Minerva Neurosciences, Inc.
Form 10-Q
August 03, 2017

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2017

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File No. 001-36517

Minerva Neurosciences, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	26-0784194
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
1601 Trapelo Road, Suite 284 Waltham, MA	02451
(Address of Principal Executive Offices)	(Zip Code)

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

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

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post 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	(Do not check if smaller reporting company)	Smaller reporting company
Emerging growth company		

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

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

The number of shares of Registrant’s Common Stock, $0.0001 par value per share, outstanding as of July 31, 2017 was 42,509,003.

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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,” “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)

	June 30, 2017	December 31, 2016
Assets		
Current assets		
Cash and cash equivalents	$50,191,362	$82,980,609
Marketable securities	27,381,492	-
Restricted cash	80,000	80,000
Prepaid expenses and other current assets	421,693	803,241
Total current assets	78,074,547	83,863,850
Equipment, net	3,036	9,640
In-process research and development	34,200,000	34,200,000
Goodwill	14,869,399	14,869,399
Deferred public offering costs	232,980	-
Total assets	$127,379,962	$132,942,889
Liabilities and Stockholders' Equity		
Current liabilities		
Notes payable - current portion	$5,066,500	$4,853,753
Accounts payable	1,431,466	1,468,341
Accrued expenses and other current liabilities	1,443,439	815,813
Accrued collaborative expenses - related party	6,646,239	2,547,952
Total current liabilities	14,587,644	9,685,859
Notes payable - noncurrent	1,326,479	3,841,062
Deferred taxes	13,433,760	13,433,760
Total liabilities	29,347,883	26,960,681
Commitments and contingencies		
Stockholders' equity		
Preferred stock; $0.0001 par value; 100,000,000 shares authorized; none issued or outstanding as of June 30, 2017 and December 31, 2016, respectively	-	-
Common stock; $0.0001 par value; 125,000,000 shares authorized; 36,759,003 and 35,024,002 shares issued and outstanding as of June 30, 2017 and December 31, 2016, respectively	3,676	3,502

Additional paid-in capital	251,311,357	238,836,940
Accumulated deficit	(153,282,954)	(132,858,234)
Total stockholders' equity	98,032,079	105,982,208
Total liabilities and stockholders' equity	$127,379,962	$132,942,889

See accompanying notes to condensed consolidated financial statements

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Operations

(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30, 2017	2016	June 30, 2017	2016
Expenses				
Research and development	$7,144,133	$2,714,298	$14,758,464	$8,089,162
General and administrative	2,601,408	2,250,206	5,472,150	4,632,248
Total expenses	9,745,541	4,964,504	20,230,614	12,721,410
Loss from operations	(9,745,541)	(4,964,504)	(20,230,614)	(12,721,410)
Foreign exchange losses	(20,115)	(15,462)	(36,798)	(24,974)
Investment income	155,657	34,613	214,319	66,977
Interest expense	(170,125)	(268,256)	(371,627)	(538,612)
Net loss	$(9,780,124)	$(5,213,609)	$(20,424,720)	$(13,218,019)
Net loss per share, basic and diluted	$(0.27)	$(0.18)	$(0.57)	$(0.47)
Weighted average shares outstanding, basic and diluted	36,719,541	29,122,411	36,048,300	28,162,561

See accompanying notes to condensed consolidated financial statements

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statement of Changes in Stockholders' Equity

(Unaudited)

	Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balances at January 1, 2016	24,721,143	$2,472	$157,129,947	$(101,812,862)	$55,319,557
Exercise of common stock warrants	3,850,051	385	22,222,109	-	22,222,494
Issuance of common stock in a public offering, net of issuance costs of $3,842,004	6,052,631	606	53,657,385		53,657,991
Issuance of common stock pursuant to a private placement	181,488	18	999,981		999,999
Stock-based compensation	-	-	1,623,003	-	1,623,003
Net loss	-	-	-	(13,218,019)	(13,218,019)
Balances at June 30, 2016	34,805,313	$3,481	$235,632,425	$(115,030,881)	$120,605,025
Balances at January 1, 2017	35,024,002	$3,502	$238,836,940	$(132,858,234)	$105,982,208
Exercise of common stock warrants	1,621,073	162	9,356,671		9,356,833
Exercise of stock options	113,928	12	576,162		576,174
Stock-based compensation	-	-	2,541,584		2,541,584
Net loss	-	-	-	(20,424,720)	(20,424,720)
Balances at June 30, 2017	36,759,003	$3,676	$251,311,357	$(153,282,954)	$98,032,079

See accompanying notes to condensed consolidated financial statements

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

	Six Months Ended June 30,	
	2017	2016
Cash flows from operating activities:		
Net loss	$(20,424,720)	$(13,218,019)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	6,604	8,639
Amortization of debt discount recorded as interest expense	124,130	186,133
(Accretion) amortization of marketable securities	(40,185)	90,734
Stock-based compensation expense	2,541,584	1,623,003
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	406,656	897,739
Accounts payable	(60,672)	(620,607)
Accrued expenses and other current liabilities	459,626	(1,071,437)
Accrued collaborative expenses	4,098,287	-
Net cash used in operating activities	(12,888,690)	(12,103,815)
Cash flows from investing activities:		
Proceeds from the maturity and redemption of marketable securities	-	9,443,000
Purchase of marketable securities	(27,366,415)	-
Net cash (used in) provided by investing activities	(27,366,415)	9,443,000
Cash flows from financing activities:		
Proceeds from sale of common stock in public offering	-	57,499,995
Costs paid in connection with public offering	(41,183)	(3,675,306)
Proceeds from exercise of common stock warrants	9,356,833	22,222,494
Proceeds from exercise of stock options	576,174	-
Repayments of notes payable	(2,425,966)	-
Proceeds from sale of common stock in private placement	-	999,999
Net cash provided by financing activities	7,465,858	77,047,182
Net (decrease) increase in cash and cash equivalents	(32,789,247)	74,386,367
Cash and cash equivalents		
Beginning of period	82,980,609	14,284,054
End of period	$50,191,362	$88,670,421
Supplemental disclosure of non-cash financing activities		
Deferred public offering costs included in accounts payable or in accrued expenses and other current liabilities	$191,797	$166,698
Supplemental disclosure of cash flow information		
Cash paid for interest	$261,749	$352,500

See accompanying notes to condensed consolidated financial statements

MINERVA NEUROSCIENCES, INC.

Notes to Condensed Consolidated Financial Statements

As of June 30, 2017 and for the Six Months Ended June 30, 2017 and 2016

(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 ("CNS") 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 MIN-101, a compound the Company is developing for the treatment of schizophrenia. In addition, the Company's portfolio includes MIN-202 (also known as 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 MIN-101 and MIN-117 from Mitsubishi Tanabe Pharma Corporation ("MTPC") with the rights to develop, sell and import MIN-101 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, MIN-202 in the European Union, Switzerland, Liechtenstein, Iceland and Norway (the "Minerva Territory"), subject to 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 June 30, 2017, the Company has an accumulated deficit of approximately $153.3 million and net cash used in operating activities was approximately $12.9 million during the six months ended June 30, 2017. Management 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.

The Company believes that its existing cash, cash equivalents 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 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 June 30, 2017, the results of operations for the three and six months ended June 30, 2017 and 2016 and cash flows for the six months ended June 30, 2017 and 2016. The results of operations for the three and six months ended June 30, 2017, 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, 2016 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, 2016 included in the Company's Annual Report on Form 10-K filed with the SEC on March 13, 2017.

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; however, these deposits may be redeemed upon demand and, therefore, bear minimal risk.

Restricted cash

Cash accounts with any type of restriction are classified as restricted. The Company maintained restricted cash balances as collateral for corporate credit cards in the amount of $80,000 at June 30, 2017 and December 31, 2016.

Marketable securities

Marketable securities consist of corporate debt securities maturing in twelve 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 at amortized cost. The Company's investments in marketable securities are classified as Level 2 within the fair value hierarchy. As of June 30, 2017, remaining final maturities of marketable securities ranged from July 2017 to August 2017, with a weighted average remaining maturity of approximately 1 months. The following table provides the amortized cost basis, aggregate fair value, net unrealized (gains)/losses and the net carrying value of investments in held-to-maturity securities as of June 30, 2017:

	June 30, 2017			
	Amortized Cost	Aggregate Fair Value	Net Unrealized (Gains)/Losses	Net Carrying Value
Marketable securities:				
Corporate bonds - current	$27,381,492	$27,380,584	$ 908	$27,381,492

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 expected 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 July 2014, the Company entered into a co-development and license agreement. The Company accounts for the co-development and license agreement as a joint risk-sharing collaboration in accordance with ASC 808, Collaboration Arrangements. Costs between the Company and the licensor with respect to each party's share of 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 financial statements due to the joint risk-sharing nature of the activities. During the three months ended June 30, 2017 and 2016, the Company recorded an expense of $3.6 million and a cost offset of $0.1 million, respectively, for certain development activities in accordance with the terms of the co-development agreement. During the six months ended June 30, 2017 and 2016, the Company recorded an expense of $6.6 million and a cost offset of $0.2 million, respectively, for certain development activities in accordance with the terms of the co-development agreement. The Company has included $6.6 million and $2.5 million in accrued collaborative expenses as of June 30, 2017 and

December 31, 2016, respectively, related to this agreement. In June 2017, we entered into an Amendment to our Co-Development and License Agreement with Janssen, pursuant to which Janssen agreed to waive the remaining payments, including accrued and unpaid balances as of June 30, 2017, due from Minerva for Phase II development of MIN-202 as well as provide certain payments to the Company. The amendment was not effective as of June 30, 2017 as its effectiveness is contingent upon approval by the European Commission amongst other normal and customary closing conditions Refer to Note 11 – Subsequent Events for additional information.

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 six months ended June 30, 2017 or 2016.

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, expected 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 and the fair value of each unvested award is adjusted at the end of each period for any change in fair value from the previous valuation until the award vests.

Foreign currency transactions

The Company's functional currency is the US dollar. The Company pays certain vendor invoices in the respective foreign currency. The Company records an expense in US 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 excludes dilution and 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 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.

Long-lived assets

The Company reviews the recoverability of all long-lived assets, including the related useful lives, whenever events or changes in circumstances indicate that the carrying amount of a long-lived asset might not be recoverable. If required, the Company compares the estimated undiscounted future net cash flows to the related asset's carrying value to determine whether there has been an impairment. If an asset is considered impaired, the asset is written down to fair value, which is based either on discounted cash flows or appraised values in the period the impairment becomes known. The Company believes that all long-lived assets are recoverable, and no impairment was deemed necessary at June 30, 2017 and 2016.

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 six months ended June 30, 2017 and 2016.

Deferred public offering costs

Deferred public offering costs include certain legal, accounting and other costs directly attributable to the Company's public offering of common stock. Upon completion of the public offering on July 5, 2017, these amounts will be offset against the proceeds of the offering.

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 Financial Accounting Standards Board ("FASB") and are adopted by the Company as of the specified effective date.

Recently Adopted Accounting Pronouncements

In March 2016, the FASB issued Accounting Standards Update ("ASU") No 2016-09, Compensation – Stock Compensation (Topic 718). The new standard simplifies several aspects of the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. Under this guidance, a company recognizes all excess tax benefits and tax deficiencies as income tax expense or benefit in the statement of operations. This change

eliminates the notion of the additional paid-in capital pool and reduces the complexity in accounting for excess tax benefits and tax deficiencies. The new standard is effective for public companies for annual reporting periods beginning after December 15, 2016, including interim periods within those annual reporting periods; however, early adoption is allowed. The Company adopted the new standard on January 1, 2017. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

Accounting Pronouncements Not Yet Adopted

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU 2014-09"). Subsequently, the FASB also issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606) , which adjusted the effective date of ASU 2014-09; ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net) , which amends the principal-versus-agent implementation guidance and illustrations in ASU 2014-09; ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing , which clarifies identifying performance obligation and licensing implementation guidance and illustrations in ASU 2014-09; and ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients , which addresses implementation issues and is intended to reduce the cost and complexity of applying the new revenue standard in ASU 2014-09 (collectively, the "Revenue ASUs").

The Revenue ASUs provide an accounting standard for a single comprehensive model for use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance. The accounting standard is effective for interim and annual periods beginning after December 15, 2017, with an option to early adopt for interim and annual periods beginning after December 15, 2016. The guidance permits two methods of adoption: retrospectively to each prior reporting period presented (the full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the modified retrospective method). The Company is currently evaluating the impact of the pending adoption of the new standard on the Company's consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases. The new standard establishes a right-of-use (ROU) 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 is 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. Refer to Note 9, Commitments and Contingencies, for the Company's current lease commitments. The Company is currently evaluating the impact of the pending adoption of the new standard on the Company's consolidated financial statements.

In August 2016, the FASB issued ASU No 2016-15, Statement of Cash Flows – Classification of Certain Cash Receipts and Cash Payments (Topic 230). The new standard clarifies the treatment of several cash flow categories. In addition, ASU 2016-15 clarifies that when cash receipts and cash payments have aspects of more than one class of cash flows and cannot be separated, classification will depend on the predominant source or use. This update is effective for annual periods beginning after December 15, 2017, 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.

In January 2017, the FASB issued ASU No 2017-4, 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.

In March 2017, the FASB issued ASU No 2017-8, 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 is currently evaluating the impact of the pending adoption of the new standard on the Company's consolidated financial statements.

NOTE 3 — ACCRUED EXPENSES

Accrued expenses and other liabilities consist of the following:

	June 30,	December 31,

	2017	2016
Research and development costs and other accrued expenses	$416,229	$ 574,290
Professional fees	527,048	192,000
Accrued bonus	398,574	-
Interest payable	35,270	49,523
Vacation payable	66,318	-
	$1,443,439	$ 815,813

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 issuances 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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net loss	$(9,780,124)	$(5,213,609)	$(20,424,720)	$(13,218,019)
Weighted average shares of common stock outstanding	36,719,541	29,122,411	36,048,300	28,162,561
Net loss per share of common stock – basic and diluted	$(0.27)	$(0.18)	$(0.57)	$(0.47)

The following securities outstanding at June 30, 2017 and 2016 have been excluded from the calculation of weighted average shares outstanding as their effect on the calculation of loss per share is antidilutive:

	June 30,	
	2017	2016
Common stock options	3,891,596	3,511,198
Restricted stock units	194,600	-
Common stock warrants	40,790	2,472,400

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 bear interest at a fixed rate of 7.05% per annum. The Company believes that the Company's debt obligations accrue interest at rates which approximate prevailing market rates for instruments with similar characteristics and, accordingly, the carrying values for these instruments approximate fair value.

In August 2015, the Lenders and the Company entered into a First Amendment to the Loan Agreement, amending certain milestones related to the six month extension of the interest-only repayment period of the Term A Loans. By raising at least $30.0 million in gross capital (including at least $20.0 million from the sale of equity securities) and completing the first dosing of its Phase I/II clinical trial for MIN-117 prior to December 31, 2015, the Company achieved the interest-only milestones under the Loan Agreement and elected to extend the interest-only period an additional six months and reduce the repayment term by six months. Through August 1, 2016, the Company was obligated only to make monthly interest payments on the outstanding principal balance on the Term A Loans, followed by 24 months of equal principal and interest payments.

