

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, 2019

OR

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

For the transition period from _____ to _____

Commission File No. 001-36517

Minerva Neurosciences, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

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

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

02451
(Zip Code)

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

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

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

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

The number of shares of Registrant's Common Stock, \$0.0001 par value per share, outstanding as of October 30, 2019 was 39,025,471.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES NO

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES NO

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

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

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

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

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

PART I – Financial Information
Item 1 – Financial Statements

MINERVA NEUROSCIENCES, INC.
Condensed Consolidated Balance Sheets
(Unaudited)

	September 30, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	\$ 37,905,972	\$ 50,234,871
Marketable securities	22,026,814	37,762,439
Restricted cash	100,000	100,000
Prepaid expenses and other current assets	1,376,637	1,921,050
Total current assets	61,409,423	90,018,360
Equipment, net	20,378	33,478
Other noncurrent assets	14,808	14,808
Operating lease right-of-use assets	299,392	—
In-process research and development	34,200,000	34,200,000
Goodwill	14,869,399	14,869,399
Total assets	\$ 110,813,400	\$ 139,136,045
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	5,330,450	1,799,666
Accrued expenses and other current liabilities	4,398,350	1,809,532
Operating leases	167,181	—
Total current liabilities	9,895,981	3,609,198
Deferred taxes	4,057,488	4,057,488
Deferred revenue	41,175,600	41,175,600
Noncurrent operating leases	156,956	—
Other noncurrent liabilities	—	28,990
Total liabilities	55,286,025	48,871,276
Commitments and contingencies (Note 9)		
Stockholders' equity		
Preferred stock; \$0.0001 par value; 100,000,000 shares authorized; none issued or outstanding as of September 30, 2019 and December 31, 2018, respectively	—	—
Common stock; \$0.0001 par value; 125,000,000 shares authorized; 39,025,471 and 38,937,971 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	3,903	3,894
Additional paid-in capital	312,341,874	304,813,603
Accumulated deficit	(256,818,402)	(214,552,728)
Total stockholders' equity	55,527,375	90,264,769
Total liabilities and stockholders' equity	\$ 110,813,400	\$ 139,136,045

See accompanying notes to condensed consolidated financial statements

**Condensed Consolidated Statements of Operations
(Unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Expenses				
Research and development	\$ 9,674,310	\$ 8,369,451	\$ 29,600,119	\$ 25,880,952
General and administrative	4,607,462	4,054,575	13,897,497	12,221,429
Total expenses	<u>14,281,772</u>	<u>12,424,026</u>	<u>43,497,616</u>	<u>38,102,381</u>
Loss from operations	(14,281,772)	(12,424,026)	(43,497,616)	(38,102,381)
Foreign exchange (losses) gains	(4,766)	(10,987)	(17,797)	178
Investment income	324,535	418,347	1,249,739	1,244,196
Interest expense	—	(4,018)	—	(110,448)
Net loss	<u>\$ (13,962,003)</u>	<u>\$ (12,020,684)</u>	<u>\$ (42,265,674)</u>	<u>\$ (36,968,455)</u>
Net loss per share, basic and diluted	<u>\$ (0.36)</u>	<u>\$ (0.31)</u>	<u>\$ (1.08)</u>	<u>\$ (0.95)</u>
Weighted average shares outstanding, basic and diluted	<u>39,025,471</u>	<u>38,781,839</u>	<u>39,006,561</u>	<u>38,760,294</u>

See accompanying notes to condensed consolidated financial statements

Condensed Consolidated Statement of Stockholders' Equity
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount			
Balances at January 1, 2018	38,749,343	\$ 3,875	\$ 295,975,010	\$ (164,381,441)	\$ 131,597,444
Stock-based compensation	—	—	2,113,936	—	2,113,936
Net loss	—	—	—	(12,418,263)	(12,418,263)
Balances at March 31, 2018	38,749,343	3,875	298,088,946	(176,799,704)	121,293,117
Stock-based compensation	—	—	1,897,873	—	1,897,873
Net loss	—	—	—	(12,529,508)	(12,529,508)
Balances at June 30, 2018	38,749,343	3,875	299,986,819	(189,329,212)	110,661,482
Exercise of stock options	97,124	10	490,819	—	490,829
Stock-based compensation	—	—	2,261,781	—	2,261,781
Net loss	—	—	—	(12,020,684)	(12,020,684)
Balances at September 30, 2018	38,846,467	\$ 3,885	\$ 302,739,419	\$ (201,349,896)	\$ 101,393,408
Balances at January 1, 2019	38,937,971	\$ 3,894	\$ 304,813,603	\$ (214,552,728)	\$ 90,264,769
Exercise of stock options	87,500	9	524,991	—	525,000
Stock-based compensation	—	—	2,461,699	—	2,461,699
Net loss	—	—	—	(15,827,200)	(15,827,200)
Balances at March 31, 2019	39,025,471	3,903	307,800,293	(230,379,928)	77,424,268
Stock-based compensation	—	—	2,320,392	—	2,320,392
Net loss	—	—	—	(12,476,471)	(12,476,471)
Balances at June 30, 2019	39,025,471	3,903	310,120,685	(242,856,399)	67,268,189
Stock-based compensation	—	—	2,221,189	—	2,221,189
Net loss	—	—	—	(13,962,003)	(13,962,003)
Balances at September 30, 2019	39,025,471	\$ 3,903	\$ 312,341,874	\$ (256,818,402)	\$ 55,527,375

See accompanying notes to condensed consolidated financial statements

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

	<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>
Cash flows from operating activities:		
Net loss	\$ (42,265,674)	\$ (36,968,455)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	13,100	13,100
Amortization of debt discount recorded as interest expense	—	38,040
Accretion of marketable securities premium	(661,830)	(92,801)
Amortization of right-of-use assets	106,600	—
Stock-based compensation expense	7,003,280	6,273,590
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	529,112	(2,400,372)
Accounts payable	3,530,784	(560,887)
Accrued expenses and other current liabilities	2,588,818	1,555,667
Operating lease liabilities, current	31,631	—
Other noncurrent liabilities	—	198
Operating lease liabilities, noncurrent	(127,175)	—
Net cash used in operating activities	<u>(29,251,354)</u>	<u>(32,141,920)</u>
Cash flows from investing activities:		
Proceeds from the maturity and redemption of marketable securities	65,845,000	104,851,000
Purchase of marketable securities	(49,447,545)	(7,934,482)
Net cash provided by investing activities	<u>16,397,455</u>	<u>96,916,518</u>
Cash flows from financing activities:		
Proceeds from exercise of stock options	525,000	490,829
Repayments of notes payable	—	(4,000,704)
Net cash provided by (used in) financing activities	<u>525,000</u>	<u>(3,509,875)</u>
Net (decrease) increase in cash, cash equivalents, and restricted cash	<u>(12,328,899)</u>	<u>61,264,723</u>
Cash, cash equivalents and restricted cash		
Beginning of period	50,334,871	26,131,821
End of period	<u>\$ 38,005,972</u>	<u>\$ 87,396,544</u>
Supplemental disclosure of cash flow information		
Cash paid for interest	<u>\$ —</u>	<u>\$ 92,916</u>
Reconciliation of the Condensed Consolidated Statements of Cash Flows to the Condensed Consolidated Balance Sheets		
Cash and cash equivalents	\$ 37,905,972	\$ 87,296,544
Restricted cash	100,000	100,000
Total cash, cash equivalents and restricted cash	<u>\$ 38,005,972</u>	<u>\$ 87,396,544</u>

See accompanying notes to condensed consolidated financial statements

MINERVA NEUROSCIENCES, INC.
Notes to Condensed Consolidated Financial Statements
As of September 30, 2019 and for the Nine Months Ended September 30, 2019 and 2018
(Unaudited)

NOTE 1 — NATURE OF OPERATIONS AND LIQUIDITY

Nature of Operations

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

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

Liquidity

The accompanying financial statements have been prepared as though the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has limited capital resources and has incurred recurring operating losses and negative cash flows from operations since inception. As of September 30, 2019, the Company has an accumulated deficit of approximately \$256.8 million and net cash used in operating activities was approximately \$29.3 million during the nine months ended September 30, 2019. The Company’s management team expects to continue to incur operating losses and negative cash flows from operations. The Company has financed its operations to date from proceeds from the sale of common stock, warrants, loans and convertible promissory notes.

As of September 30, 2019, the Company had cash, cash equivalents, marketable securities, and restricted cash of \$60.0 million. The Company believes that its existing cash, cash equivalents, restricted cash and marketable securities will be sufficient to meet its cash commitments for at least the next 12 months after the date that the interim condensed financial statements are issued. The process of drug development can be costly and the timing and outcomes of clinical trials is uncertain. The assumptions upon which the Company has based its estimates are routinely evaluated and may be subject to change. The actual amount of the Company’s expenditures will vary depending upon a number of factors including but not limited to the design, timing and duration of future clinical trials, the progress of the Company’s research and development programs, the infrastructure to support a commercial enterprise, the cost of a commercial product launch and the level of financial resources available. The Company has the ability to adjust its operating plan spending levels based on the timing of future clinical trials which will be predicated upon adequate funding to complete the trials.

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

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation

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

Consolidation

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

Significant risks and uncertainties

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

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

Use of estimates

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

Cash and cash equivalents

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

Marketable securities

Marketable securities consists of corporate and U.S. government debt securities maturing in 5.40 months or less. Based on the Company's intentions regarding its marketable securities, all marketable securities are classified as held-to-maturity and are carried under the amortized cost approach. The Company's investments in marketable securities are classified as Level 2 within the fair value hierarchy. As of September 30, 2019, remaining final maturities of marketable securities ranged from October 2019 to March 2020, with a weighted average remaining maturity of approximately 3 months. The following tables provide the amortized cost basis, aggregate fair value, unrealized gains/losses, and the net carrying value of investments in held-to-maturity securities as of September 30, 2019 and December 31, 2018:

	September 30, 2019				
	Amortized Cost	Aggregate Fair Value	Unrealized Gains	Unrealized Losses	Net Carrying Value
Marketable securities:					
Corporate bonds/notes	\$ 1,798,824	\$ 1,799,028	\$ —	\$ (204)	\$ 1,798,824
Commercial paper	16,012,842	16,012,842	—	—	\$ 16,012,842
U.S. government agency securities	2,482,684	2,483,350	—	(666)	\$ 2,482,684
Foreign bonds	1,732,464	1,734,139	—	(1,675)	\$ 1,732,464
Marketable securities current total	<u>\$ 22,026,814</u>	<u>\$ 22,029,359</u>	<u>\$ —</u>	<u>\$ (2,545)</u>	<u>\$ 22,026,814</u>

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

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 September 30, 2019 and December 31, 2018.

Research and development costs

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

In-process research and development

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

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

Stock-based compensation

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

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

Foreign currency transactions

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

Loss per share

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

Concentration of credit risk

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

Equipment

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

Leases

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

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

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

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

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

Long-lived assets

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

Goodwill

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

Revenue recognition

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

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

Deferred revenue

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

Segment information

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

Comprehensive loss

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

Recent accounting pronouncements

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

Recently adopted accounting pronouncements

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

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

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

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

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

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

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

Accounting pronouncements not yet adopted

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

NOTE 3 — ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities consist of the following:

	September 30, 2019	December 31, 2018
Research and development costs and other accrued expenses	\$ 2,532,675	\$ 1,353,987
Accrued bonus	1,407,454	—
Professional fees	374,854	455,545
Vacation pay	83,367	—
	<u>\$ 4,398,350</u>	<u>\$ 1,809,532</u>

NOTE 4 — NET LOSS PER SHARE OF COMMON STOCK

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net loss	\$ (13,962,003)	\$ (12,020,684)	\$ (42,265,674)	\$ (36,968,455)
Weighted average shares of common stock outstanding	39,025,471	38,781,839	39,006,561	38,760,294
Net loss per share of common stock – basic and diluted	\$ (0.36)	\$ (0.31)	\$ (1.08)	\$ (0.95)

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

	September 30,	
	2019	2018
Common stock options	8,508,672	6,793,026
Restricted stock units	127,300	185,950
Common stock warrants	40,790	40,790

NOTE 5 — DEBT***Loan and security agreement***

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

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

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

For the three months ended September 30, 2019 and 2018, the Company recognized interest expense of zero and \$9 thousand, respectively, including zero and \$1 thousand, respectively, related to the debt discount. For the nine months ended September 30, 2019 and 2018, the Company recognized interest expense of zero and \$0.1 million respectively, including zero and \$38 thousand, respectively, related to the debt discount.

NOTE 6 — CO-DEVELOPMENT AND LICENSE AGREEMENT

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

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

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

In June 2017, the Company entered into an amendment (“the Amendment”) to the Agreement. The effectiveness of the Amendment was contingent upon approval of its terms by the European Commission and the closing of the acquisition of Actelion Ltd. by affiliates of Janssen. These conditions were subsequently met, and the Amendment became effective on August 29, 2017. Under the Amendment, Janssen has waived its right to royalties on seltorexant insomnia sales in the Minerva Territory. The Company retains all of its rights to seltorexant, including commercialization of the molecule for the treatment of insomnia and as an adjunctive therapy for MDD, which include an exclusive license in the Minerva Territory, with royalties payable by the Company to Janssen on seltorexant sales outside of the insomnia indication. Royalties on sales outside of the Minerva Territory are payable by Janssen to the Company. Janssen made an upfront payment to the Company of \$30 million upon the effectiveness of the Amendment and agreed to make a \$20 million payment at the start of a Phase 3 insomnia trial for seltorexant and a \$20 million payment when 50% of the patients are enrolled in this trial. Janssen further agreed to waive development payments from the Company until completion of the Phase 2b development milestone. This milestone is referred to as “Decision Point 4”. Top-line results have been reported from three Phase 2b trials and one Phase 1b trial with seltorexant. The \$30 million payment and \$11.2 million in previously accrued collaborative expenses, which were forgiven upon the effective date of the Amendment, are earned and recognized as revenue as the services are performed from the commencement of Phase 3 development to the completion of the development activities using the proportional performance method. The \$30 million payment along with the \$11.2 million in previously accrued collaborative expenses have been included under deferred revenue on the Company’s balance sheet at September 30, 2019 and December 31, 2018. In connection with the Amendment, the Company repurchased all of the approximately 3.9 million shares of its common stock previously owned by Johnson & Johnson Innovation-JJDC Inc. at a per share price of \$0.0001, for an aggregate purchase price of approximately \$389.

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

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

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

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

NOTE 7 — STOCKHOLDERS' EQUITY

Term loan warrants

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

NOTE 8 — STOCK AWARD PLAN AND STOCK-BASED COMPENSATION

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

	Shares Issuable Pursuant to Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Total Intrinsic Value (in thousands)
Outstanding January 1, 2019	8,498,047	\$ 6.99	8.1	\$ 5,214
Granted	140,000	\$ 5.11		
Exercised	(87,500)	\$ 6.00		
Forfeited	(41,875)	\$ 6.49		
Outstanding September 30, 2019	8,508,672	\$ 6.97	7.4	\$ 10,972
Exercisable September 30, 2019	4,765,748	\$ 6.55	6.3	\$ 8,261
Available for future grant	671,654			

The weighted average grant-date fair value of stock options outstanding on September 30, 2019 was \$5.08 per share. Total unrecognized compensation costs related to non-vested stock options at September 30, 2019 were approximately \$17.5 million and are expected to be recognized within future operating results over a weighted-average period of 2.58 years. The total intrinsic value of the options exercised during the nine months ended September 30, 2019 was approximately \$0.2 million. The total intrinsic value of the options exercised during the nine months ended September 30, 2018 was approximately \$0.5 million.

The expected term of the employee-related options was estimated using the “simplified” method as defined by the SEC’s Staff Accounting Bulletin No. 107, *Share-Based Payment*. The volatility assumption was determined by examining the historical volatilities for industry peer companies, as the Company did not have sufficient trading history for its common stock. The risk-free interest rate assumption is based on the U.S. Treasury instruments, the term of which was consistent with the expected term of the options. The dividend assumption is based on the Company’s history and expectation of dividend payouts. The Company has never paid dividends on its common stock and does not anticipate paying dividends on its common stock in the foreseeable future. Accordingly, the Company has assumed no dividend yield for purposes of estimating the fair value of the options.

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

	September 30,	
	2019	2018
Expected term (years)	5.5	5.5-6.25
Risk free interest rate	1.91-1.96%	2.33-2.93%
Volatility	74-77%	76-83%
Dividend yield	0%	0%
Weighted average grant date fair value per share of common stock	\$ 3.26	\$ 4.97

The Company from time to time grants options to purchase common stock to non-employees for services rendered and records expense ratably over the vesting period of each award. The Company estimates the fair value of the stock options using the Black-Scholes valuation model at each reporting date. The Company granted zero stock options to non-employees and recorded stock-based compensation expenses of \$0.5 million during the nine months ended September 30, 2019. The Company granted 40,000 stock options to non-employees and recorded stock-based compensation expenses of \$1.0 million during the nine months ended September 30, 2018.

