Minerva Neurosciences, Inc.
Form 10-Q
August 07, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2014

OR

o 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.)
245 First St, Suite 1800, Cambridge, MA	**02142**
(Address of Principal Executive Offices)	(Zip Code)

Registrant s telephone number, including area code: **(617) 444-8444**

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 o NO x

Explanatory Note: The registrant became subject to the filing requirements of Section 13 of the Securities Exchange Act of 1934 on June 30, 2014.

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 o

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

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

18,439,482 shares, $0.0001 par value per share, were outstanding as of August 6, 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, projects, should, would and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Because of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not transpire. These risks and uncertainties include, but are not limited to, the risks included in this Quarterly Report on Form 10-Q under Part II, Item IA, Risk Factors and 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.

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PART I

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Balance Sheets

(Unaudited)

		June 30, 2014		December 31, 2013
Assets				
Current assets				
Cash and cash equivalents	$	480,009	$	1,818,317
Prepaid expenses		33,213		852
Total current assets		513,222		1,819,169
Equipment, net		27,165		3,232
In-process research and development		34,200,000		19,000,000
Goodwill		15,104,239		7,918,387
Deferred public offering costs		3,111,744		433,998
Total assets	**$**	**52,956,370**	**$**	**29,174,786**
Liabilities and Stockholders Equity				
Current liabilities				
Accounts payable	$	4,324,673	$	522,981
Accrued expenses and other current liabilities		2,338,465		815,239
Convertible promissory notes		2,007,518		58,270
Loans payable		1,382,817		
Derivative liability				10,093
Total current liabilities		10,053,473		1,406,583
Deferred taxes		13,668,600		7,588,600
Total liabilities		23,722,073		8,995,183
Commitments and contingencies				
Stockholders equity				
Common stock; $.0001 par value; 125,000,000 shares authorized; 8,520,925 and 6,112,738 shares issued and outstanding as of June 30, 2014 and December 31, 2013, respectively		852		611
Additional paid-in capital		69,367,316		38,008,783
Accumulated deficit		(40,133,871)		(17,829,791)
Total stockholders equity		29,234,297		20,179,603
Total liabilities and stockholders equity	**$**	**52,956,370**	**$**	**29,174,786**

See accompanying notes to condensed consolidated financial statements

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MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Operations

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	**2013**	**2014**	**2013**
Expenses				
Research and development	$ 14,554,662	$ 249,845	$ 15,140,598	$ 353,782
General and administrative	3,095,173	128,942	5,132,565	296,335
Total expenses	17,649,835	378,787	20,273,163	650,117
Loss from operations	(17,649,835)	(378,787)	(20,273,163)	(650,117)
Foreign exchange gains	10,549		3,987	
Interest expense	(1,726,380)		(2,035,583)	
Interest income	4	2,834	679	2,834
Net loss	$ (19,365,662)	$ (375,953)	$ (22,304,080)	$ (647,283)
Net loss per share, basic and diluted	$ (2.55)	$ (0.10)	$ (3.07)	$ (0.17)
Weighted average shares outstanding, basic and diluted	7,604,503	3,916,774	7,255,648	3,740,593

See accompanying notes to condensed consolidated financial statements

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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
Vesting of common shares issued	926,604	93	10,542,577		10,542,670
Stock-based compensation			4,274,270		4,274,270
Net loss				(22,304,080)	(22,304,080)
Balances at June 30, 2014	**8,520,925**	**$ 852**	**$ 69,367,316**	**$ (40,133,871)**	**$ 29,234,297**

See accompanying notes to condensed consolidated financial statements

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MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

	Six Months Ended June 30,	
	2014	**2013**
Cash flows from operating activities		
Net loss	$ (22,304,080)	$ (647,283)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4,271	
Amortization of debt discount recorded as interest expense	1,949,248	
Stock-based compensation expense	14,816,940	
Change in fair value of derivative	(10,093)	
Changes in operating assets and liabilities		
Prepaid expenses	10,565	
Accounts payable	1,229,363	
Accrued expenses and other liabilities	520,209	78,928
Net cash used in operating activities	(3,783,577)	(568,355)
Cash flows from investing activities:		
Cash acquired in business combination	1,167,869	
Net cash provided by investing activities	1,167,869	
Cash flows from financing activities		
Proceeds from working capital loans	1,882,817	
Repayments of working capital loans	(500,000)	
Proceeds from sales of common stock		1,850,000
Public offering costs paid	(105,417)	
Net cash provided by financing activities	1,277,400	1,850,000
Net (decrease) increase in cash and cash equivalents	(1,338,308)	1,281,645
Cash and cash equivalents		
Beginning of period	1,818,317	200,314
End of period	$ 480,009	$ 1,481,959
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	6,080,000	
Less assets acquired:		
Prepaid expenses	42,926	
Equipment	28,204	
In-process research and development	15,200,000	
Goodwill	7,185,852	
Cash acquired in business merger	$ 1,167,869	$
Deferred public offering costs included in accrued expenses and other liabilities	$ 3,006,327	$

See accompanying notes to condensed consolidated financial statements

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MINERVA NEUROSCIENCES, INC.

Notes to Condensed Consolidated Financial Statements

For Six Months Ended June 30, 2014

(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 development stage biopharmaceutical company focused on the development of an experimental drug for the treatment of schizophrenia (discussed further in Note 6 License Agreement). The Company has historically operated as a virtual company with no employees and managed by its Board of Directors. On November 12, 2013, Sonkei Pharmaceuticals, Inc. (Sonkei), a development stage 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 will become effective simultaneously with the closing of an IPO and an initial upfront license payment of $22.0 million. The Company completed an IPO on July 7, 2014 and paid the $22.0 million license fee in July 2014.

Going Concern

The Company has limited capital resources and has incurred recurring operating losses and negative cash flows from operations since inception. As of June 30, 2014, the Company has an accumulated deficit of approximately $40.1 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 $29.9 million, including the over allotment and the proceeds of the Mind-NRG private investment, and after deducting the underwriter discount of $2.6

million, expenses of $3.1 million, loan repayments of $1.4 million and the $0.7 million ProteoSys license fee payment. 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 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 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 June 30, 2014 and the results of operations for the three and six months ended June 30, 2014 and 2013 and cash flows for the six months ended June 30, 2014 and 2013. The results of operations for the three and six months ended June 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.

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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 consolidated financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

The Company utilizes significant estimates and assumptions in determining the fair value of its common stock. The board of directors has 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. Costs for certain development activities, such as clinical trials are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided by vendors on their actual costs incurred. 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 financial statements as prepaid or accrued expenses.

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.

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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 based on fair value over the requisite service period of the awards. The Company will determine 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. The method incorporates various assumptions such as the risk-free interest rate, expected volatility, expected dividend yield, expected forfeiture rate and expected life of the options.

Grants to non-employees are accounted for in accordance with ASC-505-50 *Equity Based Payments to Non-Employees*. The date of expense recognition is the earlier of the date at which a commitment for performance by the counterparty to earn the equity instrument is reached or the date at which the counterparty s performance is complete. The Company determines the fair value of share-based awards granted to non-employees similar to the way fair value of awards are determined for employees except that certain assumptions used in the Black-Scholes option-pricing model, such as expected life of the option, may be different and the fair value of each unvested award is adjusted at the end of each period for any change in fair value from the previous valuation until the award vests.

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. Uncertain tax positions are evaluated in accordance with this topic and if appropriate, the amount of unrecognized tax benefits are recorded within deferred tax assets. 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 clarifies the accounting for uncertainty in income taxes recognized in the consolidated financial statements. The interpretation 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 six months ended June 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 2010 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 initial public offering on July 7, 2014, these amounts will be offset against the proceeds of the offering.

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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 tested its goodwill for impairment as of November 30. There was no impairment of goodwill for the year ended December 31, 2013. The Company believes there was no impairment for the three and six months ended June 30, 2014.

Convertible promissory notes

The Company s convertible promissory notes at June 30, 2014 consist of (i) $1.3 million face value convertible promissory notes, plus accrued interest of approximately $67,000 and (ii) 518,519 face value convertible promissory notes, plus accrued interest of approximately $35,000. 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. At June 30, 2014, the fair market value and carrying of the convertible promissory notes is approximately $2.0 million.

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. The derivative is carried at fair value and is 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.

As of March 31, 2014, the fair value of the derivative liability was determined to be $4,900 using a probability-weighted valuation model applying the following assumptions: (i) discount rate of 8.0%, (ii) remaining term of approximately 3 months and (iii) the probabilities of conversion under various circumstances as at the date of measurement. The $5,193 decrease in the fair value of the derivative liability was recognized in interest expense as a gain on change in fair value of derivative liability for the three months ended March 31, 2014.

As of June 30, 2014, the fair value of the derivative liability was determined to be $0. The $4,900 decrease in the fair value of the derivative liability was recognized in interest expense as a gain on change in fair value of derivative liability for the three months ended June 30, 2014.

$3.50/ 3.50 Conversion Option

The Company s 8% convertible promissory notes contain 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 has been included in the balance sheets at June 30, 2014 and December 31, 2013 as a discount to the related convertible promissory notes. The discount was accreted as non-cash interest expense over the expected term of the debt (June 30, 2014) using the effective interest method, which totaled approximately $1.7 million and $2.0 million for the three and six months ended June 30, 2014, respectively.

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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.

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 which 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 purchase price allocation below is based on February 11, 2014 financial information and may be adjusted upon the completion of the final valuation. The final valuation is expected to be completed as soon as practicable but no later than one year from the consummation of the acquisition. 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		7,185,852
In-process research and development		15,200,000
Deferred tax liability		(6,080,000)
Accrued expenses		(321,417)
Proteosys milestone payable		(681,600)
	$	16,541,834

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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 $6.1 million has been recorded for the difference in the book and tax basis of the IPR&D, multiplied by the effective income tax.