On or prior to March 31, 2016, the Company was permitted to borrow additional term loans in the aggregate principal amount up to $5 million, subject to the satisfaction of certain borrowing conditions, including the Company's achievement of primary endpoints on its Phase IIa trials for MIN-117 and MIN-202 programs. In June 2016, the Company irrevocably elected not to borrow the additional $5 million available under the Term Loans.

The Company paid a facility fee of $75,000 for access to the Term Loans and will be required to pay a final payment of 5.1% of the total amount borrowed, which has been included as a component of the debt discount and is amortized to interest expense over the term of the loans. The outstanding Term A Loans and debt discount are as follows:

	June 30, 2017
Term A Loans	$6,003,451
Less: debt discount and financing costs	(49,454)
Less: current portion	(5,066,500)
Accrued portion of final payment	438,982
Long-term portion	$1,326,479

For the three months ended June 30, 2017 and 2016, the Company recognized interest expense of $0.2 million and $0.3 million respectively, including $0.1 million in both periods, related to the debt discount. For the six months ended June 30, 2017 and 2016, the Company recognized interest expense of $0.4 million and $0.5 million respectively, including $0.1 million and $0.2 million, respectively, related to the debt discount.

The Term Loans mature on August 1, 2018. The Company may prepay all, but not less than all, of the loaned amount upon 30 days' advance notice to the Lenders, provided that the Company will be obligated to pay a prepayment fee equal to (i) 3% of the outstanding balance, if the loan is prepaid within 24 months of the funding date, (ii) 2% of the outstanding balance, if the loan is prepaid between 24 and 36 months of the funding date and (iii) 1% of the outstanding balance, if the loan is prepaid thereafter (each, a "Prepayment Fee"). The expected remaining repayment of the $10.0 million Term A loan principal is as follows:

2017	2,512,747
2018	3,490,704
Total Term A Loans	$6,003,451

The Company's obligations under the Loan Agreement are secured by a first priority security interest in substantially all of its assets, other than its intellectual property. The Company has also agreed not to pledge or otherwise encumber its intellectual property assets, except that it may grant certain exclusive and non-exclusive licenses of its intellectual property as set forth in the Loan Agreement. In addition, the Company pledged all of its equity interests in Minerva Neurosciences Securities Corporation and 65% of its equity interests in Mind-NRG, Sarl as security for its obligations under the Loan Agreement.

Upon the occurrence of certain events, including but not limited to the Company's failure to satisfy its payment obligations under the Loan Agreement, the breach of certain of its other covenants under the Loan Agreement, or the occurrence of a material adverse change, the Lenders will have the right, among other remedies, to declare all principal and interest immediately due and payable, to take control of the Company's cash in its SVB deposit account, and will have the right to receive the final payment fee and, if the payment of principal and interest is due prior to maturity, the applicable Prepayment Fee. As of June 30, 2017, the Company was in compliance with all covenants set forth in the Loan Agreement.

NOTE 6 — CO-DEVELOPMENT AND LICENSE AGREEMENT

On February 13, 2014, the Company signed a co-development and license agreement with Janssen, subject to the completion of an initial public offering and the payment of a $22.0 million license fee. 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) MIN-202 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 MIN-202, 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 related to MIN-202 to sell MIN-202 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 will pay a quarterly royalty percentage to the licensor in the high single digits on aggregate net sales for MIN-202 products sold by the Company, its affiliates and sublicensees in the Minerva Territory. The licensor will pay a quarterly royalty percentage to the Company in the high single digits on aggregate net sales for MIN-202 products sold by the licensor outside the Minerva Territory. In accordance with the development agreement, the Company will pay 40% of MIN-202 development costs related to the joint development of any MIN-202 products. However, the Company’s share of aggregate development costs shall not exceed (i) $5.0 million for the period beginning from the effective date of the license and ending following the completion of certain Phase Ib clinical trials and animal toxicology studies, and (ii) $24.0 million for the period beginning from the effective date of the

license and ending following the completion of certain Phase II clinical trials. The licensor has a right to opt out at the end of certain development milestones, with the first milestone being the completion of a single day Phase I clinical trial in patients with MDD. Upon opt out, the licensor will not have to fund further development of MIN-202 and the Minerva Territory will be expanded to also include all of North America. The Company would then owe the licensor a reduced royalty in the mid-single digits for all sales in the Minerva Territory. The Company has the right to terminate the license following certain development milestones, the first being completion of a certain Phase Ib clinical trial in patients with insomnia and certain toxicology studies in animals. If the Company terminates the license within 45 days of this milestone, the Company must pay a termination fee equal to $3.0 million. If the Company terminates the license at any time following the last development milestone involving a certain Phase IIb clinical trial, the Company will be entitled to a royalty in the mid-single digits from sales of MIN-202 by the licensor. The licensor may also terminate the agreement for the Company's material breach or certain insolvency events, including if the Company is unable to fund its portion of the development costs.

The Company accounts for the co-development and license agreement as a joint risk-sharing collaboration in accordance with ASC 808, Collaboration Arrangements. Payments between the Company and the licensor with respect to each party's share of MIN-202 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. The Company has included $6.6 million and $2.5 million in accrued collaborative expenses, as of June 30, 2017 and December 31, 2016, respectively, related to this agreement. In the six months ended June 30, 2017 and 2016, the Company paid $2.5 million and zero, respectively, related to development activities under this agreement.

On July 6, 2016, the Company and Janssen agreed that "Decision Point 2" had been reached as defined under the co-development agreement. As neither party has exercised their right to withdraw from the agreement, the Company has paid Janssen $3.5 million and have incurred direct expenses of $0.3 million related to development activities under the current phase of development. During the three months ended June 30, 2017 and 2016, the Company recorded an expense of $3.6 million and a cost offset of $0.1 million, respectively, for certain development activities in accordance with the terms of the co-development agreement. During the six months ended June 30, 2017 and 2016, the Company recorded an expense of $6.6 million and a cost offset of $0.2 million, respectively, for certain development activities in accordance with the terms of the co-development agreement.

A number of supportive activities and studies are underway in anticipation of the next phase of clinical trials with MIN-202 in both insomnia disorder and MDD. Refer to Note 11 – Subsequent Events for additional information regarding a pending amendment to the co-development and license agreement with Janssen.

NOTE 7 — STOCKHOLDERS' EQUITY

Warrant Exercises

In January, February, June and December 2016 and in March 2017, certain investors in the Company's March 2015 private placement exercised their warrants at an exercise price of $5.772 per share and received an aggregate of 5,673,758 shares of the Company's common stock. The Company received gross proceeds of approximately $32.7 million from the exercise of these warrants. As of June 30, 2017, there are no remaining warrants outstanding under the Company's March 2015 private placement.

Public Offering of Common Stock

On June 17, 2016, the Company closed a public offering of common stock, in which the Company issued and sold 6,052,631 shares of common stock at a public offering price of $9.50, for aggregate gross proceeds to the Company of $57.5 million. All of the shares issued and sold in this public offering were registered under the Securities Act pursuant to a registration statement on Form S-3 (File No. 333-205764) and a related prospectus and prospectus supplement, in each case filed with the Securities and Exchange Commission. The Company incurred $3.8 million in underwriting discounts and commissions and transaction costs, which have been included as a component of additional paid-in capital, resulting in net proceeds of $53.7 million.

Refer to Note 11 – Subsequent Events for additional information regarding the public offering of common stock by the Company that closed on July 5, 2017.

Private Placement of Common Stock

On March 17, 2016, the Company entered into a common stock purchase agreement with a member of the Board of Directors, pursuant to which the Company, in a private placement, sold to the director an aggregate of 181,488 shares of the Company’s common stock, at a price per share of $5.51, for gross proceeds of approximately $1.0 million.

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. 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 June 30, 2017.

NOTE 8 — STOCK OPTION PLAN AND STOCK-BASED COMPENSATION

In December 2013, the Company adopted the 2013 Equity Incentive Plan (the "Plan"), which provides for the issuance of options, stock appreciation rights, stock awards and stock units. On January 1, 2017, in accordance with the terms of the Plan, the total shares authorized for issuance under the plan increased by 750,000 to 5,781,333. This increase represents the lessor 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. Stock option activity under the Plan is as follows:

	Shares Issuable Pursuant to Stock Options	Weighted-Average Exercise Price
Outstanding January 1, 2017	3,974,143	$ 6.61
Granted	222,500	$ 10.97
Exercised	(113,928)	$ 5.06
Forfeited	(191,119)	$ 7.58
Outstanding June 30, 2017	3,891,596	$ 6.85
Exercisable June 30, 2017	2,186,774	$ 5.98
Available for future grant	1,565,154	

The weighted average grant-date fair value of stock options outstanding on June 30, 2017 was $5.26 per share. Total unrecognized compensation costs related to non-vested stock options at June 30, 2017 was approximately $8.7 million and is expected to be recognized within future operating results over a weighted-average period of 2.7 years. At June 30, 2017, the weighted average contractual term of the options outstanding is approximately 7.9 years. The intrinsic value of outstanding stock options at June 30, 2017 was $10.3 million.

The Company uses the Black Scholes model to estimate the fair value of stock options granted. For stock options granted during the six months ended June 30, 2017 and 2016, the Company utilized the following assumptions:

	2017	2016
Expected term (years)	5.5-6.25	5.5-6.25
Risk free interest rate	1.83-2.02%	1.17-1.52%
Volatility	79-84%	78-79%
Dividend yield	0%	0%
Weighted average grant date fair value per share of common stock	$ 6.53	$ 5.53

Stock-Based Awards Granted to Non-employees-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 155,000 stock options to non-employees during the six months ended June 30, 2017. The Company recorded stock-based compensation expense for

stock options granted to non-employees of $0.2 million during the six months ended June 30, 2017. There were no stock option grants made to non-employees made during the six months ended June 30, 2016.

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

	June 30, 2017
Expected term (years)	9.2-9.8
Risk free interest rate	2.26-2.30%
Volatility	111-113%
Dividend yield	0%
Weighted average reporting date fair value per share of common stock	$ 8.05

The expected term of the employee-related options was estimated using the “simplified” method as defined by the Securities and Exchange Commission’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 whose term 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.

RSU activity under the Plan for the six months ended June 30, 2017 is as follows:

	RSUs	Weighted-Average Grant Date Fair Value
Unvested January 1, 2017	219,600	$ 13.45
Granted	-	$ -
Vested	-	$ -
Forfeited	(25,000)	$ 13.45
Unvested June 30, 2017	194,600	$ 13.45

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 June 30, 2017 was approximately $2.2 million and is expected to be recognized within future operating results over a period of 3.5 years.

The Company recognized stock-based compensation expense for the six months ended June 30, 2017 and 2016 of $2.5 million and $1.6 million, respectively.

NOTE 9 — COMMITMENTS AND CONTINGENCIES

In September 2014, the Company entered into a lease agreement for 4,043 square feet of office space in Waltham, MA. The term of the lease was approximately two years, and the Company was required to make monthly rental payments commencing December 2014. Estimated annual rent payable under this operating lease was approximately $0.1 million per year in each of the two years.

In April 2016, the Company entered into an agreement to extend the term of the lease through March 31, 2018. Estimated annual rent payable under this agreement is approximately $0.1 million per year.

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

NOTE 10 — RELATED PARTY TRANSACTIONS

In January 2016, the Company entered into a services agreement with V-Watch SA ("V-Watch"), for approximately $105,000 for the use of V-Watch's SomnoArt device for monitoring sleep in the MIN-101 Phase IIb and MIN-117 Phase IIa 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. During the six months ended June 30, 2017 and 2016, the Company recorded an expense of zero and $0.1 million, respectively, related to this agreement.

Also refer to Note 6 – Co-Development and License agreement, Note 7 – Stockholder's Equity and Note 11 – Subsequent Events for additional related party transactions.

NOTE 11 — SUBSEQUENT EVENTS

Amendment to Co-Development and License Agreement with Janssen

In June 2017, the Company entered into an Amendment to its Co-Development and License Agreement with Janssen (the "Amendment"), pursuant to which Janssen agreed to forgo its right to royalties on MIN-202 insomnia sales in the Minerva Territory. The Company retained all of its rights to MIN-202 including commercialization of the molecule for the treatment of insomnia and as an as adjunctive therapy for MDD, which include an exclusive license in the European Union, Switzerland, Liechtenstein, Iceland and Norway, with royalties payable by the Company to Janssen. Royalties on sales outside of the Minerva Territory are payable by Janssen to the Company. Janssen also agreed to make an upfront payment to the Company of $30 million upon the effectiveness of the Amendment; a $20 million payment at the start of a Phase III insomnia trial for MIN-202; a $20 million payment when 50% of the patients are enrolled in this trial; and further agreed to waive the remaining payments, including accrued and unpaid balances as of June 30, 2017, due from the Company until completion of the Phase II development of MIN-202, which are estimated to total approximately $13 million inclusive of the $6.6 million in accrued collaborative expenses as of June 30, 2017. Upon the effectiveness of the Amendment, the Company will assume strategic control for clinical development of MIN-202 in insomnia and all financial responsibility for Phase III development costs for MIN-202 in insomnia. In connection with the Amendment, the Company also entered into a stock repurchase agreement with Johnson & Johnson Innovation-JJDC Inc. to repurchase all of the approximately 3.9 million shares of the Company's stock held by Johnson & Johnson Innovation-JJDC Inc. at a per share price of $0.0001, for an aggregate purchase price of approximately $389. The effectiveness of the Amendment is contingent upon the closing of the stock repurchase agreement, and the closing of the stock repurchase agreement is contingent upon certain normal and customary closing conditions which include receiving either approval from the European Commission of the Amendment and the stock repurchase agreement or notification that the European Commission does not object to the Amendment and the stock repurchase agreement. The Company is currently evaluating the accounting treatment for the Amendment including aspects of revenue recognition treatment associated with the future payments that the Company expects to receive pursuant to the terms of the Agreement as well as for the waiver of remaining Phase II development costs pursuant to the Amendment. The Amendment automatically terminates if it is not effectuated prior to August 31, 2017 or if the stock repurchase agreement is terminated prior to the effectiveness of the Amendment. The stock repurchase agreement also automatically terminates if it is not effectuated prior to August 31, 2017. In the event that the Amendment is terminated, the Co-Development and License Agreement with Janssen will remain in full force and effect.

Public Offering of Common Stock

On July 5, 2017, the Company closed a public offering of its common stock, in which the Company issued and sold 5,750,000 shares of its common stock, including 750,000 shares sold pursuant to the underwriters' full exercise of their

option to purchase additional shares, at a public offering price of $7.75, for aggregate gross proceeds to the Company of $44.6 million. All of the shares issued and sold in this public offering were registered under the Securities Act pursuant to a registration statement on Form S-3 (File No. 333-205764) and a related prospectus and prospectus supplement, in each case filed with the Securities and Exchange Commission. The Company incurred $3.1 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 $41.5 million.

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, 2016 as filed with the Securities and Exchange Commission on March 13, 2017.

Historical 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, or 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: MIN-101 for the treatment of schizophrenia; MIN-202 (also known as JNJ-42847922), which we are co-developing with Janssen Pharmaceutica NV, or Janssen, for the treatment of insomnia disorder and major depressive disorder, or 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.