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

	September 30,	
	2019 ⁽¹⁾	2018
Expected term (years)	—	7.9-9.3
Risk free interest rate	—	2.46-3.04%
Volatility	—	83-88%
Dividend yield	—	0%
Weighted average reporting date fair value per share of common stock	—	\$ 10.94

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

RSU activity under the Plan for the nine months ended September 30, 2019 is as follows:

	RSUs	Weighted-Average Grant Date Fair Value
Unvested January 1, 2019	127,300	\$ 11.71
Granted	—	\$ —
Vested	—	\$ —
Forfeited	—	\$ —
Unvested September 30, 2019	<u>127,300</u>	<u>\$ 11.71</u>

RSUs awarded to employees generally vest one-fourth per year over four years from the anniversary of the date of grant, provided the employee remains continuously employed with the Company. Shares of the Company's stock are delivered to the employee upon vesting, subject to payment of applicable withholding taxes. The fair value of RSUs is equal to the closing price of the Company's common stock on the date of grant. Total unrecognized compensation costs related to non-vested RSUs at September 30, 2019 was approximately \$0.9 million and is expected to be recognized within future operating results over a period of 1.35 years. 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,	
	2019	2018	2019	2018
Research and development	\$ 651,835	\$ 718,507	\$ 2,005,816	\$ 1,827,372
General and administrative	1,569,354	1,543,274	4,997,464	4,446,218
Total	\$ 2,221,189	\$ 2,261,781	\$ 7,003,280	\$ 6,273,590

NOTE 9 — COMMITMENTS AND CONTINGENCIES

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

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

NOTE 10 — LEASES

Operating leases

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

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

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

	Nine Months Ended September 30, 2019
Sublease cost	
Operating Sublease cost	\$ 134,452
Total Sublease cost	\$ 134,452
Other information	
Operating cash flows used for operating Sublease	\$ 123,396
Weighted average remaining Sublease term	1.8 years
Weighted average discount rate	10%

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

Future Operating Sublease Payments	Waltham
2019 (excluding the nine months ended September 30, 2019)	\$ 47,384
2020	192,004
2021	114,018
Thereafter	—
Total Sublease payments	\$ 353,406
Less: imputed interest	(29,269)
Total operating Sublease liabilities at September 30, 2019	\$ 324,137

NOTE 11 — RELATED PARTY TRANSACTIONS

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

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

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

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

Overview

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

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

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

Clinical Updates

Roluperidone (MIN-101)

Phase 3 Clinical Trial

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

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

A total of 384 patients have been enrolled into the ongoing Phase 3 trial as of October 1, 2019. Due to a cyber-attack on one of our external contractors during the summer of 2019 that resulted in a disruption to patient recruitment in the study, we now expect to complete enrollment at approximately year-end 2019, and we anticipate top-line results from the 12-week, double-blind portion of the study to be available in the first half of 2020.

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

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

Chemistry, Manufacturing and Controls program

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

On September 24, 2019, we announced that we have entered into a long-term commercial supply agreement for roluperidone with Catalent, Inc. (“Catalent”), a leading global provider of advanced delivery technologies, development, and manufacturing solutions for drugs, biologics, gene therapies, and consumer health products. Under the terms of the agreement, Catalent will manufacture and package the finished dose form of the drug at its facility in Schorndorf, Germany. To date, Catalent has worked with us to enable the transfer from pilot to commercial-scale production. This has included analytical methods transfer and validation, process optimization, stability studies, and registration batch manufacturing, as well as packaging studies and assessing the influence of formulation factors on the product’s critical quality attributes as required by Quality by Design process.

Drug-Drug Interaction Studies

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

Brain-Derived Neurotrophic Factor Findings

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

Data from this study were presented at the 2019 Congress of the Schizophrenia International Research Society on April 11, 2019. These findings demonstrate that administration of roluperidone significantly increased BDNF release by astrocytes and hippocampal neurons obtained from the cerebral cortex of newborn rats, as well as the release of GDNF (Glial cell derived neurotrophic factor) in cultured astrocytes. Furthermore, data showed that roluperidone enhanced BDNF gene expression at drug concentrations comparable to those observed in humans at tested doses. Based on these results, we believe that the effect of roluperidone on BDNF and GDNF may indicate its potential for disease modification and improved neuroplasticity, in addition to its observed effects on the σ_2 , serotonergic 5-HT_{2A}, and possibly α_1 -adrenergic neurotransmitter pathways.

Publications

Schizophrenia Research has published online results demonstrating improvements in PSP in patients with schizophrenia treated with roluperidone (Personal and social adjustment effects of roluperidone in patients with schizophrenia and negative symptoms: Results from an exploratory outcome of a randomized placebo-controlled trial).

Schizophrenia Research has also published online results demonstrating improvements with roluperidone on 2 dimensions of negative symptoms (Effects of Roluperidone (MIN-101) on Two Dimensions of the Negative Symptoms Factor Score: Reduced Emotional Experience and Reduced Emotional Expression).

The Journal of American Medical Association Psychiatry has published online results demonstrating that avolition plays a central role in the successful treatment of negative symptoms (Network Analysis Indicates that Avolition is the Most Central Domain for the Successful Treatment of Negative Symptoms: Evidence from the Roluperidone Randomized Clinical Trial).

Combined with previous publications in peer-reviewed journals, a total of 6 peer-reviewed publications of Phase 2b data with roluperidone have appeared.

MIN-117

Phase 2b Trial

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

Enrollment was completed in this study in the third quarter of 2019, with a total of 360 adults with a diagnosis of moderate or severe MDD with anxious distress and without psychotic features enrolled in the U.S. and Europe. Based upon previous clinical observations, we believe that patients with MDD who also have symptoms of anxiety may benefit from treatment with MIN-117. Top-line results are expected in the fourth quarter of 2019.

Patients have been randomized to one of three arms, placebo and the two dosage arms, in a 2:1:1 ratio, resulting in 180 patients in the placebo group and 90 patients in each of the two MIN-117 treatment groups. The study design includes a screening phase of up to three weeks, a 6-week double-blind treatment phase and a 2-week post-study follow-up period.

New Patent Application Related to Pain

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

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

Seltorexant (MIN-202)

Two Phase 2b Trials in MDD

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

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

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

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

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

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

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

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

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

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

Phase 1b trial in MDD

We have recently analyzed data from an exploratory, biomarker, multicenter, placebo-controlled, randomized, double-blind Phase 1b trial of seltorexant (the “MDD1009 Trial”), administered at doses of 20 and 40 mg, as monotherapy in 128 subjects with moderate to severe MDD. The primary objective of this study was to analyze the treatment effect of seltorexant versus placebo on symptoms of depression as measured by the Hamilton Rating Scale for Depression (HDRS₁₇). The presence of subjective sleep disturbance (subjective sleep assessment, Insomnia Severity Index (ISI), and Ruminative Response Scale (RRS)) as a possible indicator of hyper-arousal was used as a stratification factor in patient randomization.

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

The seltorexant 40 mg dose did not show a statistically significant effect at week 5, although the efficacy signal was also more pronounced in the subgroups (MDD patients with presence of subjective sleep disorder, measured as having an ISI >15 or RRS ≥ 50). We believe these data further characterize the mechanism of seltorexant as an antagonist of the orexin system, which is involved in the control of several key functions in the brain, including mood, metabolism and wakefulness.

Phase 2b Trial in Insomnia Disorder

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

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

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

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

MIN-301

Results from a non-human primate study showed that treatment with an analog of MIN-301 resulted in improvements in a range of symptoms associated with a Parkinson’s disease model in primates. The results confirmed the beneficial effects of MIN-301 in non-primate pre-clinical models. We believe these data provide support for advancing MIN-301 into clinical trials for the treatment of Parkinson’s disease in humans. Building upon these data, we are continuing to conduct pre-clinical studies in preparation for an Investigational New Drug (“IND”) or Investigational Medicinal Product Dossier (“IMPD”) filing, with a Phase 1 study expected to commence thereafter.

Financial Overview

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

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

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

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

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

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

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

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

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

Results of Operations

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

Research and Development Expenses

Total research and development expenses were \$9.7 million for the three months ended September 30, 2019 compared to \$8.4 million for the same period in 2018, an increase in total expense of \$1.3 million. The increase in research and development expenses primarily reflects higher development expenses for the Phase 3 clinical trial of roluperidone and the Phase 2b clinical trial of MIN-117.

General and Administrative Expenses

Total general and administrative expenses were \$4.6 million for the three months ended September 30, 2019 compared to \$4.1 million for the same period in 2018, an increase of approximately \$0.5 million. This increase in general and administrative expenses was primarily due to higher professional fees to support pre-commercial activities.

Foreign Exchange (Losses) Gains

Foreign exchange losses were \$5 thousand for the three months ended September 30, 2019 compared to losses of \$11 thousand for the same period in 2018, a decreased loss of \$6 thousand. The decreased loss was primarily due to clinical activities denominated in Euros.

Investment Income

Investment income was \$0.3 million for the three months ended September 30, 2019 compared to \$0.4 million for the same period in 2018, a decrease of \$0.1 million. The decrease was due to a decrease in investment income on cash equivalents and marketable securities.

Interest Expense

Interest expense was zero for the three months ended September 30, 2019 compared to \$4 thousand for the same period in 2018, a decrease of \$4 thousand. The decrease was due to the repayment of principal on our Term A Loans in 2018.

Comparison of Nine Months Ended September 30, 2019 versus September 30, 2018

Research and Development Expenses

Total research and development expenses were \$29.6 million for the nine months ended September 30, 2019 compared to \$25.9 million for the same period in 2018, an increase in total expense of \$3.7 million. The increase in research and development expenses primarily reflects higher development expenses for the Phase 3 clinical trial of roluperidone and the Phase 2b clinical trial of MIN-117. We expect research and development expenses to increase during 2019 as we increase patient enrollment and related support activities for the roluperidone and MIN-117 clinical trials.

General and Administrative Expenses

Total general and administrative expenses were \$13.9 million for the nine months ended September 30, 2019 compared to \$12.2 million for the same period in 2018, an increase of approximately \$1.7 million. This increase in general and administrative expenses was primarily due to an increase in non-cash stock-based compensation expenses, increased salary costs and professional fees to support pre-commercial activities. We expect general and administrative expenses to increase during 2019 as we begin to prepare for the transition from clinical development to commercialization.

Foreign Exchange (Losses) Gains

Foreign exchange losses were \$18 thousand for the nine months ended September 30, 2019 compared to gains of \$0.2 thousand for the same period in 2018, a decrease of \$18 thousand. The loss was primarily due to clinical activities denominated in Euros.

Investment Income

Investment income was \$1.2 million in both nine months ended September 30, 2019 and 2018.

Interest Expense

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

Liquidity and Capital Resources

Sources of Liquidity

We have incurred losses and cumulative negative cash flows from operations since our inception in April 2007 and, as of September 30, 2019, we had an accumulated deficit of approximately \$256.8 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. At September 30, 2019, we had approximately \$60.0 million in cash, cash equivalents, marketable securities, and restricted cash. We believe that our existing cash, cash equivalents, marketable securities, and restricted cash will be sufficient to meet our cash commitments for at least the next 12 months after the date that the interim condensed financial statements are issued. The process of drug development can be costly and the timing and outcomes of clinical trials is uncertain. The assumptions upon which we have based our estimates are routinely evaluated and may be subject to change. The actual amount of our expenditures will vary depending upon a number of factors including but not limited to the design, timing and duration of future clinical trials, the progress of our research and development programs, the infrastructure to support a commercial enterprise, the cost of a commercial product launch and the level of financial resources available. We have the ability to adjust our operating plan spending levels based on the timing of future clinical trials which will be predicated upon adequate funding to complete the trials.

Sources of Funds

Amendment to Co-Development and License Agreement with Janssen

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

Public Offering of Common Stock

On July 5, 2017, we closed a public offering of common stock, in which we issued and sold 5,750,000 shares of our common stock, including 750,000 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares, at a public offering price of \$7.75, for aggregate gross proceeds of \$44.6 million. All of the shares issued and sold in this public offering were registered under the Securities Act of 1933, as amended, pursuant to a registration statement on Form S-3 (File No. 333-205764) and a related prospectus and prospectus supplement, in each case filed with the SEC. We incurred \$3.0 million in underwriting discounts and commissions and transaction costs, which will be included as a component of additional paid-in capital, resulting in net proceeds of approximately \$41.6 million.

Exercise of Warrants

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

Uses of Funds

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

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

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

Cash Flows

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

	Nine Months Ended September 30,	
	2019	2018
	(dollars in millions)	
Net cash (used in) provided by:		
Operating activities	\$ (29.2)	\$ (32.1)
Investing activities	16.4	96.9
Financing activities	0.5	(3.5)
Net (decrease) increase in cash	<u>\$ (12.3)</u>	<u>\$ 61.3</u>

Net Cash Used in Operating Activities

Net cash used in operating activities of approximately \$29.2 million during the nine months ended September 30, 2019 was primarily due to our net loss of \$42.3 million and amortization of investments of \$0.7 million, partially offset by stock-based compensation expense of \$7.0 million, a \$3.6 million increase in accounts payable, a \$2.6 million increase in accrued expenses, and a decrease in prepaid expense of \$0.6 million.

Net cash used in operating activities of approximately \$32.1 million during the nine months ended September 30, 2018 was primarily due to our net loss of \$37.0 million, an increase in prepaid expense of \$2.4 million a decrease in accounts payable of \$0.5 million and amortization of investments of \$0.1 million, partially offset by stock-based compensation expense of \$6.3 million and a \$1.6 million increase in accrued expenses.

Net Cash Provided by Investing Activities

Net cash provided by investing activities of approximately \$16.4 million during the nine months ended September 30, 2019 was primarily due to the maturity and redemption of marketable securities of \$65.8 million, partially offset by the purchase of marketable securities of \$49.4 million.

Net cash provided by investing activities of approximately \$96.9 million during the nine months ended September 30, 2018 was primarily due to the maturity and redemption of marketable securities of \$104.9 million, partially offset by the purchase of marketable securities of \$7.9 million.

Net Cash Provided by (Used in) Financing Activities

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

Net cash used in financing activities of \$3.5 million during the nine months ended September 30, 2018 was due to principal repayments and payment of an end of term fee under the Term A Loans of \$4.0 million, partially offset by the proceeds from the exercise of common stock options of \$0.5 million.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Estimates

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

Recent Accounting Pronouncements

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

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

Not applicable.

Item 4. *Controls and Procedures*

Evaluation of Disclosure Controls and Procedures

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

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

Changes in Internal Control over Financial Reporting

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

PART II

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

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

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

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

We are not profitable and have incurred losses in each period since our inception in 2007. For the nine months ended September 30, 2019 and 2018, we reported net losses of \$42.3 million and \$37.0 million, respectively. As of September 30, 2019, we had an accumulated deficit of \$256.8 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 seek regulatory approvals for, our product candidates. If any of our product candidates fail in clinical trials or do not gain regulatory approval, or if any of our product candidates, if approved, fail to achieve market acceptance, we may never generate revenue or become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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

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

As of September 30, 2019, we had cash, cash equivalents, marketable securities, and restricted cash of \$60.0 million. We believe that our existing cash, cash equivalents, restricted cash, and marketable securities will be sufficient to meet our cash commitments for at least the next 12 months after the date that our interim condensed financial statements are issued. The process of drug development can be costly and the timing and outcomes of clinical trials is uncertain. The assumptions upon which we have based our estimates are routinely evaluated and may be subject to change. The actual amount of our expenditures will vary depending upon a number of factors including but not limited to the design, timing and duration of future clinical trials, the progress of our research and development programs, the infrastructure to support a commercial enterprise, the cost of a commercial product launch and the level of financial resources available.

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

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

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

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. For example, a cyber-attack on one of our external contractors during the summer of 2019 resulted in a disruption to patient recruitment in our Phase 3 clinical trial of roluperidone. Further similar events could occur and cause interruptions in our operations and result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

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

Recent Sales of Unregistered Securities

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

Issuer Purchases of Equity Securities

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

Item 3. Defaults upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

On November 1, 2019, the Board of Directors of the Company amended and restated the Amended and Restated Bylaws of the Company, as amended (the “Restated Bylaws”), effective as of November 1, 2019, to, among other things, update and align the Company’s bylaws with what the Company believes to be appropriate corporate governance standards. Specifically, the Restated Bylaws provide for the Court of Chancery of the State of Delaware to be the exclusive forum for (a) any derivative action brought on behalf of the Company, (b) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Company to the Company or the Company’s stockholders, (c) any action asserting a claim arising pursuant to any provision of the General Corporation Law of Delaware, the certificate of incorporation or the bylaws of the Company, or (d) any action asserting a claim governed by the internal affairs doctrine.