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 accompanying 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		7,918,387
In-process research and development		19,000,000
Accrued expenses		(334,423)
Derivative liability		(3,476)
Deferred taxes		(7,588,600)
Convertible promissory notes (see Note 7)		(680,000)
	$	18,943,366

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The above cash was obtained by Sonkei in a November 6, 2013 financing and thus has been classified as a financing activity in the consolidated statements of cash flows. 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 $7.6 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.

Pro Forma Results

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 six months ended June 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.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	**2013**	**2014**	**2013**
Operating loss	$ (19,365,662)	$ (928,569)	$ (22,756,955)	$ (1,571,977)
Loss per share	$ (2.55)	$ (0.13)	$ (2.99)	$ (0.22)

NOTE 4 ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities consist of the following:

	June 30, 2014	**December 31, 2013**
Research and development costs	$ 350,784	$ 58,117
Professional fees (1)	210,000	595,215
Expenses due to related parties	177,230	126,910
Interest payable	114,429	24,276
Vacation pay	26,090	5,690
Bonus (2)	486,000	
ProteoSys milestone payable (3)	682,250	
Primomed research funding (4)	236,294	
Consulting and other costs	55,388	5,031
	$ 2,338,465	$ 815,239

(1) Included in accrued professional fees at June 30, 2014 and December 31, 2013 are $0.2 million and $0.4 million, respectively, incurred in connection with the preparation of a public offering of the Company s common stock.

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(2) Under the terms of certain employment agreements, the Company is obligated to pay $0.5 million in bonuses upon the completion of an IPO. The Company s registration statement was declared effective on June 30, 2014 and thus, the bonuses became probable. The portion accrued as of June 30, 2014 represents the amortization of the bonus expense from the date of the employment agreements through June 30, 2014.

(3) Under the terms of the acquisition agreement for Mind-NRG, the Company is obligated to make a 0.5 million (or $0.7 million, as converted) milestone payment to ProteoSys by the earlier of January 1, 2015, or upon completion of an IPO, or equity financing of at least $5.0 million.

(4) 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Net loss	$ (19,365,662)	$ (375,953)	$ (22,304,080)	$ (647,283)
Weighted average shares of common stock outstanding	7,604,503	3,916,774	7,255,648	3,740,593
Net loss per share of common stock basic and diluted	$ (2.55)	$ (0.10)	$ (3.07)	$ (0.17)

The following securities outstanding at June 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:

	June 30, 2014	June 30, 2013
Non-vested stock issued (see Note 9 Stockholders Equity)		821,429
Common stock options	2,141,807	

The above table does not include the potentially dilutive securities that would be issuable under the convertible promissory notes outstanding as described in Note 7 Debt.

NOTE 6 LICENSE AGREEMENT

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 which 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 six months ended June 30, 2014 and 2013.

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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.

At June 30, 2014, the balance outstanding under the April and May Bridge Loan agreements was approximately $1.4 million, which has been included under loans payable. Interest expense related to these loans for the three and six months ended June 30, 2014 was $11 thousand.

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 June 30, 2014). These notes have a stated interest rate of 8% per annum, mature on June 30, 2014, and are payable on demand on such date. The notes contains certain terms of default, under which conditions the interest rate increases to 11% per annum.

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) contain identical terms and may be converted into common shares of the Company

under the following conditions;

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%. A qualified financing shall mean the first sale of the qualified stock, in one transaction or series of related transactions with aggregate gross proceeds to the Company of at least $5.0 million, which sale or sales shall take place on or before the maturity date; provided, however, that an IPO shall not be deemed a qualified financing. A qualified financing is defined as a transaction (or a series of transactions) with gross proceeds to the Company of at least $5.0 million, which takes place on or before June 30, 2014.

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. Under the terms of the Notes, an IPO is not considered a qualified financing.

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.

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Discount Purchase Option

The Notes contain 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.

As of March 31, 2014, the fair value of the derivative liability was determined to be $4,900 using a probability-weighted valuation model applying the following assumptions: (i) discount rate of 8.0%, (ii) remaining term of approximately 3 months and (iii) the probabilities of conversion under various circumstances as at the date of measurement. The $5,193 decrease in the fair value of the derivative liability was included as a component of interest expense for the three months ended March 31, 2014.

As of June 30, 2014, the fair value of the derivative liability was determined to be $0. The $4,900 decrease in the fair value of the derivative liability was included as a component of interest for the three months ended June 30, 2014.

$3.50/ 3.50 Conversion Option

The Notes contain 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 which 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 Notes maturity date of June 30, 2014.

On April 25, 2014, the Company amended the convertible promissory notes such that the option to convert the outstanding principal and interest into common shares at a conversion price of $3.50 per share on or after April 30, 2014 was extended to September 30, 2014. Also, in the event that the Company files a registration statement for an IPO with the Securities and Exchange Commission and it becomes effective by September 30, 2014, the $3.50/ 3.50 conversion option will be cancelled.

As of June 30, 2014 and December 31, 2013, the convertible promissory notes and debt discount are as follows:

	June 30, 2014	December 31, 2013
Convertible promissory notes	$ 1,991,754	$ 1,973,500
Debt discount		(1,937,269)
Foreign exchange effect on Euro denominated notes	15,764	22,039

	$ 2,007,518	$	58,270

For the three months ended June 30, 2014, the Company recognized interest expense of $1.7 million related to the Notes, comprised primarily of the amortization of the debt discount and $40 thousand in coupon interest. For the six months ended June 30, 2014, the Company recognized interest expense of approximately $2.0 million related to the Notes, which includes $1.9 million for the amortization of the debt discount and $79 thousand in coupon interest.

NOTE 8 CO-DEVELOPMENT AND LICENSE AGREEMENT

Upon completion of the Company s IPO and payment of a $22.0 million license fee in July 2014, the Company closed on a co-development and license agreement dated February 12, 2014, pursuant to which, among other things, 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 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. 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, the Company made an initial upfront payment of $22.0 million in July 2014 which will be expensed in the third quarter of 2014 and will pay a quarterly royalty in the high single digits on the 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 in the high single digits on the aggregate net sales for MIN-202 products sold by the licensor outside the European Union.

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.

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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 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 have 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). The reverse stock split 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 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.

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 June 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 June 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 is not deemed probable, stock-based compensation expense was not recorded for the year ended December 31, 2013 or the six months ended June 30, 2014.

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.

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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. As a change in control is not deemed probable, stock-based compensation expense will not be recorded until a change in control occurs at the then fair value of the option. 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 is still 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 will 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 six months ended June 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)
Balance 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	1,495,048	$	6.00
Outstanding June 30, 2014	2,141,807	$	7.05
Exercisable June 30, 2014	594,930	$	6.33

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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 six months ended June 30, 2014 related to these options of $0.3 million and $0.6 million, respectively, which is included in general and administrative expense.

The table above includes stock options granted on December 20, 2013 to purchase 20,089 of the Company s common stock which became fully vested and exercisable upon June 30, 2014, the effective date of the Company s IPO registration statement. The Company recognized stock-based compensation expense for the six months ended June 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. The aggregate salaries are $655,000 plus an annual bonus target of 50% of their annual salaries and a one-time bonus to one of the employees of $175,000 to be paid within seven days following the closing of an IPO. The employment agreements can be terminated with six-months notice and contain severance provisions. In addition, the employment agreements provide for the grant of (1) an aggregate of 539,116 fully vested stock options to purchase common shares of the Company at an exercise price equal to the common stock price issued to the public in connection with an IPO and (2) stock options to purchase an aggregate number of common shares such that, upon the closing of an IPO, the holders will have options equal to 2.2% of the number of fully diluted shares of the Company, which vest over four years. In addition, under the employment agreement with the CEO, the Company is obligated to grant stock options to purchase an aggregate number of common shares such that, upon the pricing of an IPO, the CEO will have options equal to 5% of the number of fully diluted shares of the Company, which vest over 4 years.

In accordance with these employment agreements, 539,116 stock options were granted upon the effective date of the Company s IPO registration statement, and were 100% vested on the grant date. The Company recognized stock-based compensation expense related to these options of approximately $2.8 million for the three and six months ended June 30, 2014. The fair value of each stock option to purchase common stock of the Company granted on June 30, 2014 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 1.94%, (iii) volatility of 113%, (iv) no dividend yield and (v) a grant date fair value of common stock of $6.00 per share.

Also in accordance with the above three employment agreements, an additional 955,932 stock options were granted upon the effective date of the Company's 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 $0.8 million for the three and six months ended June 30, 2014. The fair value of each stock option to purchase common stock of the Company granted on June 30, 2014 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 1.94%, (iii) volatility of 113%, (iv) no dividend yield and (v) a grant date fair value of common stock of $6.00 per share.

The weighted average fair value of stock options granted in June 2014 was $5.11 per share. Total unrecognized compensation costs related to non-vested awards at June 30, 2014 was approximately $8.0 million and is expected to be recognized within future operating results over a period of 3.3 years. At June 30, 2014, the weighted average contractual term of the options outstanding is approximately 9.9 years. The intrinsic value of outstanding stock options at June 30, 2014 was zero.