In November 2013, Cyrenaic Pharmaceuticals, Inc., or Cyrenaic, and Sonkei Pharmaceuticals, Inc., or Sonkei, merged, and the combined company was renamed Minerva Neurosciences, Inc. Cyrenaic had been incorporated in 2007 and had exclusively licensed MIN-101 from Mitsubishi Tanabe Pharma Corporation, or MTPC. Sonkei had been incorporated in 2008 and had exclusively licensed MIN-117 from MTPC. We executed the merger as we saw an opportunity to better serve an underserved patient population through combining a portfolio of promising product candidates targeting CNS diseases. As a result of the merger, we have the rights to develop and commercialize MIN-101 and MIN-117 globally, excluding most of Asia.

We further expanded our product candidate portfolio in February 2014 by acquiring the shares of Mind-NRG SA, or Mind-NRG, which had exclusive rights to develop and commercialize MIN-301. In addition, in February 2014 we entered into a co-development and license agreement with Janssen, one of the Janssen Pharmaceutical Companies of Johnson & Johnson, for the co-development of MIN-202. We entered into an amendment to this agreement in June 2017, and its effectiveness is contingent upon approval by the European Commission amongst other normal and customary closing conditions. Under the amended agreement, we will gain global strategic control of the development of MIN-202 to treat insomnia, and Janssen will forego its right to royalties on MIN-202 insomnia sales in the Minerva territory, which includes the European Union, Switzerland, Liechtenstein, Iceland and Norway (the "Minerva Territory"). We will retain our rights to MIN-202 as adjunctive therapy for MDD, which include an exclusive license in the Minerva Territory with royalties payable by us to Janssen, and royalties on sales payable by Janssen to Minerva elsewhere worldwide. Our relationships with Janssen and MTPC help inform our clinical development and regulatory strategies.

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 Update

MIN-101

Improved Formulation

On June 22, 2017, we announced the completion of a bridging trial to select an improved, gastric-resistant, or GR formulation of MIN-101 that we plan to use in the Phase III clinical trial with MIN-101 and to include in the potential future submission of a New Drug Application or NDA.

Data from the bridging trial of the selected new formulation demonstrated: bioequivalent exposure of MIN-101 based on area under the curve shown in the Phase IIb study; reduction of an inactive metabolite of MIN-101 known as BFB-520 by approximately 30% in the improved formulation, thereby reducing the potential for transient QTc increases observed in the Phase IIb study at the higher dose, 64 mg, but not the lower dose, 32 mg; no observations of QTc prolongations throughout the bridging trial; no observable food effect, thus allowing administration of the drug with or without food without changing its pharmacokinetic properties; and confirmation of the overall safety and tolerability profile of MIN-101.

We plan to immediately initiate Chemistry, Manufacturing and Controls, or CMC, scale-up processes. As exposures of MIN-101 in the Phase IIb study and the GR formulation to be used in the Phase III trial are comparable, we believe data from both studies can be aggregated for the purposes of evaluating efficacy. We have also filed a patent application for the GR formulation, which is in addition to an already granted patent in the U.S. that provides protection until 2035. If granted, the additional patent could potentially extend exclusivity beyond 2035.

End-of-Phase 2 Meeting

In May 2017, we announced the outcome of an "end-of-Phase 2" meeting with the FDA and announced our plans to initiate Phase III development of MIN-101. We expect that a pivotal Phase III trial with MIN-101 will be initiated in the second half of 2017.

The Phase III trial design will be a 12-week, double-blind, randomized, placebo-controlled, monotherapy study testing two doses of MIN-101 in patients with negative symptoms and a diagnosis of schizophrenia. To be eligible for the study, patients will be required to have stable negative and positive symptoms over several months prior to enrollment, with a specified minimum threshold baseline score on the Positive and Negative Syndrome Scale, or PANSS, negative sub-scale. After the double-blind phase, patients may enter a 36-week open label extension phase in which all patients will receive active treatment. This multi-center, international trial is expected to enroll approximately 500 patients at approximately 60 clinical sites across the U.S. and Europe.

Breakthrough Therapy Designation

In April 2017, we applied for Breakthrough Therapy designation for MIN-101 for the treatment of negative symptoms of schizophrenia. In recent correspondence, although denying our request, the FDA confirmed that treatment of negative symptoms of schizophrenia meets the criteria for a serious or life threatening disease and consequently for Breakthrough Therapy designation. The FDA also advised that they were not able to grant designation as a Breakthrough Therapy at this time pending receipt of additional analyses of certain data from the Phase IIb study. We are currently in dialogue with the FDA to clarify why it believes the Phase IIb data provides the analyses the FDA is seeking and expect a further review of our request in the near future.

Phase IIb Trial

In May 2016, we announced top line results from a prospective Phase IIb, 12-week, randomized, double-blind, placebo-controlled parallel clinical trial evaluating the efficacy, safety and tolerability of MIN-101 as monotherapy in patients with negative symptoms of schizophrenia using the pentagonal structure model, or PSM, of PANSS. These negative symptoms, for which no approved treatment is currently available, affect the majority of schizophrenic patients and can persist over their lifetimes. A total of 244 patients were randomized in equal groups to receive daily doses of MIN-101 32 mg, MIN-101 64 mg or placebo at 32 clinical sites in Russia and five European countries. To participate in the trial, patients were required to have stable positive and negative symptoms for three months prior to entry, a PANSS negative sub-score greater than or equal to 20, and scores < 4 on the following PANSS items: excitement, hyperactivity, hostility, suspiciousness, uncooperativeness and poor impulse control. All three cohorts were balanced with respect to demographic and baseline disease characteristics.

The study achieved its primary endpoint, as we observed a statistically significant benefit of MIN-101 over placebo in improving negative symptoms as measured by the PSM of PANSS. The effect was observed for both doses tested: 32 milligrams (mg): $p \leq 0.024$ with an effect size of 0.45, and 64 mg: $p \leq 0.004$ with effect size of 0.57.

We also observed a statistically significant benefit of MIN-101 over placebo on the PANSS three factors negative symptoms subscale for both doses tested: 32 mg: $p \leq 0.006$, with an effect size of 0.54, and 64 mg: $p \leq 0.001$ with an

effect size of 0.70.

Furthermore, we observed the statistically significant benefit of MIN-101 over placebo on the PANSS total score (not significant for the 32 mg dose; $p \leq 0.003$ for the 64 mg dose), with effect sizes of 0.34 and 0.57, respectively.

The consistency and robustness of the effect was also supported by the observed statistically significant benefit of MIN-101 over placebo in multiple secondary endpoints as measured by the following: the PANSS general psychopathology subscale, Brief Negative Symptoms Scale total score, Clinical Global Impression of Severity, Clinical Global Impression of Improvement, Personal and Social Performance total score and Brief Assessment of Cognition in Schizophrenia (BACS) total score. Positive symptoms were observed to remain stable, and the absence of extra-pyramidal symptoms (EPS) throughout the three month trial is consistent with the hypothesis that MIN-101 has a direct and specific effect on negative symptoms rather than an indirect effect mediated by improvements of positive symptoms.

Discontinuation criteria based on QTcF prolongation were incorporated in the protocol. Two patients out of 162 who received MIN-101 were discontinued based upon these criteria; both of these patients received the higher dose (64 mg).

Patients who completed the 12-week double-blind core phase of this study were provided the opportunity to enter into a 24-week, open-label extension phase. The extension phase was completed during the third quarter of 2016, and we announced data from the extension phase in October 2016. Data generated during the extension period were intended to provide longer term supportive evidence of efficacy and to complement the statistically significant results obtained during the core phase.

During the extension phase, all patients received either 32 mg or 64 mg of MIN-101. Patients who received placebo in the core phase were randomized to one of these two doses at the beginning of the extension phase. One hundred forty-two patients from the treatment and placebo groups in the core phase entered the extension phase, with 88 patients completing the extension. Seventy patients received 32 mg and 72 patients received 64 mg during the extension.

Negative symptoms, assessed based on the PANSS PSM, were observed to continue to improve during the extension phase, as shown by a reduction from the study start for the 32 and 64 mg-treated groups of 5.5 points and 4.9 points, respectively, and by a reduction of 5.4 points and 5.3 points, respectively, in the PANSS three factors negative symptoms subscale.

Positive symptoms were observed to remain stable throughout the study, as measured by PANSS positive symptom scores. This finding is consistent with the hypothesis that MIN-101 has a direct and specific effect on negative symptoms. General psychopathology was observed to improve during the extension phase for the 32 and 64 mg groups, as shown by reductions in the PANSS general psychopathology subscale score.

MIN-101 was generally reported to be well tolerated through the entire 36-week period. Based on previous non-clinical and clinical experience, QTcF, a measure of cardiac function, was closely monitored throughout the study, and discontinuation criteria based on QTcF prolongation were incorporated in the protocol. Two patients out of 162 who received MIN-101 in the core phase were discontinued based upon these criteria; both of these patients received the higher dose (64 mg). In the extension phase no additional patients were discontinued. In the extension phase, we also observed that MIN-101 at the doses tested did not have an effect on EPS, prolactin or weight gain.

Additional data analyses from the Phase IIb trial were presented at the 55th Annual Meeting of the American College of Neuropsychopharmacology, or ACNP in December 2016. These analyses concluded that MIN-101 has a direct effect on negative symptoms (rather than an indirect or pseudo effect secondary to improvements in other symptoms) as supported by the stability observed in positive symptoms, the absence of EPS and the persistence of this direct effect even after controlling for improvements in depressive symptoms. Researchers noted that since phenomena similar to negative symptoms are manifest in many psychiatric disorders and in brain degenerative disorders such as Alzheimer's disease and Parkinson's disease, future trials with MIN-101 could be designed to explore its potential benefit in these patient populations.

In post-hoc analysis presented at ACNP, improvement in negative symptoms was shown to be greatest among younger patients, especially in the cohort of patients under 33 years of age. This finding supports the potential therapeutic intervention with MIN-101 in younger patients with schizophrenia who are beginning to manifest these symptoms. It is also consistent with research showing that chronic pharmacotherapeutic intervention in schizophrenia, which includes atypical antipsychotics to treat acute positive symptoms, becomes less effective as patients age and suffer long-term consequences of the disease and side effects of current treatment options.

Additional results presented at ACNP suggest a benefit of treatment with MIN-101 32 mg in improving cognitive function in schizophrenia patients with predominant negative symptoms. Cognitive function was evaluated using the BACS scale, and data analyses demonstrated statistically significant differences between patients treated with MIN-101 at the 32 mg dose and those who received placebo. Cognitive impairment, a core feature of schizophrenia,

affects up to 75% of patients and is believed to be a good predictor of functional outcome.

Phase IIa Trial

In 2009 we completed a double-blind, randomized, placebo-controlled Phase IIa trial of MIN-101 as monotherapy in subjects suffering from schizophrenia. Enrolled subjects had previously suffered from an acute episode requiring hospitalization. This was a double-blind, placebo controlled study with a three month treatment period in which 96 subjects were randomized and 30 completed the study protocol. Patients suffered from positive, negative and cognitive symptoms and had ceased to respond well to previously prescribed medication. Subjects received either placebo or MIN-101, including doses and at a dosing schedule that may differ from the final formulated dose.

The primary endpoint of the study was the efficacy of MIN-101 versus placebo, as measured by PANSS total and sub-scores after one month of treatment. The PANSS is used to measure psychopathology in patients suffering from schizophrenia and can be split into either three factors (positive, negative and general psychopathology) or in five factors (positive, negative, activation, dysphoric mood

and autistic thoughts). Secondary and exploratory endpoints included the efficacy of MIN-101 versus placebo through the PANSS total and sub scores after three months of treatment, as well as cognition, mood, anxiety and sleep using various psychological scales at various treatment time points.

In the Phase IIa trial, subjects treated with MIN-101 showed ongoing improvements in negative symptoms, as compared to baseline, throughout the duration of the trial. After one month, improvements on the PANSS negative symptoms scale were observed. Because this Phase IIa trial was not powered to show results with statistical significance, the study's primary endpoint was not met. After three months of treatment, the MIN-101 group showed improvements in negative symptoms as compared to placebo.

Recent additional analysis of results from this Phase IIa trial presented at ACNP showed that treatment with MIN-101 was associated with significantly improved sleep induction and normalized slow wave sleep ultradian distribution during the night, which are two key sleep parameters that are disturbed in schizophrenia. Such disturbances of sleep architecture and continuity may be associated with memory consolidation, which is impaired in schizophrenia. These effects on sleep parameters may help to improve the overall symptomatology observed in patients suffering from schizophrenia and treated with MIN-101.

Subjects participating in this clinical trial receiving MIN-101 or placebo experienced adverse events, including, but not limited to gastrointestinal, nervous system, psychiatric, and cardiac events, with two subjects with increased heart rate and one subject with decreased heart rate that were deemed to be possibly related to MIN-101 by investigators. Generally, with the exception of cardiac events, which occurred in the MIN-101 subjects alone, similar adverse events were seen in the placebo group tested in this study, although at different rates. The safety results of the Phase IIa study were consistent with Phase I results observed in healthy volunteers.

Following the Phase IIb trial, we are conducting a number of supportive studies with MIN-101 that include formulation and metabolism studies designed to reduce further the potential for QTcF prolongation and to explore dose ranges for patients who metabolize this compound differently.

MIN-202

Amendment to Co-Development and License Agreement with Janssen

In June 2017, we entered into an Amendment to our Co-Development and License Agreement with Janssen (the "Amendment"), pursuant to which Janssen agreed to forgo its right to royalties on MIN-202 insomnia sales in the Minerva Territory. We retained all of our rights to MIN-202 including commercialization of the molecule for the treatment of insomnia and as an as adjunctive therapy for MDD, which include an exclusive license in the European Union, Switzerland, Liechtenstein, Iceland and Norway, with royalties payable by us to Janssen. Royalties on sales outside of the Minerva Territory are payable by Janssen us. Janssen also agreed to make an upfront payment to us of $30 million upon the effectiveness of the Amendment; a $20 million payment at the start of a Phase III insomnia trial for MIN-202; a $20 million payment when 50% of the patients are enrolled in this trial; and further agreed to waive the remaining payments, including accrued and unpaid balances as of June 30, 2017, due from us until completion of the Phase II development of MIN-202, which are estimated to total approximately $13 million inclusive of the $6.6 million in accrued collaborative expenses as of June 30, 2017. Upon the effectiveness of the Amendment, we will assume strategic control for clinical development of MIN-202 in insomnia and all financial responsibility for Phase III development costs for MIN-202 in insomnia. In connection with the Amendment, we also entered into a stock repurchase agreement with Johnson & Johnson Innovation-JJDC Inc. to repurchase all of the approximately 3.9 million shares of our stock held by Johnson & Johnson Innovation-JJDC Inc. at a per share price of $0.0001, for an aggregate purchase price of approximately $389. The effectiveness of the Amendment is contingent upon the closing of the stock repurchase agreement, and the closing of the stock repurchase agreement is contingent upon

certain normal and customary closing conditions which include receiving either approval from the European Commission of the Amendment and the stock repurchase agreement or notification that the European Commission does not object to the Amendment and the stock repurchase agreement. We are currently evaluating the accounting treatment for the Amendment including aspects of revenue recognition treatment associated with the future payments that we expect to receive pursuant to the terms of the Agreement as well as for the waiver of remaining Phase II development costs pursuant to the Amendment. The Amendment automatically terminates if it is not effectuated prior to August 31, 2017 or if the stock repurchase agreement is terminated prior to the effectiveness of the Amendment. The stock repurchase agreement also automatically terminates if it is not effectuated prior to August 31, 2017. In the event that the Amendment is terminated, the Co-Development and License Agreement with Janssen will remain in full force and effect.