The foregoing description of the Restated Bylaws does not purport to be complete and is qualified in its entirety by reference to the full text of the Restated Bylaws attached hereto as Exhibit 3.2 and incorporated herein by reference.

Item 6. Exhibits

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

<u>Exhibit Number</u>	<u>Description</u>	<u>SEC File No.</u>
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's registration statement on Form S-1/A filed with the SEC on June 10, 2014)	333-195169
3.2	Amended and Restated Bylaws of the Registrant	
10.1†	Commercial Supply Agreement with Catalent Germany Schorndorf GmbH, dated as of September 18, 2019	
31.1	Certification of Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002	
31.2	Certification of Chief Financial Officer (Principal Financial Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002	
32.1+	Certification of Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer) pursuant to Section 906 of Sarbanes-Oxley Act of 2002	
101.INS	XBRL Instance Document	
101.SCH	XBRL Taxonomy Extension Schema Document	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	

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

† Confidential treatment requested under 17 C.F.R. §§ 200.80(c) and 230.406 and Rule 24b-2. The confidential portions of this exhibit have been omitted and are marked accordingly. The confidential portions have been provided separately to the SEC pursuant to the confidential treatment request.

SIGNATURE

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

MINERVA NEUROSCIENCES, INC.

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

Date: November 4, 2019

COMMERCIAL SUPPLY AGREEMENT
MIN-101 Tablets

THIS COMMERCIAL SUPPLY AGREEMENT (“**Agreement**”) is made as of this 2 day of September, 2019 (“**Effective Date**”)

BETWEEN

- (1) Minerva Neurosciences, Inc., an US company, with a place of business at 1601 Trapelo Road, Suite 286, Waltham, Massachusetts 02451 USA (“**Client**”); and
- (2) Catalent Germany Schorndorf GmbH, a German company., with a place of business at Steinbeisstrasse 1-2, 73614 Schorndorf, Germany (“**Catalent**”).

RECITALS

- A. Client is a company that develops, markets and sells pharmaceutical products.
- B. Catalent is a leading provider of advanced technologies, and development, manufacturing and packaging services for pharmaceutical, biotechnology and consumer healthcare companies.
- C. Client desires to engage Catalent to provide certain services to Client in connection with the processing of Client's Product, and Catalent desires to provide such services, all pursuant to the terms and conditions set out in this Agreement.

THEREFORE, the parties agree as follows:

1. DEFINITIONS

The following terms have the following meanings in this Agreement:

- 1.1 “**Acknowledgement**” has the meaning set out in Clause 4.3.
 - 1.2 “**Affiliate(s)**” means, with respect to Client or any third party, any company, corporation, firm, partnership or other entity that controls, is controlled by or is under common control with such entity; and with respect to Catalent, Inc. and any company, corporation, firm, partnership or other entity controlled by Catalent, Inc. For the purposes of this definition, “**control**” means the ownership of at least 50% of the voting share capital of an entity or any other comparable equity or ownership interest.
 - 1.3 “**Agreement**” has the meaning set out in the introductory paragraph, and includes all its Attachments and other appendices (all of which are incorporated herein by reference).
 - 1.4 “**API**” means the compound MIN-101 (Risperidone), as further described in the Specifications.
 - 1.5 “**API Inventions**” has the meaning set out in Clause 11.
-

- 1.6 “**Applicable Laws**” means, with respect to Client, all laws, statutes, statutory provisions or subordinate legislation, currently in effect or enacted or promulgated during the Term, and as amended from time to time, of each jurisdiction in which API or Product is produced, marketed, distributed, used or sold; and with respect to Catalent, all laws, statutes, statutory provisions and subordinate legislation, currently in effect or enacted or promulgated during the Term, and as amended from time to time, of the jurisdiction in which Catalent Processes Product, including cGMP.
- 1.7 “**Batch**” means a defined quantity of Product that has been or is being Processed in accordance with the Specifications.
- 1.8 “**Catalent Defective Processing**” has the meaning set out in Clause 5.2.
- 1.9 “**Catalent**” has the meaning set out in the introductory paragraph. Catalent shall have the right to cause any of its Affiliates to perform any of its obligations hereunder, and Client shall accept such performance as if it were performance by Catalent. Catalent may not subcontract its obligations under this Agreement without Client’s written consent.
- 1.10 “**Catalent Indemnitees**” has the meaning set out in Clause 13.2.
- 1.11 “**Catalent IP**” has the meaning set out in Clause 11.
- 1.12 “**cGMP**” means current Good Manufacturing Practices promulgated by the Regulatory Authorities in the jurisdictions included in Applicable Laws (as applicable to Client and Catalent respectively). This includes 2003/94/EEC Directive (as supplemented by Volume 4 of EudraLex published by the European Commission), as amended, if and as implemented in the relevant constituent country.
- 1.13 “**Client**” has the meaning set out in the introductory paragraph, or any successor or permitted assign.
- 1.14 “**Client Indemnitees**” has the meaning set out in Clause 13.1.
- 1.15 “**Client IP**” has the meaning set out in Clause 11.
- 1.16 “**Client-supplied Materials**” means any materials to be supplied by or on behalf of Client to Catalent for Processing, as provided in Attachment A, including API and reference standards.
- 1.17 “**Commencement Date**” means the first date upon which a Regulatory Authority approves Catalent as a manufacturer of any Product.
- 1.18 “**Confidential Information**” has the meaning set out in Clause 10.1.
- 1.19 “**Contract Year**” means each consecutive 12 months period beginning on the Commencement Date or anniversary thereof, as applicable.
- 1.20 “**Defective Product**” has the meaning set out in Clause 5.2.
- 1.21 “**Delayed Approval Fee**” has the meaning set out in Clause 7.3.
- 1.22 “**Discloser**” has the meaning set out in Clause 10.1.
- 1.23 “**Effective Date**” has the meaning set out in the introductory paragraph.

- 1.24 “**Exception Notice**” has the meaning set out in Clause 5.2.
- 1.25 “**Facility**” means Catalent’s facility located in Schorndorf, Germany or such other facility as agreed by the parties.
- 1.26 “**Firm Commitment**” has the meaning set out in Clause 4.2.
- 1.27 “**Invention**” has the meaning set out in Clause 11.
- 1.28 “**Losses**” has the meaning set out in Clause 13.1.
- 1.29 “**Minimum Revenue Requirement**” has the meaning set out in Clause 4.1.
- 1.30 “**Process**” or “**Processing**” means the compounding, filling or pressing, producing and bulk packaging and secondary or retail packaging of Client-supplied Materials and Raw Materials into Product by Catalent, in accordance with the Specifications and under the terms of this Agreement.
- 1.31 “**Processing Date**” means the day on which the first step of physical Processing is scheduled to occur, as identified in an Acknowledgement.
- 1.32 “**Process Inventions**” has the meaning set out in Clause 11.
- 1.33 “**Product**” means the bulk pharmaceutical product containing the API, as more specifically described in the Specifications.
- 1.34 “**Purchase Order**” has the meaning set out in Clause 4.3.
- 1.35 “**Quality Agreement**” has the meaning set out in Clause 9.7.
- 1.36 “**Raw Materials**” means all raw materials, supplies, components and packaging necessary to manufacture and ship Product in accordance with the Specifications, as provided in Attachment A, but excluding Client-supplied Materials.
- 1.37 “**Recall**” has the meaning set out in Clause 9.6.
- 1.38 “**Recipient**” has the meaning set out in Clause 10.1.
- 1.39 “**Regulatory Approval**” means any approvals, permits, product and/or establishment licences, registrations or authorisations, including European marketing authorisations and applications and U.S. Investigational New Drug applications, New Drug Applications and Abbreviated New Drug Applications, as applicable, of any Regulatory Authorities that are necessary or advisable in connection with the development, manufacture, testing, use, storage, exportation, importation, transport, promotion, marketing, distribution or sale of API or Product in the Territory.
- 1.40 “**Regulatory Authority**” means the regulatory bodies or agencies in the Territory that are responsible for (A) the regulation (including pricing) of any aspect of pharmaceutical or medicinal products intended for human use or (B) health, safety or environmental matters generally. This includes the European Medicines Agency; and in the United States, this includes the United States Food and Drug Administration.

- 1.41 “**Representatives**” of an entity means such entity’s duly-authorized officers, directors, employees, agents, accountants, attorneys or other professional advisors.
- 1.42 “**Review Period**” has the meaning set out in Clause 5.2.
- 1.43 “**Rolling Forecast**” has the meaning set out in Clause 4.2.
- 1.44 “**Specifications**” means the procedures, requirements, standards, quality control testing and other data and the scope of services as set out in Attachment A, as modified from time to time in accordance with Clause 8.
- 1.45 “**Term**” has the meaning set out in Clause 16.1.
- 1.46 “**Territory**” means the European Union, United Kingdom, and the United States of America, and any other country that the parties agree in writing to add to this definition of Territory in an amendment to this Agreement; except shall not include countries that are targeted by the comprehensive sanctions, restrictions or embargoes administered by the United Nations, European Union, United Kingdom, or the United States.
- 1.47 “**Unit Pricing**” has the meaning set out in Clause 7.1(B).
- 1.48 “**Vendor**” has the meaning set out in Clause 3.2(B).

2. VALIDATION, PROCESSING & RELATED SERVICES

- 2.1 Validation Services and Tech Transfer Services. Catalent shall perform the Product qualification, validation and stability services and the tech transfer services as outlined in a separately agreed quotation.
- 2.2 Supply and Purchase of Product. Catalent shall Process Product in accordance with the Specifications, Applicable Laws and this Agreement.
- 2.3 Other Related Services. Catalent shall provide any other Product-related services as the parties may agree in writing. The terms and conditions of this Agreement shall govern such services.

3. MATERIALS

3.1 Client-supplied Materials.

A. Client shall supply to Catalent for Processing, at Client’s cost, all Client-supplied Materials, in quantities sufficient to meet Client’s requirements for Product. Client shall deliver such items and associated certificates of analysis to the Facility no later than 60 days (but not earlier than 90 days) before the Processing Date. Client shall be responsible at its cost for securing necessary export or import, or similar clearances, permits or certifications required in respect of such supply. Catalent shall use such items solely for Processing. Prior to delivery of any such items, Client shall provide to Catalent a copy of all associated material safety data sheets, safe handling instructions and health and environmental information and any regulatory certifications or authorizations that may be required under Applicable Laws relating to the API and Product, and shall promptly provide any updates thereto.

B. Following receipt of Client-supplied Materials, Catalent shall inspect such items to verify their identity. Unless otherwise expressly required by the Specifications, Catalent shall have no obligation to test such items to confirm that they meet the associated specifications or certificate of analysis or otherwise; but in the event that Catalent detects a nonconformity with Specifications, Catalent shall give Client prompt notice of such nonconformity. Catalent shall not be liable for any defects in Client-supplied Materials, or in Product as a result of defective Client-supplied Materials, unless Catalent failed to properly perform the foregoing obligations. Catalent shall follow Client's reasonable written instructions in respect of return or disposal of defective Client-supplied Materials, at Client's cost.

C. Client shall retain title to Client-supplied Materials at all times and shall bear the risk of loss thereof.

3.2 Raw Materials.

A. Catalent shall be responsible for procuring Raw Materials as necessary to meet the Firm Commitment. Catalent shall not be liable for any delay in delivery of Product if (i) Catalent is unable to obtain, in a timely manner, a particular Raw Material necessary for Processing and (ii) Catalent placed orders for such Raw Materials promptly following receipt of Client's Firm Commitment. In the event that any Raw Material becomes subject to purchase lead time beyond the Firm Commitment time frame, the parties will negotiate in good faith an appropriate amendment to this Agreement, including Clause 4.2.

B. Catalent shall exercise control over its supply chain and shall audit its own suppliers according to Catalent's supplier qualification processes. In certain instances, Client may require a specific supplier, manufacturer or vendor ("**Vendor**") to be used for Raw Material. In such an event, (i) such Vendor will be identified in the Specifications and (ii) the Raw Materials from such Vendor shall be deemed Client-supplied Materials for purposes of this Agreement. If the cost of the Raw Material from any such Vendor is greater than Catalent's costs for the same raw material of equal quality from other vendors, Catalent shall add the difference between Catalent's cost of the Raw Material and the Vendor's cost of the Raw Material to the Unit Pricing. Client will be responsible for all costs associated with qualification of any such Vendor who has not been previously qualified by Catalent.

C. In the event of (i) a Specification change for any reason, (ii) obsolescence of any Raw Material or (iii) termination or expiry of this Agreement, Client shall bear the cost of any unused Raw Materials (including packaging), so long as Catalent purchased such Raw Materials in quantities consistent with Client's most recent Firm Commitment and the vendor's minimum purchase obligations.

3.3 Artwork and Labeling. Client shall provide or approve, prior to the commencement of Processing, all artwork, advertising and labeling information necessary for Processing, if any. Such artwork, advertising and labeling information is and shall remain the exclusive property of Client, and Client shall be solely responsible for the content thereof. Such artwork, advertising and labeling information or any reproduction thereof may not be used by Catalent in any manner other than performing its obligations hereunder.

4. MINIMUM COMMITMENT, PURCHASE ORDERS & FORECASTS

4.1 Minimum Revenue Requirement. First starting with the Commencement Date, during each Contract Year, Client shall commit to an annual Minimum Revenue Requirement of one million five hundred thousand Euro (€1.500.000) .

4.2 Forecast. On or before [***] of each calendar month, beginning at least [***] prior to the anticipated Commencement Date, Client shall furnish to Catalent a written [***] rolling forecast of the quantities of Product that Client intends to order from Catalent during such period ("**Rolling Forecast**"); provided, that as of the second Contract Year the quantities forecasted to be purchased in any rolling [***] period shall not be less than [***] of the minimum threshold to be purchased according to the Minimum Revenue Requirement for the relevant Contract Year. The first [***] of such Rolling Forecast shall constitute a binding order for the quantities of Product specified therein ("**Firm Commitment**") and the following [***] of the Rolling Forecast shall be non-binding, good faith estimates.

4.3 Consequences of Minimum Revenue Requirements and Firm Commitment. If Client does not purchase the quantities of Product equivalent to the Minimum Revenue Requirement during any Contract Year, then within 30 days after the end of such Contract Year, Client shall pay Catalent the difference between (A) the total amount Client would have paid to Catalent if the Minimum Revenue Requirement had been fulfilled for the Product and (B) the sum of all purchases of Product from Catalent during such Contract Year. Additionally, if Client fails to place Purchase Orders sufficient to satisfy the Firm Commitment, Client shall pay to Catalent in accordance with Clause 7 the Unit Pricing for all Units that would have been Processed if Client has placed Purchase Orders sufficient to satisfy the Firm Commitment.

4.4 Purchase Orders.

A. From time to time as provided in this Clause 4.3(A), Client shall submit to Catalent a binding, non-cancelable purchase order for Product specifying the number of Batches to be Processed, the Batch size (to the extent the Specifications permit Batches of different sizes) and the requested delivery date for each Batch ("**Purchase Order**"); *provided*, that no Purchase Order may be for less than one (1) Batch. Concurrently with the submission of each Rolling Forecast, Client shall submit a Purchase Order for the Firm Commitment. Purchase Orders for quantities of Product in excess of the Firm Commitment shall be submitted by Client at least [***] in advance of the delivery date requested in the Purchase Order.

B. Promptly following receipt of a Purchase Order, Catalent shall issue a written acknowledgement ("**Acknowledgement**") that it accepts or rejects such Purchase Order. Each acceptance Acknowledgement shall either confirm the delivery date set out in the Purchase Order or provide a reasonable alternative delivery date, and shall include the Processing Date. Catalent may reject any Purchase Order in excess of the Firm Commitment or otherwise not given in accordance with this Agreement.

C. Notwithstanding Clause 4.3(B), Catalent shall use commercially reasonable efforts to supply Client with quantities of Product which are up to [***] in excess of the quantities specified in the Firm Commitment, subject to Catalent's other supply commitments and manufacturing, packaging and equipment capacity.

D. In the event of a conflict between the terms of any Purchase Order or Acknowledgement and this Agreement, the terms of this Agreement shall control.

E. In the event of any Inability to Supply, Supplier will immediately notify Minerva as to the cause and anticipated extent of the delay.

F.

4.5 Catalent's Cancellation of Purchase Orders. Notwithstanding Clause 4.5, Catalent reserves the right to cancel all, or any part of, a Purchase Order upon written notice to Client, and Catalent shall have no further obligations or liability with respect to such Purchase Order, if Client refuses or fails to timely supply conforming Client-supplied Materials in accordance with Clause 3.1. Any such cancellation of Purchase Orders shall not constitute a breach of this Agreement by Catalent nor shall it absolve Client of its obligation in respect of the Minimum Revenue Requirement.

4.6 Client's Modification or Cancellation of Purchase Orders.

A. Client may modify the delivery date or quantity of Product in a Purchase Order only by submitting a written change order to Catalent at least 60 days in advance of the earliest Processing Date covered by such change order. Such change order shall be effective and binding against Catalent only upon the written approval of Catalent, and notwithstanding the foregoing, Client shall remain responsible for the Firm Commitment.

