Minerva Neurosciences, Inc.
Form 10-Q
November 06, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2014

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, Waltham, MA	02451
(Address of Principal Executive Offices)	(Zip Code)

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

245 First St, Suite 1800, Cambridge, MA, 02142

(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 x 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 x NO ¨

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer x (Do not check if smaller reporting company)	Smaller reporting company ¨

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

18,439,482 shares, $0.0001 par value per share, were outstanding as of November 5, 2014.

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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 and beginning on Page 9 under the heading “Risk Factors” of our prospectus dated June 30, 2014, filed pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the “Securities Act”), with the Securities and Exchange Commission on July 1, 2014 (the “Prospectus”).

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.

PART I

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Balance Sheets

(Unaudited)

	September 30, 2014	December 31, 2013
Assets		
Current assets		
Cash and cash equivalents	$23,639,558	$1,818,317
Prepaid expenses	583,539	852
Total current assets	24,223,097	1,819,169
Equipment, net	35,566	3,232
In-process research and development	34,200,000	19,000,000
Goodwill	14,869,399	7,918,387
Deferred public offering costs	—	433,998
Total assets	$73,328,062	$29,174,786
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$942,228	$522,981
Accrued expenses and other current liabilities	850,424	815,239
Accrued collaborative expenses	1,386,493	—
Convertible promissory notes	—	58,270
Derivative liability	—	10,093
Total current liabilities	3,179,145	1,406,583
Deferred taxes	13,433,760	7,588,600
Total liabilities	16,612,905	8,995,183
Commitments and contingencies		
Stockholders' equity		
Preferred stock; $.0001 par value; 100,000,000 shares authorized; none issued or outstanding as of September 30, 2014 and December 31, 2013, respectively	—	—
Common stock; $.0001 par value; 125,000,000 shares authorized; 18,439,482 and 6,112,738 shares issued and outstanding as of September 30, 2014 and December 31, 2013, respectively	1,844	611
Additional paid-in capital	124,002,381	38,008,783
Accumulated deficit	(67,289,068)	(17,829,791)
Total stockholders' equity	56,715,157	20,179,603
Total liabilities and stockholders' equity	$73,328,062	$29,174,786

See accompanying notes to condensed consolidated financial statements

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Operations

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Expenses				
Research and development	$ 24,737,835	$ 190,663	$ 39,939,958	$ 544,445
General and administrative	2,413,516	291,809	7,484,556	588,144
Total expenses	27,151,351	482,472	47,424,514	1,132,589
Loss from operations	(27,151,351)	(482,472)	(47,424,514)	(1,132,589)
Foreign exchange gains (losses)	10,989	(2,887)	14,975	(2,887)
Interest (expense) income	(14,835)	(2,834)	(2,049,738)	—
Net loss	$ (27,155,197)	$ (488,193)	$ (49,459,277)	$ (1,135,476)
Net loss per share, basic and diluted	$ (1.53)	$ (0.12)	$ (4.58)	$ (0.29)
Weighted average shares outstanding, basic and diluted	17,752,371	4,091,027	10,798,432	3,858,687

See accompanying notes to condensed consolidated financial statements

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Stockholders' Equity

(Unaudited)

	Common Stock		Additional	Accumulated	
	Shares	Amount	Paid-In Capital	Deficit	Total
Balances at December 31, 2013	6,112,738	$ 611	$ 38,008,783	$ (17,829,791)	$ 20,179,603
Issuance of shares for business acquisition	1,481,583	148	16,541,686	—	16,541,834
Issuance of common stock pursuant to an initial public offering and concurrent private placements, net of issuance costs	9,566,557	956	51,620,030	—	51,620,986
Vesting of common shares issued	926,604	93	10,542,577	—	10,542,670
Stock-based compensation	—	—	5,177,341	—	5,177,341
Conversion of debt and interest to common stock	352,000	36	2,111,964	—	2,112,000
Net loss	—	—	—	(49,459,277)	(49,459,277)
Balances at September 30, 2014	18,439,482	$ 1,844	$ 124,002,381	$ (67,289,068)	$ 56,715,157

See accompanying notes to condensed consolidated financial statements

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

	Nine months Ended September 30,	
	2014	2013
Cash flows from operating activities:		
Net loss	$ (49,459,277)	$ (1,135,476)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	29,879	—
Amortization of debt discount recorded as interest expense	1,952,309	—
Stock-based compensation expense	15,720,011	—
Unrealized foreign exchange gain	—	(2,626)
Change in fair value of derivative	(10,093)	—
Changes in operating assets and liabilities		
Prepaid expenses	(539,761)	7,125
Accounts payable	658,863	—
Accrued expenses and other liabilities	(682,549)	180,919
Accrued collaborative expenses	1,386,493	-
Net cash used in operating activities	(30,944,125)	(950,058)
Cash flows from investing activities:		
Cash acquired in business combination	1,167,869	—
Purchases of equipment	(33,739)	—
Net cash provided by investing activities	1,134,130	—
Cash flows from financing activities:		
Proceeds from working capital loans	1,882,817	—
Repayments of working capital loans	(1,882,817)	—
Proceeds from sales of common stock in initial public offering	31,334,702	—
Proceeds from sales of common stock in private placements	23,706,118	1,850,000
Fees paid in connection with private placements	(280,000)	—
Public offering costs paid	(3,129,584)	—
Net cash provided by financing activities	51,631,236	1,850,000
Net increase in cash and cash equivalents	21,821,241	899,942
Cash and cash equivalents		
Beginning of period	1,818,317	200,314
End of period	$ 23,639,558	$ 1,100,256
Supplemental disclosure of noncash investing and financing activities		
Common stock issued as consideration for business acquisition	$ 16,541,834	$ —
Plus liabilities assumed:		
Accrued expenses and other	321,417	—
ProteoSys milestone payable	681,600	—
Deferred tax liability	5,970,560	—
Less assets acquired:		
Prepaid expenses	42,926	—

Equipment	28,204	—
In-process research and development	15,200,000	—
Goodwill	7,076,412	—
Cash acquired in business merger	$ 1,167,869	$ —
Incurred but unpaid public offering costs	$ 10,250	$ —
Conversion of debt and interest to common stock	$ 2,112,000	$ —

See accompanying notes to condensed consolidated financial statements

MINERVA NEUROSCIENCES, INC.

Notes to Condensed Consolidated Financial Statements

As of September 30, 2014 and for the

Nine Months Ended September 30, 2014 and 2013

(unaudited)

NOTE 1 — NATURE OF OPERATIONS AND LIQUIDITY

Nature of Operations

Minerva Neurosciences, Inc. ("Minerva" or the "Company"), formerly known as Cyrenaic Pharmaceuticals Inc. ("Cyrenaic") was incorporated on April 23, 2007. The Company is a biopharmaceutical company focused on the development of an experimental drug for the treatment of schizophrenia (discussed further in Note 6 — License Agreement). On November 12, 2013, Sonkei Pharmaceuticals, Inc. ("Sonkei"), a biopharmaceutical company focused on the development of an experimental drug for the treatment of depression and an affiliated company through certain common ownership, was merged into Cyrenaic with Cyrenaic being the surviving company. Subsequent to the merger, Cyrenaic changed its name to Minerva Neurosciences, Inc.

On February 11, 2014, the Company acquired Mind-NRG (discussed further in Note 3 — Business Combinations). Mind-NRG is a Swiss development stage biopharmaceutical company focused on the development and commercialization of an experimental drug for the treatment of Parkinson's disease. The Company acquired 100% of the share capital of Mind-NRG largely to obtain the intellectual property estate which underpins Mind-NRG's lead product candidate, renamed MIN-301.

On February 12, 2014, subject to the completion of an initial public offering ("IPO"), the Company entered into a co-development and license agreement (discussed further in Note 8 — Co-Development and License Agreement) pursuant to which the licensor granted the Company an exclusive license, in certain territories, under 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, or MIN-202, for any use in humans. The license became effective on July 7, 2014 at the closing of the IPO and the payment of the $22.0 million license fee was made at that date.

Going Concern

The Company has limited capital resources and has incurred recurring operating losses and negative cash flows from operations since inception. As of September 30, 2014, the Company has an accumulated deficit of approximately $67.3 million. Management expects to continue to incur operating losses and negative cash flows from operations. The Company has financed its business to date from proceeds from the sale of common stock, loans and convertible promissory notes. On July 7, 2014, the Company completed an IPO and received net proceeds of $28.2 million, including the over allotment. In addition, on July 7, 2014, the Company sold shares of its common stock in two private placements resulting in net proceeds to the Company of approximately $23.4 million.

The Company will need to raise additional capital in order to continue to fund operations and fully fund its clinical development programs. The Company believes that it will be able to obtain additional working capital through equity financings or other arrangements to fund 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.

The accompanying condensed consolidated financial statements have been prepared as though the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation

The accompanying unaudited financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial reporting and as required by Regulation S-X, Rule 10-01. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of the Company's management, the accompanying unaudited financial statements contain all adjustments (consisting of items of a normal and recurring nature) necessary to present fairly the financial position as of September 30, 2014 and the results of operations for the three and nine months ended September 30, 2014 and 2013 and cash flows for the nine months ended September 30, 2014 and 2013. The results of operations for the three and nine months ended September 30, 2014, 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 balance sheet as of December 31, 2013 was derived from the audited financial statements. The accompanying unaudited condensed consolidated financial statements and notes thereto should be read in conjunction with the audited financial statements for the years ended December 31, 2013 and 2012.

From its inception the Company has devoted substantially all of its efforts to business planning, engaging regulatory, manufacturing and other technical consultants, planning and executing clinical trials and raising capital.

Consolidation

The accompanying consolidated financial statements include the results of the Company and its wholly-owned subsidiary, Mind-NRG. 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 consolidated 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 condensed consolidated financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Prior to the completion of the Company's IPO, the Company utilized significant estimates and assumptions in determining the fair value of its common stock. The board of directors determined the estimated fair value of the Company's common stock based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector, discounted cash flows and the likelihood of achieving a liquidity event, such as an IPO of common stock or a sale of the Company. The Company utilized various valuation methodologies in accordance with the framework of the 2013 American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation, to estimate the fair value of its common stock. The methodologies included a probability-weighted expected return methodology that determined an estimated value under an IPO scenario and a sale scenario based upon an assessment of the probability of occurrence of each scenario. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates include assumptions regarding future performance, including the successful completion of preclinical studies and clinical trials and the time to complete an IPO or sale. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

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. We determine our expenses related to clinical studies based on our 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 our 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, we estimate 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 our estimate, we adjust the accrual 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 condensed consolidated financial statements as prepaid or accrued expenses.

In July 2014, the Company paid a $22.0 million license fee, which has been included as a component of research and development expense since the licensed rights were not deemed to have an alternative future use. The Company accounts for the co-development and license agreement pursuant to which the license fee was paid 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 expense or general and administrative expense, as applicable, in the accompanying condensed consolidated financial statements due to the joint risk-sharing nature of the activities. The Company has included $1.4 million in accrued expenses as of September 30, 2014 related to this agreement.