NOTE 11 INCOME TAXES

There was no provision for income taxes for the three and six month periods ended June 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 (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 November 2013, the Company hired a Chief Executive Officer (CEO) pursuant to an employment contract, which calls for a base salary of $425,000 plus bonus of up to 50% of base salary, a special bonus of $250,000 upon successful consummation of an IPO and severance arrangements if terminated for cause or terminated not for cause. In addition, on December 20, 2013, the CEO was granted an option to purchase 5%, or 540,722 shares, of the outstanding common stock of the Company with an exercise price equal to the per share fair value of the Company on such date, which was $9.49 per share. The option will vest ratably over 4 years. Further, upon the pricing of an IPO, which occured on June 30, 2014, the CEO was granted an anti-dilution option to purchase a number of shares of common stock of the Company, with an exercise price equal to $6.00, such that when the option and anti-dilution option are aggregated, the CEO will hold 5% of fully diluted outstanding shares expected to be outstanding on the closing of the IPO. In accordance with this agreement, the Company granted options to purchase 498,621 common shares of the Company discussed in Note 10 - Stock Option Plan.

On February 11, 2014, the Company entered into an agreement with Quotient Ltd, a Contract Research Organization based in Nottingham, UK to conduct a two-part study to evaluate the pharmacokinetic profile of MIN-101 modified release prototype formulations, and to evaluate the relationship between the pharmacokinetic profile and cardiovascular parameters following multiple dose administration. The total cost of the project is 1.6 million (or $2.2 million, as converted).

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NOTE 13 RELATED PARTY TRANSACTIONS

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

The Company retained the services of certain consultants who were also stockholders of the Company. For the six months ended June 30, 2014 and 2013, the expense recognized by the Company in connection with these services was $0.3 million and $0.2 million, respectively. For the three months ended June 30, 2014 and 2013, the expense recognized by the Company in connection with these services was $0.2 million and $0.1 million, respectively.

The Company s convertible promissory notes and loans payable are held by certain stockholders and their affiliates. Accrued interest payable of approximately $0.1 million as listed in Note 7 at June 30, 2014 relates to these promissory notes and bridge loans. Interest expense for the six month periods ended June 30, 2014 and 2013 was $2.0 million and $0, respectively.

NOTE 14 SUBSEQUENT EVENTS

The Company evaluated subsequent events for financial reporting purposes through August 7, 2014, the date which the financial statements were available to be issued to determine whether any events occurred that required disclosure in the accompanying financial statements.

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. Net proceeds to the Company were 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 7, 2014, 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 of $0.3 million.

On July 7, 2014, in accordance with the license agreement for MIN-202, Johnson & Johnson Development Corporation, or JJDC, an affiliate of Janssen Pharmaceutica N.V., or Janssen, 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.

In July 2014, in accordance with the Company s license agreement for MIN-202 (see Note 8), the Company paid a $22.0 million license fee to Janssen which will be expensed in the third quarter of 2014.

In conjunction with the IPO, the Company s 8% convertible promissory notes due June 30, 2014 in the face amount of $1.3 million and 518,519 ($0.7 million as of June 30, 2014), including $0.1 million in accrued interest, were converted at the IPO price of $6.00 per share into 352,000 shares of the Company s common stock.

In July 2014, the Company repaid its outstanding working capital loans and accrued interest of approximately $1.4 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, resulting in net proceeds to the Company of approximately $0.9 million, after deducting the underwriting discount of approximately $0.1 million.

In July 2014, in accordance with certain employment agreements, the Company granted stock options to purchase an aggregate of 366,562 shares of common stock at an exercise price of $6.00 per share to certain employees and directors of the Company for which the Company will begin to recognize stock-based compensation expense in the third quarter of 2014. These options vest over four years.

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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 the consolidated financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q and with our annual audited consolidated financial statements included in the Prospectus for the year ended December 31, 2013 as filed with the Securities and Exchange Commission on June 30, 2014.

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-117, a compound we are developing for the treatment of patients suffering from major depressive disorder, or MDD. In addition, our portfolio includes MIN-202, a compound we are co-developing for the treatment of patients suffering from primary and secondary insomnia, and MIN-301, a compound we are developing 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 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. In addition, neither Sonkei nor Mind-NRG have received any regulatory approvals to sell any product candidates and have also incurred significant operating losses since their respective inceptions in 2008 and 2010.

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 76% of our capital stock at June 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.

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 an aggregate 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 of $0.3 million.

On July 7, 2014, in accordance with our license agreement for MIN-202, 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 conjunction with the private placement and in accordance with our license agreement for MIN-202, on July7, 2014 we paid a $22.0 million license fee to Janssen. 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.

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Financial Overview

Presentation

Our results include the accounts of Mind-NRG from February 12, 2014 to June 30, 2014, reflecting the Mind-NRG Acquisition, which was effective on February 11, 2014 and accounted for using the acquisition method. The purchase price of approximately $16.5 million was primarily assigned to in-process research and development of $15.2 million and goodwill of $7.2 million, offset by a deferred tax liability of $6.1 million. On the effective date of the acquisition, Mind-NRG had no employees and minimal clinical activity.

Financial Operations Overview

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

Research and Development Expense. Research and development expense consists of costs incurred in connection with the development of our product candidates, including: fees paid to consultants and clinical research organizations, or CROs, including in connection with our non-clinical and clinical trials, and other related clinical trial fees, such as for investigator grants, patient screening, laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis; licensing fees; costs related to acquiring clinical trial materials; costs related to compliance with regulatory requirements; and costs related to salaries, 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.

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 in 2011 through 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 subsequent to October 2013. Other costs primarily include salaries, bonuses, facility costs and professional fees for accounting, consulting and legal services.

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 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.

Costs Associated with the Acquisitions and Financings

On November 12, 2013, Cyrenaic Pharmaceuticals, Inc., or Cyrenaic, merged with Sonkei, with Cyrenaic being the surviving company, which was renamed Minerva. In the merger, 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 of Cyrenaic common stock to the former Sonkei stockholders. Although there were certain venture funds that were common stockholders of each of Sonkei and Cyrenaic, 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 our accompanying financial statements commencing November 12, 2013. We merged with Sonkei in order to acquire Sonkei s lead product candidate, MIN-117.

At the date of the merger, a Sonkei consultant 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, we issued 426,176 shares of common stock to this consultant in order to replace the holder s common stock in Sonkei. Due to the nonrecourse note, these shares were treated as stock options for accounting purposes and the holder of the option could only vest in the stock options if the holder continues to provide services to us through the time of a change in control. As a change in control was not deemed probable as of the merger date, the value of the options have not been included as part of the consideration transferred in the merger for accounting purposes. Rather, we will recognize all of the non-cash stock-based compensation expense of approximately $10.5 million for these stock options in our statement of operations upon the effective date of the IPO. The merger accounting purchase price was therefore determined based upon the remaining 1,997,192 shares of common stock issued in the merger at a valuation of $9.49 per share for a total purchase price of approximately $18.9 million.

The fair value of our common stock issued in the merger 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 initial public offering of common stock or our sale. Substantially all of the purchase price was allocated to in-process research and development and goodwill. As part of the acquisition, we also assumed 0.5 million ($0.7 million as of June 30, 2014) of convertible notes, which have a stated interest rate of 8%. The outstanding principal balance of the notes and accrued but unpaid interest was converted into common stock on July 7, 2014 at the IPO offering price of $6.00 per share.

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We acquired Mind-NRG in February 2014 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. The fair value of the common shares issued and the allocation of the purchase price was based upon our valuation of our common stock as approved by our board of directors. Substantially all of the purchase price was allocated to in-process research and development and goodwill.

In connection with the acquisition, we entered into loan agreements for working capital up to a maximum of $0.6 million. The Mind-NRG loans have an interest rate of 8% per annum that is added to the principal. The Mind-NRG loans, including accrued interest, were repaid in full in April 2014 for $0.5 million. We subsequently entered into two loan agreements with certain stockholders for $0.6 million and $1.0 million, the April Bridge Loan and the May Bridge Loan, respectively. The outstanding balance of these loans as of June 30, 2014 was $0.6 million and $0.8 million, respectively. Both bridge loans and accrued interest thereon were repaid in full in July 2014. As part of the Mind-NRG Acquisition, we have agreed to pay ProteoSys a final license payment of 0.5 million ($0.7 million as of June 30, 2014) following the closing of the IPO. This payment was made in July 2014.

Results of Operations

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

Research and Development Expenses

Research and development expenses totaled $14.6 million for the three months ended June 30, 2014 compared to $0.3 million for the same period in 2013, an increase of $14.3 million. Research and development expenses are summarized in the following table (in thousands):

	Three Months Ended June 30,	
	2014	2013
Research and development expenses (1)	$ 1,589	$ 250
Non-cash stock-based compensation (2)	12,966	
Total research and development expenses	$ 14,555	$ 250

(1) Research and development expenses were $1.6 million for the three months ended June 30, 2014 compared to $0.3 million for the same period in 2013, an increase of $1.3 million. This increase was principally attributable to $0.5 million higher drug development program costs primarily due to a study initiated in 2014 to evaluate the pharmacokinetic profile of MIN-101, $0.3 million higher development costs in 2014 due to the addition of MIN-117 as a result of the Sonkei Merger in November 2013 and $0.5 million in additional development costs related to MIN-301 as a result of the Mind-NRG Acquisition in February 2014.

(2) Research and development expenses included $13.0 million in non-cash stock-based compensation expense for the three months ended June 30, 2014 as compared to $0 for the same period in 2013. The increase in stock-based compensation expense was due to $10.5 million related to previously issued common shares that became probable of vesting upon the effective date of our IPO registration statement. An additional $2.3 million was related to an option grant to one employee on the effective date of the IPO registration statement that was 100% vested on that date.

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, including MIN-202, which we licensed from Janssen upon the completion of our IPO in July 2014. Under this license agreement we made a $22.0 million license fee payment in July 2014, which will be included in research and development expense in the third quarter of 2014.

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 the Company s 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.