B. Neither changes to nor postponement of any Batch of Product by Client, nor the payment of the fees described in this Clause 4.5, will reduce or in any way effect Client's Minimum Revenue Requirement obligations set out in Clause 4.1.

4.7 Unplanned Delay or Elimination of Processing. In case of an unplanned delay in Processing, Catalent shall use commercially reasonable efforts to meet the Purchase Orders, subject to the terms and conditions of this Agreement. Catalent shall provide Client with as much advance notice as practicable if Catalent determines that any Processing will be delayed or eliminated for any reason.

5. TESTING; SAMPLES; RELEASE

5.1 Batch Records and Data; Release. Unless otherwise agreed to by the parties during their ordinary course of dealings, after Catalent completes Processing of a Batch, Catalent shall provide Client with copies of Batch records prepared in accordance with the Specifications; *provided*, that if testing reveals an out-of-Specification result, Catalent shall provide such Batch records promptly following resolution of the out-of Specification result. After Catalent completes Processing of a Batch, Catalent shall also provide Client or its designee with a certificate of analysis for such Batch. Issuance of a certificate of analysis constitutes release of the Batch by Catalent to Client. Client shall be responsible for final release of Product (including testing), at its cost to the market.

5.2 Testing; Rejection. Following Client's receipt of a shipment of a Batch, Client or Client's designee may test samples of such Batch to confirm that the Specifications have been met. Unless within 20 days after Client's receipt of a Batch or, in the case of a latent defect within the meaning of section 377 German Commercial Code (HGB) that was not detectable through customary testing within such 20-day period, without any undue delay after discovery of such latent defect ("**Review Period**"), Client or its designee notifies Catalent in writing (an "**Exception Notice**") that such Batch is not in compliance with Clause 12.1 ("**Defective Product**"), and provides a sample of the alleged Defective Product, the Batch shall be deemed accepted by Client

and Client shall have no right to reject such Batch. Upon timely receipt of an Exception Notice from Client, Catalent shall conduct an appropriate investigation in its discretion to determine whether or not it agrees with Client that Product is Defective Product and to determine the cause of any nonconformity. If Catalent agrees that Product is Defective Product and determines that the cause of nonconformity is attributable to Catalent's negligence or willful misconduct ("**Catalent Defective Processing**"), then Clause 5.4 shall apply. For avoidance of doubt, where the cause of nonconformity cannot be determined or assigned, it shall be deemed not Catalent Defective Processing.

5.3 Discrepant Results. If the parties disagree as to whether Product is Defective Product and/or whether the cause of the nonconformity is Catalent Defective Processing, and this is not resolved within 30 days of the Exception Notice date, the parties shall cause a mutually acceptable independent third party to review records, test data and to perform comparative tests and/or analyses on samples of the alleged Defective Product and its components, including Client-supplied Materials. The independent party's results as to whether or not Product is Defective Product and the cause of any nonconformity shall be final and binding. Unless otherwise agreed to by the parties in writing, the costs associated with such testing and review shall be borne by Catalent if Product is Defective Product attributable to Catalent Defective Processing, and by Client in all other circumstances.

5.4 Defective Processing. Catalent shall, at its option, either (A) re-Process at its cost another Batch of Product (as a replacement for any Batch of Defective Product attributable to Catalent Defective Processing) using Client-supplied Materials provided at Client's cost or (B) credit any payments made by Client for such Batch. This shall be Client's sole and exclusive remedy under this Agreement for Defective Product.

6. DELIVERY

6.1 Delivery. Catalent shall deliver Product Ex Works (Incoterms 2010) the Facility promptly following Catalent's release of Product. Catalent shall segregate and store all Product until tender of delivery. Title to Product shall transfer to Client upon Catalent's tender of delivery. Client shall qualify at least 3 carriers to ship Product and then designate the priority of such qualified carriers to Catalent. All Product shall be bulk-packaged and shall be accompanied by the appropriate documentation as defined in the applicable Quality Agreement.

6.2 Storage Fees. If Client fails to take delivery of any Product on any scheduled delivery date, Catalent shall store such Product and Client shall be invoiced on the first day of each month following such scheduled delivery for reasonable administration and storage costs. Catalent shall store and handle all Products in accordance with the applicable Product Specifications and under appropriate conditions of temperature, humidity, light and cleanliness as outlined in the Quality Agreement to avoid any material adverse effect on the identity, strength, quality and purity of such Products. In addition to the foregoing, Catalent shall store and handle all Products so as to prevent the commingling of same with Catalent's own inventories and supplies, or those held by Catalent for third parties.

6.3 Bill and Hold. From time to time, at the Client's request, the agreed delivery date of the Purchase Order may be extended under a bill and hold arrangement as more fully set forth below. For each such Batch of stored Product, Client agrees that: (A) Client has made a fixed commitment to purchase the Product, (B) risk of loss for such Product passes to Client upon placement into storage, (C) such Product shall be on a bill and hold basis for legitimate business purposes, (D) the Client shall identify a fixed delivery date for the Product and (E) Client agree to be invoiced and to pay such invoice in accordance with the Payment terms set forth in this Agreement. Upon making a request for a bill and hold arrangement, Client shall provide Catalent with a letter confirming items (A) through (E) of this Section for each Batch of stored Product.

7. PAYMENTS

7.1 Fees. In consideration for Catalent performing services hereunder:

A. Client shall pay to Catalent the fees for validation and tech transfer services as set out in the separately agreed quotation.

B. Client shall pay Catalent the unit pricing for Product set out on Attachment B ("**Unit Pricing**"). Catalent shall submit an invoice to Client for such fees upon tender of delivery of Product as provided in Clause 6.1.

C. Other Fees. Client shall pay Catalent for all other fees and expenses of Catalent owing in accordance with the terms of this Agreement, including pursuant to Clauses 2.4, 4.1, 6.2 and 16.4. Client shall pay Catalent for serialization maintenance fees and capacity reservation fees as outlined in Attachment B. Catalent shall submit an invoice to Client for such fees as and when appropriate.

7.2 Unit Pricing Increase. The Unit Pricing shall be adjusted on an annual basis, effective on each January 1st of every calendar year, upon 60 days' prior written notice from Catalent to Client provided, however, than no such adjustment shall result in an increase of Unit Pricing exceeding [***] in any one calendar year or [***] in the aggregate during the Term. In addition, price increases for raw materials, labor, utilities and components shall be passed through to Client upon reasonable documentation.

7.3 Product Approval. If any Regulatory Approval necessary for Catalent to commence Processing at the Facility has not been obtained by Client within 12 months following the Effective Date, then Client shall pay to Catalent a fee as provided in Attachment B ("**Delayed Approval Fee**") until such Regulatory Approval has been obtained and Catalent is able to commence Processing.

7.4 Payment Terms. Payment of all Catalent invoices shall be due [***] days after the date of invoice. Client shall make payment in Euro, and otherwise as directed in the applicable invoice. If any payment is not received by Catalent by its due date, then Catalent may, in addition to any other remedies available, charge interest on the outstanding sum from the due date (both before and after any judgment) at [***] per month until paid in full (or, if less, the maximum amount permitted by Applicable Laws).

7.5 Advance Payment. Notwithstanding any other provision of this Agreement, if at any time Catalent determines that Client's credit is impaired, Catalent may require payment in advance before performing any further services or making any further shipment of Product. If Client shall fail, within a reasonable time, to make such payment in advance, or if Client shall fail to make any payment when due, Catalent shall have the right, at its option, to suspend any further performance hereunder until such default is corrected, without thereby releasing Client from its obligations under this Agreement.

7.6 Taxes.

A. All taxes, duties and other levies assessed (excluding tax based on net income) on or in connection with Client-supplied Materials, services or Product in connection with provision or sale to Catalent or Client, shall be reimbursed by Client to Catalent (and shall be included in invoices) and all charges are exclusive of any applicable taxes, duties and levies which shall be added to invoices directed at Client. If any deduction or withholding in respect of tax or otherwise is required by law to be made from any of the sums payable hereunder, Client shall be obliged to pay to Catalent such greater sum as will leave Catalent, after deduction or withholding, with the same amount as it would have been entitled to receive in the absence of such deduction or withholding.

B. If any amount paid by one party pursuant to an indemnity provision in this Agreement is or will be chargeable to tax, such payer shall pay an increased amount as will, after payment of the tax, leave the other party with the same amount that would otherwise have been payable under the provision if tax had not been so chargeable.

7.7 Client and Third Party Expenses. Except as may be expressly covered by Product Maintenance Service fees, Client shall be responsible for 100% of its own and all third-party expenses associated with the development, Regulatory Approvals and commercialization of Product, including regulatory filings and post-approval marketing studies.

7.8 Development Batches. Each Batch produced under this Agreement, including those necessary to support the validation portion of Client's submissions for Regulatory Approvals, will be considered to be a "development batch" unless and until Processing has been validated. Client shall be responsible for the cost of each such Batch, even if such Batch fails to meet the Specifications, unless Catalent was grossly negligent in the Processing of the out-of-Specification Batch. Catalent and Client shall cooperate in good faith to resolve any problems causing the out-of-Specification Batch.

8. **CHANGES TO SPECIFICATIONS**

All Specifications and any changes thereto agreed to by the parties from time to time shall be in writing, dated and signed by the parties. Any change to the Process shall be deemed a Specification change. No change in the Specifications shall be implemented by Catalent, whether requested by Client or requested or required by any Regulatory Authority, until the parties have agreed in writing to such change, the implementation date of such change, and any increase or decrease in costs, expenses or fees associated with such change (including any change to Unit Pricing). Catalent shall respond promptly to any request made by Client for a change in the Specifications, and both parties shall use commercially reasonable, good faith efforts to agree to the terms of such change in a timely manner. As soon as possible after a request is made for any change in Specifications, Catalent shall notify Client of the costs associated with such change and shall provide such supporting documentation as Client may reasonably require. Client shall pay all costs associated with such agreed upon changes. If there is a conflict between the terms of this Agreement and the terms of the Specifications, this Agreement shall control. Catalent reserves the right to postpone effecting changes to the Specifications until such time as the parties agree to and execute the required written amendment.

9. RECORDS; REGULATORY MATTERS

9.1 Record Keeping. Catalent shall maintain materially complete and accurate Batch, laboratory data, reports and other technical records relating to Processing in accordance with Catalent standard operating procedures. Such information shall be maintained for a period of at least 2 years from the relevant finished Product expiry date or longer if required under Applicable Laws or the Quality Agreement.

9.2 Regulatory Compliance. Catalent shall obtain and maintain all permits and licences with respect to general Facility operations required by any Regulatory Authority in the jurisdiction in which Catalent Processes Product. Client shall obtain and maintain all other Regulatory Approvals, authorizations and certificates, including those with respect to API and Product and those that are necessary for Catalent to commence Processing. Client shall not identify Catalent in any regulatory filing or submission without Catalent's prior written consent. Such consent shall not be unreasonably withheld and shall be memorialized in a writing signed by authorized representatives of both Parties. Upon written request, Client shall provide Catalent with a copy of any Regulatory Approvals required to distribute, market and sell Product in the Territory. If Client is unable to provide such information, Catalent shall have no obligation to deliver Product to Client, notwithstanding anything to the contrary in this Agreement. During the Term, Catalent will assist Client with all regulatory matters relating to Processing, at Client's request and expense. The parties intend and commit to cooperate to allow each party to satisfy its obligations under Applicable Laws relating to Processing under this Agreement.

9.3 Governmental Inspections and Requests. Catalent shall promptly advise Client if an authorised agent of any Regulatory Authority notifies Catalent that it intends to or does visit the Facility for the purpose of reviewing the Processing. Upon request, Catalent shall provide Client with a copy of any report issued by such Regulatory Authority received by Catalent following such visit, redacted as appropriate to protect any confidential information of Catalent and Catalent's other customers. Client acknowledges that it may not direct the manner in which Catalent fulfills its obligations to permit inspection by and to communicate with Regulatory Authorities. Client shall reimburse Catalent for all reasonable and documented costs associated with inspections by Regulatory Authorities in connection with Product.

9.4 Client Facility Audits. During the Term, Client's Representatives shall be granted access upon at least 10 business days' prior notice, at reasonable times during regular business hours, to (A) the portion of the Facility where Catalent performs Processing, (B) relevant personnel involved in Processing and (C) Processing records described in Section 9.2, in each case solely for the purpose of verifying that Catalent is Processing in accordance with cGMPs, the Specifications and the Product master Batch records. Client may not conduct an audit under this Section more than once during any 12-month period; provided, that additional inspections may be conducted in the event there is a material quality or compliance issue concerning Product or its Processing. Client's Quality Assurance Manager will arrange Client audits with Catalent Quality Management. Audits shall be designed to minimize disruption of operations at the Facility. Client's Representatives shall be required to sign Catalent's standard visitor confidentiality agreement prior to being allowed access to the Facility. Such Representatives shall comply with the Facility's rules and regulations. Client shall indemnify and hold harmless Catalent for any action or activity of such Representatives while on Catalent's premises.

9.5 **Recall.** If Catalent believes a recall, field alert, Product withdrawal or field correction ("**Recall**") may be necessary with respect to any Product supplied under this Agreement, Catalent shall promptly notify Client. Catalent will not act to initiate a Recall without the express prior written approval of Client, unless otherwise required by Applicable Laws. If Client believes a Recall may be necessary with respect to any Product supplied under this Agreement, Client shall promptly notify Catalent and Catalent shall provide all necessary cooperation and assistance to Client. Client shall provide Catalent with an advance copy of any proposed submission to a Regulatory Authority in respect of any Recall, and shall consider in good faith any comments from Catalent. The cost of any Recall shall be borne by Client, and Client shall reimburse Catalent for expenses incurred in connection with any Recall, in each case reduced to the extent such expenses are caused solely by Catalent's breach of its obligations under this Agreement, violation of Applicable Laws or its negligence or willful misconduct, then such cost shall be borne by Catalent. For purposes hereof, such cost shall be limited to reasonable, actual and documented administrative costs incurred by Client for such Recall and replacement of the Product subject to Recall in accordance with Clause 5.

9.6 **Quality Agreement.** Within 6 months after the Effective Date, and in any event prior to the first Processing of Product hereunder, the parties shall negotiate in good faith and enter into a quality or technical agreement on Catalent's standard template (the "**Quality Agreement**"). The Quality Agreement shall in no way determine liability or financial responsibility of the parties for the responsibilities set out therein. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to quality-related activities, including compliance with cGMP, the provisions of the Quality Agreement shall govern. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to any commercial matters, including allocation of risk, liability and financial responsibility, the provisions of this Agreement shall govern.

9.7 **Regulatory Authority Fees.** Catalent reserves the right to assess Client for any Regulatory Authority fees that may be established by any regulatory authority, which fees result directly from Catalent's formulation, development, manufacturing, processing, filling, packaging, storing or testing of Client's product or Client-supplied materials. Without limiting the foregoing, Client shall reimburse Catalent for any Regulatory Authority fees Catalent may be required to pay pursuant to the Generic Drug User Fee Amendments of 2017, ("GDUFA Fees"), where such fees result directly from Catalent's formulation, development, manufacturing, processing, filling, packaging, storing or testing of Client's product or Client-supplied materials. A Catalent facility incurs GDUFA Fees when that Catalent facility is referenced in an approved ANDA. GDUFA Fees are assessed by the FDA on October 1st of each year and shall be paid by Client annually, where applicable. On or after October 1st of each year, Catalent will invoice Client for Client's pro-rata share of the annual GDUFA Fee Catalent incurs for each Catalent manufacturing or packaging facility identified in Client's approved ANDA(s). This includes, but is not limited to, any Catalent facility which manufactured or packaged Client's registration batches. Catalent will invoice Client for reimbursement of all other payments or fees at the time they are incurred by Catalent. Client shall pay all such invoices within 30 days from the date of such invoice.

10. CONFIDENTIALITY AND NON-USE

10.1 **Definition.** As used in this Agreement, the term “**Confidential Information**” includes all information furnished by or on behalf of Catalent or Client (the “**Discloser**”), its Affiliates or any of its or their respective Representatives, to the other party (the “**Recipient**”), its Affiliates or any of its or their respective Representatives, whether furnished before, on or after the Effective Date and furnished in any form, including written, verbal, visual, electronic or in any other media or manner and information acquired by observation or otherwise during any site visit at the other party’s facility. Confidential Information includes all proprietary technologies, know-how, trade secrets, discoveries, inventions and any other intellectual property (whether or not patented), analyses, compilations, business or technical information and other materials prepared by either party, their respective Affiliates, or any of its or their respective Representatives, containing or based in whole or in part on any information furnished by the Discloser, its Affiliates or any of its or their respective Representatives. Confidential Information also includes the existence of this Agreement and its terms.