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 fair value of the research projects is 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.

Stock-based compensation

The Company recognizes compensation cost relating to share-based payment transactions in operating results using a fair-value measurement method, in accordance with Financial Accounting Standards Board ("FASB") Accounting Series Codification ("ASC") -718 Compensation-Stock Compensation. ASC-718 requires all share-based payments to employees, including grants of employee stock options, to be recognized in operating results as compensation expense over the requisite service period of the awards based on fair value of the granted instruments. The Company determines the fair value of share-based awards using the Black-Scholes option pricing model, which uses both historical and current market data to estimate fair value. This model incorporates various assumptions such as the risk-free interest rate, the expected volatility of the Company's stock price, the stock's expected dividend yield and the expected life of the options. The Company reduces the amount of compensation expense it recognizes for the expected amount of pre-vesting forfeitures.

Grants to non-employees are accounted for in accordance with ASC-505-50 Equity — Based Payments to Non-Employees. The fair value of the instruments awarded are remeasured until 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 share-based awards granted to non-employees using the Black-Scholes option pricing model.

Loss per share

Basic loss per share excludes dilution and is computed by dividing net loss by the weighted-average number of common shares 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.

Income taxes

The Company utilizes the liability method of accounting for income taxes as required by ASC Topic 740 Income Taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Deferred tax assets are evaluated for realization based on a more-likely-than-not criterion in determining if a valuation allowance should be provided. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

ASC Topic 740 also covers the accounting for uncertainty in income taxes recognized in the consolidated financial statements. The guidance prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken, or expected to be taken, in a tax return. ASC Topic 740 provides guidance on the recognition of interest and penalties related to income taxes. There were no interest or penalties related to income taxes for the three and nine months ended September 30, 2014 and 2013. The Company has elected to treat interest and penalties, to the extent they arise, as a component of income taxes. Income tax years beginning in 2011 for federal and state purposes are generally subject to examination by taxing authorities, although net operating losses from all prior years are subject to examinations and adjustments for at least three years following the year in which the tax attributes are utilized.

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 Company's IPO on July 7, 2014, these amounts were offset against the proceeds of the offering.

Business combinations

For business combinations the Company utilizes the acquisition method of accounting in accordance with ASC Topic 805, Business Combinations. These standards require that the total cost of an acquisition be allocated to the tangible and intangible assets acquired and liabilities assumed based their respective fair values at the date of acquisition. The allocation of the purchase price is dependent upon certain valuations and other studies. Acquisition costs are expensed as incurred. The Company recognizes separately from goodwill the fair value of assets acquired and the liabilities assumed. Goodwill as of the acquisition date is measured as the excess of consideration transferred and the acquisition date fair values of the assets acquired and liabilities assumed. While the Company uses its best estimates and assumptions as a part of the purchase price allocation process to accurately value assets acquired and liabilities assumed at the acquisition date, the Company's estimates are subject to refinement. As a result, during the measurement period, which may be up to one year from the acquisition date, the Company may retroactively record adjustments to the fair value of the assets acquired and liabilities assumed, with the corresponding offset to goodwill. Upon the conclusion of the measurement period or final determination of the fair value of assets acquired or liabilities assumed, whichever comes first, any subsequent adjustments are recorded to the Company's consolidated statements of operations.

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 implied 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 annually at November 30 and more frequently if events or changes in circumstances indicate that it is more likely than not that the asset is impaired. There was no impairment of goodwill for the year ended December 31, 2013 and the Company believes there was no impairment for the three and nine months ended September 30, 2014.

Convertible promissory notes

The Company had issued 8% convertible promissory notes consisting of (i) $1.3 million face value convertible promissory notes and(ii) €518,519 face value convertible promissory notes. The Euro denominated notes were acquired in conjunction with the merger with Sonkei (discussed further in Note 3 — Business Combinations), and recorded at their fair value of approximately $0.7 million on the date of the merger.

In conjunction with the IPO, the Company's 8% convertible promissory notes in the face amount of $1.3 million and €518,519 including $0.1 million in accrued interest, were converted on July 7, 2014 at the IPO price of $6.00 per share into 352,000 shares of the Company's common stock. There were no debt instruments outstanding on September 30, 2014.

Discount Purchase Option

The Company's 8% convertible promissory notes contain an embedded derivative related to the conversion option containing a discount purchase feature in a qualified financing, as defined in such convertible promissory notes. The derivative was carried at fair value and was classified as Level 3 in the fair value hierarchy due to the use of significant unobservable inputs. As of December 31, 2013, the fair value of the derivative liability was determined to be $10,093 using a probability-weighted valuation model applying the

following assumptions: (i) discount rate of 8.0%, (ii) remaining term of approximately 6 months and (iii) the probabilities of conversion under various circumstances as at the date of measurement. The fair value of the derivative liability was remeasured at the July 7, 2014 conversion date and the fair value of the liability was determined to be $0. The $10,093 decrease in the fair value of the derivative liability was included as a component of interest for the nine months ended September 30, 2014. No amounts were charged to interest during the three months ended September 30, 2014.

$3.50/€3.50 Conversion Option

The Company's 8% convertible promissory notes contained an embedded derivative related to the beneficial conversion feature of the notes. The initial fair value of the derivative liability at the date of issuance in November 2013 was determined by measuring the difference between the conversion price and the fair value of common stock at the commitment date. The Company recorded a debt discount for the fair value of the derivative, which was limited to the proceeds received of approximately $2.0 million, with an offsetting increase to additional paid-in capital. The beneficial conversion charge was included in the balance sheet at December 31, 2013 as a discount to the related convertible promissory notes. The discount was accreted as non-cash interest expense over the term of the debt using the effective interest method. The debt was converted into common stock in conjunction with the Company's IPO on July 7, 2014 and the Company recognized approximately $0 and $2.0 million in non-cash interest expense within interest expense (income), net during the three and nine month periods ended September 30, 2014, respectively.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by FASB and are adopted by the Company as of the specified effective date. The Company believes that the impact of other recently issued but not yet adopted accounting pronouncements will not have a material impact on the financial position, results of operations, and cash flows, or do not apply to the Company's operations.

In June 2014, the FASB issued Accounting Standards Update No. 2014-10, Development Stage Entities (Topic 915) which eliminates the definition of a development stage entity and removes the financial reporting distinction between development stage entities and other reporting entities under GAAP. The Company early adopted this standard and thus has eliminated its historical inception to date information in the financial statements.

In August 2014, the FASB issued Accounting Standards Update No. 2014-15, Presentation of Financial Statements—Going Concern (Subtopic 205-40) which provides guidance on disclosure requirements when there is substantial doubt about an entity's ability to continue as a going concern. The amendments in this update are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter, with early adoption permitted. The Company will evaluate this amendment but does not believe that it will have a material impact on its financial position, results of operations or cash flows.

NOTE 3 — BUSINESS COMBINATIONS

Mind-NRG

On February 11, 2014, the Company acquired Mind-NRG, a Swiss development stage biopharmaceutical company focused on the development and commercialization of an experimental drug for the treatment of Parkinson's disease. This transaction was accounted for as a business combination by the Company. The purchase price consists of 1,481,583 shares of the Company's common stock (which includes 148,160 shares held in escrow until the expiration of the holdback period, February 11, 2015) with an estimated fair value of $11.17 per share, or approximately

$16.5 million. The Company acquired 100% of the share capital of Mind-NRG largely to obtain the intellectual property estate that underpins Mind-NRG's lead product candidate, recently renamed MIN-301.

The fair value of the Company's common stock issued was determined based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector, discounted cash flows and the likelihood of achieving a liquidity event, such as an IPO or a sale of the Company. The purchase price allocation was based upon an analysis of the fair value of the assets and liabilities acquired from Mind-NRG. The final purchase price may be adjusted up to one year from the date of the merger. Identifying the fair value of the tangible and intangible assets and liabilities acquired required the use of estimates by management, and were based upon currently available data, as noted below.

- The fair value of current assets and liabilities approximated their book value.
- The Company measured the value of the acquired IPR&D using the income approach — multi period excess earnings method and assembled workforce using the cost approach (for contributory asset charge calculations). The multi-period excess earning method measures the present value of the future earnings expected to be generated during the remaining lives of the subject assets.
- The Company recorded a deferred tax liability for the difference in the book and tax basis of the IPR&D, multiplied by the effective income tax rate.

The establishment of the fair value of the consideration for an acquisition, and the allocation to identifiable tangible and intangible assets and liabilities requires the extensive use of accounting estimates and management judgment. The fair values assigned to the assets acquired and liabilities assumed are from estimates and assumptions based on data currently available.

The Company allocated the excess of purchase price over the identifiable intangible and net tangible assets to goodwill. The goodwill recorded recognizes the value of the overall development program, both the current pre-clinical development program in process and the future clinical trial development strategy. Such goodwill is not deductible for tax purposes. The aggregate consideration of $16.5 million has been allocated to assets acquired and liabilities assumed based on estimated fair values at the February 11, 2014 as follows:

Cash	$1,167,869
Other assets	71,130
Goodwill	7,076,412
In-process research and development	15,200,000
Deferred tax liability	(5,970,560)
Accrued expenses	(321,417)
ProteoSys milestone payable	(681,600)
	$16,541,834

IPR&D, an indefinite-lived asset, will be included as an asset on the Company's balance sheet until such time that: (i) a marketing approval to commercially sell the drug is received from a regulatory agency, in which case it will be amortized over its expected commercial life, or (ii) such time as the IPR&D is deemed to be impaired, in which case it will be expensed. The transaction is being treated as a stock purchase for income tax purposes and accordingly, the tax bases of Mind-NRG's assets and liabilities are not adjusted for the effect of purchase accounting. A deferred tax liability of $6.0 million has been recorded for the difference in the book and tax basis of the IPR&D, multiplied by the effective income tax. As of September 30, 2014, the Company corrected the deferred tax rate used to record a deferred tax liability at the acquisition date by recording a $0.1 million reduction to deferred tax liability with a corresponding reduction to goodwill.

Sonkei

On November 12, 2013, Cyrenaic was merged with Sonkei, with Cyrenaic being the survivor company. Each share of Sonkei common stock was converted into 0.383 shares of Cyrenaic common stock, resulting in the issuance of 2,423,368 shares. There were certain common stockholders between Sonkei and Cyrenaic however, since the underlying investors in the venture funds were not "substantially similar", the merger was accounted for a business combination with Cyrenaic being treated as the acquirer. The results of Sonkei are included in the consolidated financial statements commencing November 12, 2013. The Company merged with Sonkei in order to acquire Sonkei's lead product candidate, MIN-117.

At the date of the merger, a Sonkei non-employee held 1,112,500 shares of Sonkei common stock with a nonrecourse note due to Sonkei, which was being treated as a stock option for accounting purposes. In connection with the merger, the Company issued 426,176 shares to the holder with a nonrecourse note (discussed further in Note 9 — Stockholders' Equity) in order to replace the holder's stock options in Sonkei. Due to the nonrecourse note, these shares of the Company were treated as stock options for accounting purposes and the holder of the option can only vest in the stock options if the holder continues to provide services to the Company through the time of a change in control, as defined.