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General and Administrative Expenses

General and administrative expenses totaled $3.1 million for the three months ended June 30, 2014 compared to $0.1 million for the same period in 2013, representing an increase of approximately $3.0 million. General and administrative expenses are summarized in the following table (in thousands):

	Three Months Ended June 30,	
	2014	2013
General and administrative expenses (1)	$ 1,061	$ 129
IPO bonus expense (2)	486	
Non-cash stock-based compensation (3)	1,548	
Total general and administrative expenses	$ 3,095	$ 129

(1) General and administrative expenses were $1.1 million for the three months ended June 30, 2014 compared to $0.1 million for the same period in 2013, representing an increase of approximately $1.0 million. The increase in general and administrative expenses in 2014 was due primarily to higher legal and professional fees of $0.6 million related to intellectual property matters and preparing for our operation as a public reporting company and $0.4 million related to staffing, office leases and information systems as we invest in the infrastructure necessary to support the Company s operations.

(2) In accordance with three employment agreements, we recorded $0.5 million for IPO related bonus payments that were probable on June 30, 2014.

(3) General and administrative expenses included $1.5 million in non-cash stock-based compensation expense for the three months ended June 30, 2014 as compared to $0 for the same period in 2013. The increase in stock-based compensation expense was due to $0.3 million related to options granted in December 2013. An additional $1.2 million was due to certain option grants made on the effective date of the IPO registration statement.

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 including non-cash stock-based compensation. 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 that general and administrative expenses will increase as a result of merging with Sonkei, the acquisition of Mind-NRG and licensing MIN-202 from Janssen. In addition, we expect to incur greater expenses relating to 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 were $11 thousand for the three months ended June 30, 2014 compared to $0 for the same period in 2013. The increase in foreign exchange gains was due primarily to certain expenses of Mind-NRG and certain clinical activities being denominated in Euros, with more positive currency movements in 2014.

Interest (Income)/Expense, Net

Interest expense was $1.7 million for the three months ended June 30, 2014 compared to $0 for the same period in 2013. For the three months ended June 30, 2014, we recognized interest expense of approximately $1.7 million related to our convertible promissory notes, comprised primarily of the amortization of the debt discount related to the debt discount created upon allocation of proceeds to the beneficial conversion feature of the notes and $40 thousand in coupon interest. For the three months ended June 30, 2014, we also recorded $11 thousand in interest expense related to our 8% short term working capital loans.

The convertible promissory notes contain 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. On April 25, 2014, the convertible promissory notes were amended to provide for conversion only after September 30, 2014. The notes were converted into common stock in conjunction with our IPO on July 7, 2014. 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. We recorded a debt discount for the intrinsic value of the beneficial conversion feature which was limited to the proceeds of the convertible promissory 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 notes maturity date of June 30, 2014.

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Comparison of Six Months Ended June 30, 2014 versus June 30, 2013

Research and Development Expenses

Research and development expenses totaled approximately $15.1 million for the six months ended June 30, 2014 compared to $0.4 million for the same period in 2013, an increase of $14.7 million. Research and development expenses are summarized in the following table (in thousands):

	Six Months Ended June 30,	
	2014	**2013**
Research and development expenses (1)	$ 2,175	$ 354
Non-cash stock-based compensation (2)	12,966	
Total research and development expenses	$ 15,141	$ 354

(1) Research and development expenses were approximately $2.2 million for the six months ended June 30, 2014 compared to $0.4 million for the same period in 2013, an increase of $1.8 million. This increase was principally attributable to $0.6 million in higher drug development program costs associated with a study initiated in 2014 to evaluate the pharmacokinetic profile of MIN-101, $0.5 million in higher development costs in 2014 due to the addition of MIN-117 as a result of the Sonkei Merger in November 2013 and $0.7 million in additional development costs related to MIN-301 as a result of the Mind-NRG Acquisition in February 2014.

(2) Research and development expenses included $13.0 million in non-cash stock-based compensation expense for the six months ended June 30, 2014 as compared to $0 for the same period in 2013. The increase in stock-based compensation expense was due to $10.5 million related to previously issued common shares that became probable of vesting upon the effective date of our IPO registration statement. An additional $2.3 million was related to an option grant to one employee on the effective date of the IPO registration statement that was 100% vested on that date.

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, including MIN-202, which we licensed from Janssen upon the completion of our IPO in July 2014. Under this license agreement we made a $22.0 million license fee payment in July 2014, which will be included in research and development expense in the third quarter of 2014.

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 the Company s available resources, as well as an ongoing assessment as to each product candidate s commercial potential. We will need to raise additional capital or may seek additional product collaborations in the future in order to complete the development and commercialization of our product candidates.

General and Administrative Expenses

General and administrative expenses totaled $5.1 million for the six months ended June 30, 2014 compared to $0.3 million for the same period in 2013, representing an increase of approximately $4.8 million. General and administrative expenses are summarized in the following table (in thousands):

	Six Months Ended June 30,	
	2014	**2013**
General and administrative expenses (1)	$ 2,796	$ 296
IPO bonus expense (2)	486	
Non-cash stock-based compensation (3)	1,851	
Total general and administrative expenses	$ 5,133	$ 296

(1) General and administrative expenses totaled $2.8 million for the six months ended June 30, 2014 compared to $0.3 million for the same period in 2013, representing an increase of approximately $2.5 million. The increase in general and administrative expenses in 2014 was due primarily to $1.1 million in higher legal and professional fees related to intellectual property matters and preparing for our operation as a public reporting company, and $1.4 million in higher costs related to staffing, consultants, office leases and information systems as we build the infrastructure necessary to support the Company s operations. We incurred legal and other professional fees associated with the acquisition of Mind-NRG in February 2014, which costs are expensed as incurred. We also incurred professional fees associated with entering into the co-development and licensing agreement with Janssen in February 2014 and engaging valuation specialists.

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(2) In accordance with three employment agreements, we recorded $0.5 million for IPO related bonus payments that were probable as of June 30, 2014.

(3) General and administrative expenses included approximately $1.9 million in non-cash stock-based compensation expense for the six months ended June 30, 2014 as compared to $0 for the same period in 2013. The increase in stock-based compensation expense was due to $0.6 million related to options granted in December 2013. An additional $1.3 million was due to certain option grants that became vested upon the effective date of the IPO registration statement.

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 including non-cash stock-based compensation. 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 that general and administrative expenses will increase as a result of merging with Sonkei, the acquisition of Mind-NRG and licensing MIN-202 from Janssen. In addition, we expect to incur greater expenses relating to 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 were $4 thousand for the three months ended June 30, 2014 compared to $0 for the same period in 2013. The increase in foreign exchange gains was due primarily to certain expenses of Mind-NRG and certain clinical activities being denominated in Euros, with more positive currency movements in 2014.

Interest (Income)/Expense, Net

Interest expense was approximately $2.0 million for the six months ended June 30, 2014 compared to $0 for the same period in 2013. For the six months ended June 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 related to the debt discount created upon allocation of proceeds to the beneficial conversion feature of the notes and $79 thousand in coupon interest. For the six months ended June 30, 2014, we also recorded $11 thousand in interest expense related to our 8% short term working capital loans.

The convertible promissory notes contain 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. On April 25, 2014, the convertible promissory notes were amended to provide for conversion only after September 30, 2014. The notes were converted into 352,000 common stock in conjunction with our IPO on July 7, 2014. 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. We recorded a debt discount for the intrinsic value of the beneficial conversion feature which was limited to the proceeds of the convertible promissory 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 notes maturity date of June 30, 2014.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred losses and cumulative negative cash flows from operations since our inception in April 2007 and, as of June 30, 2014, we had an accumulated deficit of approximately $40.1 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 incur additional costs associated with being a public company. At June 30, 2014, we had $0.5 million in cash and cash equivalents.

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 an aggregate 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.

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, in accordance with our license agreement for MIN-202, 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 conjunction with the private placement and in accordance with our license agreement for MIN-202, on July7, 2014 we paid a $22.0 million license fee to Janssen.

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Convertible Promissory Notes

During November 2013, we issued 8% convertible promissory notes for approximately $1.3 million in aggregate to certain stockholders which are 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 (or $0.7 million, as converted) in aggregate to certain stockholders which we assumed at the time of the merger with Sonkei and which are payable by us on June 30, 2014. The notes have 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 common stock at the offering price of $6.00 per share, resulting in the issuance of 352,000 shares of common stock.

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.

On April 30, 2014 we entered into the April Bridge Loan with certain stockholders and their affiliates. The April Bridge Loan provides loan facilities of $0.6 million, of which we have drawn $0.6 million, with an annual interest rate of 8% and is repayable at the time we complete an IPO or December 1, 2015. The April Bridge Loan contains standard terms of default, under which the interest rate would increase to 11% per annum. Any amount outstanding may be repaid at any time without penalty. As of June 30, 2014, the balance outstanding under these loans was $0.6 million, which were repaid in full with accrued interest in July 2014.

On May 22, 2014, we entered into the May Bridge Loan with certain stockholders and their affiliates. The May Bridge Loan provides loan facilities up to a maximum of $1.0 million, at an annual interest rate of 8% and is repayable at the time we complete an IPO or December 1, 2015. The May Bridge Loan contains standard terms of default, under which the interest rate would increase to 11% per annum. Any amount outstanding may be repaid at any time without penalty. As of June 30, 2014, the balance outstanding under these loans was $1.4 million, which 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 six months ended June 30, 2014 and 2013:

	Six Months Ended June 30,	
	2014	**2013**
	(dollars in millions)	
Net cash provided by (used in):		
Operating activities	$ (3.8)	$ (0.6)

Investing activities		1.2		
Financing activities		1.3		1.9
Net (decrease) increase in cash	$	(1.3)	$	1.3

Net Cash Used in Operating Activities

Net cash used in operating activities of approximately $3.8 million during the six months ended June 30, 2014 was due primarily to our net loss of $22.3 million, partially offset by non-cash interest expense of $1.9 million, non-cash stock-based compensation expense of $14.8 million and a $1.8 million increase in accounts payable, accrued expenses and other liabilities. Net cash used in operating activities of $0.6 million during the six months ended June 30, 2013 was primarily a result of our net loss of $0.6 million.