10.2 **Exclusions.** Notwithstanding Clause 10.1, Confidential Information does not include information that (A) is or becomes generally available to the public or within the industry to which such information relates other than as a result of a breach of this Agreement, (B) is already known by the Recipient at the time of disclosure as evidenced by the Recipient’s written records, (C) becomes available to the Recipient on a non-confidential basis from a source that is entitled to disclose it on a non-confidential basis or (D) was or is independently developed by or for the Recipient without reference to the Confidential Information of the Discloser as evidenced by the Recipient’s written records.

10.3 **Mutual Obligation.** The Recipient agrees that it will not use the Discloser’s Confidential Information except in connection with the performance of its obligations hereunder and will not disclose, without the prior written consent of the Discloser, Confidential Information of the Discloser to any third party, except that the Recipient may disclose the Discloser’s Confidential Information to any of its Affiliates and its or their respective Representatives that (A) need to know such Confidential Information for the purpose of performing under this Agreement, (B) are advised of the contents of this Clause and (C) are bound to the Recipient by obligations of confidentiality at least as restrictive as the terms of this Clause. Each party shall be responsible for any breach of this Clause by its Affiliates or any of its or their respective Representatives.

10.4 **Permitted Disclosure.** The Recipient may disclose the Discloser’s Confidential Information to the extent required by law or regulation; *provided*, that prior to making any such legally required disclosure, the Recipient shall give the Discloser as much prior notice of the requirement for and contents of such disclosure as is practicable under the circumstances. Any such disclosure, however, shall not relieve the Recipient of its obligations contained herein.

10.5 **No Implied Licence.** Except as expressly set out in Clause 10.1, the Recipient will obtain no right of any kind or licence under any Confidential Information of the Discloser, including any patent application or patent, by reason of this Agreement. All Confidential Information will remain the sole property of the Discloser, subject to Clause 11.

10.6 **Return of Confidential Information.** Upon expiry or termination of this Agreement, the Recipient will (and will cause its Affiliates and its and their respective Representatives to) cease its use and, upon written request, within 30 days either return or destroy (and certify as to such destruction) all Confidential Information of the Discloser, including any copies thereof, except for a single copy which may be retained for the sole purpose of ensuring compliance with its obligations under this Agreement.

10.7 Survival. The obligations of this Clause will terminate 5 years from the expiry or termination of this Agreement, except with respect to trade secrets, for which the obligations of this Clause will continue for so long as such information remains a trade secret under applicable law.

11. INTELLECTUAL PROPERTY

For purposes hereof, "**Client IP**" means all intellectual property and embodiments thereof owned by or licenced to Client as of the date hereof or developed by Client other than in connection with this Agreement; "**Catalent IP**" means all intellectual property and embodiments thereof owned by or licenced to Catalent as of the date hereof or developed by Catalent other than in connection with this Agreement; "**Invention**" means any intellectual property developed by either party or jointly by the parties in connection with this Agreement; "**API Inventions**" means any Invention that relates exclusively to the Client IP or Client's patented API; and "**Process Inventions**" means any Invention, other than an API Invention, that relates exclusively to the Catalent IP or relates to developing, formulating, manufacturing, filling, processing, packaging, analyzing or testing pharmaceutical products generally. All Client IP and API Inventions shall be owned solely by Client and no right therein is granted to Catalent under this Agreement, except that Catalent shall have during the Term a non-exclusive, royalty-free licence to such items solely to the extent necessary to perform its obligations under this Agreement. All Catalent IP and Process Inventions shall be owned solely by Catalent and no right therein is granted to Client under this Agreement. The parties shall cooperate to achieve the allocation of rights to Inventions anticipated herein and each party shall be solely responsible for costs associated with the protection of its intellectual property.

12. REPRESENTATIONS AND WARRANTIES

12.1 Catalent. Catalent represents, warrants and undertakes to Client that at the time of delivery by Catalent as provided in Clause 6.1, Product shall have been Processed in accordance with Applicable Laws and in conformance with the Specifications and shall not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws; *provided*, that Catalent shall not be liable for defects attributable to Client-supplied Materials (including artwork, advertising and labeling).

12.2 Client. Client represents, warrants and undertakes to Catalent that:

A. all Client-supplied Materials shall have been produced in accordance with Applicable Laws, shall comply with all applicable specifications, including the Specifications, shall not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws, and shall have been provided in accordance with the terms and conditions of this Agreement;

B. the content of all artwork provided to Catalent shall comply with all Applicable Laws;

C. all Product delivered to Client by Catalent will be held, used and disposed of by or on behalf of the Client in accordance with all Applicable Laws, and Client will otherwise comply with all laws, rules, regulations and guidelines applicable to Client's performance under this Agreement;

D. Client will not release any Batch of Product if the required certificates of conformance indicate that Product does not comply with the Specifications or if Client does not hold all necessary Regulatory Approvals to market and sell the Product;

E. Client has all necessary authority to use and to permit Catalent to use pursuant to this Agreement all intellectual property related to Product or Client-supplied Materials (including artwork), and the Processing of the foregoing, including any copyrights, trademarks, trade secrets, patents, inventions and developments; there are no patents owned by others related to the Client IP utilised with the Product that would be infringed or misused by Client's performance of the Agreement; and, to its knowledge, no trade secrets or other proprietary rights of others related to the Client IP utilised with the Product that would be infringed or misused by Client's performance of this Agreement; and

F. the work to be performed by Catalent under this Agreement will not violate or infringe upon any trademark, tradename, copyright, patent, trade secret, or other intellectual property or other right held by any person or entity.

12.3 Mutual representation. Furthermore, Catalent and Client both represent, warrant and undertake that no transactions or dealings under this Agreement shall be conducted with or for an individual or entity that is designated as the target of any sanctions, restrictions or embargoes administered by the United Nations, European Union, United Kingdom, or the United States.

12.4 Limitations. Save as expressly set out in this Agreement, neither party gives any representation or warranty in respect of the subject matter of this Agreement, and all representations and warranties that may be implied (by statute or otherwise) are hereby excluded to the maximum extent permitted by law.

13. INDEMNIFICATION

13.1 Indemnification by Catalent. Catalent shall indemnify and hold harmless Client, its Affiliates, and their respective directors, officers and employees ("**Client Indemnitees**") from and against any and all claims, losses, demands, liabilities, damages, costs and expenses (including reasonable attorneys' fees and reasonable investigative costs) in connection with any claim or action by any third party ("**Losses**") arising out of or resulting from (A) any breach of its representations, warranties or obligations set out in this Agreement or (B) any negligence or willful misconduct by Catalent; in each case except to the extent that any of the foregoing arises out of or results from any Client Indemnitee's negligence, willful misconduct or breach of this Agreement.

13.2 Indemnification by Client. Client shall indemnify and hold harmless Catalent, its Affiliates, and their respective directors, officers and employees ("**Catalent Indemnitees**") from and against any and all Losses arising out of or resulting from (A) any breach of its representations, warranties or obligations set out in this Agreement, (B) any manufacture, packaging, sale, promotion, distribution or use of or exposure to Product or Client-supplied Materials, including product liability or strict liability, (C) Client's exercise of control over the Processing, to the extent that Client's instructions or directions violate Applicable Laws, (D) the conduct of any clinical trials utilising Product or API, (E) any actual or alleged infringement or violation of any third party patent, trade secret, copyright, trademark or other proprietary rights by intellectual property or other information provided by Client, including Client-supplied Materials, or (F) any negligence or willful misconduct by Client; in each case except to the extent that any of the foregoing arises out of or results from any Catalent Indemnitee's negligence, willful misconduct or breach of this Agreement.

13.3 Indemnification Procedures. All indemnification obligations in this Agreement are conditioned upon the indemnified party (A) promptly notifying the indemnifying party of any claim or liability of which the indemnified party becomes aware (including a copy of any related complaint, summons, notice or other instrument); *provided*, that failure to provide such notice within a reasonable period of time shall not relieve the indemnifying party of any of its obligations hereunder except to the extent the indemnifying party is prejudiced by such failure, (B) allowing the indemnifying party, if the indemnifying party so requests, to conduct and control the defense of any such claim or liability and any related settlement negotiations (at the indemnifying party's expense), (C) cooperating with the indemnifying party in the defense of any such claim or liability and any related settlement negotiations (at the indemnifying party's expense) and (D) not compromising or settling any claim or liability without prior written consent of the indemnifying party.

14. LIMITATIONS OF LIABILITY

14.1 Client-supplied Materials. Catalent shall have no liability under this Agreement for any and all claims for lost, damaged or destroyed Client-supplied Materials, whether or not such Client-supplied Materials are incorporated into Product.

14.2 Total Liability. Catalent's total liability under this Agreement shall in no event exceed the total charges paid by Client to Catalent under this Agreement in the previous twelve (12) months period from the Batch or services giving rise to the claim.

14.3 Nothing in this Agreement shall, to the extent applicable, limit the liability of Catalent for:

- A. its indemnification obligations for death or personal injury arising from Catalent's negligence;
- B. death or personal injury arising from Catalent's or any of its Affiliate's negligence;
- C. direct or conditional intent, gross negligence or the fraud of Catalent; or
- D. any matter for which it would be illegal for Catalent or any of its Affiliates to exclude or to attempt to exclude liability.

14.4 Indirect Damages. Unless it has caused such damages or losses of the other party intentionally, neither party shall be liable to the other party for indirect, incidental, special, punitive or consequential loss or damages, or for loss of revenues, profits or data, arising out of performance under this Agreement, whether in contract or in tort or otherwise, even if such party has been advised of the possibility of such damages.

15. INSURANCE

Each party shall, at its own cost and expense, obtain and maintain in full force and effect during the Term the following in US dollars or foreign currency equivalent: (A) Commercial General Liability Insurance with a per-occurrence limit of not less than US \$1,000,000; (B) Products and Completed Operations Liability Insurance with a per-occurrence limit of not less than US \$10,000,000; and (C) Workers' Compensation Insurance with statutory limits and Employers Liability Insurance with limits of not less than \$1,000,000 per accident. Client shall maintain All Risk Property Insurance, including transit coverage, in an amount equal to the full replacement value of its property while in, or in transit to, a Catalent facility as required under this Agreement. Each party may self-insure all or any portion of the required insurance as long as, together with its Affiliates, its US GAAP or foreign currency equivalent net worth is greater than US \$100 million or its annual EBITDA (earnings before interest, taxes, depreciation and amortization) is greater than US \$75 million. Each required insurance policy, other than self-insurance, shall be obtained from an insurance carrier with an A.M. Best rating of at least A- VII. If any of the required policies of insurance are written on a claims made basis, such policies shall be maintained throughout the Term and for a period of at least 3 years thereafter. Each party shall obtain a waiver of subrogation clause from its property insurance carriers in favor of the other party, and such waivers will operate the same whether insurance is carried through third parties or self-insured. Upon the other party's written request from time to time, each party shall promptly furnish to the other party a certificate of insurance or other evidence of the required insurance.

16. TERM AND TERMINATION

16.1 Term. This Agreement shall commence on the Effective Date and shall continue until the end of the fifth Contract Year, unless earlier terminated in accordance with Clause 16.3 (as may be extended in accordance with this Clause, the "**Term**").

16.2 Renewal. The Term shall automatically be extended for successive 1-year periods unless and until one party gives the other party at least 12 months' prior written notice of its desire to terminate as of the end of the then-current Term.

16.3 Termination. This Agreement may be terminated immediately without further action:

A. by either party if steps are taken by or against the other party for the appointment of a liquidator, an administrator, a receiver, administrative receiver, manager, interim receiver, trustee, trustee in bankruptcy, nominee or supervisor or the other party proposes or enters into an agreement or arrangement with its creditors generally or makes an assignment for the benefit of its creditors generally, or otherwise suffers or permits the taking of any steps for adjudicating it to be bankrupt or insolvent and any such process, if reasonably shown to be warranted, frivolous or vexatious, is not withdrawn, dismissed or discharges within 20 days, or any equivalent or similar action to the above in consequence of the insolvency of that party is taken in any jurisdiction and is not withdrawn, dismissed or discharged in the circumstances described above; or

B. by either party if the other party materially breaches any of the provisions of this Agreement and such breach is not cured within 60 days after the giving of written notice requiring the breach to be remedied; *provided*, that in the case of a failure of Client to make payments in accordance with the terms of this Agreement, Catalent may terminate this Agreement if such payment breach is not cured within 10 days of receipt of notice of non-payment from Catalent.

C. by either party if any Regulatory Approval necessary for Catalent to commence Processing at the Facility has not been obtained by Client within 12 months following the Effective Date and Catalent is unable to commence Processing.

D. by either party upon 12 months' prior written notice to the other party if Regulatory Approval has been withdrawn, or Client has ceased commercialization of the Product.

16.4 **Effect of Termination.** Expiry or termination of this Agreement shall be without prejudice to any rights or obligations that accrued to the benefit of either party prior to such expiry or termination. In the event of a termination of this Agreement:

A. Catalent shall promptly return to Client, at Client's expense and direction, any remaining inventory of Product or Client-supplied Materials; *provided*, that all outstanding invoices have been paid in full;

B. Client shall pay Catalent all invoiced amounts outstanding, plus, upon receipt of invoice therefor, for any (i) Product that has been shipped pursuant to Purchase Orders but not yet invoiced, (ii) Product Processed pursuant to Purchase Orders that has been completed but not yet shipped, and (iii) in the event that this Agreement is terminated for any reason other than by Client pursuant to Clause 16.3(A) or (B), or by Catalent pursuant to Clause 16.3(C), all Product in process of being Processed pursuant to Purchase Orders (or, alternatively, Client may instruct Catalent to complete such work in process, and the resulting completed Product shall be governed by clause (ii)); and

C. in the event that this Agreement is terminated for any reason other than by Client pursuant to Clause 16.3(A) or (B), or by Catalent pursuant to Clause 16.3(C), Client shall pay Catalent for all costs and expenses incurred, and all noncancellable commitments made, in connection with Catalent's performance of this Agreement, so long as such costs, expenses or commitments were made by Catalent consistent with Client's most recent Firm Commitment and the vendor's minimum purchase obligations.

16.5 **Survival.** The rights and obligations of the parties shall continue under Clauses 11 (Intellectual Property), 13 (Indemnification), 14 (Limitations of Liability), 17 (Notice), 18 (Miscellaneous); under Clauses 10 (Confidentiality and Non-Use) and 15 (Insurance), in each case to the extent expressly stated therein; and under Clauses 7.4 (Payment Terms), 7.6 (Taxes), 7.7 (Client and Third Party Expenses), 9.2 (Recordkeeping), 9.6 (Recall), 12.3 (Limitations on Warranties), 16.4 (Effect of Termination) and 16.5 (Survival), in each case in accordance with their respective terms if applicable, notwithstanding expiry or termination of this Agreement.

17. NOTICE

All notices and other communications hereunder shall be in writing and shall be deemed given: (A) when delivered personally or by hand; (B) when delivered by facsimile transmission (receipt verified); or (C) when received or refused, if sent by registered or certified or recorded post (return receipt requested), postage prepaid; in each case, to the parties at the following addresses (or at such other address for a party as shall be specified by like notice; *provided*, that notices of a change of address shall be effective only upon receipt thereof):

To Client:

Minerva Neurosciences, Inc.
1601 Trapelo Road, Suite 286
Waltham, Massachusetts 02451 USA
Attn: President

With a copy to: Minerva Neurosciences, Inc.
1601 Trapelo Road, Suite 286
Waltham, Massachusetts 02451 USA
Attn: General Counsel

To Catalent: Catalent Germany Schorndorf GmbH
Steinbeisstrasse 1 -2
71643 Schorndorf
Germany
Attn: General Manager
Facsimile: +49 7181 7000 100

With a copy to: Catalent Pharma Solutions
14 Schoolhouse Road
Somerset, NJ 08873
USA
Attn: General Counsel (Legal Department)
GenCouns@catalent.com

18. MISCELLANEOUS

18.1 Entire Agreement; Amendments. This Agreement, together with the Quality Agreement and each Purchase Order, constitutes the entire understanding between the parties, and supersedes any contracts, agreements or understandings (oral or written) of the parties, with respect to the subject matter hereof. For the avoidance of doubt, this Agreement does not supersede any existing generally applicable confidentiality agreement between the parties as it relates to time periods prior to the date hereof or to business dealings not covered by this Agreement. No term of this Agreement may be amended except upon written agreement of both parties, unless otherwise expressly provided in this Agreement.

18.2 Captions; Certain Conventions. The headings used in this Agreement are for convenience only and are not to be interpreted or construed as a substantive part of this Agreement. Unless otherwise expressly provided herein or the context of this Agreement otherwise requires, (A) words of any gender include each other gender, (B) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (C) words using the singular shall include the plural, and vice versa, (D) the words "include(s)" and "including" shall be deemed to be followed by the phrase "but not limited to", "without limitation" or words of similar import, (E) the word "or" shall be deemed to include the word "and" (e.g., "and/or") and (F) references to "Clause" or other subdivision, or to an Attachment or other appendix, without reference to a document are to the specified provision or Attachment of this Agreement. This Agreement shall be construed as if it were drafted jointly by the parties.