In summary, the Company issued replacement stock options of the Company for the old Sonkei stock options. As a change in control was not deemed probable as of the merger date, the options have not been included as part of the consideration transferred in the merger accounting. Accordingly, the Company will recognize all of the compensation expense for these stock options in the consolidated statement of operations once achievement of the performance condition becomes probable (see Note 9 — Stockholders' Equity). The merger accounting purchase price was therefore determined based upon the common stock shares issued of 1,997,192 at a valuation of $9.49 per common share for a total purchase price of approximately $18.9 million.

The fair value of the Company's common stock issued was determined based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector, discounted cash flows and the likelihood of achieving a liquidity event, such as an IPO or a sale of the Company. The purchase price allocation was based upon an analysis of the fair value of the assets and liabilities acquired from Sonkei. Identifying the fair value of the tangible and intangible assets and liabilities acquired required the use of estimates by management, and were based upon currently available data, as noted below.

- The fair value of current assets and liabilities approximated their book value.
- The fair value of the convertible promissory notes was determined based upon a number of factors including (i) interest rate, (ii) creditworthiness of the Company, (iii) the applicable foreign exchange rate and (iv) the conversion features (described in Note 7 — Debt). The face amount of the note acquired is €518,519 (approximately $0.7 million at November 12, 2013).

- The Company measured the value of the acquired IPR&D using the income approach — multi period excess earnings method and assembled workforce using the cost approach (for contributory asset charge calculations). The multi-period excess earning method measures the present value of the future earnings expected to be generated during the remaining lives of the subject assets.
- The Company recorded a deferred tax liability for the difference in the book and tax basis of the IPR&D, multiplied by the effective income tax rate.

The Company allocated the excess of purchase price over the identifiable intangible and net tangible assets to goodwill. The goodwill recorded recognizes the synergies and value of the overall combined development programs, both the current pre-clinical development program in process and the future clinical trial development strategy. Such goodwill is not deductible for tax purposes. The aggregate consideration of $18.9 million has been allocated to assets acquired and liabilities assumed based on estimated fair values at the date of merger November 12, 2013 as follows:

Cash	$	631,478
Goodwill		7,792,987
In-process research and development		19,000,000
Accrued expenses		(334,423)
Derivative liability		(3,476)
Deferred taxes		(7,463,200)
Convertible promissory notes (see Note 7)		(680,000)
	$	18,943,366

The IPR&D, an indefinite-lived asset, will be included as an asset on the Company's consolidated balance sheet until such time that: (i) a marketing approval to commercially sell the drug is received from a regulatory agency, in which case it will be amortized over its expected commercial life, or (ii) such time as the IPR&D is deemed to be impaired, in which case it will be expensed. The transaction is being treated as a stock purchase for income tax purposes and accordingly, the tax bases of Sonkei's assets and liabilities are not adjusted for the effect of purchase accounting. A deferred tax liability of $7.5 million has been recorded for the difference in the book and tax basis of the IPR&D, multiplied by the effective income tax. The acquired net operating losses of Sonkei of approximately $5.3 million had a full valuation allowance, however, will be not limited under Internal Revenue Code Section 382 as the amount that could be utilized after limitation exceeds the amount of the net operating loss carryforward. As of September 30, 2014, the Company corrected the deferred tax rate used to record a deferred tax liability at the acquisition date by recording a $0.1 million reduction to deferred tax liability with a corresponding reduction to goodwill.

The unaudited financial information in the table below summarizes the combined results of operations for the Company, Sonkei and Mind-NRG on a pro forma basis as though the companies had been combined as of January 1, 2013. The unaudited pro forma financial information for the three and nine months ended September 30, 2014 and 2013 combines the Company's historical results for these years with the historical results for the comparable reporting periods for Sonkei and Mind-NRG. The unaudited pro forma financial information below is for informational purposes only and is not indicative of the results of operations or financial condition that would have been achieved if the merger would have taken place at the beginning of each of the periods presented and should not be taken as indicative of the Company's future results of operations or financial condition. Included in our results of operations for the nine months ended September 30, 2014 is $1.3 million in operating expenses attributable to Mind-NRG.

	Three Months Ended September 30,		Nine months Ended September 30,	
	2014	2013	2014	2013
Operating loss	$(27,155,197)	$(1,110,023)	$(49,912,152)	$(2,682,000)
Loss per share	$(1.53)	$(0.15)	$(4.53)	$(0.37)

NOTE 4 — ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities consist of the following:

	September 30, 2014	December 31, 2013
Accrued payroll	$ 229,785	$ 126,910
Accrued excise and franchise taxes	203,991	—
Research and development costs	168,640	58,117
Primomed research funding (1)	132,721	—
Professional fees (2)	70,445	595,215
Consulting and other costs	27,024	5,031
Vacation pay	17,818	5,690
Interest payable	—	24,276
	$ 850,424	$ 815,239

(1) Under the terms of a research agreement with Primomed, the Company received grant funds that will be used to offset certain costs under the MIN-301 development program.
(2) Accounts payable and accrued professional fees at December 31, 2013 included $0.4 million that was incurred in connection with the preparation for the Company's IPO.

NOTE 5 — 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 September 30,		Nine months Ended September 30,	
	2014	2013	2014	2013
Net loss	$(27,155,197)	$(488,193)	$(49,459,277)	$(1,135,476)
Weighted average shares of common stock outstanding	17,752,371	4,091,027	10,798,432	3,858,687
Net loss per share of common stock – basic and diluted	$(1.53)	$(0.12)	$(4.58)	$(0.29)

The following securities outstanding at September 30, 2014 and 2013 have been excluded from the calculation of weighted average shares outstanding as their effect on the calculation of loss per share is antidilutive:

	September 30, 2014	September 30, 2013

Non-vested stock issued (see Note 9 – Stockholders' Equity)	—	821,429
Common stock options	2,621,910	—

NOTE 6 — LICENSE AGREEMENTS

In January 2014, the Company renegotiated the structure of the license for MIN-101 such that the Company is required to make milestone payments upon the achievement of one development milestone totaling $0.5 million and certain commercial milestones, which could total up to $47.5 million. In addition, in the event that the Company sells the rights to the license, the licensor will be entitled to a percentage of milestone payments in the low teens and a percentage of royalties received by the Company in the low double digits. Under the terms of the amended agreement, the Company is required to meet a certain diligence obligation to commence a clinical pharmacology study of the licensed compound by the end of April 2015. The Company may extend this deadline for a further year by making an extension payment of $0.5 million. The number of extension payments that may be made is unlimited. In addition, if the Company fails to achieve this development milestone by end of April 2015 or make an extension payment, the licensor may elect to terminate the agreement.

In January 2014, the Company renegotiated the structure of the license for MIN-117 such that the Company is required to make certain milestone payments upon the achievement of certain commercial milestones up to $47.5 million. In addition, in the event that the Company sells the rights to the license, the licensor will be entitled to a percentage of milestone payments in the low teens and a percentage of royalties received by the Company in the low double digits. Under the terms of the amended agreement, the Company is required to meet a certain diligence obligation to initiate either a Phase II(a) or Phase II(b) study with the licensed compound in

patients suffering major mood disorders where initiation is defined as first patient enrolled in the study by the end of April 2015. If the Company fails to achieve this milestone, the Company may elect to extend the timeline to achieve the milestone by one year increments by making an extension payment of $0.5 million. The number of extension payments which may be made is unlimited. In addition, if the Company fails to achieve this development milestone by end April 2015 or make an extension payment, the licensor may elect to terminate the agreement.

The Company did not make any license payments under the agreements for the three and nine months ended September 30, 2014 and 2013.

NOTE 7 — DEBT

Loans Payable

In conjunction with the Mind-NRG acquisition on February 11, 2014 (discussed further in Note 3 — Business Combinations), working capital loans were executed between Mind-NRG and several stockholders or affiliates of stockholders for a maximum drawdown of $0.6 million. The loans bear interest at 8% and are repayable at the time the Company completes an IPO or December 1, 2015. The loans may be repaid at any time and contains standard terms of default, under which the interest rate would increase to 11%.

In April 2014, Mind-NRG repaid the working capital loans plus accrued interest, and certain stockholders and their affiliates subsequently executed new working capital loan agreements, with substantially identical terms, directly with the Company (the April Bridge Loan). The Company drew down the maximum $0.6 million available under the agreement in May 2014.

In May 2014, the Company entered into a new loan agreement (the May Bridge Loan) with certain stockholders and their affiliates. The Third Loan Agreement provides loan facilities to the Company up to a maximum of $1.0 million. The Third Loan Agreement bears interest at 8% per annum and is repayable at the time the Company completes an IPO or on December 1, 2015. The Third Loan Agreement contains standard terms of default, under which the interest rate would increase to 11% per annum. The Third Loan Agreement provides that any amount outstanding may be repaid at any time without penalty.

The Company drew down $1.4 million under the April and May Bridge Loan Agreements. In conjunction with the closing of the Company’s IPO on July 7, 2014, the Company repaid the outstanding principal balance under the April and May Bridge Loan agreements plus accrued interest of $11 thousand. Interest expense related to these loans for the three and nine months ended September 30, 2014 was $5 thousand and $16 thousand, respectively, and was included within interest expense (income), net.

Convertible Promissory Notes

On November 6, 2013, the Company issued $1.3 million 8% convertible promissory notes due June 30, 2014 to certain stockholders that are payable on demand at maturity. The notes contain certain terms of default, under which conditions the interest rate increases to 11% per annum.

In conjunction with the merger of Sonkei on November 12, 2013, the Company assumed convertible promissory notes held by certain stockholders with a principal amount of €518,519 ($0.7 million as of July 7, 2014). These notes have a stated interest rate of 8% per annum and a maturity date of June 30, 2014. The notes contains certain terms of default, under which conditions the interest rate increases to 11% per annum. In conjunction with the IPO, the Company’s 8% convertible promissory notes were converted on July 7, 2014 at the IPO price of $6.00 per share into 352,000 shares of the Company’s common stock.

The notes issued by the Company on November 6, 2013 and the notes issued by Sonkei on November 6, 2013 and subsequently acquired by the Company on November 12, 2013 (collectively, the "Notes") contained identical terms and were convertible into common shares of the Company under the conditions described below.

i) Discount Purchase Option. If the Company sells shares of its capital stock in the qualified financing, as defined, and the convertible promissory notes have not been paid in full, then the outstanding principal balance of these convertible promissory notes and accrued interest thereon shall convert into the common stock sold at the first closing of the qualified financing at a conversion price equal to the price per share paid by the Investors for each share of common stock multiplied by 80%.

ii) Initial Public Offering. If the Company conducts an IPO of its common shares before June 30, 2014, then the convertible promissory notes plus accrued interest will convert at the price per share issued in the IPO.

iii) $3.50/€3.50 Conversion Option. Subsequent to April 30, 2014, investors may elect to convert the Notes, and accrued interest into common stock of the Company at a conversion price of $3.50 per common share.