Net Cash Provided by Investing Activities

Net cash provided by investing activities in the six months ended June 30, 2014 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 $1.3 million during the six months ended June 30, 2014 was due to the net proceeds from several working capital loan agreements of $1.4 million, partially offset by IPO costs paid during the period of $0.1 million. Net cash provided by financing activities of $1.9 million during the six months ended June 30, 2013 was due to the proceeds from the sale of common stock.

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Contractual Obligations and Commitments

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

Payments Due by Period (in millions)

	TOTAL	LESS THAN A YEAR	1-3 YEARS	3-5 YEARS	MORE THAN FIVE YEARS
Contractual Obligations:					
Operating lease obligations(1)	$ 0.1	$ 0.1			
Bridge Loans(2)	$ 1.4	$ 1.4			
License fee(3)	0.7	0.7			
Total contractual cash obligations	$ 2.2	$ 2.2	$	$	$

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

(2) Represent amounts payable under the April and May 2014 Bridge Loans as of June 30, 2014, discussed below.

(3) Represents license fee payable with respect to MIN-301 to ProteoSys SA for 0.5 million ($0.7 million as of June 30, 2014). This license fee was paid in July 2014.

Payments under our licenses described below are not considered contractual obligations 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.

In April 2014 we entered into the April Bridge Loan for a maximum of $0.6 million. In May 2014 we entered into the May Bridge Loan for up to a maximum of $1.0 million. All loan facilities were repaid with interest upon the completion of the IPO in July 2014.

On February 11, 2014, we entered into an agreement with Quotient Ltd, a Contract Research Organization based in Nottingham, UK to conduct a two-part study to evaluate the pharmacokinetic profile of MIN-101 modified release prototype formulations, and to evaluate the relationship between the pharmacokinetic profile and cardiovascular parameters following multiple dose administration. The total cost of the project is 1.6 million, ($2.2 million, as converted). As of June 30, 2014 we have paid approximately $0.4 million under the contract.

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

Our management s discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our financial statements appearing elsewhere in this Form 10-Q, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

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Stock-Based Compensation

Stock-based compensation for non-employees has been a significant expense of the Company. We had one warrant issuance which required stock based compensation consideration and which was terminated in 2012, as described below. We also had a share issuance to a non-employee subject to a non-recourse promissory note (described below in the section titled Consultant Equity Issuance), which is treated for accounting purposes as if it were a stock option, and therefore we would recognize expense under this accounting policy. We issued stock options to an employee and two consultants in December 2013.

We determine the fair value of share-based awards using the Black-Scholes option-pricing model to determine the fair value of stock option awards. Inputs to this model requires management to apply judgment and make assumptions and estimates, including with respect to:

- the expected term of the issuance;

- the risk free interest rate, which we estimate based on the U.S. Treasury instruments whose term was consistent with the term of the warrants;

- the expected volatility of the underlying common stock, which we estimate based on the historical volatility of a peer group of comparable publicly traded life sciences and biotechnology companies with product candidates in similar stages of clinical development, as we do not have significant trading history for our common stock; and

- the fair value of our common stock determined on the date of grant, as described below.

Consultant Equity Issuance

In February 2009, we entered into a warrant agreement with an affiliate of a consultant who provides services associated with the clinical development of our drug compound. The warrant was exercisable at any time through February 28, 2014. The number of shares of our common stock subject to this warrant was dependent upon an anti-dilution formula based upon maintaining a 20% ownership after each of the common stock purchase agreement closings by the Care Capital and Index Ventures family of venture capital funds, with the total warrant shares not to exceed 1,785,714 shares, or the Warrant Shares. The exercise price of the warrant equaled the sum of $3.50, or the Numerator, plus the quotient obtained by $142 thousand divided by the number of Warrant Shares outstanding, however the Numerator would increase by 2% for each quarter the warrant was outstanding. The warrant agreement also included a performance based provision for the quantity of the Warrant Shares that could be exercised. The warrant became fully vested on May 31, 2010 upon our successful completion of specific clinical milestones. Subsequent to the date of vesting, we increased the number of warrant shares on October 26, 2011 and April 25, 2012, as a result of the anti-dilution provision described above. We determined that the warrant qualified as an equity instrument.

As of April 25, 2012, the warrant was exercisable for 821,429 shares of common stock issuable at an exercise price of $3.71 per share. On April 26, 2012, the warrant agreement was cancelled and replaced with a common stock subscription agreement for the purchase of 821,429 shares of common stock, which was immediately exercised. We have accounted for the warrant cancellation and the concurrent replacement with a common stock subscription agreement as a modification in accordance with ASC 718-20-35-8 as further discussed below.

We estimated the fair value of the warrant using the Black-Scholes option-pricing model. On April 26, 2012 we issued 821,429 shares of common stock in exchange for a nonrecourse note payable in principal amount of $3.1 million (equivalent to approximately $3.71 per share, or the original price). The note payable was originally due in a single installment on February 28, 2014, which was extended to March 31, 2014. We have the option (a call option) to repurchase the shares if the holder ceases to provide services to us or after February 28, 2014, which was extended to March 31, 2014, at the original price. The holder has the option (a put option) to require us to repurchase the shares at any time at the original price. Through December 31, 2013, neither the put nor call options were exercised and the notes were settled as described below in March 2014.

In accordance with ASC 718-10-25, the purchase of stock in exchange for a non-recourse loan effectively is the same as granting a stock option. If the value of the underlying shares falls below the loan amount, the stockholder will relinquish the stock in lieu of repaying the loan 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, we have not recorded a note or reflected these shares as outstanding on our balance sheets. The ultimate holder of the option can only benefit from the instrument if he continues to provide services to us through the time of a change in control, as defined. As a change in control is not deemed probable, stock-based compensation expense will not be recorded until a change in control occurs at the then fair value of the option.

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Our arrangements with the holder of the 821,429 shares noted above include a continuing anti-dilution obligation with respect to the shares owned by that holder through the date of the our initial public offering. In connection with such arrangement, we have an obligation to issue additional shares to the holder each time we issue shares to certain investors, such that the holder s ownership percentage remains constant relative to the shares held by certain investors. Subsequent to the April 26, 2012 issuance of 821,429 shares to the holder discussed above, we sold an additional 171,429 and 528,571 shares to certain investors during 2012 and 2013, respectively. We issued 27,925 shares to the holder at a purchase price of $3.50 per share (subject to the corresponding note payable) in December 2013 in accordance with the anti-dilution agreement. Since Sonkei had a similar arrangement with the holder, upon the Sonkei Merger 426,176 shares of our common stock were issued under the same arrangement. The accounting for the additional share issuance is consistent with the 821,429 shares discussed above as the stock was purchased for a non-recourse loan, which is effectively the same as the granting of a stock option. At December 31, 2013 there were 1,275,530 shares issued under this arrangement subject to the promissory notes in the aggregate principal amount of $4.7 million.

Share Repurchase in Settlement of Nonrecourse Notes

In March 2014, the issuer of the $4.7 million nonrecourse notes, which includes accrued interest, remitted to us 348,926 shares of common stock with a fair value of $13.51 per share in full settlement of the outstanding notes in a cashless transaction. Additionally, we further modified the awards by cancelling the put option and adding a term providing for the award to vest. The original issuance of the shares and the nonrecourse notes were accounted for as a stock option, with no stock-based compensation expense recognized, as the ultimate holder of the option could only vest in the stock option if he continued to provide services to us through the time of a change in control, which is not deemed probable until the change in control occurs.

The remittance of the shares in exchange for settling the outstanding notes, the cancellation of the put option, and the addition of the vesting provision if an IPO occurs, represents a modification of the awards. This modification resulted in the conversion of approximately 1.3 million stock options with an aggregate exercise price of $4.7 million to 926,604 shares of stock that are considered non-vested stock for accounting purposes with no exercise price. These shares became probable of vesting for accounting purposes upon the effective date of the IPO registration statement on June 30, 2014. Accordingly we recognized stock-based compensation expense of approximately $10.5 million for 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.

Stock Options

We established our stock option plan in the fourth quarter of 2013, and we amended and restated our stock option plan in the second quarter of 2014. The amended and restated plan provides for the issuance of up to 3,543,754 shares of common stock, subject to automatic annual increases pursuant to the terms of the plan, each to be issued at the then fair value of our underlying common stock. We will recognize compensation cost relating to share-based payment transactions in net loss using a fair-value measurement method, in accordance with Financial Accounting Standards Board Accounting Standards Codification (ASC) 718 *Compensation-Stock Compensation*.

The following table presents the grant dates of stock options outstanding as of June 30, 2014 with the corresponding exercise price for each option grant and our current estimate of the fair value per share of our common stock on each grant date, which we utilize to calculate stock-based compensation.

DATE OF GRANT	NUMBER OF SHARES UNDERLYING OPTIONS GRANTED	EXERCISE PRICE PER SHARE	CURRENT ESTIMATE OF COMMON STOCK FAIR VALUE PER SHARE ON GRANT DATE
December 20, 2013	646,759	$ 9.49	$ 9.49
June 30, 2014	1,495,048	6.00	$ 6.00

We estimated the fair value of the options granted on June 30, 2014 using the Black-Scholes option pricing model with the following assumptions: (i) expected term of 6.25 years, (ii) volatility of 113%, (iii) risk free interest rate of 1.94% and (iv) a dividend yield of zero. At June 30, 2014, options to purchase 2,141,807 shares of our common stock were outstanding, 594,930 of which are vested as of June 30, 2014. The intrinsic value of outstanding options as of June 30, 2014 is zero.