Phase IIa Trial

In January 2016, we announced top line results from a Phase IIa clinical trial of MIN-202 for the treatment of insomnia disorder. The trial was a randomized, two way, cross-over, placebo-controlled double-blind study to evaluate the effect of MIN-202 on sleep and daytime functioning in 28 patients with insomnia disorder without psychiatric co-morbidity. Patients were given 40 mg of MIN-202 or placebo in a cross-over design for treatment periods of five days, separated by a washout period. The trial was conducted at clinical

sites in the United States and Europe. Patients treated with MIN-202 in this trial were observed to have statistically significant improvements in key sleep parameters, compared to patients treated with placebo. These parameters include sleep efficiency, or SE, as measured by objective polysomnography, the primary endpoint of the trial, for which a positive efficacy signal was detected for 40 milligrams MIN-202 versus placebo ($p<0.001$).

Additional significant positive efficacy signals were observed for key secondary parameters in this trial, including latency to persistent sleep, or LPS, wake after sleep onset, or WASO, and total sleep time, or TST. Compared to placebo, MIN-202 was observed to significantly improve polysomnography parameters ($p<0.001$) on Days 1 and 5. On Day 5, LPS and WASO were observed to be reduced by 23.2 and 11 minutes, respectively, and TST and SE increased by 39 minutes and 8.12 percent, respectively. Objective and subjective evaluations were significantly correlated. Subjectively estimated TST, LPS, and WASO were also observed to be improved versus placebo by 43.1, -38.8, and -14.8 minutes, respectively. No serious adverse events were observed in this trial, and preliminary data indicate that MIN-202 was well tolerated by patients. The most common treatment-emergent adverse events associated with exposure to MIN-202 during the double-blind phase of the study were somnolence and abnormal dreams.

Phase Ib Trial

In March 2016, we announced top line results from the Phase Ib clinical trial in MDD with MIN-202 conducted in Europe. Data from this trial were subsequently presented at the ACNP Annual Meeting in December 2016. The Phase Ib trial was a randomized, double-blind, parallel group study including 20 mg of MIN-202 administered in the evening, a positive control, 25 mg of diphenhydramine, and placebo, to evaluate treatment with MIN-202 in 48 subjects ages 18 to 65 years with a diagnosis of MDD who could be treated with marketed antidepressants. MIN-202 was observed to be well tolerated by study participants over a one-month treatment duration, with no serious adverse events. Consistently greater improvements in depressive symptomatology were observed in patients randomized to receive MIN-202 compared to those randomized to receive placebo or diphenhydramine, as measured by clinician administered rating scales, including the Hamilton Depression Rating Scale. These findings support the potential of MIN-202 to have a direct effect on mood independent from its effect on sleep. Core symptoms of depression (as measured by the HAM-D 6) were observed to be significantly improved in the MIN-202 arm when compared with placebo.

Phase I Trial in Japan

In February 2016, we announced top line data from a Phase I clinical trial with MIN-202 conducted in Japan. It was observed that single dose morning administration of MIN-202 was well tolerated at all three dose levels tested, 5 mg, 20 mg and 40 mg. The observed plasma pharmacokinetic features were comparable to those observed in previous trials carried out in healthy non-Asian study participants. No clinically relevant safety concerns were observed based on the assessment of multiple safety endpoints. Somnolence was the most frequently reported adverse event at the two higher doses, an expected finding as this compound is being developed as a treatment for patients suffering from insomnia disorder and as adjunctive treatment to concomitant antidepressant drug therapy in MDD. This trial was a single center, double blind, placebo-controlled randomized single ascending dose study to investigate the safety, tolerability and pharmacokinetics of MIN-202 in 24 healthy Japanese adult male study participants.

A number of supportive activities and clinical pharmacology studies are being conducted in anticipation of the next phase of clinical development with MIN-202 in both insomnia and MDD.

MIN-117

Phase IIa Trial

In May 2016, we announced top line results from a Phase IIa clinical trial in MDD with MIN-117. Data from this trial were subsequently presented at the ACNP Annual Meeting in December 2016. This study was a four-arm, parallel-group, randomized double-blind, placebo- and positive-control trial which tested two daily administered doses of MIN-117: 0.5 mg and 2.5 mg. The study included 84 patients (21 per arm) with moderate to severe MDD in four European countries. The goals of the trial were to test efficacy, safety and tolerability of MIN-117 over six weeks of treatment. The antidepressant paroxetine was used as an active control and confirmed assay sensitivity. Change on the Montgomery-Asberg Depression Rating Scale, or MADRS, was used as the main outcome measurement. As established prospectively in the statistical analysis plan, this trial was designed for signal detection and effect size estimation. As such, the study was not powered to demonstrate statistically significant differences between MIN-117 and placebo.

We observed the dose-dependent benefit of MIN-117 over placebo as measured by change in the MADRS. We observed that MIN-117 at the 0.5 mg daily dose had an effect size, as compared to the placebo group, of 0.24 while the 2.5 mg daily dose had an effect size of 0.34. This magnitude of effect size is similar to those observed with currently marketed antidepressants. Improvement in MADRS with MIN-117 against placebo was observed at two weeks. Furthermore, data also showed that 24 % of the patients treated with 2.5 mg of MIN-117 achieved remission as prospectively defined.

Both doses of MIN-117 were reported to be well tolerated, and the incidence and types of side effects did not differ significantly between the MIN-117 group and the placebo group. No unexpected adverse events were reported. Treatment with MIN-117 was not associated with cognitive impairment, sexual dysfunction, suicidal ideation or weight gain.

Pharmacodynamic measurements based on sleep recordings showed that MIN-117 preserved sleep continuity and architecture and therefore is not expected to have detrimental effects on rapid eye movement sleep distribution and duration.

In September 2016, we announced that the FDA accepted our IND for MIN-117, allowing us to begin clinical trials with this compound in the United States, building upon the results from the Phase IIa trial in Europe. Planning is underway for these trials, which are expected to begin in late 2017.

MIN-301

In January 2015, we announced results from a non-human primate study showing 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 preclinical 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 preclinical development with MIN-301 as a treatment for Parkinson's disease. Our next steps for the development of MIN-301 include continuing to conduct preclinical studies in preparation for an Investigational New Drug, or IND, or Investigational Medicinal Product Dossier, or IMPD filing, with a Phase I study expected to commence thereafter.

Financial Overview

Revenue. None of our product candidates have been approved for commercialization and we have not received any revenue in connection with the sale or license of our product candidates. We are evaluating the revenue implications of our Amendment to Co-Development and License Agreement with Janssen.

Research and Development Expense. 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, or 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 continue 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 Expense. 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.

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 June 30, 2017 versus June 30, 2016

Research and Development Expenses

Total research and development expenses were $7.1 million for the three months ended June 30, 2017 compared to $2.7 million for the same period in 2016, an increase in total expense of $4.4 million. Research and development expense in the three months ended June 30, 2017 and 2016 included non-cash stock-based compensation expenses of $0.5 million and $0.2 million, respectively. This increase in research and development expenses primarily reflects higher development expenses under the MIN-202 program for Phase II clinical trial preparation, increased expenses for the MIN-101 program and an increase in non-cash stock-based compensation expenses. These amounts were partially offset by reduced costs related to our Phase IIa clinical trial of MIN-117 due to its completion in May 2016.

General and Administrative Expenses

Total general and administrative expenses were $2.6 million for the three months ended June 30, 2017 compared to $2.3 million for the same period in 2016, an increase of approximately $0.3 million. General and administrative expense in the three months ended June 30, 2017 and 2016 included non-cash stock-based compensation expenses of $0.7 million and $0.6 million, respectively. This increase was primarily due to an increase in professional fees during the three months ended June 30, 2017.

Foreign Exchange (Losses) Gains

Foreign exchange losses were $20 thousand for the three months ended June 30, 2017 compared to $15 thousand for the same period in 2016, an increased loss of $5 thousand. The loss was primarily due to clinical activities denominated in Euros.

Investment Income

Investment income was $156 thousand for the three months ended June 30, 2017 compared to $35 thousand for the same period in 2016, an increase of $121 thousand. This increase was due to an increase in investment income on cash equivalents and marketable securities.

Interest Expense

Interest expense was $0.2 million for the three months ended June 30, 2017 compared to $0.3 million for the same period in 2016, a decrease of $0.1 million. This decrease was due to a lower outstanding principal balance on our Term A loans.

Comparison of Six Months Ended June 30, 2017 versus June 30, 2016

Research and Development Expenses

Total research and development expenses were $14.8 million for the six months ended June 30, 2017 compared to $8.1 million for the same period in 2016, an increase in total expense of $6.7 million. Research and development expense in the six months ended June 30, 2017 and 2016 included non-cash stock-based compensation expenses of $1.0 million and $0.5 million, respectively. This increase in research and development expenses primarily reflects higher development expenses under the MIN-202 program for Phase II clinical trial preparation, increased expenses for the MIN-101 program and an increase in non-cash stock-based compensation expenses. These amounts were partially offset by lower costs due to the completion of our Phase IIa clinical trial of MIN-117.

General and Administrative Expenses

Total general and administrative expenses were $5.5 million for the six months ended June 30, 2017 compared to $4.6 million for the same period in 2016, an increase of approximately $0.9 million. General and administrative expense in the six months ended June 30, 2017 and 2016 included non-cash stock-based compensation expenses of $1.5 million and $1.2 million, respectively. This increase was primarily due to an increase in professional fees during the six months ended June 30, 2017.

Foreign Exchange (Losses) Gains

Foreign exchange losses were $37 thousand for the six months ended June 30, 2017 compared to $25 thousand for the same period in 2016, an increased loss of $12 thousand. The loss was primarily due to certain expenses of Mind-NRG and clinical activities denominated in Euros.

Investment Income

Investment income was $214 thousand for the six months ended June 30, 2017 compared to $67 thousand for the same period in 2016, an increase of $147 thousand. The increase was due to investment income on cash equivalents and marketable securities.

Interest Expense

Interest expense was $0.4 million for the three months ended June 30, 2017 compared to $0.5 million for the same period in 2016, a decrease of $0.1 million. The decrease was due to a lower outstanding principal balance on our Term A loans.

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 June 30, 2017, we had an accumulated deficit of approximately $153.3 million. We anticipate that we will continue to incur net losses for the foreseeable future as we continue the development and potential commercialization of our product candidates and to support our operations as a public company. At June 30, 2017, we had approximately $77.6 million in cash, cash equivalents and marketable securities. We believe that our existing cash, cash equivalents and marketable securities will be sufficient to meet our cash commitments for at least the next 12 months after the date that the interim condensed financial statements are issued. The process of drug development can be costly and the timing and outcomes of clinical trials is uncertain. The assumptions upon which we have based our estimates are routinely evaluated and may be subject to change. The actual amount of our expenditures will vary depending upon a number of factors including but not limited to the design, timing and duration of future clinical trials, the progress of our research and development programs 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

In June 2017, we entered into an Amendment to our Co-Development and License Agreement with Janssen (the "Amendment"), pursuant to which Janssen agreed to forgo its right to royalties on MIN-202 insomnia sales in the Minerva Territory. We retained all of our rights to MIN-202 including commercialization of the molecule for the treatment of insomnia and as an as adjunctive therapy for MDD, which include an exclusive license in the European Union, Switzerland, Liechtenstein, Iceland and Norway, with royalties payable by us to Janssen. Royalties on sales outside of the Minerva Territory are payable by Janssen us. Janssen also agreed to make an upfront payment to us of $30 million upon the effectiveness of the Amendment; a $20 million payment at the start of a Phase III insomnia trial for MIN-202; a $20 million payment when 50% of the patients are enrolled in this trial; and further agreed to waive the remaining payments, including accrued and unpaid balances as of June 30, 2017, due from us until completion of the Phase II development of MIN-202, which are estimated to total approximately $13 million inclusive of the $6.6 million in accrued collaborative expenses as of June 30, 2017. Upon the effectiveness of the Amendment, we will assume strategic control for clinical development of MIN-202 in insomnia and all financial responsibility for Phase III development costs for MIN-202 in insomnia. In connection with the Amendment, we also entered into a stock repurchase agreement with Johnson & Johnson Innovation-JJDC Inc. to repurchase all of the approximately 3.9 million shares of our stock held by Johnson & Johnson Innovation-JJDC Inc. at a per share price of $0.0001, for an aggregate purchase price of approximately $389. The effectiveness of the Amendment is contingent upon the closing of the stock repurchase agreement, and the closing of the stock repurchase agreement is contingent upon certain normal and customary closing conditions which include receiving either approval from the European Commission of the Amendment and the

stock repurchase agreement or notification that the European Commission does not object to the Amendment and the stock repurchase agreement. We are currently evaluating the accounting treatment for the Amendment including aspects of revenue recognition treatment associated with the future payments that we expect to receive pursuant to the terms of the Agreement as well as for the waiver of remaining Phase II development costs pursuant to the Amendment. The Amendment automatically terminates if it is not effectuated prior to August 31, 2017 or if the stock repurchase agreement is terminated prior to the effectiveness of the Amendment. The stock repurchase agreement also automatically terminates if it is not effectuated prior to August 31, 2017. In the event that the Amendment is terminated, the Co-Development and License Agreement with Janssen will remain in full force and effect.

Public Offering of Common Stock

On July 5, 2017, we closed a public offering of common stock, in which we issued and sold 5,750,000 shares of our common stock, including 750,000 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares, at a public offering price of $7.75, for aggregate gross proceeds to us of $44.6 million. All of the shares issued and sold in this public offering were registered under the Securities Act pursuant to a registration statement on Form S-3 (File No. 333-205764) and a related prospectus and prospectus supplement, in each case filed with the Securities and Exchange Commission. We incurred $3.1 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 $41.5 million.

Exercise of Warrants

In January, February, June and December 2016 and in March 2017, certain investors in our March 2015 private placement exercised their warrants and received an aggregate of 5,673,758 shares of our common stock. We received gross proceeds of approximately $32.7 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 and marketable securities will be sufficient to meet our cash commitments for at least the next 12 months after the date that the interim condensed financial statements are issued. The timing of future capital requirements depends upon many factors including the size and timing of future clinical trials, the timing and scope of any strategic partnering activity and the progress of other research and development activities.

On July 6, 2016, we and Janssen agreed that “Decision Point 2” had been reached as defined under the co-development agreement. As neither party have exercised their right to withdraw from the agreement, we have paid Janssen $3.5 million and have incurred direct expenses of $0.3 million related to development activities under the current phase of development. During the three months ended June 30, 2017 and 2016, we recorded an expense of $3.6 million and a cost offset of $0.1 million, respectively, for certain development activities in accordance with the terms of the co-development agreement. During the six months ended June 30, 2017 and 2016, we recorded an expense of $6.6 million and a cost offset of $0.2 million, respectively, for certain development activities in accordance with the terms of the co-development agreement. We have included $6.6 million in accrued collaborative expenses as of

June 30, 2017. We will not incur any additional Phase II development costs for the program. We will assume all financial responsibility for Phase III development costs for MIN-202 in insomnia.