Discount Purchase Option

The Notes contained an embedded derivative related to the discount purchase feature. The initial fair value of the derivative liability at the date of initial recognition was determined to be $9,976 using a probability-weighted valuation model applying the following assumptions: (i) discount rate of 8.0%, (ii) remaining term of approximately 7 months and (iii) the probabilities of conversion under various circumstances as at the date of measurement. The proceeds allocated to this conversion option of $9,976 were deducted from the initial fair value of the debt obligation. As of December 31, 2013, the fair value of the derivative liability was determined to be $10,093 using a probability-weighted valuation model applying the following assumptions: (i) discount rate of 8.0%, (ii) remaining term of approximately 6 months and (iii) the probabilities of conversion under various circumstances as at the date of measurement.

Upon conversion of the Notes on July 7, 2014, the fair value of the derivative liability was determined to be $0 and the $10,093 decrease in the fair value of the derivative liability was included as a component of interest for the nine months ended September 30, 2014. No amounts were charged to interest expense during the three months ending September 30, 2014.

$3.50/€3.50 Conversion Option

The Notes contained a beneficial conversion feature. The intrinsic value of the beneficial conversion feature was calculated by measuring the difference between the effective conversion price and the fair value of the common stock at initial recognition. The Company recorded a debt discount for the intrinsic value of the beneficial conversion feature that was limited to the proceeds of the Notes received of approximately $2.0 million, with an offsetting increase to additional paid-in capital. The discount was amortized to interest expense using the effective interest method through the date of the Notes' conversion of July 7, 2014.

For the three and nine months ended September 30, 2014, the Company recognized interest expense of approximately $3 thousand and $2.0 million related to the Notes, respectively, within interest expense (income), net.

NOTE 8 — CO-DEVELOPMENT AND LICENSE AGREEMENT

On February 12, 2014, the Company signed a co-development and license agreement with Janssen Pharmaceutica N.V. ("Janssen") and Janssen Research & Development, LLC ("JJDC"), subject to the completion of an IPO and the payment of a $22.0 million license fee. Under the agreement, the licensor granted the Company an exclusive license, with the right to sublicense, in the European Union, Switzerland, Liechtenstein, Iceland and Norway, referred to as 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. 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 on July 7, 2014, which was included as a component of research and development expense in the third quarter of 2014. The Company will pay a quarterly royalty percentage in the high single digits on aggregate net sales for MIN-202 products sold by the Company, its affiliates and sublicensees in the European Union. 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 European Union.

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 Major Depressive Disorder ("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 included the $22.0 million license fee payment as a component of research and development expense since the licensed rights were not deemed to have an alternative future use. 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 expense or general and administrative expense, as applicable, in the accompanying condensed consolidated financial statements due to the joint risk-sharing nature of the activities. The Company has included $1.4 million in accrued expenses as of September 30, 2014 related to this agreement.

The Company entered into a common stock purchase agreement with an affiliate of the above mentioned licensor, dated as of February 12, 2014, pursuant to which, among other things, the affiliate agreed to purchase from the Company up to $26.0 million of common stock in a private placement concurrent with the closing of the IPO at a price equal to the IPO price. This investment was consummated simultaneously with the closing of an IPO in July 2014 with the purchase by the affiliate of 3,284,353 shares of common stock resulting in net proceeds to the Company of $19.7 million.

NOTE 9 — STOCKHOLDERS' EQUITY

Reverse Stock Split

The board of directors and holders of the requisite number of outstanding shares of our common stock approved an amendment to our restated certificate of incorporation to effect a 3.5-to-1 reverse stock split of our outstanding common stock (the "reverse stock split") that became effective on June 9, 2014 upon the filing of our Certificate of Amendment of the Restated Certificate of Incorporation with the Delaware Secretary of State. The reverse stock split did not result in an adjustment to par value. All issued and outstanding common stock, warrants for common stock, options to purchase common stock, share transactions, and related per share amounts contained in the consolidated financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented. On June 9, 2014, the Company amended its Amended and Restated Certificate of Incorporation to increase the total number of authorized shares to 225,000,000 shares, consisting of 125,000,000 shares of common stock, par value $0.0001 per share and 100,000,000 shares of preferred stock, par value $0.0001 per share.

Initial Public Offering and Concurrent Private Placements

On July 7, 2014, the Company closed the sale of 5,454,545 shares of its common stock at a price to the public of $6.00 per share, or an aggregate of approximately $32.7 million. On July 29, 2014, the Company closed the sale of an over-allotment of 160,993 shares of its common stock at a price of $6.00 per share. Net proceeds to the Company from the offering and the over allotment were approximately $28.2 million, after deducting the underwriting discount and expenses of approximately $3.1 million. In addition, the Company closed the sale in a private placement of 666,666 shares of its common stock at a price of $6.00 per share, or an aggregate of approximately $4.0 million. Net proceeds to the Company were approximately $3.7 million, after deducting the underwriting discount. JJDC purchased 3,284,353 shares of the Company's common stock in a private placement resulting in net proceeds to the Company of approximately $19.7 million.

Common Stock Issued for Nonrecourse Notes

On April 26, 2012, the Company issued 821,429 shares of its common stock in exchange for a nonrecourse note of $3,058,026 (or approximately $3.71 per share, the "Original Price"). The note payable was due in a single installment on February 28, 2014, and was amended to extend the maturity date to September 30, 2014. The note bears interest at the rate of 0.19% per annum and is secured solely by the underlying stock. The stock purchase agreement contains i) a

right of first refusal held by the Company, whereby if a third party buyer offers to buy the holder's stock at a certain price, then the Company has the right to purchase the stock at that same price; and ii) a standard drag-along in case of a sale of the Company. In lieu of payment, the holder is entitled to offset amounts owed under the nonrecourse note in connection with the Company repurchasing common stock from the holder. The Company has the option (a call option) to repurchase the shares if the holder ceases to provide services to the Company or after September 30, 2014, at the Original Price. The holder has the option (a put option) to require the Company to repurchase the shares at any time at the Original Price.

In accordance with ASC 718-10-25, the purchase of stock in exchange for a nonrecourse note effectively is the same as granting a stock option. If the value of the underlying shares falls below the note amount, the stockholder will relinquish the stock in lieu of repaying the note and would be in the same position as if he or she never purchased the stock. Further, as the shares sold subject to the nonrecourse note are considered an option for accounting purposes, the Company did not record a nonrecourse note or shares outstanding on the balance sheet. The Company also did not recognize interest income on the note as that interest is included in the exercise price of the option. The ultimate holder of the option can only benefit from the instrument if he continues to provide services to the Company through the time of a change in control, as defined. As a change in control was not deemed probable, stock-based compensation expense was not recorded for the year ended December 31, 2013.

In December 2013, the Company issued 27,925 shares of common stock to the holder, subject to a $97,737 nonrecourse note payable by the holder. The accounting for the additional share issuance is consistent with the 821,429 shares discussed above.

Sonkei had a similar arrangement with the consultant, whereby Sonkei issued 1,112,500 shares of its common stock in exchange for a nonrecourse note of €1,119,017 (approximately $1.5 million at December 31, 2013). The note payable is due in a single installment on April 30, 2015. The note bears interest at the rate of 0.19% per annum and is secured solely by the underlying stock. As the shares sold subject to the nonrecourse note are considered an option for accounting purposes, the Company did not record a note or shares outstanding on the balance sheet. The Company also did not recognize interest income on the note as that interest is included in the exercise price of the option.

The ultimate holder of the option can only benefit from the instrument if he continues to provide services to the Company through the time of a change in control, as defined in the applicable agreement. Until a change in control is deemed probable, stock-based compensation expense will not be recorded. The Company assumed this agreement upon the merger with Sonkei, and the Sonkei shares were converted into the Company's common shares in accordance with the terms of the merger agreement (see Note 3 — Business Combinations).

On March 31, 2014, the issuer of the $4.7 million nonrecourse notes, which includes accrued interest, remitted to the Company 348,926 shares of common stock with a fair value of $13.51 per share in full settlement of the outstanding note due in a cashless transaction. Additionally, the Company further modified the awards by cancelling the put option and adding a term whereby upon an IPO the award will vest. The remittance of the shares in exchange for settling the outstanding note, the cancellation of the put option, and the addition of the IPO performance condition, represents a modification of the original terms of the stock options. The effect of these changes is that the Company has modified the awards and has converted approximately 1.3 million stock options with an exercise price of $4.7 million to 926,604 shares of non-vested stock (with no exercise price). The non-vested stock remained subject to the above mentioned vesting conditions of a change in control and IPO, which are not deemed probable until they occur. As described in the preceding sentence, the effect of the modification was to replace stock options that were improbable of vesting with non-vested stock that is improbable of vesting and accordingly, the Company did not recognize stock-based compensation expense for the non-vested stock at the time that the vesting conditions are deemed probable of occurrence. The following is a summary of common shares issued in exchange for nonrecourse notes for the years December 31, 2012 and 2013 and the nine months ended September 30, 2014:

	Common Shares
Outstanding January 1, 2012	—
Issued	821,429
Outstanding December 31, 2012	821,429
Assumed in Sonkei merger	426,176
Issued	27,925
Outstanding December 31, 2013	1,275,530
Repurchased	(348,926)
Shares vested June 30, 2014	926,604

The 926,604 shares of non-vested common stock held by the consultant became probable of vesting upon the effectiveness of the Company's IPO registration statement on June 30, 2014, resulting in a charge for stock-based compensation of approximately $10.5 million, representing the 926,604 shares multiplied by the fair value per share on May 1, 2014, the date the consultant became an employee, less previous compensation expense recorded.

NOTE 10 — STOCK OPTION PLAN

The Company adopted the 2013 Equity Incentive Plan (the Plan) in December 2013, which provides for the issuance of options, stock appreciation rights, stock awards and stock units. On April 30, 2014, the Company increased the shares reserved for issuance under the 2013 Equity Incentive Plan to 3,543,754. 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:

	Stock Options	Weighted-Average Exercise Price
Outstanding January 1, 2013	—	—
Granted	646,759	$ 9.49
Outstanding December 31, 2013	646,759	$ 9.49
Granted	1,975,151	$ 6.05
Outstanding September 30, 2014	2,621,910	$ 6.90
Exercisable September 30, 2014	633,996	$ 6.33

The fair value of each stock option to purchase common stock of the Company granted on December 20, 2013 was estimated by management using the Black-Scholes option pricing model applying the following assumptions: (i) expected term of 5.8 to 10 years, (ii) risk free interest rate of 1.9 to 2.9%, (iii) volatility of 102 to 107%, (iv) no dividend yield and (v) a grant date fair value of common stock of $9.49 per share. The Company recognized stock-based compensation expense for the three and nine months ended September 30, 2014 related to these options of $0.3 million and $0.9 million, respectively, which is included in general and administrative expense.