Fair Value of Common Stock

We were a private company with no active public market for our common stock. We utilized significant estimates and assumptions in determining the fair value of our common stock. We performed these valuations as of April 26, 2012, November 12, 2013, December 31, 2013, February 11, 2014, and March 31, 2014, or the Valuation Dates. The April 26, 2012 and November 12, 2013 valuation dates were based upon the dates of warrants issued pursuant to the above warrant agreement. The November 13, 2013 and February 11, 2014 valuation dates were related to the date of the issuance of shares in connection with the Sonkei Merger on November 11, 2013 and the Mind-NRG Acquisition. The March 31, 2014 valuation date related to the share repurchase in settlement of non-recourse notes described above.

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In conducting the valuations, our board of directors, with input from management considered objective and subjective factors that we believed to be relevant for each valuation conducted, including our best estimate of our business condition, prospects and operating performance at each valuation date. Within the valuations performed, we used a range of factors, assumptions and methodologies. The significant factors included:

- our results of operations, financial position and the status of research and development efforts;
- the lack of liquidity of our common stock as a private company;
- our stage of development and business strategy and the material risks related to our business and industry;
- the achievement of enterprise milestones, including entering into collaboration and license agreements, and the likelihood of entering into such agreements;
- the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies;
- any external market conditions affecting the life sciences and biotechnology industry sectors;
- the likelihood of achieving a liquidity event for the holders of our common stock and stock options, such as an initial public offering, or IPO, or a sale of our company, given prevailing market conditions;
- the state of the IPO market for similarly situated privately held biotechnology companies;
- general U.S. and global economic conditions; and
- our most recent valuations prepared in accordance with methodologies outlined in the 2013 American Institute of Certified Public Accountants Technical Practice Aid.

We 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 our common stock. The Practice Aid prescribes several valuation approaches for setting the value of an enterprise, such as the cost, income and market approaches, and various methodologies for allocating the value of an enterprise to its common stock. The cost approach establishes the value of an enterprise based on the cost of reproducing or replacing the property, less depreciation and functional or economic obsolescence, if present. The income approach establishes the value of an enterprise based on the present value of future cash flows that are reasonably reflective of our company s future operations, discounting to the present value with an appropriate risk-adjusted discount rate or capitalization rate. The market approach is based on the assumption that the value of an asset is equal to the value of a substitute asset with the same characteristics. Given our stage of development we did not utilize the cost approach or market approach to determine our enterprise value for any of the periods discussed below. We utilized the income approach for the valuation periods.

The various methods for allocating the enterprise value across our classes and series of capital stock to determine the fair value of our common stock in accordance with the Practice Aid include the following:

- *Current Value Method, or CVM.* Under the current value method, once the fair value of the enterprise is established, the value is allocated to the various series of preferred and common stock based on their respective seniority, liquidation preferences or conversion values, whichever is greatest. This method was utilized in the valuations discussed below.

- *Option Pricing Method, or OPM.* Under the OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The values of the preferred and common stock are inferred by analyzing these options. Given that we had one class of stock and one warrant arrangement issued through November 2013, this method was not utilized in the valuations discussed below.

- *Probability-Weighted Expected Return Method, or PWERM.* The PWERM is a scenario-based analysis that estimates the value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class. We utilized the PWERM in the valuations dated November 12, 2013, December 31, 2013, February 11, 2014, and March 31, 2014 to quantify the effect on valuation of common stock associated with the Sonkei Merger, the Mind-NRG Acquisition and implementation of the plan towards the IPO.

There are significant judgments and estimates inherent in the determination of the fair value of our common stock. These judgments and estimates include assumptions regarding our future operating performance, the time to completing an IPO or other liquidity event and the determination of the appropriate valuation methods. If we had made different assumptions, our stock-based compensation expense, net loss and net loss per common share could have been significantly different.

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We estimated the per share common stock fair value by allocating the enterprise value using the CVM or PWERM for the Valuation Dates. One of the key inputs into this model is the future estimated cash flows of us using management s estimate of patient populations, market penetration and compliance rates, expected launch date, price and costs per unit sold, selling, general and administrative expenses, capital expenditures, and long term growth factors. We used comparable companies to develop growth and other trend rates that we built into our expected cash flow model. We selected companies within the biopharmaceutical industry and in Phase II development, or those that were in Phase III with similar characteristics. We selected a group of comparable publicly traded companies and we calculated market multiples using each company s stock price and other financial data. We used industry standard studies to assess cumulative technical success probabilities for each phase of development. Using this data, we computed an estimate of our enterprise value. This expected future cash flows model was utilized for all periods in which the valuations were done, without changes to expected timing or net financial outcome. The December 2013, November 2013, February 11, 2014 and March 31, 2014 valuations utilized this discounted expected future cash flows, and also the expected outcomes as derived from the PWERM model.

The estimated future cash flows were then converted to present value using a 20% discount rate. The 20% discount was based on studies done of similar-stage biopharmaceutical companies, and reflected the single capital instrument that we had outstanding (common stock) until November 2013 when our capital structure also included the convertible bridge loans. After the issuance of the bridge loans we changed our discount rate to 17% to reflect the change in capital structure.

In addition, we applied a discount to reflect the lack of marketability of our common stock for those PWERM scenarios that did not utilize an IPO option. We based this discount on various put option analyses and considered the degree of risk for companies in the biotechnology industry.

Valuation of the Net Assets Acquired in the Sonkei Merger and Mind-NRG Acquisition

Pursuant to Accounting Standards Codification Topic 805, we are required to determine the fair value of the assets and liabilities acquired to provide insight as to the combined condensed pro forma balance sheet. The following summarizes the principle considerations utilized:

- The purchase price was determined based upon the fair value of the shares issued utilizing the above discussed value of the Minerva shares ($9.49 per share) on the date of the Sonkei Merger and $11.17 on the date of the Mind-NRG Acquisition.

- The fair value acquired net current assets and assumed convertible promissory notes are approximate to the book value of such assets and liabilities due to the short term nature of the net current assets. The terms of the convertible promissory notes are similar to other venture stage instruments in the biotechnology industry, and given the short term nature of the notes, the fair value of the notes is considered to be approximate to its carrying value.

- The intangible assets acquired are the significant assets of each company are valued at fair value as discussed below. The methods commonly used to develop indications of value for an intangible asset are the Income, Market, and Cost approaches.

- The Income Approach focuses on the income-producing capability of an asset. The Income Approach incorporates the calculation of the present value of future economic benefits, such as cash earnings, cost savings, tax deductions and proceeds from disposition proceeds. Indications of value are developed by discounting expected cash flows to the present value at a rate of return that incorporates the risk-free rate for the use of funds, the expected rate of inflation and risks associated with the particular investment. The discount rate selected is generally based on rates of return available from alternative investments of similar type and quality.

- The Market Approach measures the benefits of an asset through an analysis of recent sales or offerings of comparable property. Sales and offering prices are adjusted for differences in location, time of sale, utility and the terms and conditions of sale between the asset being appraised and comparable properties.

- The Cost Approach measures the benefits related to an asset by the cost to reconstruct or replace it with another of like utility. To the extent that the assets being analyzed provide less utility than new assets, the reproduction or replacement cost new would be adjusted to reflect appropriate physical deterioration, functional obsolescence and economic obsolescence.

We 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 computed fair value of the IPR&D represented substantially all of the purchase price, after consideration of the net current assets acquired and the assumed convertible promissory notes.

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Prior to determining the value of each intangible asset described above, it is standard methodology as part of an acquisition to perform a business enterprise value analysis. This analysis incorporates all potential economics that the acquired business would theoretically recognize under a fair value scenario. The business enterprise analysis incorporates a stand-alone forecast of us. The purpose of this is to provide a reasonableness check to substantiate the assumptions used in other portions of the analysis. The basis of the business enterprise analysis includes management s estimates regarding projected operating cash flows for the acquired businesses.

We utilized the net present value model under the Income Approach to arrive at the net cash flows attributable to each asset acquired. The estimated future cash flows were then converted to present value using a 17.5% discount rate in the case of the Sonkei acquisition and 19.9% in the case of Mind-NRG Acquisition. The 17.5% discount was based on studies done of similar-stage biopharmaceutical companies, and reflects the weighted average cost of capital including the convertible promissory notes. The 19.9% discount rate reflects the similar weighted average cost of capital, except that there was a greater weight to equity instruments after the issuance of the Sonkei merger shares.

We evaluated whether the fair value per share would be significantly different between December 31, 2013 and February 11, 2014, the date of the Mind-NRG Acquisition, and concluded that there was a change in fair value per share based upon the Mind-NRG Acquisition and proximity to the IPO. We estimated that a share of our common stock had a value of $11.17 per share at February 11, 2014, an increase of $1.68 from the prior valuation at December 31, 2013. This valuation utilized a 17% discount factor and a 10% discount for lack of marketability. We utilized a PWERM methodology to assign the possible enterprise values assuming various IPO pricing and technology sale scenarios in light of the closer proximity to our initial public offering. The discount factor reflects the weighted average cost of capital between the common stock and the convertible promissory notes. The board of directors did not believe there was a significant change in our clinical or regulatory status between December 2013 and February 2014.

IPO

We note that, as is typical in IPOs, the public offering price for the offering was not derived using a formal determination of fair value, but was determined by negotiation between us and the underwriters. Among the factors that were considered in setting this public offering price were the following: an analysis of the typical valuations seen in recent IPOs for companies in our industry; the general condition of the securities markets and the recent market prices of, and the demand for, publicly traded common stock of generally comparable companies; an assumption that there would be a receptive public trading market for clinical stage biopharmaceutical companies such as us; and an assumption that there would be sufficient demand for our common stock to support an offering of the size contemplated.