Under our $10.0 million Term A Loan, we have made principal repayments of approximately $4.0 million. We expect to make additional principal repayments of approximately $2.5 million in 2017 and $3.5 million in 2018, in accordance with the terms of the agreement.

Cash Flows

The table below summarizes our significant sources and uses of cash for the six months ended June 30, 2017 and 2016:

	Six Months Ended June 30,	
	2017	2016
	(dollars in millions)	
Net cash provided by (used in):		
Operating activities	$ (12.9)	$ (12.1)
Investing activities	(27.4)	9.4
Financing activities	7.5	77.1
Net (decrease) increase in cash	$ (32.8)	$ 74.4

Net Cash Used in Operating Activities

Net cash used in operating activities of approximately $12.9 million during the six months ended June 30, 2017 was primarily due to our net loss of $20.4 million and an increase in accounts payable of $0.1 million, partially offset by a $4.0 million increase in accrued collaborative expense, stock-based compensation expense of $2.5 million, a $0.6 million increase in accrued expenses, an decrease in prepaid expenses of $0.4 million and amortization of investments and debt discount of $0.1 million.

Net cash used in operating activities of approximately $12.1 million during the six months ended June 30, 2016 was primarily due to our net loss of $13.2 million, a $1.1 million decrease in accrued expenses and a $0.6 million decrease in accounts payable, partially offset by stock-based compensation expense of $1.6 million, a decrease of $0.9 million in prepaid expense and amortization of investments and debt discount of $0.3 million.

Net Cash Provided by (Used in) Investing Activities

Net cash used in investing activities of approximately $27.4 million during the six months ended June 30, 2017 was primarily due to the purchase of marketable securities.

Net cash provided by investing activities of approximately $9.4 million during the six months ended June 30, 2016 was due to the maturity and redemption of marketable securities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities of $7.5 million during the six months ended June 30, 2017 was primarily due to the proceeds from the exercise of common stock warrants of $9.4 million and the proceeds from the exercise of common stock options of $0.6 million, partially offset by the principal repayments under the Term A loans of $2.4 million and $0.1 million for fees paid in connection with the public offering of common stock.

Net cash provided by financing activities of $77.1 million during the six months ended June 30, 2016 was primarily due to gross proceeds from the June 2016 public stock offering of $57.5 million less costs of $3.6 million, proceeds from the exercise of common stock warrants of $22.2 million and proceeds from the sale of common stock in a private placement of $1.0 million.

Contractual Obligations and Commitments

As of June 30, 2017, there were no material changes in our contractual obligations and commitments from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2016 as filed with the SEC on March 13, 2017. In June 2017, the Company entered into an Amendment to its Co-Development and License Agreement with Janssen, pursuant to which Janssen agreed to waive the remaining payments, due from the Company for Phase II development of MIN-202, which total approximately

$13 million, including accrued and unpaid balances as of June 30, 2017. The effectiveness of the amendment, however, is contingent upon approval of the transaction by the European Commission, which has not yet occurred as of the date of this report.

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, 2016, 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; business combinations; goodwill; JOBS 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 six months ended June 30, 2017.

Recent Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Market risk is the potential loss arising from adverse changes in market rates and market prices such as interest rates, foreign currency exchange rates, and changes in the market value of equity instruments. We do not believe we are currently exposed to any material market risk because the interest rate under our Term A loan is fixed, our exposure for fluctuations in foreign exchange rates is not material and we do not hold equity instruments. As of June 30, 2017, we had $27.4 million of marketable securities, which consisted primarily of corporate bonds, with fixed interest rates. These securities have a weighted-average remaining maturity of 1 months. Due to the overall short-term remaining maturities of our marketable securities, our interest rate exposure is not significant.

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 its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer), evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2017. Based on the evaluation of our disclosure controls and procedures as of June 30, 2017, 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 other changes in internal control over financial reporting during the Company’s latest fiscal quarter that would have materially affected, or are reasonably likely to materially affect, the Company’s 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

This Quarterly Report on Form 10-Q contains forward-looking information based on our current expectations. Because our actual results may differ materially from any forward-looking statements that we make or that are made on our behalf, this section includes a discussion of important factors that could affect our actual future results, including, but not limited to, our capital resources, the progress and timing of our clinical programs, the safety and efficacy of our product candidates, risks associated with regulatory filings, risks associated with determinations made by regulatory agencies, the potential clinical benefits and market potential of our product candidates, commercial market estimates, future development efforts, patent protection, effects of healthcare reform, reliance on third parties, and other risks set forth below. The risk factors set forth below with an asterisk (*) next to the title are new risk factors or 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, 2016, as filed with the SEC.

Risks Related to Our Financial Position and Capital Requirements

*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., or 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 six months ended June 30, 2017, and 2016, we reported net losses of $20.4 million and $13.2 million, respectively. As of June 30, 2017, we had an accumulated deficit of $153.3 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, particularly as we advance our product candidates into clinical trials.

As of June 30, 2017, we had cash, cash equivalents and marketable securities of $77.6 million. We believe that our existing cash, cash equivalents and marketable securities will be sufficient to meet our cash commitments for at least the next 12 months after the date that the interim condensed financial statements are issued. The process of drug development can be costly and the timing and outcomes of clinical trials is uncertain. The assumptions upon which we have based our estimates are routinely evaluated and may be subject to change. The actual amount of our expenditures will vary depending upon a number of factors including but not limited to the design, timing and duration of future clinical trials, the progress of our research and development programs 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.

Changes in estimates regarding fair value of intangible assets may result in an adverse impact on our results of operations.

We test goodwill and in-process research and development for impairment annually or more frequently if changes in circumstances or the occurrence of events suggest impairment exists. The test for impairment of in-process research and development requires us to make several estimates about fair value, most of which are based on projected future cash flows. Changes in these estimates may result in the recognition of an impairment loss in our results of operations. An impairment analysis is performed whenever events or changes in circumstances indicate that the carrying amount of any individual asset may not be recoverable. For example, if we or our counterparties fail to perform our respective obligations under an agreement, or if we lack sufficient funding to develop our product candidates, an impairment may result. In addition, any significant change in market conditions, estimates or judgments used to determine expected future cash flows that indicate a reduction in carrying value may give rise to impairment in the period that

the change becomes known.

*We plan to use potential future operating losses and our federal and state net operating loss, or NOL, carryforwards to offset taxable income from revenue generated from operations or corporate collaborations. However, our ability to use existing NOL carryforwards may be limited as a result of issuance of equity securities.

As of December 31, 2016, we had approximately $49.3 million of Federal NOL carryforwards. These Federal NOL carryforwards will begin to expire at various dates beginning in 2027, if not utilized. We plan to use our operating losses to offset any potential future taxable income generated from operations or collaborations. To the extent we generate taxable income, we plan to use our existing NOL carryforwards and future losses to offset income that would otherwise be taxable. If substantial changes in ownership have occurred, there could be annual limitations on the amount of carryforwards that can be realized in future periods. We have not performed a detailed analysis to determine whether an ownership change occurred upon consummation of the merger between us and Sonkei, upon the acquisition of Mind-NRG or our initial public offering or the concurrent private placements. However, as a result of

these transactions, it is likely that an ownership change has occurred. Therefore, it is likely that some or all of our existing NOL carryforwards would be limited by the provisions of Section 382 of the United States Internal Revenue Code of 1986, as amended. Further, state NOL carryforwards may be similarly limited. We had approximately $41.4 million of state net operating carryforwards at December 31, 2016. It is also possible that future changes in ownership, including as a result of subsequent sales of securities by us or our stockholders, could similarly limit our ability to utilize NOL carryforwards. It is possible that all of our existing NOL carryforwards have been or will be disallowed. Any such disallowances may result in greater tax liabilities than we would incur in the absence of such a limitation and any increased liabilities could adversely affect our business, results of operations, financial condition and cash flow.

Risks Related to Our Business and Industry

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

The regulatory approval process is expensive and the time required to obtain approval from the EMA, FDA or other regulatory authorities in other jurisdictions to sell any product is uncertain and may take years.

Whether regulatory approval will be granted is unpredictable and depends upon numerous factors, including the substantial discretion of the regulatory authorities. Moreover, the filing of a marketing application, including a New Drug Application, or NDA, or Biologics License Application, or BLA, requires a payment of a significant user fee upon submission. The filing of marketing applications for our product candidates may be delayed due to our lack of financial resources to pay such user fee.

If, following submission, our application is not accepted for substantive review or approval, the EMA, FDA or other comparable foreign regulatory authorities may require that we conduct additional clinical or pre-clinical trials, provide additional data, manufacture additional validation batches or develop additional analytical tests methods before they will reconsider our application. If the EMA, FDA or other comparable foreign regulatory authorities requires additional studies or data, we would incur increased costs and delays in the marketing approval process, which may require us to expend more resources than we have available. In addition, the EMA, FDA or other comparable foreign regulatory authorities may not consider sufficient any additional required trials, data or information that we perform or provide, or we may decide, or be required, to abandon the program.

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

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

- The EMA, FDA or other regulatory authorities may disagree with the design or implementation of our clinical trials. We have not yet consulted with the EMA or the FDA on the design and conduct of the clinical trials that have already been conducted or that we intend to conduct. Thus, the EMA, FDA and other comparable foreign authorities may not agree with the design or implementation of these trials. We intend to seek guidance from the EMA in relation to the European Union clinical trial program and the FDA on the design and conduct of clinical trials of our compounds when we initiate a clinical program in the United States in the future.
- We may be unable to demonstrate to the satisfaction of the EMA, FDA or other regulatory authorities that a product candidate is safe and effective for its proposed indication.
-

The results of clinical trials may not meet the level of statistical significance required by the EMA, FDA or other regulatory authorities for approval.

- We may be unable to demonstrate that a product candidate's clinical and other benefits outweigh any safety risks.
- The EMA, FDA or other regulatory authorities may disagree with our interpretation of data from pre-clinical studies or clinical trials.
- The data collected from clinical trials of our product candidates may not be sufficient to support an NDA or other submission or to obtain regulatory approval in the United States or elsewhere.
- The EMA, FDA or other regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies.
- The approval policies or regulations of the EMA, FDA or other regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

Results of earlier clinical trials may not be predictive of the results of later-stage clinical trials.

The results of pre-clinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Interpretation of results from early, usually smaller, trials that suggest positive trends in some subjects, require caution. Results from later stages of clinical trials enrolling more subjects may fail to show the desired safety and efficacy results or otherwise fail to be consistent with the results of earlier trials of the same product candidate. This may occur for a variety of reasons, including differences in trial design, trial endpoints (or lack of trial endpoints in exploratory studies), subject population, number of subjects, subject selection criteria, trial duration, drug dosage and formulation or due to the lack of statistical power in the earlier trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials.

The results of clinical trials conducted at sites outside the United States may not be accepted by the FDA and the results of clinical trials conducted at sites in the United States may not be accepted by international regulatory authorities.

We plan to conduct our clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data would be subject to certain conditions imposed by the FDA. For example, the clinical trial must be well-designed and conducted and performed by qualified investigators in accordance with ethical safeguards such as institutional review board, or IRB, or ethics committee approval and informed consent. The study population must also adequately represent the applicable United States population, and the data must be applicable to the American population and medical practice in ways that the FDA deems clinically meaningful. In addition, while clinical trials conducted outside of the United States are subject to the applicable local laws, FDA acceptance of the data from such trials will be dependent upon its determination that the trials were conducted consistent with all applicable United States laws and regulations. There can be no assurance the FDA will accept data from trials conducted outside of the United States as adequate support of a marketing application, and it is not unusual for the FDA to require some Phase III clinical trial data to be generated in the United States. If the FDA does not accept the data from our international clinical trials, it would likely result in the need for additional trials in the United States, which would be costly and time-consuming and could delay or permanently halt the development of one or more of our product candidates.

If we experience delays in clinical testing, we will be delayed in commercializing our product candidates, our costs may increase and our business may be harmed.

We do not know whether our clinical trials will be completed on schedule, or at all. Our product development costs will increase if we experience delays in clinical testing. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may harm our business, results of operations and prospects.

The commencement and completion of clinical development can be delayed or halted for a number of reasons, including:

- difficulties obtaining regulatory approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;
- delays in reaching or failure to reach agreement on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- deviations from the trial protocol by clinical trial sites and investigators, or failing to conduct the trial in accordance with regulatory requirements;
- failure of our third parties, such as CROs, to satisfy their contractual duties or meet expected deadlines;
- insufficient or inadequate supply or quantity of product material for use in trials due to delays in the importation and manufacture of clinical supply, including delays in the testing, validation, and delivery of the clinical supply of the investigational drug to the clinical trial sites;
- delays in identification and auditing of central or other laboratories and the transfer and validation of assays or tests to be used;

- delays in having subjects complete participation in a trial or return for post-treatment follow-up;
- difficulties obtaining IRB or ethics committee approval to conduct a trial at a prospective site, or complying with conditions imposed by IRBs or ethics committees;
- challenges recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including competition from other programs for the treatment of similar conditions;
- severe or unexpected drug-related adverse events experienced by subjects in a clinical trial;
- difficulty retaining subjects who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, which are common among schizophrenia and MDD subjects who we require for our clinical trials of two of our product candidates, MIN-101 and MIN-117;
- delays in adding new investigators and clinical sites;
- withdrawal of clinical trial sites from clinical trials;
- lack of adequate funding; and
- clinical holds or termination imposed by the European Union national regulatory authorities, the FDA or IRBs or ethics committees.

Clinical trials may also be delayed as a result of ambiguous or negative interim results. In addition, clinical trials may be suspended or terminated by us, an IRB or ethics committee overseeing the clinical trial at a trial site (with respect to that site), the European Union national regulatory authorities or the FDA due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements, the trial protocols and applicable laws;
- observations during inspection of the clinical trial operations or trial sites by the EMA, FDA or other comparable foreign regulatory authorities that ultimately result in the imposition of a clinical hold;
- unforeseen safety issues; or
- lack of adequate funding to continue the clinical trial.

Failure to conduct a clinical trial in accordance with regulatory requirements, the trial protocols and applicable laws may also result in the inability to use the data from such trial to support product approval. Additionally, changes in regulatory requirements and guidance may occur, and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to the EMA, FDA, IRBs or ethics committees for reexamination, which may impact the costs, timing and successful completion of a clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of a clinical trial may also ultimately lead to the denial of regulatory approval of the associated product candidate. If we experience delays in completion of, or if we terminate any of our clinical trials, our ability to obtain regulatory approval for our product candidates may be materially harmed, and our commercial prospects and ability to generate product revenues will be diminished.

We have no experience in advancing product candidates beyond Phase II, which makes it difficult to assess our ability to develop and commercialize our product candidates.

We have no experience in progressing clinical trials past Phase II, obtaining regulatory marketing approvals or commercializing product candidates. We merged with Sonkei and acquired Mind-NRG and have limited operating history since the respective merger and acquisition. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in pursuing our business objectives. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

If we are unable to enroll subjects in clinical trials, we will be unable to complete these trials on a timely basis or at all.