The table above includes stock options granted on December 20, 2013 to purchase an aggregate of 20,089 shares of the Company's common stock which became fully vested and exercisable on June 30, 2014, the effective date of the Company's IPO registration statement. The Company recognized stock-based compensation expense for the nine months ended September 30, 2014 related to these options of $0.1 million, which is included in general and administrative expense.

The Company entered into two employment agreements effective May 1, 2014. In accordance with the employment agreements, on June 30, 2014, the Company granted 539,116 fully vested stock options to purchase shares of the Company's common shares at an exercise price of $6.00 per share and recognized stock based compensation expense of approximately $2.8 million related to these grants on the grant date. The fair value of each such option was estimated by management using the Black Scholes option pricing model applying the following assumptions: (i) expected term of 6.25 years, (ii) risk free interest rate of 1.9%, (iii) volatility of 113%, (iv) no dividend yield and (v) a grant date fair value of common stock of $6.00 per share.

Under the terms of three employment agreements, the Company issued 955,932 stock options upon the effective date of the Company's IPO registration statement, which vest over a four-year period beginning from November 12, 2013, the date of the Sonkei Merger. The Company recognized stock-based compensation expense related to these options of approximately $0.3 million and $1.1 million for the three and nine months ended September 30, 2014, respectively. The fair value of each such option was estimated by management using the Black Scholes option pricing model applying the following assumptions: (i) expected term of 6.25 years, (ii) risk free interest rate of 1.9%, (iii) volatility of 113%, (iv) no dividend yield and (v) a grant date fair value of common stock of $6.00 per share.

An additional 480,103 options were granted to employees and directors at and following the IPO of which 352,590 options vest over a four year period and 127,513 options vest over a three year period beginning with the date each recipient began providing service. The Company recognized stock-based compensation expense related to these options of approximately $0.3 million and $0.3 million for the three and nine months ended September 30, 2014, respectively. The fair value of each of these options to purchase common stock of the Company granted was estimated by management using the Black Scholes option pricing model applying the following assumptions: (i) expected term of 6-6.25 years, (ii) risk free interest rate of 1.9%, (iii) volatility of 113%, (iv) no dividend yield.

The weighted average grant-date fair value of stock options outstanding on September 30, 2014 was $5.81 per share. Total unrecognized compensation costs related to non-vested awards at September 30, 2014 was approximately $9.6 million and is expected to be recognized within future operating results over a period of 3.1 years. At September 30, 2014, the weighted average contractual term of the options outstanding is approximately 9.6 years. The intrinsic value of outstanding stock options at September 30, 2014 was $0.1 million.

NOTE 11 — INCOME TAXES

There was no provision for income taxes for the three and nine month periods ended September 30, 2014 and 2013 due to losses.

As of December 31, 2013, the Company has approximately $16.0 million of Federal net operating losses that will begin to expire in 2027. As of December 31, 2013, the Company had approximately $11.0 million of New Jersey operating losses that will begin to expire in 2014. As of December 31, 2013, the Company had approximately $0.2 million of federal research and development credits that will begin to expire in 2027. The Internal Revenue Code of 1986, as amended ("IRC") limits the amounts of net operating loss carryforwards that a company may use in any one year in the event of certain cumulative changes in ownership over a three-year period as described in Section 382 of the IRC. The Company has not performed a detailed analysis to determine whether an ownership change has occurred as of December 31, 2013.

Deferred tax liabilities related to indefinite-lived assets typically are not used as a source of income to support realization of deferred tax assets in jurisdictions where tax attributes expire (e.g., jurisdictions where net operating loss carryforwards expire) unless the deferred tax liability is expected to reverse prior to the expiration date of the tax attribute. Therefore, the net operating losses of Sonkei cannot be used to offset the deferred tax liability resulting from the IPR&D due to the fact that the IPR&D currently has an indefinite life while the NOLs have a maximum life of 20 years.

NOTE 12 — COMMITMENTS

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 is approximately 2 years, and the Company is required to make monthly rental payments commencing December 2014. Estimated annual rent payable under this operating lease is approximately $0.1 million per year in each of the two years.

NOTE 13 — RELATED PARTY TRANSACTIONS

An investor provided accounting and other services to the Company and Sonkei for $60 thousand in the aggregate per year during 2013 and early 2014. For the nine months ended September 30, 2014 and 2013, the expense recognized in operating results in connection with these services was $35 thousand and $45 thousand, respectively. For the three months ended September 30, 2014 and 2013, the expense recognized in operating results in connection with these services was $0 and $15 thousand, respectively.

The Company retained the services of certain consultants who were also stockholders of the Company. For the nine months ended September 30, 2014 and 2013, the expense recognized by the Company in connection with these services was $0.3 million and $0.3 million, respectively. For the three months ended September 30, 2014 and 2013, the expense recognized by the Company in connection with these services was $0 and $0.1 million, respectively.

Also refer to Note 8 – Co-Development and License Agreement and Note 9 – Stockholder's Equity for additional related party transactions.

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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 financial statements included in the Prospectus for the year ended December 31, 2013 as filed with the Securities and Exchange Commission on June 30, 2014.

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 domain expertise, we have acquired or in-licensed four development-stage proprietary compounds that we believe have innovative mechanisms of action with potentially positive therapeutic profiles. Our lead product candidates are MIN-101, a compound we are developing for the treatment of patients with schizophrenia, and MIN-202, a compound we are co-developing for the treatment of patients suffering from primary and secondary insomnia. In addition, our portfolio includes MIN-117, a compound for the treatment of patients suffering from major depressive disorder, or MDD and MIN-301, a compound for the treatment of patients suffering from Parkinson's disease. We believe our innovative product candidates have significant potential to transform the lives of a large number of affected patients and their families who are currently not well-served by available therapies in each of their respective indications.

We exclusively licensed MIN-101 from Mitsubishi Tanabe Pharma Corporation, or MTPC, in 2007 with the rights to develop, sell and import MIN-101 globally, excluding most of Asia. In November 2013, we merged with Sonkei Pharmaceuticals Inc., or Sonkei, a clinical-stage biopharmaceutical company and, in February 2014, we acquired Mind-NRG SA, or Mind-NRG, a pre-clinical-stage biopharmaceutical company. We refer to these transactions as the Sonkei Merger and Mind-NRG Acquisition, respectively. Sonkei licensed MIN-117 from MTPC in 2008 with the rights to develop, sell and import MIN-117 globally, excluding most of Asia. With the acquisition of Mind-NRG, we obtained exclusive rights to develop and commercialize MIN-301. We have also entered into a co-development and license agreement with Janssen Pharmaceutica N.V., or Janssen, for the exclusive rights to develop and commercialize MIN-202 in the European Union, subject to royalty payments to Janssen, and royalty rights for any sales outside the European Union.

We have not received regulatory approvals to sell 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 have historically financed our operations, including the development of MIN-101, through the sale of common stock and convertible promissory notes. Likewise, Sonkei raised capital to fund the development of MIN-117 through the sale of common stock and convertible promissory notes. Funds managed by Care Capital and Index Ventures are our principal investors, and were the principal investors of Sonkei, and collectively owned approximately 50% of our capital stock at September 30, 2014. The operations of Mind-NRG were financed through the sale of preferred stock. Funds managed by Index Ventures were among the investors in Mind-NRG.

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.

Operational Update

On June 30, 2014, our registration statement on Form S-1 was declared effective by the Securities and Exchange Commission for our initial public offering, or IPO, pursuant to which we sold an aggregate of 5,454,545 shares of our common stock pursuant to an underwriting agreement dated June 30, 2014, at a price to the public of $6.00 per share, or gross proceeds of approximately $32.7 million. On July 7, 2014, we closed the sale of all such shares, resulting in net proceeds to us of approximately $25.2 million, after deducting the underwriting discount of $2.3 million, expenses

of approximately $3.1 million, the repayment of the bridge loans of $1.4 million and the ProteoSys license fee payment of $0.7 million. On July 7, 2014, we also closed the sale of a private placement of 666,666 common shares resulting in net proceeds to us of approximately $3.7 million, after deducting the underwriting discount. On July 7, 2014, Janssen Research & Development, LLC, or JJDC, purchased 3,284,353 shares of our common stock in a private placement resulting in net proceeds to us of approximately $19.7 million, representing approximately 18% of our outstanding common shares. In accordance with our license agreement for MIN-202, on July 7, 2014 we paid a $22.0 million license fee to Janssen.

On September 22, 2014, we announced that the United States Food and Drug Administration completed its review of the Investigational New Drug Application, or IND, for MIN-202, our selective antagonist for the orexin-2 receptor in development for the treatment of insomnia. A bioavailability study to advance development of MIN-202, which is being developed by us in collaboration with Janssen and JJDC is being initiated by Janssen. The bioavailability study will be the first clinical trial initiated for MIN-202 in the United States. The study will be a randomized, open-label, 3-way crossover study in healthy male subjects to evaluate the bioavailability, food effect, safety and tolerability of solid dosage formulation of MIN-202.

In addition to this study, Janssen is conducting two other phase 1 studies with MIN-202, including a Phase 1b study in patients suffering from secondary insomnia and MDD and a randomized, double-blind, placebo-controlled multiple ascending dose, or MAD, study in healthy male and female subjects. The primary objective of the MAD study is to investigate pharmacokinetic data for several doses of MIN-202 and to explore the safety and tolerability of MIN-202 versus placebo during 10 days of consecutive dose administration.

We are conducting a once daily dose formulation study to evaluate MIN-101 modified release prototype formulations and to evaluate the relationship between the pharmacokinetic profile and cardiovascular parameters following multiple dose administration through our contract research organization, or CRO. We continue to make progress under this study and intend to select a formulation to be used in a Phase IIb study for MIN-101 during 2015. We are currently preparing the necessary regulatory approvals to conduct this Phase IIb multi-country study in Europe, which will evaluate the efficacy of MIN-101 in stabile subjects with schizophrenia suffering from predominantly negative symptoms.

Subject to the receipt of additional financing, we plan to conduct additional clinical trials of MIN-117. We also plan to explore the potential for a collaboration for the future clinical development and commercialization of MIN-117 for the treatment of MDD. We are conducting material scale-up for IND-enabling studies for MIN-301 and will need to obtain additional funding to initiate human trials of MIN-301.

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. 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. We may also selectively explore collaborations with leading pharmaceutical companies to maximize the value of our current product candidate portfolio.

Financial Overview

Presentation

On November 12, 2013, we merged with Sonkei, in order to acquire Sonkei’s lead product candidate, MIN-117. The results of Sonkei are included in our accompanying financial statements commencing November 12, 2013. The fair value of our common stock issued in the merger was determined based on a number of objective and subjective factors, and substantially all of the purchase price was allocated to in-process research and development and goodwill. As part of the acquisition, we assumed $0.7 million of convertible notes, which were converted into 352,000 shares of our common stock on July 7, 2014 at the IPO offering price of $6.00 per share.