In-Process Research and Development

In-process research and development, or IPR&D, assets represent a capitalized incomplete research project that we acquired through a business combination. 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. IPR&D represents projects that have not yet received regulatory approval and are required to be classified as indefinite-lived assets until the successful completion or the abandonment of the associated research and development efforts. These project costs include expenses incurred over the course of drug development programs such as previous and current pre-clinical trial expenses, intellectual property costs, drug product development, testing expenses and other related activities. These IPR&D projects represent a material demand on liquid resources to fund the completion of the development programs.

If regulatory approval is received, the associated IPR&D is amortized over the expected useful life. The determination of the useful life is estimated by management based on many inputs including: the number and types of patents that cover the drug product, the period of time before the related patent or patents expire, changes in the regulatory environment, the approval of competing therapies or compounds, changes in applicable laws or regulations and a variety of other circumstances.

Impairment testing is performed on the IPR&D asset at least annually or when a potential triggering event occurs, to determine whether the asset may be impaired. Potential triggering events that could indicate whether an impairment to the IPR&D may have occurred include: clinical trial results where the compound under investigation did not meet pre-established criteria or clinical endpoints, failure to obtain regulatory approval, the inability to fund future clinical trials, failure to obtain patent protection, adverse changes in the regulatory environment, the approval of competing therapies or compounds, adverse changes in applicable laws or regulations and a variety of other circumstances. The impairment of IPR&D could have a material adverse impact on our financial condition. In order to determine whether an impairment has occurred, management must evaluate the events and incorporate multiple assumptions including: costs associated with continuing the development program, competing therapies or compounds, potential market size, estimated future cash flows and other factors.

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Acquisitions

The Sonkei Merger and the acquisition of Mind-NRG were accounted for using the acquisition method of accounting, which requires 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. We engaged a third party advisor to assist in the valuation of the intangible assets. These valuations incorporated many assumptions including calculations for projected cash flows based on estimates for market size, patient populations, expected launch dates, product development costs, capital expenditures and long term growth rates.

Acquisition costs are expensed as incurred. We recognize separately from goodwill the fair value of assets acquired and the liabilities assumed. We 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.

Impairment testing is performed at least annually on November 30, or when a potential triggering event occurs, to determine whether the asset may be impaired. The impairment of goodwill could have a material adverse impact on our financial condition. In order to determine whether an impairment has occurred, management must evaluate the events and incorporate multiple assumptions about future cash flows including costs associated with continuing the development program, changes in strategy or potential market size and other factors.

Research and Development Expenses and Clinical Trial Accruals

Since our inception, we have focused our resources on our research and development activities, including conducting non-clinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for our products. Substantially all of these services are recognized on an outsourced basis. We recognize research and development expenses as they are incurred.

We expense payments for the acquisition and development of technology as research and development costs if, at the time of payment: the technology is under development; is not approved by the U.S. Food and Drug Administration or other regulatory agencies for marketing; has not reached technical feasibility; or otherwise has no foreseeable alternative future use.

As part of the process of preparing our financial statements, we are required to estimate our expenses resulting from our obligations under contracts with vendors and consultants and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. Our clinical trial accrual is dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors.

Our objective is to reflect the appropriate clinical trial expenses in our financial statements by matching those expenses with the period in which services and efforts are expended. We account for these expenses according to the progress of the trial as measured by patient progression and

the timing of various aspects of the trial. We determine accrual estimates through discussion with applicable personnel and outside service providers as to the progress or state of completion of clinical trials, or the services completed. During the course of a clinical trial, we adjust the rate of clinical trial expense recognition if actual results differ from the estimates. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known at that time. Although we do not expect that our estimates will be materially different from amounts actually incurred, our understanding of status and timing of services performed relative to the actual status and timing of services performed may vary and may result in our reporting amounts that are too high or too low for any particular period. Through June 30, 2014, there had been no material adjustments to our prior period estimates of accrued expenses for clinical trials. However, due to the nature of estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical trials.

Recent Accounting Pronouncements

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

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. We early adopted this standard and thus we eliminated the historical inception to date information in the financial statements.

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 June 30, 2014 would not have had a material effect on the fair market value of our portfolio.

Our convertible promissory notes issued in November 2013 contain a fixed interest rate of 8%, accordingly changes in the interest rates for similar types of debt instruments would not have a material effect on our operating results. Such convertible promissory notes were converted into common stock at the IPO.

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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 GBP. 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 June 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 six months ended June 30, 2014.

Item 4. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

As of December 31, 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. If one or more material weaknesses persist or if we fail to establish and maintain effective internal control over financial reporting, our ability to accurately report our financial results could be adversely affected. As of June 30, 2014, certain material weaknesses and significant deficiencies continued to exist, including material weaknesses related to (1) lack of segregation of duties, (2) lack of financial statement disclosure controls and (3) not performing a risk assessment.

As of June 30, 2014, we had six full-time employees. We are increasing our finance staff and management is taking steps to remediate the material weakness in our internal control over financial reporting, including the implementation of new accounting processes and control

procedures and the identification of gaps in our skills base and expertise of the staff required to meet the financial reporting requirements of a public company. We have introduced procedures for proper management and control of payroll, accounts payable, treasury, equity and financial reporting, retaining third-party consultants to review our internal controls and to recommend improvements, and implementing improvements to the design and operation of internal control over financial reporting.

We will be required, pursuant to Section 404(a) of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for the year following our first annual report required to be filed with the SEC. This assessment will need to include disclosure of any material weaknesses identified by management over our internal control over financial reporting. However, our independent registered public accounting firm will not be required to report on the effectiveness of our internal control over financial reporting pursuant to Section 404(b) until we are no longer an emerging growth company.

We are in the very early stages of the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing or any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are designed and operating effectively, which could result in a loss of investor confidence in the accuracy and completeness of our financial reports. This could cause the price of our common stock to decline, and we may be subject to investigation or sanctions by the SEC.

Changes in Internal Control over Financial Reporting

During the quarter ended June 30, 2014, we began to hire finance staff in order to further develop our internal controls over financial reporting and mitigate the control deficiencies identified at December 31, 2013 and 2012.

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PART II

Item 1. *Legal Proceedings*

In the ordinary course of business, we are from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements and other matters. While the outcome of these proceedings and claims cannot be predicted with certainty, as of June 30, 2014, we were not party to any legal or arbitration proceedings that may have, or have had in the recent past, significant effects on our financial position or profitability. No governmental proceedings are pending or, to our knowledge, contemplated against us. We are not a party to any material proceedings in which any director, member of senior management or affiliate of ours is either a party adverse to us or our subsidiaries or has a material interest adverse to us or our subsidiaries.

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.

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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 six months ended June 30, 2014, we reported a net loss of $22.3 million. As of June 30, 2014, we had an accumulated deficit of $40.1 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.

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As of June 30, 2014, we had cash and cash equivalents of $0.5 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 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 pre-clinical development of MIN-301. However, circumstances may cause us to consume capital more rapidly than we currently anticipate. We will require significant additional capital to fund the development of one of our two lead product candidates, MIN-117, and to fund future clinical trials of our other product candidate, 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 EMA, FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more studies than those that we currently expect;

- the cost to establish, maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;

- the effect of competing technological and market developments;

- market acceptance of any approved product candidates;

- the costs of acquiring, licensing or investing in additional businesses, products, product candidates and technologies; and

- the cost of establishing sales, marketing and distribution capabilities for our product candidates for which we may receive regulatory approval and that we determine to commercialize ourselves or in collaboration with our partners.

When we need to secure additional financing, such additional fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. 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. After completing our initial public offering and the concurrent private placements, based upon our currently expected level of operating expenditures, we expect to be able to fund our operations to 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.

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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 would likely be limited as a result of issuance of equity securities.

As of December 31, 2013, we had approximately $16.0 million of federal net operating 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 would occur or has occurred, and such ownership change could also be triggered by subsequent sales of securities by us or our stockholders. Therefore, it is likely that some or all of our existing NOL carryforwards would be limited by the provisions of Section 382 of the U.S. 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 could similarly limit our ability to utilize NOL carryforwards. It is possible that all of our existing NOL carryforwards would be disallowed. Any such disallowances may result in greater tax liabilities than we would incur in the absence of such a limitation and any increased liabilities could adversely affect our business, results of operations, financial condition and cash flow.

Risks Related to Our Business and Industry

We 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 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.

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We currently hold no Investigational New Drug, or IND, approvals in the United States, and as a result do not intend to initiate human clinical trials of our product candidates (with the exception of MIN-301) in the United States 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 to member state regulatory authorities. Good Clinical Practice (in the EU under ICH 1997), or GCP, as incorporated into the EU Clinical Trials Directive 2001/20 and national implementing regulations sets out most issues in the conduct of trials but national divergences exist especially in relation to insurance and compensation, which will require a thorough understanding of the specific procedures and requirements for the specific 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. The ethics committee may ask questions, may require re-writing or amending the protocol, any and all of which would require more time and expense. 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 incur 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 and complete or generate, or we may decide 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 and which 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 EU 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 its safety risks;

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- 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 the submission of 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; and

- the approval policies or regulations of the EMA, FDA or other regulatory authorities outside of the United States 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 any of our product candidates 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 candidate. Any of the foregoing scenarios 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 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, requires 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 candidates. Later clinical trial results may not replicate earlier clinical trials for a variety of reasons, including differences in trial design, different trial endpoints (or lack of trial endpoints in exploratory studies), subject population, number of subjects, subject selection criteria, trial duration, drug dosage and formulation and 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 is 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 principles such as institutional review board, or IRB, or ethics committee approval and informed consent. The study population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the subject population for any clinical trials conducted outside of the United States must be representative of the U.S. population. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials were conducted consistent with all applicable U.S. 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.