The timely completion of clinical trials largely depends on subject enrollment. Many factors affect subject enrollment, including:

- the size and nature of the subject population;
- the number and location of clinical sites we enroll;
- competition with other companies for clinical sites or subjects;
- the eligibility and exclusion criteria for the trial;
- the design of the clinical trial;
- inability to obtain and maintain subject consents;
- risk that enrolled subjects will drop out before completion; and
- clinicians' and subjects' perceptions as to the potential advantages or disadvantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials in Europe and, we expect, eventually in the United States and, while we have agreements governing their committed activities, we have limited influence over their actual performance. We may also experience difficulties enrolling subjects for our clinical trials relating to MIN-101 and MIN-117 due to the mental health of the subjects that we will need to enroll, related diagnoses and drop-out rates.

Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which could prevent or delay regulatory approval and commercialization, and also increase costs.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive pre-clinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication, and failures can occur at any stage of testing. Clinical trials often fail to demonstrate safety and statistically significant efficacy of the product candidate studied for the target indication in later stages of clinical development. For example, although we believe our Phase IIb trial with MIN-101 met its primary endpoint as we observed the statistically significant benefit of MIN-101 over placebo in improving negative symptoms in patients with schizophrenia, we must conduct pivotal, Phase III trials with MIN-101 that may fail to demonstrate safety and efficacy. Our Phase IIa trial with MIN-117, while we observed a reduction in depressive symptoms, was designed to detect a signal of efficacy and not to demonstrate statistically significant differences between MIN-117 and placebo. Further clinical trials with MIN-117 will need to be statistically powered to demonstrate such differences. Regulatory authorities may find that our studies do not support, in combination with other studies, approval of our product candidates for the target indication. In addition, our product candidates may be associated with undesirable side effects or have characteristics that are unexpected, which may result in abandoning their development or regulatory authorities restricting or denying marketing approval. For instance, prior clinical studies indicated that MIN-101 and MIN-117 may cause adverse events, including, but not limited to, dizziness, vital sign changes, central nervous system events, cardiac events, including prolongation of the QT/QTc interval, and gastrointestinal events. Most product candidates that commence clinical trials are never approved by the applicable regulatory authorities.

In the case of our product candidates, MIN-101 and MIN-117, we are seeking to develop treatments for schizophrenia and MDD, which adds a layer of complexity to our clinical trials and may delay regulatory approval. We do not fully understand the cause and pathophysiology of schizophrenia and MDD, and our results will rely on subjective subject feedback, which is inherently difficult to evaluate, can be influenced by factors outside of our control and can vary widely from day to day for a particular subject, and from subject to subject and site to site within a clinical study. The placebo effect may also have a more significant impact on our clinical trials.

If our product candidates are not shown to be both safe and effective in clinical trials, we will not be able to obtain regulatory approval or commercialize our product candidates.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and management resources, we focus on a limited number of research programs and product candidates. For instance, at the present time we are prioritizing the clinical trials and development of the most advanced of our product candidates, MIN-101. As a result, we may forego or delay pursuit of opportunities with other product candidates, including MIN-117, MIN-202 and MIN-301, or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish

valuable rights to that product candidate through collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

Even if we complete the necessary clinical trials, we cannot predict when or if we will obtain marketing approval to commercialize a product candidate or the approval may be for a more narrow indication than we expect.

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our product candidates demonstrate safety and efficacy in clinical trials, the regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain marketing approval from the relevant regulatory agencies. Additional delays may result if the EMA, FDA, an FDA Advisory Committee, or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials and the review process.

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

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

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

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

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

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

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

- issue adverse inspectional findings;
- issue Warning Letters or Untitled Letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- amend and update labels or package inserts;

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

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

Our product candidates and the activities associated with their development and commercialization in the United States, including, but not limited to, their advertising and promotion, will further be heavily scrutinized by the FDA, the United States Department of Justice, the United States Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress and the public. Violations of applicable law, including advertising, marketing and promotion of our products for unapproved (or off-label) uses, are subject to enforcement letters, inquiries and investigations, and civil, criminal and/or administrative sanctions by regulatory agencies. Additionally, comparable foreign regulatory authorities will heavily scrutinize advertising and promotion of any product candidate that obtains approval outside of the United States. In this regard, advertising and promotion of medicines in the European Union is governed by Directive 2001/83 EC, as amended, and any such activities which we may undertake in the European Union will have to be in strict compliance with the same. Any advertising of a prescription medicinal product to the public and any promotion of a medicinal product that does not have marketing authorization or is not promoted in accordance with that marketing authorization is prohibited. Advertisements and promotions of medicinal products are monitored nationally in the European Union, and each country will have its own additional advertising laws and industry governing bodies, whose obligations may go further than those set out in Directive 2001/83. For instance, in the United Kingdom the code of practice of the Association of the British Pharmaceutical Industry (the lead United Kingdom trade association) is considerably stricter than applicable legislative requirements. Any violations and sanctions will similarly be decided and administered by the relevant country's national authority.

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

person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to substantial civil and criminal settlements regarding certain sales practices, including promoting off-label drug uses. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claims action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and/or be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our products, we may become subject to such litigation, which may have a material adverse effect on our business, financial condition and results of operations.

While no definition of “off-label use” exists at the European Union level, promotion of a medicinal product for a purpose that has not been approved is strictly prohibited. Such promotion also gives rise to criminal prosecution in the European Union, and national healthcare supervisory authorities may impose administrative fines. Engaging in such promotions in the European Union could also lead to product liability claims, in accordance with EU product liability regime under Directive 85/374.

The EMA's, FDA's, and other applicable government agencies' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval and marketing authorization, and the sale and promotion of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and be subject to civil, criminal and administrative enforcement, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

The regulatory pathway for our product candidate, MIN-301, has not yet been determined. Depending on the pathway, we may be subject to different regulatory requirements.

MIN-301 is a peptide, and, as a peptide, may be subject to the Public Health Service Act, or PHSA, and the Food, Drug, and Cosmetic Act, or FDCA. We have yet to meet with the FDA regarding the approval pathway for this product candidate. Based on the definition of a biologic in the PHSA, we believe that MIN-301 meets the definition of a biologic and, thus, we will need to submit a Biologics License Application, or BLA, for product approval. Moreover, based on an FDA intercenter agreement, we believe that MIN-301 will be regulated by the FDA's Center for Drug Evaluation and Research. However, we intend to discuss jurisdiction with the FDA to determine the appropriate regulatory pathway and corresponding requirements. Depending on the pathway, we may be subject to different regulatory requirements, including different regulatory and testing requirements, shorter or longer periods of market exclusivity, and different approval processes for generic drug and biosimilar competitors.

If the market opportunities for any product that we or our collaborators develop are smaller than we believe, our revenue may be adversely affected and our business may suffer.

Our product candidates are intended for the treatment of schizophrenia, MDD, insomnia and Parkinson's disease. Our projections of both the number of people who have these disorders or disease, as well as the subsets of people who have the potential to benefit from treatment with our product candidates and who will pursue such treatment, are based on our beliefs and estimates that may prove to be inaccurate. For instance, with respect to schizophrenia and MDD, our estimates are based on the number of patients that suffer from schizophrenia and MDD, but these disorders are difficult to accurately diagnose and high rates of patients may not seek or continue treatment. Our estimates and beliefs are also based on the potential market of other drugs in development for schizophrenia and MDD, which may prove to be inaccurate and our advantages over such drugs may not be, or may not be perceived to be, as significant as we believe they are. If our estimates prove to be inaccurate, even if our products are approved, we may not be able to successfully commercialize them. In addition, the cause and pathophysiology of schizophrenia and MDD are not fully understood, and additional scientific understanding and future drug or non-drug therapies may make our product candidates obsolete.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates are developed through pre-clinical to late stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or future clinical trials to be conducted with the altered materials. Such changes may also require additional testing, EMA or FDA notification or EMA or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and/or jeopardize our ability to commence product sales and generate revenue.

Our failure to obtain regulatory approval in additional international jurisdictions would prevent us from marketing our product candidates outside the European Union and the United States.

We plan to seek regulatory approval to commercialize our product candidates in the European Union and, other than MIN-202, in the United States. We also expect to seek regulatory approval in additional foreign countries. To market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain EMA or FDA approval. The regulatory approval process outside the European Union and United States generally includes risks substantially similar to those associated with obtaining EMA or FDA approval. In addition, in many countries outside the United States, we must secure product price and reimbursement approvals before regulatory authorities will approve the product for sale in that country or within a short time after receiving such marketing approval. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the

regulatory approval process in others. Also, regulatory approval for any of our product candidates may be withdrawn. If we fail to comply with the regulatory requirements in international markets or do not receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all, especially because some foreign jurisdictions require prior approval of a treatment by the domestic regulatory agency. Our failure to obtain approval of any of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business prospects could decline.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than us.

The biopharmaceutical industry is intensely competitive and subject to rapid and significant technological change. We face competition with respect to our current product candidates and will face competition with respect to any future product candidates from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Many of our competitors have significantly greater financial, technical and human resources. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our competitors may obtain regulatory approval of their products more rapidly than us or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used, less costly and/or have a better safety profile than our products, and competitors may also be more successful than us in manufacturing and marketing their products.

Our competitors will also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

There are numerous currently approved therapies for treating the same diseases or indications for which our product candidates may be useful and many of these currently approved therapies act through mechanisms similar to our product candidates. Many of these approved drugs are well-established therapies or products and are widely accepted by physicians, patients and third-party payors. Some of these drugs are branded and subject to patent protection and regulatory exclusivity, while others are available on a generic basis. Insurers and other third-party payors may encourage the use of generic products or specific branded products. Moreover, it is difficult to predict the effect that introduction of biosimilars into the market will have on sales of the reference biologic product, which will depend on the FDA’s standards for interchangeability, the structure of government and commercial managed care formularies, and state laws on substitution of biosimilars. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generics and biosimilars. This may make it difficult for us to differentiate our products from currently approved therapies, which may adversely impact our business strategy. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability, and safety in order to overcome price competition and to be commercially successful. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer. Moreover, many companies are developing new therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through clinical development.

Even if any of our drug candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our drug candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant revenue from drug sales and we may not become profitable. Our commercial success also depends on coverage and adequate reimbursement of our products by third-party payors, including government payors, which may be difficult or time-consuming to obtain, may be limited in scope or may not be obtained in all jurisdictions in which we may seek to market our products. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and perceived and potential advantages compared to alternative treatments, including any similar generics and biosimilars;
- the timing of market introduction relative to alternative treatment;
    - our ability to offer our drugs for sale at competitive prices relative to alternative treatments;
- the clinical indications for which the product candidate is approved;
- the convenience and ease of administration compared to alternative treatments;

- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of our marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement for our products or the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors;
- unfavorable publicity relating to the products;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our drugs together with other medications.

Our focus on CNS disorders, in particular, exposes us to an increased risk that serious side effects and disease events, including suicide, will occur during patient use of our products, even if such side effects and disease events are unrelated to the use of our products. Most approved CNS medicines carry boxed warnings for clinically significant adverse events, and our products may categorically need to carry such warnings as well.

We currently have no marketing and sales organization. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to effectively market and sell our product candidates, if approved, or generate product revenues.

We currently do not have a marketing or sales organization for the marketing, sales and distribution of pharmaceutical products. In order to commercialize any product candidates, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so on commercially reasonable terms or at all.

If our product candidates receive regulatory approval, we intend to establish our sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time consuming and may require substantial investments prior to any product candidate being granted regulatory approval. In selling, marketing and distributing our products ourselves, we face a number of additional risks, including:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the clinical benefits of our products to achieve market acceptance;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- the costs associated with training sales personnel on legal compliance matters and monitoring their actions;
    - liability for sales personnel failing to comply with the applicable legal requirements; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products.

We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we enter into arrangements with third parties to perform sales, marketing and distribution services for our products, the resulting revenues or the profitability from these revenues to us are likely to be lower than if we had sold, marketed and distributed our products ourselves. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval. Depending on the nature of the third party relationship, we may have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell, market and distribute our products effectively.

If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

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

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

In the European Union, the pricing and reimbursement of prescription drugs is controlled by each member state. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures in the current economic climate in Europe. There is very limited harmonization on member state pricing and reimbursement practices in the European Union.

Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In particular, Germany, Portugal and Spain have all introduced a number of short-term measures to lower healthcare spending, including mandatory discounts, clawbacks and price referencing rules, which could have a material adverse effect on our business.

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

Government authorities and other third-party payors are developing increasingly sophisticated methods of controlling healthcare costs, such as by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices as a condition of coverage, are using restrictive formularies and preferred drug lists to leverage greater discounts in competitive classes, and are challenging the prices charged for medical products. In addition, in the United States, federal programs impose penalties on drug manufacturers in the form of mandatory additional rebates and/or discounts if commercial prices increase at a rate greater than the Consumer Price Index-Urban, and these rebates and/or discounts, which can be substantial, may impact our ability to raise commercial prices. Further, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the

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

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

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

*Recently enacted and future legislation may increase the difficulty and cost for us to commercialize our product candidates and affect the prices we may obtain.

In the United States and many foreign jurisdictions, the legislative landscape continues to evolve. There have been a number of enacted or proposed legislative and regulatory changes affecting the healthcare system and pharmaceutical industry that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidate for which we obtain marketing approval.

For example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the ACA, a law intended to, among other things, broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers and impose additional health policy reforms. Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA. In addition, the current administration and Congress will likely continue to seek legislative and regulatory changes, including repeal and replacement of certain provisions of the ACA. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceutical or medical devices. We continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some countries, particularly in the

European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a health technology assessment that compares the cost-effectiveness of our drug candidate to other available therapies. There can be no assurance that our products will be considered cost-effective, that an adequate level of reimbursement will be available or that a foreign country's reimbursement policies will not adversely affect our ability to sell our products profitably.

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

*Our international operations are subject to foreign currency and exchange rate risks.

Because we plan to continue to conduct our clinical trials in Europe, we are exposed to currency fluctuations and exchange rate risks. The costs of our CROs may be incurred in Euros and we may pay them in Euros, however, we expect to keep the substantial portion of our cash, cash equivalents and marketable securities and private placement transactions, in United States Dollars. Therefore, fluctuations in foreign currencies, especially the Euro, could significantly impact our costs of conducting clinical trials. In addition, we may have to seek additional funding earlier than expected, which may not be available on acceptable terms or at all. Changes in the applicable currency exchange rates might negatively affect the profitability and business prospects of the third parties conducting our future clinical trials. This might cause such third parties to demand higher fees or discontinue their operations. These situations could in turn increase our costs or delays our clinical development, which could have a material adverse effect on our business, financial condition and results of operations.

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

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

- different regulatory requirements for maintaining approval of drugs in foreign countries;
- reduced protection for contractual and intellectual property rights in certain countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in North America;
- tighter restrictions on privacy and the collection and use of patient data; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

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

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, especially Dr. Remy Luthringer, whose services are critical to the successful implementation of our product candidate development and regulatory strategies. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. In order to induce valuable employees to continue their employment with us, we have provided stock options that vest over time. The value to employees of stock options that vest over time is significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies.

Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Pursuant to their employment arrangements, each of our executive officers may voluntarily terminate their employment at any time by providing as little as thirty days advance notice. Our employment arrangements, other than those with our executive officers, provide for at-will employment, which means that any of our employees (other than our executive officers) could leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or other key employees and our

inability to find suitable replacements could potentially harm our business, financial condition and prospects. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level, and senior managers as well as junior, mid-level, and senior scientific and medical personnel.

We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical, biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we have to offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize product candidates will be limited.