At the date of the merger, a Sonkei consultant held 1,112,500 shares of Sonkei common stock paid for with a nonrecourse note, which was treated as a stock option for accounting purposes. For accounting purposes, this stock option would only vest if the consultant continued to provide services to Sonkei through the effective date of a change in control. In connection with the merger, we issued 426,176 shares of common stock to this consultant in order to replace his common stock in Sonkei. We recognized stock-based compensation expense of approximately $10.5 million for this stock grant in our statement of operations upon the effective date of the IPO.

On February 11, 2014, we acquired Mind-NRG in order to acquire Mind-NRG’s lead product candidate, MIN-301. The fair value of the 1,481,583 shares of common stock issued to the stockholders of Mind-NRG was approximately $16.5 million, substantially all of which was allocated to in-process research and development and goodwill.

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

Research and Development Expense. Research and development expense consists of costs incurred in connection with the development of our product candidates, including: fees paid to consultants and 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, bonuses and stock-based compensation granted to consultants and employees in research and development functions. We expense research and development costs as they are incurred.

In the future, we expect research and development expense to consist of the items described above as well as expense incurred in performing research and development activities, including compensation and benefits for full-time research and development employees and facilities expenses. These costs may also include non-cash stock-based compensation expense as part of our

compensation strategy to attract and retain qualified staff. We expect research and development expense to be our largest category of operating expense and to increase as we continue our planned pre-clinical and clinical trials for our product candidates.

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 consulting and professional services costs for functions in executive, finance, business development, legal, auditing and taxes. Historically, substantially all of these services were provided by third party consultants, as none of the three former companies had employees until October 2013. Our general and administrative expenses in 2014 include non-cash stock-based compensation expense with respect to option grants to consultants and employees hired and directors who joined our board of directors subsequent to October 2013. Other costs primarily include salaries, bonuses, facility costs and professional fees for accounting, consulting and legal services.

In the future, we expect general and administrative expenses to consist primarily of salaries and related benefits, facility costs, information technology, travel expenses and professional fees for auditing, tax 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 general and administrative expenses to be higher in 2014 versus the prior year in order to support our operations as a public reporting company, including increased payroll, consulting, legal and compliance, accounting, insurance and investor relations costs.

Foreign Exchange Gains. Foreign exchange gains are comprised primarily of foreign currency exchange gains or losses resulting from clinical trial expenses denominated in Euros. Since our initial planned clinical trials are expected to be in Europe, we expect to continue to incur expenses in Euros. We record 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 gain or loss.

Interest Expense (Income), Net. Interest expense consists of interest incurred under our former debt obligations, including our 8.0% convertible promissory notes and our 8.0% working capital loans. Interest expense under our 8.0% convertible promissory notes includes the amortization of the debt discount related to the beneficial conversion feature of the convertible promissory notes as well as coupon interest. Interest income consists of interest earned on our cash and cash equivalents.

Results of Operations

Comparison of Three Months Ended September 30, 2014 versus September 30, 2013

Research and Development Expenses

Total research and development expenses were $24.7 million for the three months ended September 30, 2014 compared to $0.2 million for the same period in 2013, an increase of $24.5 million. The increase was primarily due to a $22.0 million license fee paid to Janssen pursuant to our co-development agreement for MIN-202, $1.4 million in program costs related to MIN-202 and $1.0 million in higher development costs related to a once daily dose formulation study initiated in 2014 for MIN-101.

General and Administrative Expenses

Total general and administrative expenses were $2.4 million for the three months ended September 30, 2014 compared to $0.3 million for the same period in 2013, an increase of approximately $2.1 million. The increase was primarily due to $1.0 million in expenses related to staffing, office leases and information systems necessary to support our operations, $0.8 million in stock-based compensation expense and $0.3 million in higher legal and professional fees related to intellectual property matters and our operations as a public company.

Foreign Exchange Gains (Losses)

Foreign exchange gains (losses) were $11 thousand for the three months ended September 30, 2014 compared to ($3) thousand for the same period in 2013, an increase of $14 thousand. The increase was primarily due to certain expenses of Mind-NRG and certain clinical activities denominated in Euros, with more positive currency movements in 2014.

Interest (Income)/Expense, Net

Interest expense was $15 thousand for the three months ended September 30, 2014 compared to $3 thousand for the same period in 2013, an increase of $12 thousand. For the three months ended September 30, 2014, we recognized interest expense related to our convertible promissory notes and our 8% short term working capital loans.

Comparison of Nine months Ended September 30, 2014 versus September 30, 2013

Research and Development Expenses

Total research and development expenses was $39.9 million for the nine months ended September 30, 2014 compared to $0.5 million for the same period in 2013, an increase of $39.4 million. The increase was primarily due to a $22.0 million license fee paid to Janssen pursuant to our co-development agreement for MIN-202, $13.0 million in stock-based compensation expense, $1.8 million in higher development costs related to a once daily dose formulation study initiated in 2014 for MIN-101, $1.4 million in program costs related to MIN-202 and $1.2 million in costs related to our other drug development programs. The increase in stock-based compensation expense was primarily due to 926,604 shares of common stock that became vested and resulted in a $10.5 million charge and the issuance of an option to purchase 441,973 shares of common stock to one of our founders.

General and Administrative Expenses

General and administrative expenses totaled $7.5 million for the nine months ended September 30, 2014 compared to $0.6 million for the same period in 2013, representing an increase of approximately $6.9 million. The increase was primarily due to $2.7 million in stock-based compensation expense, $1.9 million in higher legal fees related to intellectual property matters, our IPO and our operations as a public company and $2.3 million in expenses related to staffing, office leases and information systems necessary to support our operations.

Foreign Exchange Gains (Losses)

Foreign exchange gains (losses) were $15 thousand for the three months ended September 30, 2014 compared to ($3) thousand for the same period in 2013, an increase of $18 thousand. The increase was primarily due to certain expenses of Mind-NRG and certain clinical activities denominated in Euros, with more positive currency movements in 2014.

Interest (Income)/Expense, Net

Interest expense was approximately $2.1 million for the nine months ended September 30, 2014 as compared to $0 for the same period in 2013. For the nine months ended September 30, 2014, we recognized interest expense of approximately $2.0 million related to our convertible promissory notes, comprised primarily of the amortization of the debt discount created upon the allocation of proceeds to the beneficial conversion feature of the notes and $82 thousand in coupon interest. For the nine months ended September 30, 2014, we also recorded $16 thousand in interest expense related to our 8% short-term working capital loans.

The convertible promissory notes contained a beneficial conversion feature allowing noteholders to convert the notes and accrued interest into shares of our common stock at a conversion price of $3.50 per common share at any time after April 30, 2014. In conjunction with the IPO, the notes were converted into 352,000 common stock on July 7, 2014. The debt discount related to the intrinsic value of the beneficial conversion feature of approximately $2.0 million was amortized to interest expense using the effective interest method.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred losses and cumulative negative cash flows from operations since our inception in April 2007 and, as of September 30, 2014, we had an accumulated deficit of approximately $67.3 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 September 30, 2014, we had approximately $23.6 million in cash and cash equivalents. We believe that our cash and cash equivalents will be sufficient to fund our operations through the end of 2015.

Initial Public Offering

On June 30, 2014, our registration statement on Form S-1 was declared effective by the Securities and Exchange Commission for our initial public offering pursuant to which we sold an aggregate of 5,454,545 shares of our common stock pursuant to an underwriting agreement dated June 30, 2014, at a price to the public of $6.00 per share, or gross proceeds of approximately $32.7 million. On July 7, 2014, we closed the sale of all such shares, resulting in net proceeds to us of approximately $25.2 million, after deducting the underwriting discount of $2.3 million, expenses of approximately $3.1 million, repayment of the bridge loans of $1.4 million and the

ProteoSys license payment of $0.7 million. On July 29, 2014, we closed the sale of an over-allotment of 160,993 shares of its common stock at a price of $6.00 per share, resulting in net proceeds to us of approximately $0.9 million, after deducting the underwriting discount of approximately $0.1 million.

Private Placement

On July 7, 2014 we also closed the sale of a private placement of 666,666 common shares resulting in net proceeds to us of approximately $3.7 million, after deducting the underwriting discount of $0.3 million.

Janssen Co-Development and License Agreement

On July 7, 2014, JJDC purchased 3,284,353 shares of our common stock in a private placement resulting in net proceeds to us of approximately $19.7 million, representing approximately 18% of our outstanding shares of common stock. In accordance with our license agreement for MIN-202, we paid a $22.0 million license fee to Janssen on July 7, 2014.

Convertible Promissory Notes

During November 2013, we issued 8% convertible promissory notes in the aggregate principal amount of approximately $1.3 million to certain stockholders which were payable by us on June 30, 2014. During November 2013, prior to the merger of Sonkei into us, Sonkei issued convertible promissory notes for €0.5 million (approximately $0.7 million as of July 7, 2014) in aggregate to certain of its stockholders, which we assumed at the time of the merger with Sonkei. The notes had a stated interest rate of 8% per annum. Upon completion of the IPO in July 2014, the outstanding principal balance of the notes and accrued interest were converted into an aggregate of 352,000 shares of common stock at the IPO offering price of $6.00 per share.

Working Capital Loans

In February 2014, we entered into loan agreements for working capital up to a maximum of $0.6 million in connection with the Mind-NRG Acquisition. As of March 31, 2014, the balance outstanding under these loans was $0.5 million, which were repaid in full with accrued interest in April 2014.

In April 2014, we entered into bridge loans with certain Mind-NRG stockholders and their affiliates that provided loan facilities of up to $0.6 million at an annual interest rate of 8.0%, subject to prepayment at any time without penalty. In May 2014, we entered into additional bridge loans with certain Mind-NRG stockholders and their affiliates which provided loan facilities up to a maximum of $1.0 million, at an annual interest rate of 8%, subject to repayment at any time without penalty. The balance outstanding under all such bridge loans were repaid in full with accrued interest in July 2014.

Cash Flows

The table below summarizes our significant sources and uses of cash for the nine months ended September 30, 2014 and 2013:

	Nine months Ended September 30,	
	2014	2013
	(dollars in millions)	
Net cash provided by (used in):		

Operating activities	$ (30.9)	$ (1.0)
Investing activities	1.1	—
Financing activities	51.6	1.9
Net increase in cash	$ 21.8	$ 0.9

Net Cash Used in Operating Activities

Net cash used in operating activities of approximately $30.9 million during the nine months ended September 30, 2014 was due primarily to our net loss of $49.5 million, partially offset by stock-based compensation expense of $15.7 million, interest expense of $2.0 million and a $1.4 million increase in accounts payable and accrued expenses. The net loss included a $22.0 million license fee paid to Janssen pursuant to our co-development agreement for MIN-202.

Net cash used in operating activities of $1.0 million during the nine months ended September 30, 2013 was primarily a result of our net loss of $1.1 million, partially offset by changes in working capital.

Net Cash Provided by Investing Activities

Net cash provided by investing activities in the nine months ended September 30, 2014 primarily consisted of $1.2 million of cash acquired in February 2014 in conjunction with the Mind-NRG Acquisition.