18.3 Further Assurances. The parties agree to execute such further instruments and to undertake such other acts as may be reasonably necessary or appropriate to give full effect to the terms of this Agreement.

18.4 No Waiver. In no event shall any delay, failure or omission (in whole or in part) in enforcing, exercising or pursuing any right, power, privilege, claim or remedy conferred by or arising under this Agreement or by law, be deemed to be or construed as a waiver of that or any other right, power, privilege, claim or remedy in respect of the circumstances in question, or operate so as to bar the enforcement of that, or any other right, power, privilege, claim or remedy, in any other instance at any time or times subsequently.

18.5 Severability. If any term of this Agreement is declared invalid or unenforceable by a court or other body of competent jurisdiction, the remaining terms of this Agreement will continue in full force and effect.

18.6 Independent Contractors. The relationship of the parties is that of independent contractors, and nothing in this Agreement is intended to create or will be construed as creating between the parties the relationship of joint venture, co-partners, employer/employee or principal/agent.

18.7 Successors and Assigns. Neither party may assign this Agreement, in whole or in part, without the prior written consent of the other party, except that either party may, without the other party's consent (but subject to prior written notice), assign this Agreement in its entirety to an Affiliate or to a successor to substantially all of the business or assets of the assigning party or the assigning party's business unit responsible for performance under this Agreement.

18.8 Third Party Rights. This Agreement shall not confer any rights or remedies upon any person or entity other than the parties to this Agreement and their respective successors and permitted assigns, and a person or entity who is not a party to this Agreement has no rights to enforce any term of this Agreement.

18.9 Governing Law. This Agreement shall be governed by and construed under the laws of New York, USA, provided that any conflicts of laws provisions or principles to the contrary shall be inapplicable. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.

18.10 Alternative Dispute Resolution. Any dispute that arises between the parties in connection with this Agreement shall first be presented to the senior executives of the parties for consideration and resolution. If such executives cannot reach a resolution of the dispute within a reasonable time, then such dispute shall be resolved by binding alternative dispute resolution in accordance with the Swiss Rules of International Arbitration of the Swiss Chambers by one (1) or three (3) arbitrators appointed in accordance with the said Rules. The place of the arbitration shall be Zurich, Switzerland. The language of the arbitration shall be English.

18.11 Prevailing Party. In any dispute resolution proceeding between the parties in connection with this Agreement, the prevailing party will be entitled to recover its reasonable attorney's fees and costs in such proceeding from the other party.

18.12 Publicity. Neither party will make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby without the other party's express prior written consent, except as required under Applicable Laws, by any governmental agency or by the rules of any stock exchange on which the securities of the disclosing party are listed, in which case the party required to make the press release or public disclosure shall use commercially reasonable efforts to obtain the approval of the other party as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure.

18.13 Right to Dispose and Settle. If Catalent requests in writing from Client direction with respect to disposal of any inventories of Product, Client-supplied Materials, equipment, samples or other items belonging to Client and is unable to obtain a response from Client within a reasonable time period after making reasonable efforts to do so, Catalent shall be entitled in its sole discretion to (A) dispose of all such items and (B) set-off any and all amounts due to Catalent or any of its Affiliates from Client against any credits Client may hold with Catalent or any of its Affiliates.

18.14 Force Majeure. Except as to payments required under this Agreement, neither party shall be liable in damages for, nor shall this Agreement be capable of termination by reason of, any delay in such party's performance, or breach of its obligations, hereunder if such delay or breach is caused by events beyond such party's reasonable control, including acts of God, law or regulation or other action or failure to act of any government or agency thereof, war or insurrection, civil commotion, destruction of production facilities or materials by earthquake, fire, flood or weather, labor disturbances, epidemic or failure of suppliers, public utilities or common carriers. If the events shall continue unabated for 180 days, then both parties shall meet to discuss and negotiate in good faith what modifications to this Agreement should result from such events.

18.15 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have caused their respective duly authorised representatives to execute this Agreement effective as of the Effective Date.

Catalent Germany Schorndorf GmbH

By: /Hanns-Cord Walter/

Name: Dr. Hanns-Cord Walter

Title: Managing Director

By: /Roel de Nobel/

Name: Roel de Nobel

Title: Global VP Ops CSS

Minerva Neurosciences, Inc.

By: /Remy Luthringer/

Name: Dr. Remy Luthringer

Title: Chief Executive Officer

ATTACHMENT A

SPECIFICATIONS

- I. **Client-Supplied Materials (and associated specifications)**
- II. **Raw Materials (and associated specifications)**
- III. **Product Specifications (including Batch size)**

To be agreed by the parties and attached separately before Commencement Date.

ATTACHMENT B**UNIT PRICING AND FEES****Section 1. Executive summary and scope of work**

Catalent Germany Schorndorf GmbH ("Catalent") is delighted to quote for the commercial manufacturing and packaging of MIN-101 for **Minerva** ("Minerva" or "Customer") using MIN-101 ("MIN-101" or API).

This quote is based on the forecast as detailed in Section 3.1.

Section 2. Project overview

The following is an overview of the various steps in this project.

Section reference	Activity
Section 3	Commercial price estimate
Section 4	Pharmaceutical details
Section 5	Packaging details
Section 6	Analytical service
Section 7	Serialization and aggregation
Section 8	Project price proposal

Section 3. Commercial Price estimate

[***]

Section 4. Pharmaceutical details

[***]

Section 5. Packaging technical details

[***]

Section 6. Analytical support

[***]

Section 7. Serialization and Aggregation

[***]

Section 8. Project price proposal

[***]

Section 9. General other costs

[***]

Section 10. Quote subject to

- Customer will sign the quote and provide a PO to cover the project. **The project will start once the written purchase order, with billing address and delivery address has been received by Catalent.**
 - The Customer will supply Catalent with up to date information on the API for an OEB assessment. Catalent will perform an internal OEB assessment once all information has been provided. All products with an OEB 3 or 4 classification, will be sent for an external assessment if such an assessment has not been provided by the Customer. The same will apply for the ignition energy of the API.
 - API's with an OEB assessment of up to OEB 3 can be handled on the small scale development equipment in the R&D area. For scale-up to pilot scale and commercial batch sizes, the use of equipment and processes in our commercial manufacturing and packaging area is required. In this area some process restrictions for the handling of products containing OEB3 substances are in place. Every product with an OEB 3 assessment will have to be evaluated on a case to case basis to determine whether it is possible to handle these in the commercial area, as well as the necessary safety measure required. Additional safety measures may include additional costs and or investments.
 - Customer will provide specification for all API's, excipients and packaging materials that will be used. In cases where these are not supplied by Customer, Catalent materials, as agreed with the customer, will be used.
 - Supplied by Customer, free of charge:
 - Analytical methods
 - Customer will provide released API in sufficient quantity with a CoA, and Catalent will only do ID testing on receipt. If the analytical methods for the goods-in analytical testing of the API have to be validated, then additional costs will incur.
 - All other excipients and or components will be purchased by Catalent. It is assumed that Catalent already qualified raw materials can be used. If raw materials with special specifications have to be used then the manufacturing prices have to be adjusted and additional costs for goods-in analytical testing and possible analytical method validation may incur.
 - Print artwork
 - If according to the MSDS there will be additional Safety Equipment needed and as such additional costs arose. These costs will be invoiced according to expenditure. (See section "Other costs")
 - Reference compounds and other cost-intensive chemicals, consumables chromatographic columns need to be provided by Customer, if not, the costs can be charged separately. In this case where Customer supplies these materials, the supplier names as well as article numbers have to be stated. Possible required analytical validations and/or other change control tests are charged separately. If unforeseeable problems occur, Catalent reserves the right to charge for these extra, errors and omissions excluded.
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- In order to produce GMP batches, at least one technical batch per strength is required to confirm the manufacturing process parameters. If more technical batches are required, these will be done in agreement with Customer. In the case where Customer decides not to have at least one technical batch manufactured, any costs that may arise out of deviations and Out of Spec (“OOS”) product and OOS investigations, will be for the account of Customer.
 - Each batch of Product manufactured under this Quotation will be considered a “Development Batch” unless and until the manufacturing process has been validated, and is not for commercial sale or distribution. Client shall be responsible for the cost of each Development Batch, even if such batch fails to meet the specifications, unless Catalent was grossly negligent in the manufacture of the out-of-specification batch. Catalent and Client shall cooperate in good faith to resolve any problems causing the out-of-specification batch. All shipment terms are Ex Works Catalent.
 - Customer shall pay for all product batches including batches that do not conform to applicable specifications, unless all methods and processes associated with the manufacture, testing, and storage of that product have been fully validated in accordance with generally accepted standards of the pharmaceutical industry.
 - This quote is subject to:
 - Exact material specification
 - Agreement regarding the aim of the quote needs to be reached.
 - Confirmation of the manufacturing and or packaging details
 - The supply of a product sample (where available)
 - Analytical methods and specifications
 - Significant changes in project scope or design will be re-quoted.
 - Final results and process parameters from the development and validation activities by R&D.
 - Agree and signing of the relevant LOI's and Supply Agreement
 - Agreement on all quality and regulatory details with the responsible Qualified Person and product specialist.
 - Catalent retains the right to renegotiate prices after the validation or technical trials, if significantly different parameters than estimated occurred.
 - Final packaging requirements (such as pallet load, pallet height, etc.)
 - Catalent may revise the prices provided in this quotation if reasonably unforeseeable circumstances affect the work required to complete the Project. Catalent will notify Customer immediately if the costs to complete the project exceed the prices stated in this quotation. Catalent will not commence work involving charges in excess of those stated in this quotation without Customer approval unless such advance notice was not possible due to the circumstances. In addition the quoted costs are subject to annual review to account for changes in inflation, increased overhead charges, changes in scope etc. Any additional work will be performed based on written agreement from Customer and will be documented on a Catalent Quotation Amendment Record (QAR).
 - Quality by design (QbD) and Design of Experiments (DoE) strategies and details will be discussed and agreed with the customer based on critical process parameters and based on the critical material attributes impacting the quality of the drug products. These costs will be quoted for separately if required, and when defined.
-

10.1 Minimum order quantities (MOQ)

Costs for materials which exceed the ordered call off quantities are not included in the unit prices. When these materials cannot be used for following orders, Catalent would charge the surplus materials according the procurement costs plus handling fee (organization, financing, storage etc.) and either ship it back to your company at your expenses. Alternatively the option can be to have these destroyed at the abovementioned costs after issuing a formal order for this destruction activity.

Section 11. Scheduling and deliverables

11.1 Scheduling

Catalent must receive a signed Quotation, a signed protocol, and all raw materials / intermediates / final product samples in order for this project to be scheduled. Subsequently, a Purchase Order number (where applicable) must be received within [***] of receipt of the signed quote. Once scheduled, Customer will be notified by Catalent of the anticipated start and completion date of the project activities.

11.2 Deliverables

11.2.1 Reports and certificates of analysis

A report and/or Certificate of Analysis will be issued upon completion of each project phase/the project.

11.2.2 Communication

In order to establish a collaborative relationship between Customer and Catalent, both parties will appoint a Project Manager to serve as a point of contact to oversee progress on this project. Upon initiation of the project, Catalent and Customer will establish a communication plan that may include conference calls, visits, and timelines. To foster project planning, reviews/updates, and coordination meetings, Catalent will administer project team conference calls as reasonably required.

The project's viability from a regulatory and quality systems standpoint will be assessed by Catalent and Customer in collaboration throughout the project to determine if the project should proceed to validation and commercial launch.

Section 12. Additional project terms

12.1 Safety

12.1.1 Catalent's responsibilities

Catalent will assess all vendor and Customer MSDS and all handling data for the samples/materials associated with this project. If categorized as a Controlled API (CDS) and/or Category 4 or 5 and OEB 3 above, the samples/materials will require special handling precautions and will be subject to a Hazardous Material Fee for all handling and testing directly associated with the samples/materials. If applicable, this Hazardous Materials Handling Surcharge has been included in the project costs.

12.1.2 Customer's responsibilities

Customer will provide MSDS and all sample/material handling data for the samples/materials associated with this project. If any sample/material has any special handling considerations, Customer will notify Catalent prior to the initiation of the project.

12.2 Patent challenges and litigation

Catalent reserves the right to invoice Customer for Catalent's costs and expenses (including reasonable attorneys' fees) associated with Catalent's obligation to respond to third party or government subpoenas relating to Customer, this Project or the Product, including without limitation, such costs and expenses incurred with respect to disputes regarding the filing of an ANDA Paragraph IV patent challenge which involves this Project and/or Product(s) hereunder, such as Catalent's time and materials costs of responding to subpoena (es), compiling and delivering documents, providing access to Catalent personnel for depositions, in-house and outside counsel review, and any other items related to such Paragraph IV challenge.

12.3 Import of APIs into the European Union (EU)

12.3.1 Requirements for the import of API's into the EU

As of 2 July 2013 EU regulation requires that any API manufactured outside of the EU, that is intended for import into the EU, must be accompanied by a "written confirmation" issued by the competent authority of the country where the API manufacturer is located. This "written confirmation" states that:

- Standards of good manufacturing practices (GMP) at the plant in question are at least equivalent to those of EU GMP requirements for APIs
- That the plant is subject to regular inspections
- That findings of non-compliance are reported to the EU authorities

A copy of the "written confirmation" must accompany each API batch or shipment. Without this "written confirmation" API will not be allowed to enter the EU, and even when, Catalent will not be able to use this API for manufacturing of pharmaceutical products. When the API is supplied by the Customer, it is the responsibility of the Customer to ensure that this "written confirmation" is provided with the shipment.

12.3.2 Import tax on expensive API's

Please note that materials imported from non-EU countries, Catalent generally cross-charges any costs associated with the importation (import sales tax, customs, etc.) according to expenses, unless the materials are sent back to the country of origin in full.

12.4 Methods/Documentation

12.4.1 Catalent's responsibilities

Catalent will review all project-related documentation and methods received from Customer associated with this project.

12.4.2 Customer's responsibilities

Customer will provide all available project-related documentation and methods to be used for this project.

12.4.3 Samples/Materials

If available, Customer will provide all samples/materials necessary to perform this project. The samples/materials should arrive at Catalent with all proper documentation. If samples/materials are not available, upon request from Customer, Catalent will purchase all samples/materials necessary to perform the project. Where standard materials, such as excipients or columns are required, or needed to maintain the Project timeline, Catalent will purchase such materials. Catalent will invoice Customer monthly at cost plus reasonable and customary acquisition and handling costs for any material purchased as described above. Non-standard or special instrumentation or equipment required solely for this project will be invoiced to Customer following Customer's approval.

If return shipment is requested, Customer will notify Catalent prior to the disposition of samples/materials.

All materials shipped to Catalent on wood pallets must be heat treated in accordance with IPPC-ISPM 15 International Export regulations. Specifically, Heat Treated (HT) pallets must be marked with the IPPC logo in accordance with the International Standard. No chemicals or chemical treatments, including Haloanisoles or brominated phenols including 2, 4, 6-tribromianisole (TBA) or 2, 4, 6-trichloroanisole (TCA), shall be applied to any wood pallets used to ship materials to Catalent.

Upon issuance of the final report or Certificate of Analysis, Catalent will issue a request for approval of destruction of any remaining clinical supply materials/samples, during which time samples/materials will be stored at Catalent for a period of 30 days. After a 30-day period, if additional storage is required, Catalent will issue a QAR for the additional cost.

12.5 Equipment failure

Catalent is not in any manner responsible for material, scheduling or financial losses due to equipment failure (beyond the direct cost of materials contained within the respective product container). In the event of equipment failure, every effort will be made to repair the equipment and reschedule the order in the timeliest manner.

12.6 Analytical rush

Rush services are available at the Customer request. If rush services are agreed between Customer and Catalent, additional costs will be invoiced based on the schedule below.

[***]

AMENDED AND RESTATED
BYLAWS
OF
MINERVA NEUROSCIENCES, INC.

(a Delaware Corporation)

Adopted as of November 1, 2019

ARTICLE I
OFFICES AND FISCAL YEAR

SECTION 1.01. Registered Office. The registered office of the corporation shall be Corporation Service Company, 2711 Centerville Road, Suite 400, City of Wilmington, County of New Castle, State of Delaware until otherwise established by resolution of the board of directors, and a certificate certifying the change is filed in the manner provided by statute.

SECTION 1.02. Other Offices. The corporation may also have offices at such other places within or without the State of Delaware as the board of directors may from time to time determine or the business of the corporation requires.

SECTION 1.03. Fiscal Year. The fiscal year of the corporation shall end on the 31st of December in each year.