*We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of June 30, 2017, we had eight full-time employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including:

- managing our clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, collaborators, contractors and other third parties;
- improving our managerial, development, operational and finance systems; and
- developing our compliance infrastructure and processes to ensure compliance with complex regulations and industry standards regarding us and our product candidates.

As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, collaborators, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

We are party to a loan and security agreement that contains operating and financial covenants that may restrict our business and financing activities.

On January 16, 2015, we entered into a Loan and Security Agreement with Oxford Finance LLC and Silicon Valley Bank, providing for term loans to us in an aggregate principal amount of up to $15 million, in two tranches of $10 million and $5 million, respectively. We borrowed the first tranche in January 2015. In June 2016, we irrevocably elected not to borrow the additional $5 million available under the term loans. Borrowings under this loan and security agreement are secured by substantially all of our assets, excluding certain intellectual property rights. The loan and security agreement restricts our ability, among other things, to:

- sell, transfer or otherwise dispose of any of our business or property, subject to limited exceptions;
- make material changes to our business or management;
- enter into transactions resulting in significant changes to the voting control of our stock;
- make certain changes to our organizational structure;
- consolidate or merge with other entities or acquire other entities;
- incur additional indebtedness or create encumbrances on our assets;
- pay dividends, other than dividends paid solely in shares of our common stock, or make distributions on and, in certain cases, repurchase our stock;
- enter into transactions with our affiliates;
- repay subordinated indebtedness; or
- make certain investments.

In addition, we are required under our loan agreement to comply with various affirmative operating covenants. The operating covenants and restrictions and obligations in our loan and security agreement, as well as any future financing agreements that we may enter into, may restrict our ability to finance our operations, engage in business activities or expand or fully pursue our business strategies. Our ability to comply with these covenants may be affected by events beyond our control, and we may not be able to meet those covenants. A breach of any of these covenants could result in a default under the loan and security agreement, which could cause all of the outstanding indebtedness under the facility to become immediately due and payable and eliminate our eligibility to receive

additional loans under the agreement.

If we are unable to generate sufficient cash available to repay our debt obligations when they become due and payable, either as when such obligations become due, when they mature, or in the event of a default, we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our business operations and financial condition.

Future acquisitions, mergers or joint ventures could disrupt our business and otherwise harm our business.

We actively evaluate various strategic transactions on an ongoing basis and may acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures or investments in complementary businesses. We merged with Sonkei in November 2013 and acquired Mind-NRG in February 2014, but otherwise do not have any substantial experience integrating or managing acquired businesses or assets. Strategic transactions expose us to many risks, including:

- disruption in our relationships with collaborators or suppliers as a result of such a transaction;
- unanticipated liabilities related to acquired companies;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- retention of key employees;
- diversion of management time and focus from operating our business to management of strategic alliances or joint ventures or acquisition integration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses; and
- possible write-offs or impairment charges relating to acquired businesses.

Foreign acquisitions, such as the acquisition of Mind-NRG, a Swiss company, involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

Also, the anticipated benefit of any strategic alliance, joint venture or acquisition may not materialize. Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt (including on terms that are unfavorable to us that we are unable to repay or that may place burdensome restrictions on our operations), contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties brought by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates, if approved. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or products that we may develop;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;

- product recalls, withdrawals or labeling revisions, marketing or promotional restrictions;
- loss of revenues from product sales; and
- the inability to commercialize our product candidates.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We do not currently carry any product liability insurance. Although we anticipate obtaining and maintaining such insurance in line with our needs for our upcoming trials, such insurance may be more costly than we anticipate and any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by such insurance or that is in excess of the limits of such insurance coverage. We also expect our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

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. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could 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.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

We are required to comply with the SEC's rules that implement Section 404 of the Sarbanes-Oxley Act and the Committee on Sponsoring Organizations, or COSO, Report on Internal Control – Integrated Framework, which require, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. Under Section 404 of the Sarbanes-Oxley Act, we are required to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment must include disclosure of any material weaknesses identified by management in our internal control over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Further, in our first annual report required to be filed with the SEC following the date we are no longer an "emerging growth company," as defined in the JOBS Act, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting.

Our compliance with Section 404 requires that we compile the system and process documentation necessary to perform an appropriate evaluation. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. While we have established certain procedures and control over our financial reporting processes, we cannot assure you that these efforts will prevent restatements of our financial statements in the future. If we identify any future significant deficiencies or material weaknesses, the accuracy and timing of our financial reporting may be adversely affected and we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and business prospects. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act. We designed our disclosure controls and procedures to reasonably assure us that the information we disclose in reports we file in accordance with the Exchange Act is accurate, complete, reviewed by management and reported within the required time period. We believe that any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control

system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Prior to November 2013, we operated without full time employees, relying on the services of consultants, including representatives of our former affiliate, Care Capital LLC, to provide certain accounting and finance functions. We have since hired personnel and continue to develop our disclosure control procedures; however, if we are unsuccessful in building an appropriate infrastructure, or unable to develop procedures and controls to ensure timely and accurate reporting, we may be unable to meet our disclosure requirements under the Exchange Act, which could adversely affect the market price of our common stock and impair our access to the capital markets.

Our employees, independent contractors, principal investigators, CROs, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees and independent contractors, such as principal investigators, CROs, manufacturers, consultants, commercial partners and vendors, could include failures to comply with EMA or FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with European, federal and state healthcare fraud and abuse laws, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including, but not limited to certain activities related to research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee and independent contractor misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in sanctions, monetary penalties, and serious harm to our reputation. In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct.

We have adopted a code of business ethics and conduct, but it is not always possible to identify and deter employee and independent contractor misconduct, and the precautions we take to detect and prevent improper activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

Any relationships with healthcare professionals, principal investigators, consultants, customers (actual and potential) and third-party payors in connection with our current and future business activities may and may continue to be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, marketing expenditure tracking and disclosure (or “sunshine”) laws, government price reporting, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face penalties, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations.

Our business operations and activities may be directly, or indirectly, subject to various federal, state and local healthcare laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as proposed and future sales, marketing and education programs. In addition, we may be subject to patient data privacy and security regulation by the federal government, state governments and foreign jurisdictions in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the referral of an individual for the furnishing or arranging for the furnishing of any item or service, or the purchase, lease, order, arrangement for, or

recommendation of the purchase, lease, or order of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs.

- The federal civil False Claims Act, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; conspiring to defraud the government by getting a false or fraudulent claim paid or approved by the government; or knowingly making, using or causing to be made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government.
- The federal criminal False Claims Act, which imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing such claim to be false, fictitious or fraudulent.
- The civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

- The Veterans Health Care Act of 1992 that requires manufacturers of "covered drugs" to offer them for sale to certain federal agencies, including but not limited to, the Department of Veterans Affairs, on the Federal Supply Schedule, which requires compliance with applicable federal procurement laws and regulations and subjects manufacturers to contractual remedies as well as administrative, civil and criminal sanctions.
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their respective business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements.
- The federal Physician Payments Sunshine Act and its implementing regulations requires manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace and other activities that potentially harm consumers.
- State law equivalents of each of the above federal laws, such as anti-kickback, false claims, consumer protection and unfair competition laws which may apply to our business practices, including but not limited to our research, distribution, sales and marketing arrangements and our practices for submitting claims involving healthcare items or services reimbursed by any third-party payors, including commercial insurers. State laws may also (1) require that pharmaceutical companies comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restrict the payments that may be made to healthcare providers, (2) require that drug manufacturers file reports with states regarding marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative effect on a pharmaceutical company's business and/or increase enforcement scrutiny of its activities) and (3) govern the privacy and security of health information in certain circumstances. State laws are not uniform, may differ from each other in significant ways and may be applied with differing effects.

In addition, any sales of our products or product candidates once commercialized outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws such as, for instance, the UK Bribery Act 2010 other national anti-corruption legislation made as a consequence of a member states' adherence to the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, the European Union data protection regime set out in Directive 95/46/EC as implemented nationally by the member states, and European Union consumer laws protecting against defective products, including Directive 85/374/EEC. In addition, there are national laws and codes which are comparable to the United States "sunshine laws," including certain provisions under the UK ABPI Code of Practice and French disclosure requirements on manufacturers to publicly disclose interactions with French health care professionals.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to, without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

We are subject to the Foreign Corrupt Practices Act.

The Foreign Corrupt Practices Act, or FCPA, is a United States law that generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments, offers or promises to foreign officials for the purpose of obtaining or retaining business or other advantages. In addition, the FCPA imposes recordkeeping and internal controls requirements on publicly traded corporations and their foreign affiliates, which are intended to, among other things, prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of "off books" slush funds from which such improper payments can be made.

We and our service providers are subject to EU data protection laws. Failure to comply with such laws could harm our financial condition and operating results and involve distraction from other aspects of our business.

In October 2015, the Court of Justice of the European Union, or CJEU, invalidated the EU-U.S. Safe Harbor Framework, which had established a means for legitimating the transfer of personal data, as the term is used in the context of the EU Data Protection Directive, to the U.S. and required U.S.-based companies that have certified with the Department of Commerce as part of the Safe Harbor Framework to provide assurance that they are adhering to relevant European standards for data protection. As Minerva is not Safe Harbor certified, the CJEU's ruling invalidating the Safe Harbor has no direct effect on Minerva's own compliance with EU data protection laws; however, in light of the CJEU's recent decision, we are reviewing the practices of third party service providers with whom we work, which include the transfer of personal data between the European Economic Area, or EEA, and the U.S. to ensure that all data transfers to us comply with EU data protection laws. In February 2016, the EU Commission announced that it had reached agreement with the U.S. replacement regime to the Safe Harbor Framework, which is expected to be ratified in the EU in the next three to four months. We require our EEA-based services providers, and U.S.-based service providers undertaking clinical trials on our behalf in the EEA, to confirm that all of the personal data which we receive from them is legitimately transferred to us. In many cases we believe that patients and subjects consent to the transfer of their data in a manner which satisfies the requirements of EU data protection law. Where appropriate and pending the ratification of the replacement regime, we may require third party service providers to adopt an alternative means of legitimizing data transfers from the EEA, such as the Standard Contractual Clauses which have been approved by the EU Commission as a means of transferring data to the U.S. These confirmations and, if necessary, additional actions may involve substantial time and expense to both Minerva and its third party service providers, and could divert management's attention and resources from other aspects of our business. If data transfers to the U.S. are not legitimized, the EU data protection authorities can impose a number of different sanctions, including fines and, ultimately, a prohibition on transfers, any of which could harm our business, financial condition and operating results.

*The effectiveness of the amendment to our Co-Development Agreement with Janssen Pharmaceutica NV and the closing of the related Stock Repurchase Agreement is subject to certain conditions that are outside our control and there can be no assurance that the conditions will be met in a timely fashion, or at all.

In June 2017, we signed an amendment to our Co-Development and License Agreement with Janssen, pursuant to which Janssen agreed to forgo its right to royalties on MIN-202 insomnia sales in Minerva territories and agreed to make an upfront payment to us of $30 million upon effectiveness, in addition to other payments. In connection with this amendment, we also entered into a stock repurchase agreement with Johnson & Johnson Innovation-JJDC Inc. to repurchase all of the approximately 3.9 million shares of our stock held by Johnson & Johnson Innovation-JJDC Inc. at a per share price of $0.0001, for an aggregate purchase price of approximately $389.

The effectiveness of both the amendment and the stock repurchase agreement are contingent upon approval of the transaction by the European Commission amongst other normal and customary closing conditions. While custom dictates an approval within thirty (30) days, as of the date of this prospectus, the European Commission has not yet

approved the transaction. If the European Commission does not approve the transaction and our amendment is not effective and the repurchase does not close, it could have a material adverse effect on our business and cause the price of our common stock to decline.

*There can be no assurance we will achieve Breakthrough Therapy designation with the FDA for any of our product candidates. Even if we are able to achieve Breakthrough Therapy designation with the FDA for our product candidates, it may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

Our MIN-101 product candidate was initially denied Breakthrough Therapy designation by the FDA in June 2017, but we may in the future re-submit our request or seek Breakthrough Therapy designation for one or more of our other product candidates. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For drugs that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most

efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. The availability of Breakthrough Therapy designation was established recently with the passage of the Food and Drug Administration Safety and Innovation Act of 2012. We cannot be sure that any evaluation we may make of our product candidates as qualifying for Breakthrough Therapy designation will meet the FDA's expectations. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as Breakthrough Therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Risks Related to Our Dependence on Third Parties

We currently rely and continue to expect to rely on third parties to conduct our future clinical trials. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may not obtain regulatory approval for or commercialize our product candidates in a timely manner or at all.

We plan to rely upon third-party CROs to monitor and manage data for our future clinical programs. We will rely on these parties for execution of our clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with current GCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the EMA, FDA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, we must conduct our clinical trials with product produced under cGMP requirements. Failure to comply with these regulations may require us to repeat pre-clinical and clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical and pre-clinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If necessary, switching or adding CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, prospects, financial condition and results of operations.

If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, we may need to conduct additional trials, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be adversely affected.

We contract with third parties for the manufacturing of our product candidates for pre-clinical and clinical testing and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products, or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities. For our product candidates, we rely, and expect to continue to rely, on third parties for the manufacturing of our drug candidates for pre-clinical and clinical testing, as well as for commercial manufacture if any of our drug candidates receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of

our drug candidates or drugs, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our ability to timely conduct our clinical trials or our other development or commercialization efforts.

We also expect to rely on third-party manufacturers or third-party collaborators for the manufacturing of commercial supply of any other drug candidates for which we or our collaborators obtain marketing approval. We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- disruption and costs associated with changing suppliers, including additional regulatory filings; and
- the possible termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient for us.

Moreover, the facilities used by our contract manufacturers to manufacture our products must be approved by the FDA pursuant to inspections that will be conducted after we submit our marketing application to the FDA. Other national regulatory authorities have comparable powers. While we are ultimately responsible for the manufacture of our product candidates, other than through our contractual arrangements, we do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP requirements, for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, other than through our contractual agreements, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved.

Further, our suppliers are subject to regulatory requirements, covering manufacturing, testing, quality control, and record keeping relating to our product candidates, and subject to ongoing inspections by the regulatory agencies. Failure by any of our suppliers to comply with applicable regulations may result in long delays and interruptions to our manufacturing capacity while we seek to secure another supplier that meets all regulatory requirements, as well as market disruption related to any necessary recalls or other corrective actions.

Third-party manufacturers may not be able to comply with cGMP, regulations or similar regulatory requirements outside the United States. Additionally, our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical hold or termination, fines, imprisonment, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures, refusal to allow product import or export, Warning Letters, Untitled Letters, or recalls of drug candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our drugs.

Our drug candidates and any drugs that we may develop may compete with other drug candidates and drugs for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If our current contract manufacturers cannot perform as

agreed, we may be required to replace such manufacturers and we may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacturing of our drug candidates or drugs may adversely affect our future profit margins and our ability to commercialize any drugs that receive marketing approval on a timely and competitive basis.

If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers. Our manufacturers are or will be subject to federal, state and local laws in the United States and in Europe governing the use, manufacture, storage, handling and disposal of medical, radioactive and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical, radioactive or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state, federal authorities or other equivalent national authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical radioactive or hazardous materials. Compliance with applicable environmental laws is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

We may engage third party collaborators to market and commercialize our product candidates, who may fail to effectively commercialize our product candidates.

