; (iv) to clarify the manner of exemption from, or to bring the Award into compliance with or qualify it for an exemption from, Section 409A; or (v) to comply with other Applicable Laws.

(ff) "***Non-Employee Director***" means a Director who either (i) is not a current employee or officer of the Company or an Affiliate, does not receive compensation, either directly or indirectly, from the Company or an Affiliate for services rendered as a consultant or in any capacity other than as a Director (except for an amount as to which disclosure would not be required under Item 404(a) of Regulation S-K promulgated pursuant to the Securities Act ("***Regulation S-K***")), does not possess an interest in any other transaction for which disclosure would be required under Item 404(a) of Regulation S-K, and is not engaged in a business relationship for which disclosure would be required pursuant to Item 404(b) of Regulation S-K; or (ii) is otherwise considered a "non-employee director" for purposes of Rule 16b-3.

(gg) "***Nonstatutory Stock Option***" means any option granted pursuant to Section 4 of the Plan that does not qualify as an Incentive Stock Option.

(hh) "***Officer***" means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act.

(ii) "***Option***" means an Incentive Stock Option or a Nonstatutory Stock Option to purchase shares of Common Stock granted pursuant to the Plan.

(jj) "***Option Agreement***" means a written agreement between the Company and the Optionholder evidencing the terms and conditions of the Option grant. The Option Agreement includes the Grant Notice for the Option and the agreement containing the written summary of the general terms and conditions applicable to the Option and which is provided to a Participant along

with the Grant Notice. Each Option Agreement will be subject to the terms and conditions of the Plan.

(kk) "***Optionholder***" means a person to whom an Option is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Option.

(ll) "***Other Award***" means an award based in whole or in part by reference to the Common Stock which is granted pursuant to the terms and conditions of Section 5(c).

(mm) "***Other Award Agreement***" means a written agreement between the Company and a holder of an Other Award evidencing the terms and conditions of an Other Award grant. Each Other Award Agreement will be subject to the terms and conditions of the Plan.

(nn) "***Own,***" "***Owned,***" "***Owner,***" "***Ownership***" means that a person or Entity will be deemed to "Own," to have "Owned," to be the "Owner" of, or to have acquired "Ownership" of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

(oo) "***Participant***" means an Employee, Director or Consultant to whom an Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Award.

(pp) "***Performance Award***" means an Award that may vest or may be exercised or a cash award that may vest or become earned and paid contingent upon the attainment during a Performance Period of certain Performance Goals and which is granted under the terms and conditions of Section 5(b) pursuant to such terms as are approved by the Board. In addition, to the extent permitted by Applicable Law and set forth in the applicable Award Agreement, the Board may determine that cash or other property may be used in payment of Performance Awards. Performance Awards that are settled in cash or other property are not required to be valued in whole or in part by reference to, or otherwise based on, the Common Stock.

(qq) "***Performance Criteria***" means the one or more criteria that the Board will select for purposes of establishing the Performance Goals for a Performance Period. The Performance Criteria that will be used to establish such Performance Goals may be based on any measure of performance selected by the Board.

(rr) "***Performance Goals***" means, for a Performance Period, the one or more goals established by the Board for the Performance Period based upon the Performance Criteria. Performance Goals may be based on a Company-wide basis, with respect to one or more business units, divisions, Affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by the Board (i) in the Award Agreement at the time the Award is granted or (ii) in such other document setting forth the Performance Goals at the time the Performance Goals are established, the Board will appropriately make adjustments in the method of calculating the attainment of Performance Goals for a Performance Period as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of items that

are “unusual” in nature or occur “infrequently” as determined under generally accepted accounting principles; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any business divested by the Company achieved performance objectives at targeted levels during the balance of a Performance Period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of common stock of the Company by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock based compensation and the award of bonuses under the Company’s bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to expensed under generally accepted accounting principles; (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles; and (12) to exclude the effects of the timing of acceptance for filing, review and/or approval of submissions to the U.S. Food and Drug Administration or any other regulatory body. In addition, the Board retains the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of Performance Goals and to define the manner of calculating the Performance Criteria it selects to use for such Performance Period. Partial achievement of the specified criteria may result in the payment or vesting corresponding to the degree of achievement as specified in the Award Agreement or the written terms of a Performance Cash Award.

(ss) “***Performance Period***” means the period of time selected by the Board over which the attainment of one or more Performance Goals will be measured for the purpose of determining a Participant’s right to vesting or exercise of an Award. Performance Periods may be of varying and overlapping duration, at the sole discretion of the Board.