Net Cash Provided by Financing Activities

Net cash provided by financing activities of $51.6 million during the nine months ended September 30, 2014 was due to the net proceeds from our IPO and concurrent private placements of $54.8 million, partially offset by IPO costs paid during the period of $3.1 million.

Net cash provided by financing activities of $1.9 million during the nine months ended September 30, 2013 was due to the proceeds from the sale of common stock.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at September 30, 2014 and the effects such obligations are expected to have on our liquidity and cash flows in future periods (in millions):

	TOTAL	LESS THAN A YEAR	1-3 YEARS	3-5 YEARS	MORE THAN FIVE YEARS
Contractual Obligations:					
Operating lease obligations (1)	$ 0.2	$ 0.1	$ 0.1	—	—
Total contractual cash obligations	$ 0.2	$ 0.1	$ 0.1	—	—

(1) Represents operating lease costs, consisting of leases for office space in Waltham, MA.

Payments under our licenses are not included as contractual obligations in the table above due to the uncertainty of the occurrence of the events requiring payment under these agreements, including our share of potential future milestone and royalty payments. These payments generally become due and payable only upon the achievement of certain clinical development, regulatory or commercial milestones.

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 Securities and Exchange Commission rules.

Critical Accounting Policies and Estimates

In preparing our Condensed Consolidated Financial Statements in accordance with accounting principles generally accepted in the United States of America, or GAAP, and pursuant to the rules and regulations of the SEC, we make assumptions, judgments and estimates that affect the reported amounts of assets, liabilities and expenses, and related disclosures of contingent assets and liabilities. We base our assumptions, judgments and estimates on historical experience and various other factors that we believe to be reasonable under the circumstances. Actual results could differ materially from these estimates under different assumptions or conditions. On a regular basis, we evaluate our assumptions, judgments and estimates. We also discuss our critical accounting policies and estimates with the Audit Committee of our Board of Directors.

We believe that the assumptions, judgments and estimates involved in the accounting for stock-based compensation, stock options, fair value of common stock, in-process research and development, acquisitions, research and development expenses and clinical trial accruals have the greatest potential impact on our Condensed Consolidated Financial Statements. These areas are key components of our results of operations and are based on complex rules requiring us to make judgments and estimates, so we consider these to be our critical accounting policies. Historically, our assumptions, judgments and estimates relative to our critical accounting policies have not differed materially from actual results.

There have been no significant changes in our critical accounting policies and estimates during the nine months September 30, 2014, as compared to the critical accounting policies and estimates disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Prospectus.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, and are adopted by us as of the specified effective date. Our significant accounting policies are described in Note 2 to our financial statements appearing elsewhere in this Form 10-Q. We believe that the impact of 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

Interest Rate Fluctuation Risk

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term duration and limited funds available for investment, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our investment portfolio. A 10% change in interest rates on September 30, 2014 would not have had a material effect on the fair market value of our portfolio.

Foreign Currency Exchange Risk

We contract with CROs and investigational sites and third-party manufacturers in several foreign countries, including several countries in Europe and Russia. Several of these contracts are denominated in Euros, and we are therefore subject to fluctuations in foreign currency rates in connection with these agreements, and recognize foreign exchange gains or losses in our statement of operations. We have not historically hedged our foreign currency exchange rate risk. To date we have not incurred any material effects from foreign currency changes on these contracts.

Further, substantially all of the Mind-NRG operations were conducted in Europe. We have translated their historical financial statements from Euros into U.S. dollars using appropriate exchange rates for purposes of presenting the combined pro forma financial statements. Subsequent to our acquisition of Mind-NRG in February 2014, the U.S. Dollar has become the functional currency of Mind-NRG. We will continue to incur expenses under our development programs primarily in U.S. Dollars and Euros. We may manage our exposure to foreign currency risk with exchange rate contracts based on our forecasted operational needs. A 10% change in the euro-to-dollar exchange rate on September 30, 2014 would not have had a material effect on our results of operations or financial condition.

Inflation Risk

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our business, financial condition or results of operations during the nine months ended September 30, 2014.

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 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 and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2014. Based on the evaluation of our disclosure controls and procedures as of September 30, 2014, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were not effective at a reasonable assurance level because of the identification of the material weaknesses discussed below.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting, other than as set forth below, identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

As of December 31, 2013 and 2012, our independent registered public accounting firm concluded that there were material weaknesses and significant deficiencies in our internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses that we identified related to (1) lack of segregation of duties, (2) lack of personnel competent to perform complex accounting, including stock-based compensation, the convertible promissory notes beneficial conversion features, and income tax disclosures, (3) lack of financial statement disclosure controls, and (4) not performing a risk assessment.

During the period covered by this Quarterly Report on Form 10-Q, we took steps to remediate the material weaknesses in our internal control over financial reporting and have hired additional finance and legal staff to effectively address segregation of duties, develop internal controls over financial reporting and mitigate the control deficiencies identified at December 31, 2013 and 2012. We have also implemented procedures for the effective control and approval of payroll, disbursements, cash management and equity transactions and are performing a formal risk assessment.

Although we have taken measures to remediate the material weaknesses identified by our independent registered public accounting firm, we cannot conclude that we have remediated such material weaknesses. We plan to continue to evaluate our internal controls and make improvements as appropriate.

Notwithstanding our continued material weakness, we have concluded that the financial statements and other financial information included in this Quarterly Report on Form 10-Q fairly present in all material respects our financial condition, results of operations and cash flows as of, and for, the periods presented.

Limitations of the Effectiveness of Internal Controls

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the internal control system are met. Because of inherent limitations in any control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. We are continuously seeking to improve the efficiency and effectiveness of our operations and of our internal controls.

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PART II

Item 1. Legal Proceedings

We are not currently subject to any material litigation or other legal proceeding.

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.

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 year ended December 31, 2013, we reported a net loss of $3.3 million. For the nine months ended September 30, 2014, we reported a net loss of $49.5 million. As of September 30, 2014, we had an accumulated deficit of $67.3 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 September 30, 2014, we had cash and cash equivalents of $23.6 million. We believe that the net proceeds from our initial public offering and the concurrent private placements and our existing cash and cash equivalents, will fund our projected operating requirements through 2015. In particular, we expect these funds will allow us to substantially complete our planned Phase II clinical development for one of our two lead product candidates, MIN-101, as well as to complete the planned Phase Ib clinical development of MIN-202 with Janssen and additional pre-clinical development of MIN-301. However, circumstances may cause us to consume capital more rapidly than we currently anticipate. In any event, we will require significant additional capital to fund the development of our other product candidate, MIN-117, and to fund future clinical trials of our other product candidates, and to obtain regulatory approval for, and to commercialize, our product candidates.

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

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

Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern.

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern, and as a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2013 with respect to this uncertainty. Our ability to continue as a going concern could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. Future reports on our financial statements may include an explanatory paragraph with respect to our ability to continue as a going concern. We have not generated revenues or been profitable since inception, and it is possible we will never achieve profitability. None of our product candidates can be marketed until governmental approvals have been obtained. Accordingly, there is no current source of revenues, much less profits, to sustain our present activities, and no revenues will likely be available until, and unless, our product candidates are approved by the EMA, FDA or comparable regulatory agencies in other countries and successfully marketed, either by us or a partner, an outcome which may not occur. Based upon our currently expected level of operating expenditures, we expect to be able to fund our operations through 2015. This period could be shortened if there are any significant increases in planned spending on development programs or more rapid progress of development programs than anticipated. There is no assurance that other financing will be available when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations and may negatively impact the market price of our common stock.

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, 2013, we had approximately $16.0 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. However, under the Tax Reform Act of 1986, the amount of benefits from our NOL carryforwards may be impaired or limited if we incur a cumulative ownership change of more than 50%, as interpreted by the U.S. Internal Revenue Service, over a three year period. 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 $11.0 million of state net operating carryforwards at December 31, 2013. 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.

Changes in estimates regarding fair value of goodwill and IPR&D 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 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. For intangible assets, 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 conterparties 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.

Risks Related to Our Business and Industry

We are heavily dependent on the success of our two lead product candidates and 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.

We have invested a significant portion of our efforts and financial resources in the licensing and development of our two lead product candidates: (i) MIN-101 for the treatment of schizophrenia and (ii) MIN-117 for the treatment of major depressive disorder, or MDD. We plan to use the substantial majority of our current cash and cash equivalents, including the remaining net proceeds from our initial public offering, to fund a Phase IIb clinical trial of MIN-101 in Europe. In order to develop MIN-117, we will need to obtain additional financing. We may never successfully develop, obtain regulatory approval for, and then successfully commercialize MIN-101 or MIN-117.

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.

We currently hold no Investigational New Drug, or IND, approvals in the United States (other than the IND held by Janssen, our co-development partner for MIN-202), and as a result do not intend to initiate human clinical trials of our product candidates in the United States (other than the clinical trial being initiated in the United States by Janssen, our co-development partner for MIN-202) until 2015 or later. 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, 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.

Initially, we plan to conduct clinical trials in Europe. Applications to commence clinical trials in the European Union are made to member state regulatory authorities. Good Clinical Practice (in the European Union under ICH 1997), or GCP, as incorporated into the EU Clinical Trials Directive 2001/20 and national implementing regulations, set forth the majority of the requirements and procedures for the conduct of trials but national divergences exist especially in relation to insurance and compensation, which will require that we develop a thorough understanding of the specific procedures and requirements for the individual member states in which we chose to conduct the clinical trials. Clinical trials in the European Union also require an ethics committee or institutional review board opinion, and there is often inconsistency as to ethics committee decisions. An ethics committee may ask questions and/or require re-writing or amending a trial protocol, any of which may require that we incur additional expense in order to commence a clinical trial. Even after re-submission to the relevant ethics committee, the application may still ultimately be rejected. After clinical trial authorization, we may be inspected for compliance with GCP by inspectors from the national regulatory authorities. If the inspections provide warnings or require changes, this will cause further delays and cost and we may be restricted from completing the trials.

If, following submission, our NDA or marketing authorization 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 clinical trials related to our product candidates have been limited to six Phase I trials completed between 2002 and 2004 for MIN-101, a Phase IIa trial for MIN-101 completed in 2009, two Phase I trials for MIN-117 completed between 2005 and 2009, and a Phase I trial for MIN-202 completed in 2011. Each of our product candidates has also undergone pre-clinical studies. 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, studies 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 studies. 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;
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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 our two lead 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 IIa, which makes it difficult to assess our ability to develop and commercialize our product candidates.

We commenced operations in 2007 under the name Cyrenaic Pharmaceuticals, Inc., or Cyrenaic, and our operations to date (and those of Sonkei and Mind-NRG, which we have acquired) have been limited to raising capital, identifying potential drug candidates, and undertaking pre-clinical and Phase I and IIa clinical trials. Neither we nor Sonkei have conducted any clinical trials of our two lead product candidates, MIN-101 and MIN-117, since 2009, resulting in our lead product candidates losing patent life without clinical advancement toward potential commercialization.