We may utilize strategic partners or contract sales forces, where appropriate, to assist in the commercialization of our product candidates, if approved. We currently possess limited resources and may not be successful in establishing collaborations or co-promotion arrangements on acceptable terms, if at all. We also face competition in our search for collaborators and co-promoters. By entering into strategic collaborations or similar arrangements, we will rely on third parties for financial resources and for development, commercialization, sales and marketing and regulatory expertise. Any collaborators may fail to develop or effectively commercialize our product candidates because they cannot obtain the necessary regulatory approvals, they lack adequate financial or other resources or they decide to focus on other initiatives. Any failure to enter into collaboration or co-promotion arrangements or the failure of our third party collaborators to successfully market and commercialize our product candidates would diminish our revenues and harm our results of operations. In addition, conflicts may arise with our collaborators, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property. If any conflicts arise with our collaborators, they may act in their self-interest, which may be adverse to our best interest.

We depend on our collaborations with Mitsubishi Tanabe Pharma Corporation, or MTPC, and Janssen Pharmaceutica NV and could be seriously harmed if our license agreements with MTPC and Janssen were terminated.

We exclusively license MIN-101 and MIN-117 from MTPC, with the rights to develop, sell and import MIN-101 and MIN-117 globally, excluding most of Asia.

Our co-development and license agreement with Janssen provides us with European Union commercialization rights for MIN-202 and the right to royalties on any sales of MIN-202 outside of the European Union. We are obligated to pay 40% of the development costs for MIN-202, subject to certain limits, and will only realize revenues from MIN-202 if it is approved and if our license agreement with Janssen is not terminated by Janssen. Janssen may terminate our license agreement following a material breach by us or certain insolvency events, including if we are unable to fund our portion of the development costs. As a result, we may never realize any revenues from the commercialization of MIN-202, even if approved. In addition, at certain development milestones, including the completion of a single dose Phase I clinical trial of MIN-202 in patients with MDD, Janssen has the right to opt out of its obligation to fund further development, and we may be unable to fund such development without Janssen's

financial support.

Even if we receive revenues on European Union sales or royalties on sales outside of the European Union under the Janssen license agreement, we may not receive revenues that equal or exceed the amount we are obligated to invest in MIN-202's clinical development under the agreement. As a result, the license agreement for MIN-202 may never result in any profits to us and may have a material adverse effect on us or our business prospects.

We may not be successful in establishing new collaborations which could adversely affect our ability to develop future product candidates and commercialize future products.

We are collaborating with Janssen on the development of MIN-202. We may also seek to enter into additional product collaborations in the future, including alliances with other biotechnology or pharmaceutical companies, to enhance and accelerate the development of our future product candidates and the commercialization of any resulting products. We face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish collaborations or other alternative arrangements for any future product candidates because our research and development pipeline may be insufficient, our product candidates may be deemed to be at too early of a stage of development for

collaboration efforts and/or third parties may view our product candidates as lacking the requisite potential to demonstrate safety and efficacy. As a result, we may have to delay the development of a product candidate and attempt to raise significant additional capital to fund development. Even if we are successful in our efforts to establish collaborations, the terms that we agree upon may not be favorable to us and we may not be able to maintain such collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing.

Risks Related to Intellectual Property

If we are unable to obtain or protect intellectual property rights, we may not be able to compete effectively in our market.

Our success depends in significant part on our and our licensors', licensees' or collaborators' ability to establish, maintain and protect patents and other intellectual property rights and operate without infringing the intellectual property rights of others. We have filed numerous patent applications both in the United States and in foreign jurisdictions to obtain patent rights to inventions we have discovered. We have also licensed from third parties rights to patent portfolios. None of these licenses give us the right to prepare, file and prosecute patent applications and maintain patents we have licensed, although we may provide comments on prosecution matters, which our licensors may or may not choose to follow. If our licensors elect to discontinue prosecution or maintenance of our licensed patents, we have the right, at our expense, to pursue and maintain those patents and applications.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors, licensees or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors, licensees or collaborators. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaborators fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors, licensees or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or have licensed from third parties may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' patent rights are highly uncertain. Our and our licensors', licensees' or collaborators' pending and future patent applications may not result in patents being issued that protect our technology or products, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our licensors, licensees or collaborators to narrow the scope of the claims of our or our licensors', licensees' or collaborators' pending and future patent applications, which may limit the scope of patent protection that may be obtained. Our and our licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues

from such applications, and then only to the extent the issued claims cover the technology.

One or more of our owned or licensed patents directed to our proprietary products or technologies may expire or have limited commercial life before the proprietary product or technology is approved for marketing in a relevant jurisdiction.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after our product candidates obtain regulatory approval, which may subject us to increased competition and reduce or eliminate our ability to recover our development costs. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. For example, our in-licensed U.S. and European patents covering composition of matter and pharmaceutical compositions of MIN-101, respectively, are expected to expire as soon as 2021. In addition, our in-licensed U.S. and European patents relating to pharmaceutical compositions and uses of MIN-117 to treat depression are expected to expire as soon as 2020. Finally, any patent that grants from our U.S. patent applications relating to methods of using MIN-301 to treat neurologic and psychiatric diseases is expected to expire as early as 2028. Although we expect to seek extensions of patent terms where available, including in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, which permits a patent term extension of up to five years beyond the expiration of the patent, we cannot be certain that an extension will be granted, or if granted, what the applicable time period or the scope of patent protection afforded during any extended period will be. The applicable authorities, including the EMA, FDA, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and pre-clinical data and launch their product earlier than might otherwise be the case.

The expiration of composition of matter patent protection with respect to one or more of our product candidates may diminish our ability to maintain a proprietary position for our intended uses of a particular product candidate. Moreover, we cannot be certain that we will be the first applicant to obtain an FDA approval for any indication of one or more of our product candidates and we cannot be certain that it will be entitled to new chemical entity, or NCE, exclusivity. Such diminution of our proprietary position could have a material adverse effect on our business, results of operations and financial condition.

We have in-licensed or acquired a portion of our intellectual property necessary to develop our product candidates, and if we fail to comply with our obligations under any of these arrangements, we could lose such intellectual property rights.

We are a party to and rely on several arrangements with third parties, which give us rights to intellectual property that is necessary for the development of our product candidates. In addition, we may enter into similar arrangements in the future. Our current arrangements impose various development, royalty and other obligations on us. If we materially breach these obligations or if our counterparts fail to adequately perform their respective obligations, these exclusive arrangements could be terminated, which would result in our inability to develop, manufacture and sell products that are covered by such intellectual property.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our issued patents or other intellectual property. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult. Accordingly, for such undetectable infringement or misappropriation our ability to recover damages will be negligible and we could be at a market disadvantage because we may lack the resources of some of our competitors to monitor for and detect

infringement. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in any patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly.

We may need to license or acquire additional patents and intellectual property rights.

One or more third parties may hold intellectual property rights, including patent rights, important or necessary to the development of our products. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties on commercially reasonable terms. If we were not able to obtain a license, or were not able to obtain a license on commercially reasonable terms, our business could be harmed, possibly materially.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could harm our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our products, and to use our related proprietary technologies. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products, including interference or derivation proceedings before the U.S. Patent and Trademark Office, or the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our products. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Under certain circumstances, we could be forced, including by court order, to cease commercializing our products. In addition, in any such proceeding or litigation, we could be found liable for monetary damages. Regardless of the outcome, such claims or litigation may be time-consuming and costly to defend, divert management resources and have other adverse effects on our business.

Restrictions on our patent rights relating to our product candidates may limit our ability to prevent third parties from competing against us.

Our success will depend, in part, on our ability to obtain and maintain patent protection for our product candidates, preserve our trade secrets, prevent third parties from infringing upon our proprietary rights and operate without infringing upon the proprietary rights of others. Composition-of-matter patents on the biological or chemical active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection without regard to any method of use. We have filed and in-licensed composition-of-matter patent applications for all of our product candidates. However, we cannot be certain that the claims in our patent applications to inventions covering our product candidates will be considered patentable by the USPTO and courts in the United States or by the patent offices and courts in foreign countries.

In addition to composition-of-matter patents and patent applications, we also have filed method-of-use patent applications. This type of patent protects the use of the product only for the specified method. However, this type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if these competitors do not actively promote their product for our targeted indication, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

Patent applications in the United States and most other countries are confidential for a period of time until they are published, and publication of discoveries in scientific or patent literature typically lags actual discoveries by several months or more. As a result, we cannot be certain that we and the inventors of the issued patents and applications that we may in-license were the first to conceive of the inventions covered by such patents and pending patent applications or that we and those inventors were the first to file patent applications covering such inventions. Also, we have a number of issued patents and numerous patent applications pending before the USPTO and foreign patent offices and the patent protection may lapse before we manage to obtain commercial value from them, which might result in increased competition and materially affect our position in the market.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve

technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time-consuming, and inherently uncertain. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' or collaborators' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the United States Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors' or collaborators' ability to obtain new patents or to enforce existing and future patents.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents. For example, the Leahy-Smith America Invents Act, or the America Invents Act, includes provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO developed new regulations and procedures to govern administration of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and in particular, the first to file provisions, are now effective. While it is still not clear what, if any, impact the America Invents Act will have on the operation of our business, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents, all of which could have a material adverse effect on our business and financial condition.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or our licensors or strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed.
-

We or our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions.

- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- It is possible that our pending patent applications will not lead to issued patents.
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.
- We may not develop additional proprietary technologies that are patentable.
- The patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets of our employees' or consultants' former employers or their clients. These claims may be costly to defend and if we do not successfully do so, we may be required to pay monetary damages and may lose valuable intellectual property rights or personnel.

Many of our employees and contractors were previously employed at universities or biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper our ability to commercialize, or prevent us from commercializing our product candidates, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into invention and patent assignment agreements with our employees and consultants that obligate them to assign their inventions to us. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Ownership of Our Common Stock

We cannot predict what the market price of our common stock will be and, as a result, it may be difficult for you to sell your shares of our common stock.

An inactive market may impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations may be below the expectations of public market analysts and investors and, as a result of these and other factors, the price of our common stock may fall.

The market price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock is likely to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. In addition to the factors discussed in this "Risk Factors" section these factors include:

- the success of competitive products or technologies;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- results of clinical trials of our product candidates or those of our competitors;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the results of our efforts to in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;

- sales of our common stock by us, our insiders or our other stockholders;
- changes in the structure of healthcare payment systems, including coverage and reimbursement;
- market conditions in the pharmaceutical and biotechnology sectors; and
- general economic, industry and market conditions.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

To our knowledge, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially own approximately 68% of our voting stock as of December 31, 2016. Accordingly, these stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our existing stockholders sell, or if the market perceives that our existing stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

Our management will continue to have broad discretion over the use of the proceeds we received in our public offerings, private placements, warrant exercises and term loans and might not apply the proceeds in ways that increase the value of your investment.

Our management will continue to have broad discretion to use the net proceeds from our public offerings, private placements warrant exercises and term loans and you will be relying on the judgment of our management regarding the application of these proceeds. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment. Because of the number and variability of factors that will determine our use of the remaining net proceeds from our initial public offering, follow-on public offering and other financing transactions, their ultimate use may vary substantially from their currently intended use. If we do not invest or apply the net proceeds from our public offerings, private placements, warrant exercises and term loans in ways that enhance stockholder value, we may fail to achieve the expected financial results, which could cause our stock price to decline.

Future sales and issuances of equity and debt securities could result in additional dilution to our stockholders and could place restrictions on our operations and assets, and such securities could have rights, preferences and privileges senior to those of our common stock.

We expect that significant additional capital will be needed in the future to fund our planned operations, including to complete clinical trials for our product candidates. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, existing stockholders may be materially diluted by subsequent sales, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

Pursuant to our Amended and Restated 2013 Equity Incentive Plan, our management is authorized to grant up to 5,781,333 stock options or awards to our employees, directors and consultants, and the number of shares of our common stock reserved for future issuance under the plan will be subject to automatic annual increases in accordance with the terms of the plan. To the extent that new options are granted and exercised or we issue additional shares of common stock in the future, our stockholders may experience additional dilution, which could cause our stock price to fall.

We are an “emerging growth company” and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act, or JOBS Act, and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” including not being required to comply with the auditor attestation requirements of section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from

the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we completed our initial public offering, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds $700.0 million as of any June 30 before that time or if we have total annual gross revenue of $1.0 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 or, if we issue more than $1.0 billion in non-convertible debt during any three year period before that time, we would cease to be an emerging growth company immediately. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We incur increased costs and demands upon management as a result of being a public company.

As a public company listed in the United States, we incur significant additional legal, accounting and other costs. We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the Securities and Exchange Commission, or the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and The NASDAQ Stock Market, may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We invest resources to comply with evolving laws, regulations and standards, and this investment results in increased general and administrative expenses and a diversion of management’s time and attention. If we do not comply with new laws, regulations and standards, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile, and in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management’s attention from other business concerns, which could seriously harm our business.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change in control was considered favorable by you and other stockholders. For example, our board of directors has the authority to issue up to 100,000,000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change in control transaction. As a result, the market price of our common stock and the voting and other

rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents also contain other provisions that could have an anti-takeover effect, including:

- establishing a classified board of directors such that not all members of the board are elected at one time;
- allowing the authorized number of directors to be changed only by resolution of our board of directors;
- limiting the removal of directors by the stockholders;
- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders;

- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters than can be acted upon at stockholder meetings; and
- requiring the approval of the holders of at least 66 2/3% of the votes that all of our stockholders would be entitled to cast to amend or repeal our bylaws.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

If securities or industry analysts cease publishing research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

We have never paid dividends on our capital stock, and because we do not anticipate paying any cash dividends in the foreseeable future, capital appreciation, if any, of our common stock will be your sole source of gain on an investment in our common stock.

We have paid no cash dividends on any of our classes of capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of our credit facility limit our ability to pay cash dividends on our capital stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which you purchase shares of our common stock.

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

Recent Sales of Unregistered Securities

We did not sell any unregistered securities during the six months ended June 30, 2017.

Issuer Purchases of Equity Securities

We did not repurchase any securities during the three months ended June 30, 2017.

Item 3. Defaults upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

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

Exhibit Number	Description	SEC File No.
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's registration statement on Form S-1/A filed with the SEC on June 10, 2014)	333-195169
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's registration statement on Form S-1/A filed with the SEC on June 10, 2014)	333-195169
10.1	Amendment No. 1 to Co-Development and License Agreement dated June 13, 2017, by and between Minerva Neurosciences, Inc. and Janssen Pharmaceutica NV (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on June 14, 2017)	001-36517
10.2	Stock Repurchase Agreement dated June 13, 2017 by and between Minerva Neurosciences, Inc. and Johnson & Johnson Innovation-JJDC Inc. incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on June 14, 2017)	001-36517
31.1	Certification of Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002	
31.2	Certification of Chief Financial Officer (Principal Financial Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002	
32.1+	Certification of Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer) pursuant to Section 906 of Sarbanes-Oxley Act of 2002	
101.INS	XBRL Instance Document	
101.SCH	XBRL Taxonomy Extension Schema Document	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	

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

any general incorporation language in such filing.

SIGNATURE

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

MINERVA NEUROSCIENCES, INC.

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

Date: August 3, 2017