ARTICLE II
NOTICE - WAIVERS - MEETINGS

SECTION 2.01. Notice of Meetings of Board of Directors. Notice of a regular meeting of the board of directors need not be given. Notice of every special meeting of the board of directors shall be given to each director by telephone or in writing at least 24 hours (in the case of notice by telephone, telex, TWX or facsimile transmission) or 48 hours (in the case of notice by telegraph, courier service or express mail) or five days (in the case of notice by first class mail) before the time at which the meeting is to be held. Every such notice shall state the time and place of the meeting. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the board need be specified in a notice of the meeting.

SECTION 2.02. Notice of Meetings of Stockholders. Notice of the place, if any, date and time of all meetings of stockholders of the Corporation, and the means of remote communications, if any, by which stockholders and proxy holders may be deemed present and vote at such meeting, and, in the case of all special meetings of stockholders, the purpose of the meeting, shall be given, not less than 10 nor more than 60 days before the date on which such meeting is to be held, to each stockholder entitled to notice of the meeting.

The Corporation may postpone or cancel any previously called annual or special meeting of stockholders of the Corporation by making a public announcement (as defined in Section 3.03(e)) of such postponement or cancellation prior to the meeting. When a previously called annual or special meeting is postponed to another time or place, if any, notice of the place (if any), date and time of the postponed meeting and the means of remote communications, if any, by which stockholders and proxy holders may be deemed present and vote at such postponed meeting, shall be given in conformity with this Section 2.02 unless such meeting is postponed not more than 60 days after initial notice of the meeting was provided in conformity with this Section 2.02.

When a meeting is adjourned to another time or place, notice need not be given of the adjourned meeting if the time and place, if any, thereof and the means of remote communication, if any, by which stockholders and proxy holders may be deemed to be present and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken; however, if the date of any adjourned meeting is more than 30 days after the date for which the meeting was originally noticed, or if a new record date is fixed for voting at the adjourned meeting, notice of the place, if any, date and time of the adjourned meeting and the means of remote communication, if any, by which stockholders and proxy holders may be deemed present and vote at such adjourned meeting, shall be given in conformity herewith. At any adjourned meeting, any business may be transacted that may have been transacted at the original meeting.

SECTION 2.03. Method of Notice. If mailed, notice to a stockholder of the Corporation shall be deemed given when deposited in the mail, postage prepaid, directed to a stockholder at such stockholder's address as it appears on the records of the Corporation. Without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders of the Corporation may be given by electronic transmission in the manner provided in Section 232 of the DGCL.

SECTION 2.04. Waiver of Notice. A written waiver of any notice, signed by a stockholder or director, or a waiver by electronic transmission by such person or entity, whether given before or after the time of the event for which notice is to be given, shall be deemed equivalent to the notice required to be given to such person or entity. Neither the business nor the purpose of any meeting need be specified in the waiver. Attendance at any meeting shall constitute waiver of notice except attendance for the sole purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened.

SECTION 2.05. Conference Telephone Meetings. One or more directors may participate in a meeting of the board, or of a committee of the board, by means of conference telephone or similar communications equipment by means of which all persons participating in the meeting can hear each other. Participation in a meeting pursuant to this section shall constitute presence in person at such meeting.

ARTICLE III MEETINGS OF STOCKHOLDERS

SECTION 3.01. Place of Meeting. All meetings of the stockholders of the corporation shall be held at the registered office of the corporation, or at such other place within or without the State of Delaware as shall be designated by the board of directors in the notice of such meeting.

SECTION 3.02. Annual Meeting. The board of directors may fix and designate the date and time of the annual meeting of the stockholders, and at said meeting the stockholders then entitled to vote shall elect directors and shall transact such other business as may properly be brought before the meeting.

SECTION 3.03. Advance Notice of Nominations and Proposals of Business.

(a) Nominations of persons for election to the Board of Directors and proposals for business to be transacted by the stockholders at an annual meeting of stockholders may be made (i) pursuant to the Corporation's notice with respect to such meeting, (ii) by or at the direction of the Board of Directors or (iii) by any stockholder of record of the Corporation who (A) was a stockholder of record at the time of the giving of the notice contemplated in Section 3.03(b), (B) is entitled to vote at such meeting and (C) has complied with the notice procedures set forth in this Section 3.03. Except as otherwise required by law, clause (iii) of this Section 3.03(a) shall be the exclusive means for a stockholder to make nominations or propose other business (other than nominations and proposals properly brought pursuant to applicable provisions of federal law, including the Securities Exchange Act of 1934 (as amended from time to time, the "Act") and the rules and regulations of the Securities and Exchange Commission thereunder) before an annual meeting of stockholders.

(b) Except as otherwise required by law, for nominations or proposals to be properly brought before an annual meeting by a stockholder pursuant to clause (iii) of Section 3.03(a), (i) the stockholder must have given timely notice thereof in writing to the Secretary of the Corporation with the information contemplated by Section 3.03(c), and (ii) the business must be a proper matter for stockholder action under the GCL.

(c) To be timely for purposes of Section 3.03(b), a stockholder's notice must be delivered to the Secretary of the Corporation at the principal executive offices of the Corporation a date (i) not less than 90 nor more than 120 days prior to the anniversary date of the prior year's annual meeting or (ii) if there was no annual meeting in the prior year or if the date of the current year's annual meeting is more than 30 days before or after the anniversary date of the prior year's annual meeting, on or before 15 days after the day on which the date of the current year's annual meeting is first disclosed in a public announcement. In no event shall any adjournment or postponement of an annual meeting or the announcement thereof commence a new time period for the delivery of such notice. Such notice from a stockholder must state (i) as to each nominee that the stockholder proposes for election or reelection as a director, (A) all information relating to such nominee that would be required to be disclosed in solicitations of proxies for the election of such nominee as a director pursuant to Regulation 14A under the Act and such nominee's written consent to serve as a director if elected, and (B) a description of all direct and indirect compensation and other material monetary arrangements, agreements or understandings during the past three years, and any other material relationship, if any, between or concerning such stockholder and its respective affiliates or associates, on the one hand, and the proposed nominee, and his or her respective affiliates or associates, on the other hand; (ii) as to each proposal that the stockholder seeks to bring before the meeting, a brief description of such proposal, the reasons for making the proposal at the meeting, and any material interest that the stockholder has in the proposal; (iii) (A) the name and address of the stockholder, (B) the class (and, if applicable, series) and number of shares of stock of the Corporation that are, directly or indirectly, owned beneficially or of record by the stockholder or any Stockholder Associated Person (as defined below), (C) any option, warrant, convertible security, stock appreciation right or similar right with an exercise or conversion privilege or a settlement payment or mechanism at a price related to any class (or, if applicable, series) of shares of stock of the Corporation or with a value derived in whole or in part from the value of any class (or, if applicable, series) of shares of stock of the Corporation, whether or not such instrument or right shall be subject to settlement in the underlying class or series of capital stock of the Corporation or otherwise (each, a "Derivative Instrument") directly or indirectly owned beneficially or of record by such stockholder or any Stockholder Associated Person and any other direct or indirect opportunity to profit or share in any profit derived from any increase or decrease in the value of shares of stock of the Corporation of the stockholder or any Stockholder Associated Person, (D) any proxy, contract, arrangement, understanding or relationship pursuant to which such stockholder or any Stockholder Associated Person has a right to vote any securities of the Corporation, (E) any proportionate interest in shares of the Corporation or Derivative Instruments held, directly or indirectly, by a general or limited partnership in which such stockholder or any Stockholder Associated Person is a general partner or beneficially owns an interest in a general partner, (F) any performance-related fees (other than an asset-based fee) that such stockholder or any Stockholder Associated Person is entitled to based on any increase or decrease in the value of the shares of stock of the Corporation or Derivative Instruments and (G) whether either the stockholder intends to deliver a proxy statement and form of proxy to holders of, in the case of a proposal, at least the percentage of the Corporation's voting shares required under applicable law to carry the proposal or, in the case of a nomination or nominations, a sufficient number of holders of the Corporation's voting shares reasonably believed by such stockholder to be sufficient to elect such nominee or nominees. For purposes of these by-laws, a "STOCKHOLDER ASSOCIATED PERSON" of any stockholder means any "affiliate" or "associate" (as those terms are defined in Rule 12b-2 under the Act) of the stockholder that owns beneficially or of record any capital stock or other securities of the Corporation. In addition, any nominee proposed by a stockholder shall complete a questionnaire, in a form provided by the Corporation, within 10 days of receipt of the form of questionnaire from the Corporation.

(d) Subject to the certificate of incorporation of the Corporation and applicable law, only persons nominated in accordance with procedures stated in this Section 3.03 shall be eligible for election as and to serve as members of the Board of Directors and the only business that shall be conducted at an annual meeting of stockholders is the business that has been brought before the meeting in accordance with the procedures set forth in this Section 3.03. The chairman of the meeting shall have the power and the duty to determine whether a nomination or any proposal has been made according to the procedures stated in this Section 3.03 and, if any nomination or proposal does not comply with this Section 3.03, unless otherwise required by law, the nomination or proposal shall be disregarded.

(e) For purposes of this Section 3.03, "public announcement" means disclosure in a press release reported by the Dow Jones News Service, Associated Press or a comparable news service or in a document publicly filed by the Corporation with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the Act.

(f) Notwithstanding the foregoing provisions of this Section 3.03, a stockholder shall also comply with applicable requirements of the Act and the rules and regulations thereunder with respect to matters set forth in this Section 3.03. Nothing in this Section 3.03 shall affect any rights, if any, of stockholders to request inclusion of nominations or proposals in the Corporation's proxy statement pursuant to applicable provisions of federal law, including the Act.

SECTION 3.04. Special Meetings. Special meetings of the stockholders of the Corporation may be called only in the manner set forth in the certification of incorporation of the Corporation. Notice of every special meeting of the stockholders of the Corporation shall state the purpose of such meeting. Except as otherwise required by law, the business conducted at a special meeting of stockholders of the Corporation shall be limited exclusively to the business set forth in the Corporation's notice of meeting, and the individual or group calling such meeting shall have exclusive authority to determine the business included in such notice.

SECTION 3.05. Quorum, Manner of Acting and Adjournment.

(a) Quorum. The holders of a majority of the shares entitled to vote, present in person or represented by proxy, shall constitute a quorum at all meetings of the stockholders except as otherwise provided by the GCL, by the certificate of incorporation or by these bylaws. If a quorum is not present or represented at any meeting of the stockholders, the stockholders entitled to vote thereat, present in person or represented by proxy, shall have power to adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present or represented. At any such adjourned meeting at which a quorum is present or represented, the corporation may transact any business which might have been transacted at the original meeting. If the adjournment is for more than 30 days, or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting.

(b) Manner of Acting. Directors shall be elected by a plurality of the votes of the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors. In all matters other than the election of directors, the affirmative vote of the majority of shares present in person or represented by proxy at the meeting and entitled to vote thereon shall be the act of the stockholders, unless the question is one upon which, by express provision of the applicable statute, the certificate of incorporation or these bylaws, a different vote is required in which case such express provision shall govern and control the decision of the question. The stockholders present in person or by proxy at a duly organized meeting can continue to do business until adjournment, notwithstanding withdrawal of enough stockholders to leave less than a quorum.

SECTION 3.06. Organization. At every meeting of the stockholders, the chairman of the board, if there be one, or in the case of a vacancy in the office or absence of the chairman of the board, one of the following persons present in the order stated: the vice chairman, if one has been appointed, the president, the vice presidents in their order of rank or seniority, a chairman designated by the board of directors or a chairman chosen by the stockholders entitled to cast a majority of the votes which all stockholders present in person or by proxy are entitled to cast, shall act as chairman, and the secretary, or, in the absence of the secretary, an assistant secretary, or in the absence of the secretary and the assistant secretaries, a person appointed by the chairman, shall act as secretary.

SECTION 3.07. Voting.

(a) General Rule. Unless otherwise provided in the certificate of incorporation, each stockholder shall be entitled to one vote, in person or by proxy, for each share of capital stock having voting power held by such stockholder.

(b) Voting and Other Action by Proxy.

(1) A stockholder may execute a writing authorizing another person or persons to act for the stockholder as proxy. Such execution may be accomplished by the stockholder or the authorized officer, director, employee or agent of the stockholder signing such writing or causing his or her signature to be affixed to such writing by any reasonable means including, but not limited to, by facsimile signature. A stockholder may authorize another person or persons to act for the stockholder as proxy by transmitting or authorizing the transmission of a telegram, cablegram, or other means of electronic transmission to the person who will be the holder of the proxy or to a proxy solicitation firm, proxy support service organization or like agent duly authorized by the person who will be the holder of the proxy to receive such transmission if such telegram, cablegram or other means of electronic transmission sets forth or is submitted with information from which it can be determined that the telegram, cablegram or other electronic transmission was authorized by the stockholder.

(2) No proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period.

(3) A duly executed proxy shall be irrevocable if it states that it is irrevocable and if, and only so long as, it is coupled with an interest sufficient in law to support an irrevocable power. A proxy may be made irrevocable regardless of whether the interest with which it is coupled is an interest in the stock itself or an interest in the corporation generally.

SECTION 3.08. Voting Lists. A complete list of stockholders of the corporation entitled to vote at any meeting of stockholders of the corporation, arranged in alphabetical order for each class of stock and showing the address of each such stockholder and the number of shares registered in the name of such stockholder, shall be open to the examination of any such stockholder, for any purpose germane to a meeting of the stockholders of the corporation, for a period of at least 10 days before the meeting (i) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting or (ii) during ordinary business hours at the principal place of business of the corporation; provided, however, if the record date for determining the stockholders entitled to vote is less than 10 days before the meeting date, the list shall reflect the stockholders entitled to vote as of the 10th day before such meeting date.

The stock list shall also be open to the examination of any such stockholder during the entire meeting. The corporation may look to this list as the sole evidence of the identity of the stockholders entitled to vote at a meeting and the number of shares held by each stockholder.

SECTION 3.09. Inspectors of Election. Prior to a meeting of the stockholders of the Corporation, the Corporation shall appoint one or more inspectors to act at a meeting of stockholders of the Corporation and make a written report thereof. The corporation may designate one or more persons as alternate inspectors to replace any inspector who fails to act. If no inspector or alternate is able to act at a meeting of stockholders, the person presiding at the meeting may, and to the extent required by applicable law, shall, appoint one or more inspectors to act at the meeting. Each inspector, before beginning the discharge of his or her duties, shall take and sign an oath faithfully to execute the duties of inspector with strict impartiality and according to the best of his or her ability. The inspectors may appoint or retain other persons or entities to assist the inspectors in the performance of the duties of inspectors. The inspectors shall have the duties prescribed by applicable law.

**ARTICLE IV
BOARD OF DIRECTORS**

SECTION 4.01. Powers. All powers vested by law in the corporation shall be exercised by or under the authority of, and the business and affairs of the corporation shall be managed under the direction of, the board of directors.

SECTION 4.02. Number and Term of Office. The board of directors shall consist of such number of directors, not less than 1, as may be determined from time to time by resolution of the board of directors. Each director shall hold office until the expiration of the term for which he or she was selected and until a successor shall have been elected and qualified or until his or her earlier death, resignation or removal. Directors need not be residents of Delaware or stockholders of the corporation.

SECTION 4.03. Vacancies. Vacancies and newly created directorships resulting from any increase in the authorized number of directors elected by all of the stockholders having a right to vote as a single class may be filled by a majority of the directors then in office, though less than a quorum, or by a sole remaining director, and the directors so chosen shall hold office until their successors are elected and qualified or until their earlier death, resignation or removal. If there are no directors in office, then an election of directors may be held in the manner provided by statute. Whenever the holders of any class or classes of stock or series thereof are entitled to elect one or more directors by the provisions of the certificate of incorporation, vacancies and newly created directorships of such class or classes or series may be filled by a majority of the directors elected by such class or classes or series thereof then in office, or by a sole remaining director so elected. If, at the time of filling any vacancy or any newly created directorship, the directors then in office shall constitute less than a majority of the whole board (as constituted immediately prior to any such increase), the Court of Chancery may, upon application of any stockholder or stockholders holding at least ten percent of the total number of the shares at the time outstanding having the right to vote for such directors, summarily order an election to be held to fill any such vacancies or newly created directorships, or to replace the directors chosen by the directors then in office.

SECTION 4.04. Resignations. Any director may resign at any time upon written notice to the corporation. The resignation shall be effective upon receipt thereof by the corporation or at such subsequent time as shall be specified in the notice of resignation and, unless otherwise specified in the notice, the acceptance of the resignation shall not be necessary to make it effective.

SECTION 4.05. Removal. Any director or the entire board of directors may be removed, but only with cause, by the holders of shares entitled to cast a majority of the votes which all stockholders are entitled to cast at an election of directors.

SECTION 4.06. Organization. At every meeting of the board of directors, the chairman of the board, if there be one, or, in the case of a vacancy in the office or absence of the chairman of the board, one of the following officers present in the order stated: the vice chairman of the board, if there be one, the president, the vice presidents in their order of rank and seniority, or a chairman chosen by a majority of the directors present, shall preside, and the secretary, or, in the absence of the secretary, an assistant secretary, or in the absence of the secretary and the assistant secretaries, any person appointed by the chairman of the meeting, shall act as secretary.