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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 need to be restructured or 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, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- deviations from the trial protocol by clinical trial sites and investigators, or failing to conduct the trial in accordance with regulatory requirements;

- failure of our third parties, such as CROs, to satisfy their contractual duties or meet expected deadlines;

- insufficient or inadequate supply or quantity of product material for use in trials due to delays in the importation and manufacture of clinical supply, including delays in the testing, validation, and delivery of the clinical supply of the investigational drug to the clinical trial sites;

- delays in identification and auditing of central or other laboratories and the transfer and validation of assays or tests to be used;

- delays in having subjects complete participation in a trial or return for post-treatment follow-up;

- difficulties obtaining IRB or ethics committee approval to conduct a trial at a prospective site, or complying with conditions imposed by IRBs or ethics committees;

- challenges recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including competition from other programs for the treatment of similar conditions;

- severe or unexpected drug-related adverse events experienced by subjects in a clinical trial;

- difficulty retaining subjects who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, which are common among schizophrenia and MDD subjects who we require for our clinical trials of our two lead product candidates, MIN-101 and MIN-117. For instance, 66 out of 96 subjects ceased to participate in the Phase IIa clinical trial of MIN-101;

- 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 EU national regulatory authorities or 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 EU national regulatory authorities or the FDA due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or the trial protocols;

- 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;

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- unforeseen safety issues; or

- lack of adequate funding to continue the clinical trial.

Failure to conduct the clinical trial in accordance with regulatory requirements or the trial protocols may also result in the inability to use the data 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 clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. 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 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 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

- competing clinical trials 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 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

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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, a significant number of subjects ceased to participate in our prior Phase IIa 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 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. It can also 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.

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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 subject to 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 new safety issues arise, a new or supplemental NDA, a post-implementation notification or other reporting may be required or requested depending on the change, 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 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

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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 EU cGMP guidelines are as set down in Commission Directive 2003/94/EC of October 8, 2003 laying down the principles and guidelines of good manufacturing practice. 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, 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 U.S. Department of Justice, the U.S. 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

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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 which does not have marketing authorization or promotion not in accordance with that marketing authorization (e.g. off-label) 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 bodies, whose obligations may go further than those set out in Directive 2001/83. For instance in the United Kingdom the code or practice of the Association of the British Pharmaceutical Industry (the lead United Kingdom trade association) is considerably stricter than legislation. Any violations and sanctions will similarly be decided and handled by the self regulatory body the relevant country s national authority.

In the United States, engaging in the impermissible promotion of our products for off-label uses can also subject us 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 our operations and agreements that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include, but are not limited to, the federal civil False Claims Act, which allows any individual to bring a lawsuit against an individual or entity, including a pharmaceutical company, on behalf of the federal government alleging the knowing submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment or approval by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual initiating the lawsuit will share in any fines or settlement funds. If the government does not intervene, the individual may still proceed with the suit on his or her own. These 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,

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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 they are, 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 patients that suffer from schizophrenia and MDD, but these disorders are difficult to accurately diagnose and higher rates of patients may not seek or continue treatments. 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 along the way 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 other future clinical trials 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

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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 and 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. In some foreign jurisdictions, approval by the domestic regulatory agency is required for approval in another jurisdiction. 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 we may 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 and less costly or have a better safety profile than our products and these 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, and others are available on a generic basis. Insurers and other third-party payors may also 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, as it 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 generic, including branded generic, products, 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.

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Even if any of our drug candidates receives marketing approval, they 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. 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 product candidates by third-party payors, including government payors, generally, 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 as well as alternative treatment;
- our ability to offer our drugs for sale at competitive prices;
- 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 cost of treatment in relation to alternative treatments;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement and the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors;

- unfavorable publicity relating to the product candidate;

- 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, places us at increased risk of serious side effects and disease events during use of our product candidates, including suicide. Most approved neuropsychiatric medicines carry boxed warnings for clinically significant adverse events, and we may categorically have 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. 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. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products.

To develop internal sales, distribution and marketing capabilities, we will have to invest significant amounts of financial and management resources, some of which will be committed prior to any confirmation that our product candidates will be approved. For product candidates for which we decide to perform sales, marketing and distribution functions ourselves, we could face a number of additional risks, including:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;

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- 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.

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.

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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

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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, effective the first quarter of 2010 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. Also effective in 2010, the PPACA 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, as of 2011, the new law 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.

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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, that 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 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.

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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 net proceeds from the initial public offering and the concurrent private placement transactions, in U.S. 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. 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.

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

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

As of June 30, 2014, we had six 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, 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, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

We are in the process of combining several corporate entities and assets into our company, which will increase our infrastructure and reporting burden.

The integration of the businesses of Cyrenaic, Sonkei and Mind-NRG, our predecessor and acquired companies, is of critical importance to our future success. The success of the integration will depend, in a large part, on our ability to realize the anticipated benefits, including synergies, cost savings, innovation and operational efficiencies, from combining these businesses. To realize these anticipated benefits, these three businesses must be successfully integrated. The failure to integrate successfully and to manage successfully the challenges presented by the integration process may prevent us from achieving the anticipated benefits of these mergers. Any difficulties in successfully integrating these businesses, or any delays in the integration process, could adversely affect our business, financial results and financial condition.

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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. These transactions, as well as any future 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, including 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, 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;

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- 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 were to result 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 June 30, 2014, certain material weaknesses and significant deficiencies continued to exist, including (1) lack

of segregation of duties, (2) lack of financial statement disclosure controls and (3) not performing a risk assessment.

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, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports, and the market price of our stock may decline as a result.

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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 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.

We have historically operated without full time employees, relying on the services of consultants to provide certain accounting and finance functions, including representatives of our affiliate, Care Capital LLC, as we have not previously had the need or resources to internally hire sufficient qualified personnel, and our disclosure controls are not effective. We have since hired qualified personnel and continue to develop our disclosure control procedures. 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

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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;

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- 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, with data collection required beginning August 1, 2013 and reporting to CMS required by March 31, 2014 and by the 90th day of each subsequent calendar year;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- federal government price reporting laws, changed by the PPACA to, among other things, increase the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program and offer such rebates to additional populations, that require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on our marketed drugs. Participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs and potentially limit our ability to offer certain marketplace discounts and failure to report accurate pricing information exposes us to federal False Claims Act liability;

- the Foreign Corrupt Practices Act, a United States law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals); and

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- 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, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payors, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers; state laws that require drug manufacturers to 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 our business and/or increase enforcement scrutiny of our activities); and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, 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. 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.

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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 GCP, 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 GCP 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.

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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.

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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.

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. If we fail to achieve this milestone by April 2015, as it may be extended, MTPC may elect to terminate the MIN-101 license agreement. In addition, under the MIN-117 license agreement, we have to have the first subject enrolled in either a Phase IIa trial or a Phase IIb trial in MDD with a product containing MIN-117 by the end of April 2015. We do not intend to use any of the proceeds of the initial public offering to pursue the development of MIN-117; therefore, we will need to raise additional financing to achieve this

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milestone. If we fail to achieve this milestone, we may elect to extend the timeline to achieve the milestone by making extension payments. If we fail to achieve this development milestone by April 2015, as may be extended, MTPC may elect to terminate the MIN-117 license agreement. MTPC may also terminate the licenses following a material breach 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 approved, and provided the license agreement with Janssen is not terminated by Janssen for material breach or 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 this product candidate, even if approved. In addition, at certain development milestones, including the completion of a single dose Phase I clinical trial in patients with MDD, Janssen has the right to opt out. Upon such opt out, Janssen will not have to fund further development of MIN-202 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 have a collaboration with Janssen for 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 effort 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

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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 U.S. 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 which protect our technology or products, in whole or in part, or which 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.

Furthermore, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. 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. We expect to seek extensions of patent terms where these are available in any countries where we are pursuing patents. This includes 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. However the applicable authorities, including the FDA in the United States, 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 clinical trials by referencing our clinical and pre-clinical data and launch their product earlier than might otherwise be the case.

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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 NCE exclusivity. Such diminution of its proprietary position could have a material adverse effect on our business, results of operation and financial condition.

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 these are available in any countries where we are prosecuting patents, 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. Furthermore, 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.

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. 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 a 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.

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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.

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.

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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 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 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 patents and patents we and our licensors or collaborators may obtain in the future.

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. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO recently 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, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, 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.

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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.

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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 confidentiality and invention or 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, including in foreign jurisdictions, 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;

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- 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.

As of June 30, 2014, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially own approximately 93% of our voting stock. 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.

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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 stockholders sell, or if the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market following the initial public offering, 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, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, 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.

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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 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 shareholder 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 still 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 Securities Exchange Act of 1934, or the Exchange Act which require, 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

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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 662/3% of the votes that all of our stockholders would be entitled to cast to amend or repeal our bylaws.

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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 do not publish 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. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, 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.

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

Unregistered Sales of Equity Securities

In July 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 June 30, 2014, our registration statement on Form S-1 (File No. 333-195169) 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 an aggregate of approximately $32.7 million. Jefferies LLC acted as sole book-running manager and representatives of the several underwriters. All securities registered in this registration statement have been sold pursuant to the underwriting agreement. On July 7, 2014, we closed the sale of all such shares, resulting in net proceeds to us of approximately $27.3 million, after deducting the underwriting discount of $2.3 million and expenses of approximately $3.1 million payable by us.

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

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Item 6. Exhibits

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

Exhibit Number	Description
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*

* Pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Exchange Act and otherwise are not subject to liability under those sections.

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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: August 7, 2014