(tt) “***Plan***” means this Amended and Restated Minerva Neurosciences, Inc. 2013 Equity Incentive Plan.

(uu) “***Plan Administrator***” means the person, persons, and/or third-party administrator designated by the Company to administer the day to day operations of the Plan and the Company’s other equity incentive programs.

(vv) “***Post-Termination Exercise Period***” means the period following termination of a Participant’s Continuous Service within which an Option or SAR is exercisable, as specified in Section 4(h).

(ww) “***Prior Plan’s Available Reserve***” means the number of shares available for the grant of new awards under the Prior Plan as of immediately prior to the Effective Date.

(xx) “***Prior Plan***” means the Amended and Restated Minerva Neurosciences, Inc. 2013 Equity Incentive Plan prior to the Effective Date the Plan.

(yy) “***Prospectus***” means the document containing the Plan information specified in Section 10(a) of the Securities Act.

(zz) “***Restricted Stock Award***” or “***RSA***” means an Award of shares of Common Stock which is granted pursuant to the terms and conditions of Section 5(a).

(aaa) "***Restricted Stock Award Agreement***" means a written agreement between the Company and a holder of a Restricted Stock Award evidencing the terms and conditions of a Restricted Stock Award grant. The Restricted Stock Award Agreement includes the Grant Notice for the Restricted Stock Award and the agreement containing the written summary of the general terms and conditions applicable to the Restricted Stock Award and which is provided to a Participant along with the Grant Notice. Each Restricted Stock Award Agreement will be subject to the terms and conditions of the Plan.

(bbb) "***Returning Shares***" means shares subject to outstanding stock awards granted under the Prior Plan and that following the Effective Date: (A) are not issued because such stock award or any portion thereof expires or otherwise terminates without all of the shares covered by such stock award having been issued; (B) are not issued because such stock award or any portion thereof is settled in cash; or (C) are forfeited back to or repurchased by the Company because of the failure to meet a contingency or condition required for the vesting of such shares.

(ccc) "***RSU Award***" or "***RSU***" means an Award of restricted stock units representing the right to receive an issuance of shares of Common Stock which is granted pursuant to the terms and conditions of Section 5(a).

(ddd) "***RSU Award Agreement***" means a written agreement between the Company and a holder of a RSU Award evidencing the terms and conditions of a RSU Award grant. The RSU Award Agreement includes the Grant Notice for the RSU Award and the agreement containing the written summary of the general terms and conditions applicable to the RSU Award and which is provided to a Participant along with the Grant Notice. Each RSU Award Agreement will be subject to the terms and conditions of the Plan.

(eee) "***Rule 16b-3***" means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.

(fff) "***Rule 405***" means Rule 405 promulgated under the Securities Act.

(ggg) "***Section 409A***" means Section 409A of the Code and the regulations and other guidance thereunder.

(hhh) "***Section 409A Change in Control***" means a change in the ownership or effective control of the Company, or in the ownership of a substantial portion of the Company's assets, as provided in Section 409A(a)(2)(A)(v) of the Code and Treasury Regulations Section 1.409A-3(i)(5) (without regard to any alternative definition thereunder).

(iii) "***Securities Act***" means the Securities Act of 1933, as amended.

(jjj) "***Share Reserve***" means the number of shares available for issuance under the Plan as set forth in Section 2(a).

(kkk) "***Stock Appreciation Right***" or "***SAR***" means a right to receive the appreciation on Common Stock that is granted pursuant to the terms and conditions of Section 4.

(lll) "***SAR Agreement***" means a written agreement between the Company and a holder of a SAR evidencing the terms and conditions of a SAR grant. The SAR Agreement includes the Grant Notice for the SAR and the agreement containing the written summary of the general terms and conditions applicable to the SAR and which is provided to a Participant along with the Grant Notice. Each SAR Agreement will be subject to the terms and conditions of the Plan.

(mmm) "***Subsidiary***" means, with respect to the Company, (i) any corporation of which more than 50% of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation will have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than 50%.

(nnn) "***Ten Percent Stockholder***" means a person who Owns (or is deemed to Own pursuant to Section 424(d) of the Code) stock possessing more than 10% of the total combined voting power of all classes of stock of the Company or any Affiliate.

(ooo) "***Trading Policy***" means the Company's policy permitting certain individuals to sell Company shares only during certain "window" periods and/or otherwise restricts the ability of certain individuals to transfer or encumber Company shares, as in effect from time to time.

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: November 7, 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: November 7, 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 September 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: November 7, 2023

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

/s/ Frederick Ahlholm

Date: November 7, 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.