We have no experience in progressing clinical trials past Phase IIa, obtaining regulatory approvals or commercializing product candidates. We recently merged with Sonkei and acquired Mind-NRG and have limited operating history since the respective merger and acquisition. We may encounter unforeseen expense, 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. For instance, according to Datamonitor, roughly one-third of purported schizophrenia patients may not receive an accurate diagnosis, with negative symptoms more difficult to recognize. The patient discontinuation rate for current schizophrenia drugs is also high. For instance, 66 out of 99 subjects ceased to participate in the

Phase IIa clinical trial of MIN-101. As a result, the process of finding, diagnosing and retaining subjects throughout a clinical trial targeting the negative symptoms of schizophrenia or MDD may prove difficult and costly.

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 efficacy of the product candidate studied for the target indication. For instance, our clinical studies of MIN-101 and MIN-117 did not show statistically significant differences favorable to the investigational products between the treatment and comparator groups on all the studies' primary, secondary and/or exploratory endpoints. While these studies were not powered for statistical significance, regulatory authorities may find that the 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 lead 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, we are prioritizing the clinical trials and development of one of our two lead 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, Cyber 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;

- debar us;
- 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 protein, and, as a protein, 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 subset 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 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 neuropsychiatric 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 neuropsychiatric 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. 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.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for certain pharmaceutical products. The legislation expanded Medicare coverage for outpatient prescription drugs dispensed to the elderly by establishing Medicare Part D and also introduced a new reimbursement methodology based on average sales prices for physician-administered drugs under Medicare Part B. In addition, this legislation provided authority for limiting the number of outpatient prescription drugs that Medicare will cover in any therapeutic class under the Medicare Part D program. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and reimbursement rate that we receive for any of our approved products. While the MMA applies only to pharmacy benefits for Medicare beneficiaries, private payors often follow Medicare and Medicaid coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

More recently, 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 PPACA, 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. Among other things, the PPACA expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for single-source, multiple source innovator and non-innovator drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices. This could increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The PPACA further created a separate AMP for certain categories of drugs generally provided in non-retail outpatient settings. The legislation also extended Medicaid drug rebates, previously due only on fee-for-service utilization, to Medicaid managed care utilization, and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the amount of rebates due on those drugs. The PPACA also expanded the types of entities eligible to receive discounted 340B pricing, although, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs used in orphan indications. In addition, because 340B pricing is determined based on AMP and Medicaid drug rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discounts to increase. The PPACA also imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Furthermore, the PPACA changed the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale-discount off the

negotiated price of applicable brand drugs to certain eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D. The PPACA further created a new approval pathway for biosimilars intended to encourage competition and lower prices, and it amended Medicare Part B reimbursement rules for physician-administered biologic products by making the purchase of lower cost biosimilars more attractive to providers reimbursed by Medicare Part B. As the FDA approves biosimilars, it is possible that similar rules will be adopted by commercial managed care organizations. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners. Notably, a significant number of provisions are not yet, or have only recently become, effective.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, in August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013.

Moreover, the recently enacted Drug Quality and Security Act imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements of this new legislation, manufacturers will be required to provide certain information regarding the drug products they produce to individuals and entities to which product ownership is transferred, label drug products with a product identifier, and keep certain records regarding the drug products. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers will also be required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, and FDA and trading partner notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death. In the European Union, the Falsified Medicines Directive imposes similar requirements, which are expected to add materially to product costs.

We expect that the PPACA, as well as other federal and state healthcare reform measures that have been and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

The full impact of these new laws, as well as laws and other reform measures that may be proposed and adopted in the future, remains uncertain, but may continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs, which could have a material adverse effect on our business operations.

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 harmed, possibly materially.

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

Because we plan 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 and cash equivalents, including the remaining net proceeds from the initial public offering and the concurrent 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. Rogerio Vivaldi and 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 September 30, 2014, we had seven 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.

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.

We have identified material weaknesses and significant deficiencies in our internal control over financial reporting. If we do not remediate the material weaknesses in our internal control over financial reporting, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner. In connection with the preparation of our financial statements for the years ended December 31, 2012 and 2013, we concluded that there were material weaknesses and significant deficiencies in our internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses that we identified related to (1) lack of segregation of duties, (2) lack of personnel competent to perform complex accounting, including stock-based compensation, the convertible promissory notes beneficial conversion features and income tax disclosures, (3) lack of financial statement disclosure controls, and (4) not performing a risk assessment. As of September 30, 2014, certain material weaknesses and significant deficiencies continued to exist, including a lack of segregation of duties.

While we have established certain procedures and control over our financial reporting processes, we cannot assure you that these efforts will remediate our material weaknesses and significant deficiencies in a timely manner, or at all, or prevent restatements of our financial statements in the future. If we are unable to successfully remediate our material weaknesses, or 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.

As a public company, we are required to comply with the SEC's rules that implement Section 41 of the Sarbanes-Oxley Act, which will require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of our internal control over financial reporting commencing with our second annual report. This assessment will need to include the disclosure of any material weaknesses or significant deficiencies in our internal control over financial reporting identified by our management or our independent registered public accounting firm.

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 our initial public offering, we operated without full time employees, relying on the services of consultants, including representatives of our affiliate, Care Capital LLC, to provide certain accounting and finance functions. We have since hired qualified 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 are and will 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 fraud and abuse 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 privacy regulation by the federal government, state governments and foreign jurisdictions in which we conduct our business. The laws that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits, among other things, 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 civil federal 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 criminal federal 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 new 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 Payment Sunshine Act, created under the PPACA, 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.
- Federal government price reporting laws, changed by the PPACA to, among other things, (1) increase the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program and offer such rebates to additional populations and (2) require pharmaceutical companies to calculate and report complex pricing metrics to government programs, with such reported prices to be used in the calculation of reimbursement and/or discounts on a company's marketed drugs. Participation in these programs and compliance with the applicable requirements may subject a pharmaceutical company to potentially significant discounts on its products, increased infrastructure costs and potential limitations on its ability to offer certain marketplace discounts, with any failure to report accurate pricing information resulting in potential exposure to federal False Claims Act liability.
- The Foreign Corrupt Practices Act, or FCPA, 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.
- 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.

Recent health care reform legislation has strengthened these laws. For example, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and HIPAA criminal healthcare fraud statutes such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. Moreover, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal Civil False Claims Act.

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.

Risks Related to Our Dependence on Third Parties

We 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 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. Under the MIN-101 license agreement, we have to achieve the commencement of a clinical pharmacology study containing MIN-101 by the end of April 2015. If we fail to reach this milestone, we may elect to extend the timeline to achieve the milestone by making extension payments. Subject to any extensions, if we fail to achieve this milestone, as it may be extended, MTPC may elect to terminate the MIN-101 license agreement. In addition, under the MIN-117 license agreement, we must have the first subject with MDD enrolled in either a Phase IIa trial or a Phase IIb trial with a product containing MIN-117 by the end of April 2015. We do not intend to use any of our current cash and cash equivalents, including the remaining net proceeds from our initial public offering to pursue the development of MIN-117; therefore, we will need to raise additional financing to achieve this milestone. If we fail to achieve this milestone, we may elect to extend the timeline to achieve the milestone by making extension payments. Subject to any extensions, if we fail to achieve this development milestone, MTPC may elect to terminate the MIN-117

license agreement. MTPC may also terminate the licenses following a material breach by us or certain insolvency events. If our license agreements with MTPC are terminated, our business would be seriously harmed.

Our co-development and license agreement with Janssen provides us with European 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 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 to 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. In particular, we plan to explore the potential for partnerships for the clinical development of MIN-117. 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, certain of our U.S. patents relating to methods of diagnostic indication and methods of screening for agents for MIN-301 are expected to expire as early as 2021 and 2022, respectively. 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.

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 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 Leahy-Smith 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 Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, are now effective. While it is still not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business, the Leahy-Smith 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 patent or pending patent application 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 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 Our Common Stock

The market price of our stock may be volatile, and you could 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.

In addition, companies listed on The NASDAQ Global Market, and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and material adverse impact on the market price of our common stock.

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 73% of our voting stock as of September 30, 2014. 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.

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 potential clinical trials for our two lead product candidates, MIN-101 and MIN-117. 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 3,543,754 stock options 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.

Our management will continue to have broad discretion over the use of the proceeds we received in our initial public offering 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 remaining net proceeds from our initial public offering and concurrent private placements, 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 and concurrent private placements, their ultimate use may vary substantially from their currently intended use. If we do not invest or apply the net proceeds from our initial public offering and concurrent private placements in ways that enhance stockholder value, we may fail to achieve the expected financial results, which could cause our stock price to decline.

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. Even after we no longer qualify as an emerging growth company, we may qualify as a “smaller reporting company” which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. 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.

In addition, Section 102 of the JOBS Act also provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. An “emerging growth company” can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

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

As a newly public company listed in the United States, we will 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 intend to invest resources to comply with evolving laws, regulations and standards, and this investment will result 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. 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

Unregistered Sales of Equity Securities

On July 7, 2014, concurrent with the completion of our initial public offering described below, certain of our stockholders purchased 666,666 shares of our common stock for $6.00 per share in a private placement, resulting in total net proceeds from this transaction of approximately $3.7 million and Janssen Pharmaceutica N.V. purchased 3,284,353 shares of our common stock for $6.00 per share in a private placement, resulting in total net proceeds from this transaction of approximately $19.7 million. The sales of these shares were not registered under the Securities Act of 1933, as amended, in reliance on the exemptions set forth under Section 4(2) thereof and Rule 506 of Regulation D thereunder.

Use of Proceeds

On July 7, 2014, we closed our IPO, in which we issued and sold 5,454,545 shares of common stock at a public offering price of $6.00 per share, for aggregate gross proceeds to us of $32.7 million. All of the shares issued and sold in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-195169), which was declared effective by the SEC on June 30, 2014. Jefferies LLC acted as sole book-running manager and representatives of the several underwriters. The offering commenced on June 30, 2014 and did not terminate before all of the securities registered in the registration statement were sold.

The net offering proceeds to us, after deducting underwriting discounts and commissions totaling approximately $2.3 million and offering expenses totaling approximately $3.1 million, were approximately $27.3 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates. We have invested a portion of the net offering proceeds into money market securities.

There has been no material change in the planned use of proceeds from our IPO as described in our Prospectus.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

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

Exhibit Number	Description
3.1[(1)]	Amended and Restated Certificate of Incorporation.
3.2[(2)]	Amended and Restated Bylaws.
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

(1) Incorporated herein by reference to Exhibit 3.1 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-195169), filed on June 10, 2014.

(2) Incorporated herein by reference to Exhibit 3.2 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-195169), filed on June 10, 2014.

+ 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.

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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/ Geoff Race
Geoff Race
Chief Financial Officer (Principal Financial Officer)
(On behalf of the Registrant)

Date: November 6, 2014