SECTION 4.07. Place of Meeting. Meetings of the board of directors shall be held at such place within or without the State of Delaware as the board of directors may from time to time determine, or as may be designated in the notice of the meeting.

SECTION 4.08. Regular Meetings. Regular meetings of the board of directors shall be held without notice at such time and place as shall be designated from time to time by resolution of the board of directors.

SECTION 4.09. Special Meetings. Special meetings of the board of directors shall be held whenever called by the president or by two or more of the directors.

SECTION 4.10. Quorum, Manner of Acting and Adjournment.

(a) General Rule. At all meetings of the board, a majority of the total number of directors shall constitute a quorum for the transaction of business. If a quorum is not present at any meeting of the board of directors, the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present. The vote of a majority of the directors present at any meeting at which a quorum is present shall be the act of the board of directors, except as may be otherwise specifically provided by the GCL or by the certificate of incorporation.

(b) Unanimous Written Consent. Unless otherwise restricted by the certificate of incorporation, any action required or permitted to be taken at any meeting of the board of directors may be taken without a meeting, if all members of the board consent thereto in writing, and the writing or writings are filed with the minutes of proceedings of the board.

SECTION 4.11. Committees. The board of directors may designate committees of the board of directors, with such lawfully delegable powers and duties as it thereby confers, to serve at the pleasure of the board of directors and shall, for those committees, appoint a director or directors to serve as the member or members, designating, if it desires, other directors as alternate members who may replace any absent or disqualified member at any meeting of such committee. In the absence or disqualification of any member of any committee and any alternate member in his or her place, the member or members of the committee present at the meeting and not disqualified from voting, whether or not he or she or they constitute a quorum, may by unanimous vote appoint another member of the board of directors to act at the meeting in the place of the absent or disqualified member.

SECTION 4.12. Compensation of Directors. Unless otherwise restricted by the certificate of incorporation, the board of directors shall have the authority to fix the compensation of directors.

ARTICLE V OFFICERS

SECTION 5.01. Number, Qualifications and Designation. The officers of the corporation shall be chosen by the board of directors and shall be a president, one or more vice presidents, a secretary, a treasurer, a chief financial officer and such other officers as may from time to time be appointed by the board or directors. Any number of offices may be held by the same person. Officers may, but need not, be directors or stockholders of the corporation. The board of directors may elect from among the members of the board a chairman of the board and a vice chairman of the board who shall be officers of the corporation. Unless otherwise determined by the Board of Directors, the President shall be the Chief Executive Officer of the Corporation.

SECTION 5.02. Subordinate Officers, Committees and Agents. The board of directors may from time to time elect such other officers and appoint such committees, employees or other agents as it deems necessary, who shall hold their offices for such terms and shall exercise such powers and perform such duties as are provided in these bylaws, or as the board of directors may from time to time determine. The board of directors may delegate to any officer or committee the power to elect subordinate officers and to retain or appoint employees or other agents, or committees thereof, and to prescribe the authority and duties of such subordinate officers, committees, employees or other agents.

SECTION 5.03. The Chairman and Vice Chairman of the Board. The chairman of the board, if there be one, or in the absence of the chairman, the vice chairman of the board, if there be one, shall preside at all meetings of the stockholders and of the board of directors, and shall perform such other duties as may from time to time be assigned to them by the board of directors.

SECTION 5.04. The President. The president shall have general supervision over the business and operations of the corporation, subject, however, to the control of the board of directors. The president shall, in general, perform all duties incident to the office of president, and such other duties as from time to time may be assigned by the board of directors and, if the chairman of the board is the chief executive officer, the chairman of the board.

SECTION 5.05. The Vice Presidents. The vice presidents shall perform the duties of the president in the absence of the president and such other duties as may from time to time be assigned to them by the board of directors or by the president.

SECTION 5.06. The Secretary. The secretary, or an assistant secretary, shall attend all meetings of the stockholders and of the board of directors and shall record the proceedings of the stockholders and of the directors and of committees of the board in a book or books to be kept for that purpose; shall see that notices are given and records and reports properly kept and filed by the corporation as required by law; shall be the custodian of the seal of the corporation and see that it is affixed to all documents to be executed on behalf of the corporation under its seal; and, in general, shall perform all duties incident to the office of secretary, and such other duties as may from time to time be assigned by the board of directors or the president.

SECTION 5.07. The Chief Financial Officer. The chief financial officer shall keep or cause to be kept the books of account of the corporation in a thorough and proper manner and shall render statements of the financial affairs of the corporation in such form and as often as required by the board or the president. The chief financial officer, subject to the order of the Board of Directors, shall have the custody of all funds and securities of the corporation. The chief financial officer shall perform other duties commonly incident to his office and shall also perform such other duties and have such other powers as the board or the president shall designate from time to time. The president may direct the treasurer or any assistant treasurer to assume and perform the duties of the chief financial officer in the absence or disability of the chief financial officer, and each treasurer and assistant treasurer shall perform other duties commonly incident to his office and shall also perform such other duties and have such other powers as the board of directors or the president shall designate from time to time.

SECTION 5.08. Officers' Bonds. No officer of the corporation need provide a bond to guarantee the faithful discharge of the officer's duties unless the board of directors shall by resolution so require a bond in which event such officer shall give the corporation a bond (which shall be renewed if and as required) in such sum and with such surety or sureties as shall be satisfactory to the board of directors for the faithful performance of the duties of office.

SECTION 5.09. Salaries. The salaries of the officers and agents of the corporation elected by the board of directors shall be fixed from time to time by the board of directors or a committee thereof or by the officers as may be designated by resolution of the board of directors

SECTION 5.10. Removal. The board of directors may remove any officer of the corporation at any time, with or without cause.

ARTICLE VI CERTIFICATES OF STOCK, TRANSFER, ETC.

SECTION 6.01. Form and Issuance.

(a) Issuance. The shares of the corporation shall be represented by certificates unless the board of directors shall by resolution provide that some or all of any class or series of stock shall be uncertificated shares. Any such resolution shall not apply to shares represented by a certificate until the certificate is surrendered to the corporation. Notwithstanding the adoption of any resolution providing for uncertificated shares, every holder of stock represented by certificates and upon request every holder of uncertificated shares shall be entitled to have a certificate signed by, or in the name of the corporation by, the chairman or vice chairman of the board of directors, or the president or vice president, and by the treasurer or an assistant treasurer, or the secretary or an assistant secretary, representing the number of shares registered in certificate form.

(b) Form and Records. Stock certificates of the corporation shall be in such form as approved by the board of directors. The stock record books and the blank stock certificate books shall be kept by the secretary or by any agency designated by the board of directors for that purpose. The stock certificates of the corporation shall be numbered and registered in the stock ledger and transfer books of the corporation as they are issued.

(c) Signatures. Any of or all the signatures upon the stock certificates of the corporation may be a facsimile. In case any officer, transfer agent or registrar who has signed, or whose facsimile signature has been placed upon, any share certificate shall have ceased to be such officer, transfer agent or registrar, before the certificate is issued, it may be issued with the same effect as if the signatory were such officer, transfer agent or registrar at the date of its issue.

SECTION 6.02. Transfer. Transfers of shares shall be made on the share register or transfer books of the corporation upon surrender of the certificate therefor, endorsed by the person named in the certificate or by an attorney lawfully constituted in writing. No transfer shall be made which would be inconsistent with the provisions of Article 8, Title 6 of the Delaware Uniform Commercial Code-Investment Securities.

SECTION 6.03. Lost, Stolen, Destroyed or Mutilated Certificates. The board of directors may direct a new certificate of stock or uncertificated shares to be issued in place of any certificate theretofore issued by the corporation alleged to have been lost, stolen or destroyed, upon the making of an affidavit of that fact by the person claiming the certificate of stock to be lost, stolen or destroyed. When authorizing such issue of a new certificate or certificates, the board of directors may, in its discretion and as a condition precedent to the issuance thereof, require the owner of such lost, stolen or destroyed certificate or certificates, or the legal representative of the owner, to give the corporation a bond sufficient to indemnify against any claim that may be made against the corporation on account of the alleged loss, theft or destruction of such certificate or the issuance of such new certificate or uncertificated shares.

SECTION 6.04. Record Holder of Shares. The corporation shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends, and to vote as such owner, and to hold liable for calls and assessments a person registered on its books as the owner of shares, and shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of any other person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of Delaware.

SECTION 6.05. Determination of Stockholders of Record.

(a) Meetings of Stockholders. In order that the corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, the board of directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the board of directors, and which record date shall not be more than 60 nor less than ten days before the date of such meeting. If no record date is fixed by the board of directors, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting unless the board of directors fixes a new record date for the adjourned meeting.

(d) Dividends. In order that the corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights of the stockholders entitled to exercise any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action, the board of directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted, and which record date shall be not more than 60 days prior to such action. If no record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the board of directors adopts the resolution relating thereto.

**ARTICLE VII
INDEMNIFICATION OF DIRECTORS, OFFICERS AND
OTHER AUTHORIZED REPRESENTATIVES**

SECTION 7.01. Indemnification of Authorized Representatives in Third Party Proceedings. The corporation shall indemnify any person who was or is an authorized representative of the corporation, and who was or is a party, or is threatened to be made a party to any third party proceeding, by reason of the fact that such person was or is an authorized representative of the corporation, against expenses, judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such third party proceeding if such person acted in good faith and in a manner such person reasonably believed to be in, or not opposed to, the best interests of the corporation and, with respect to any criminal third party proceeding, had no reasonable cause to believe such conduct was unlawful. The termination of any third party proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent, shall not of itself create a presumption that the authorized representative did not act in good faith and in a manner which such person reasonably believed to be in or not opposed to, the best interests of the corporation, and, with respect to any criminal third party proceeding, had reasonable cause to believe that such conduct was unlawful.

SECTION 7.02. Indemnification of Authorized Representatives in Corporate Proceedings. The corporation shall indemnify any person who was or is an authorized representative of the corporation and who was or is a party or is threatened to be made a party to any corporate proceeding, by reason of the fact that such person was or is an authorized representative of the corporation, against expenses actually and reasonably incurred by such person in connection with the defense or settlement of such corporate proceeding if such person acted in good faith and in a manner reasonably believed to be in, or not opposed to, the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or the court in which such corporate proceeding was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such authorized representative is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

SECTION 7.03. Mandatory Indemnification of Authorized Representatives. To the extent that an authorized representative or other employee or agent of the corporation has been successful on the merits or otherwise in defense of any third party or corporate proceeding or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses actually and reasonably incurred by such person in connection therewith.

SECTION 7.04. Determination of Entitlement to Indemnification. Any indemnification under section 7.01, 7.02 or 7.03 of this Article (unless ordered by a court) shall be made by the corporation only as authorized in the specific case upon a determination that indemnification of the authorized representative or other employee or agent is proper in the circumstances because such person has either met the applicable standard of conduct set forth in section 7.01 or 7.02 or has been successful on the merits or otherwise as set forth in section 7.03 and that the amount requested has been actually and reasonably incurred. Such determination shall be made:

(1) by the board of directors by a majority vote of a quorum consisting of directors who were not parties to such third party or corporate proceeding; or

(2) if such a quorum is not obtainable, or even if obtainable, a quorum of disinterested directors so directs, by independent legal counsel in a written opinion; or

(3) by the stockholders.

SECTION 7.05. Advancing Expenses. Expenses actually and reasonably incurred in defending a third party or corporate proceeding shall be paid on behalf of an authorized representative by the corporation in advance of the final disposition of such third party or corporate proceeding upon receipt of an undertaking by or on behalf of the authorized representative to repay such amount if it shall ultimately be determined that the authorized representative is not entitled to be indemnified by the corporation as authorized in this Article. The financial ability of any authorized representative to make a repayment contemplated by this section shall not be a prerequisite to the making of an advance. Expenses incurred by other employees and agents may be so paid upon such terms and conditions, if any, as the board of directors deems appropriate.

SECTION 7.06. Definitions. For purposes of this Article:

(1) “authorized representative” shall mean any and all directors and officers of the corporation and any person designated as an authorized representative by the board of directors of the corporation (which may, but need not, include any person serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise);

(2) “corporation” shall include, in addition to the resulting corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors, officers, employees or agents, so that any person who is or was a director, officer, employee or agent of such constituent corporation, or is or was serving at the request of such constituent corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under the provisions of this Article with respect to the resulting or surviving corporation as such person would have with respect to such constituent corporation if its separate existence had continued;

(3)“corporate proceeding” shall mean any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor or investigative proceeding by the corporation;

(4)“criminal third party proceeding” shall include any action or investigation which could or does lead to a criminal third party proceeding;

(5)“expenses” shall include attorneys’ fees and disbursements;

(6)“fines” shall include any excise taxes assessed on a person with respect to an employee benefit plan;

(7)“not opposed to the best interests of the corporation” shall include actions taken in good faith and in a manner the authorized representative reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan;

(8)“other enterprise” shall include employee benefit plans;

(9)“party” shall include the giving of testimony or similar involvement;

(10)“serving at the request of the corporation” shall include any service as a director, officer or employee of the corporation which imposes duties on, or involves services by, such director, officer or employee with respect to an employee benefit plan, its participants, or beneficiaries; and

(11)“third party proceeding” shall mean any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative, or investigative, other than an action by or in the right of the corporation.

SECTION 7.07. Insurance. The corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against the person and incurred by the person in any such capacity, or arising out of his or her status as such, whether or not the corporation would have the power or the obligation to indemnify such person against such liability under the provisions of this Article.

SECTION 7.08. Scope of Article. The indemnification of authorized representatives and advancement of expenses, as authorized by the preceding provisions of this Article, shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any agreement, vote of stockholders or disinterested directors or otherwise, both as to action in an official capacity and as to action in another capacity while holding such office. The indemnification and advancement of expenses provided by or granted pursuant to this Article shall, unless otherwise provided when authorized or ratified, continue as to a person who has ceased to be an authorized representative and shall inure to the benefit of the heirs, executors and administrators of such a person.

SECTION 7.09. Reliance on Provisions. Each person who shall act as an authorized representative of the corporation shall be deemed to be doing so in reliance upon rights of indemnification provided by this Article.

**ARTICLE VIII
GENERAL PROVISIONS**

SECTION 8.01. Dividends. Subject to the restrictions contained in the GCL and any restrictions contained in the certificate of incorporation, the board of directors may declare and pay dividends upon the shares of capital stock of the corporation.

SECTION 8.02. Contracts. Except as otherwise provided in these bylaws, the board of directors may authorize any officer or officers including the chairman and vice chairman of the board of directors, or any agent or agents, to enter into any contract or to execute or deliver any instrument on behalf of the corporation and such authority may be general or confined to specific instances.

SECTION 8.03. Corporate Seal. The corporation shall have a corporate seal, which shall have inscribed thereon the name of the corporation, the year of its organization and the words "Corporate Seal, Delaware". The seal may be used by causing it or a facsimile thereof to be impressed or affixed or in any other manner reproduced.

SECTION 8.04. Deposits. All funds of the corporation shall be deposited from time to time to the credit of the corporation in such banks, trust companies, or other depositories as the board of directors may approve or designate, and all such funds shall be withdrawn only upon checks signed by such one or more officers or employees as the board of directors shall from time to time determine.

SECTION 8.05. Amendment of Bylaws. These bylaws may be altered, amended or repealed in accordance with the certificate of incorporation of the corporation.

**ARTICLE IX
FORUM SELECTION BYLAW**

SECTION 9.01. Forum Selection Bylaw. Unless the corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for (1) any derivative action or proceeding brought on behalf of the corporation, (2) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer, other employee or stockholder of the corporation to the corporation or the corporation's stockholders, (3) any action asserting a claim arising pursuant to any provision of the DGCL, the certificate of incorporation or these bylaws or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, or (4) any action asserting a claim governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring or holding any interest in shares of capital stock of the corporation shall be deemed to have notice of and consented to the provisions of this Section 9.01.

CERTIFICATION

I, Remy Luthringer, certify that:

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

Date: November 4, 2019

/s/ Remy Luthringer Ph.D.

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

CERTIFICATION

I, Geoffrey Race, certify that:

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

Date: November 4, 2019

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

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

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

- (1) The Company’s Quarterly Report on Form 10-Q for the period ended September 30, 2019, to which this Certification is attached as Exhibit 32.1 (the “Quarterly Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
- (2) The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 4, 2019

/s/ Remy Luthringer, Ph.D.

Remy Luthringer, Ph.D.

Chief Executive Officer and

Chairman of the Board of Directors

Date: November 4, 2019

/s/ Geoffrey Race

Geoffrey Race

Chief Financial Officer

(Principal Financial Officer)

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