Minerva Neurosciences, Inc.
Form 10-Q
August 05, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2015

OR

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

Commission File No. 001-36517

Minerva Neurosciences, Inc.

(Exact Name of Registrant as Specified in its Charter)

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES x NO ¨

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

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

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

The number of shares of Registrant’s Common Stock, $0.0001 par value per share, outstanding as of July 31, 2015 was 24,721,143.

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

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

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

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

PART I – Financial Information

Item 1 – Financial Statements

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Balance Sheets

(Unaudited)

	June 30, 2015	December 31, 2014
Assets		
Current assets		
Cash and cash equivalents	$21,735,546	$18,545,702
Marketable securities - current portion	13,650,886	-
Restricted cash	80,000	35,014
Prepaid expenses and other current assets	308,976	756,979
Total current assets	35,775,408	19,337,695
Marketable securities - noncurrent	9,443,843	-
Equipment, net	34,809	43,446
In-process research and development	34,200,000	34,200,000
Goodwill	14,869,399	14,869,399
Total assets	$94,323,459	$68,450,540
Liabilities and Stockholders' Equity		
Current liabilities		
Notes payable - current portion	$1,087,420	$-
Accounts payable	564,289	641,813
Accrued expenses and other current liabilities	1,082,535	1,645,258
Accrued collaborative expenses	1,078,215	1,222,420
Total current liabilities	3,812,459	3,509,491
Notes payable - noncurrent	8,696,799	-
Deferred taxes	13,433,760	13,433,760
Other noncurrent liabilities	2,565	7,694
Total liabilities	25,945,583	16,950,945
Commitments and contingencies		
Stockholders' equity		
Preferred stock; $0.0001 par value; 100,000,000 shares authorized; none issued or outstanding as of June 30, 2015 and December 31, 2014, respectively	-	-
Common stock; $0.0001 par value; 125,000,000 shares authorized; 24,721,143 and 18,439,482 shares issued and outstanding as of June 30, 2015 and	2,472	1,844

December 31, 2014, respectively		
Additional paid-in capital	155,810,015	126,228,981
Accumulated deficit	(87,434,611)	(74,731,230)
Total stockholders' equity	68,377,876	51,499,595
Total liabilities and stockholders' equity	$94,323,459	$68,450,540

See accompanying notes to condensed consolidated financial statements

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Operations

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Expenses				
Research and development	$4,484,688	$14,554,662	$8,445,893	$15,140,598
General and administrative	1,847,636	3,095,173	3,764,929	5,132,565
Total expenses	6,332,324	17,649,835	12,210,822	20,273,163
Loss from operations	(6,332,324)	(17,649,835)	(12,210,822)	(20,273,163)
Foreign exchange (losses) gains	(29,112)	10,549	(13,152)	3,987
Interest (expense)	(248,698)	(1,726,376)	(479,407)	(2,034,904)
Net loss	$(6,610,134)	$(19,365,662)	$(12,703,381)	$(22,304,080)
Net loss per share, basic and diluted	$(0.27)	$(2.55)	$(0.58)	$(3.07)
Weighted average shares outstanding, basic and diluted	24,721,143	7,604,503	22,083,539	7,255,648

See accompanying notes to condensed consolidated financial statements

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Changes in Stockholders' Equity

(Unaudited)

	Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balances at December 31, 2014	18,439,482	$ 1,844	$126,228,981	$(74,731,230)	$51,499,595
Issuance of common stock and warrants pursuant to a private placement, net of issuance costs of $2,466,984	6,281,661	628	28,532,387	-	28,533,015
Issuance of warrant pursuant to loan agreement	-	-	166,344	-	166,344
Stock-based compensation	-	-	882,303	-	882,303
Net loss	-	-	-	(12,703,381)	(12,703,381)
Balances at June 30, 2015	24,721,143	$ 2,472	$155,810,015	$(87,434,611)	$68,377,876

See accompanying notes to condensed consolidated financial statements

MINERVA NEUROSCIENCES, INC.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

	Six months Ended June 30,	
	2015	2014
Cash flows from operating activities:		
Net loss	$(12,703,381)	$(22,304,080)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	8,637	4,271
Amortization of debt discount recorded as interest expense	146,219	1,949,248
Amortization of marketable securities premium recorded as interest expense	67,848	-
Stock-based compensation expense	882,303	14,816,940
Change in fair value of derivative	-	(10,093)
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	448,003	10,565
Accounts payable	(77,524)	1,229,363
Accrued expenses and other current liabilities	(562,723)	520,209
Accrued collaborative expenses	(144,205)	-
Other noncurrent liabilities	(5,129)	-
Net cash used in operating activities	(11,939,952)	(3,783,577)
Cash flows from investing activities:		
Purchases of marketable securities	(23,162,577)	-
Cash acquired in business combination	-	1,167,869
Restricted cash	(44,986)	-
Net cash (used in) provided by investing activities	(23,207,563)	1,167,869
Cash flows from financing activities:		
Proceeds from loans	10,000,000	1,882,817
Repayments of loans	-	(500,000)
Costs paid in connection with loans	(195,656)	-
Proceeds from sales of common stock and warrants in private placement	30,999,999	-
Costs paid in connection with private placement	(2,466,984)	-
Public offering costs paid	-	(105,417)
Net cash provided by financing activities	38,337,359	1,277,400
Net increase in cash and cash equivalents	3,189,844	(1,338,308)
Cash and cash equivalents		
Beginning of period	18,545,702	1,818,317
End of period	$21,735,546	$480,009
Cash paid for interest	$264,375	$-
Supplemental disclosure of noncash investing and financing activities		
Common stock issued as consideration for business acquisition	$-	$16,541,834
Plus liabilities assumed:		
Accrued expenses and other	-	321,417
ProteoSys milestone payable	-	681,600
Deferred tax liability	-	5,970,560
Less assets acquired:		

Prepaid expenses	-	42,926
Equipment	-	28,204
In-process research and development	-	15,200,000
Goodwill	-	7,076,412
Cash acquired in business merger	$-	$1,167,869
Deferred public offering costs included in accrued expenses and other liabilities	$-	$3,006,327

See accompanying notes to condensed consolidated financial statements

MINERVA NEUROSCIENCES, INC.

Notes to Condensed Consolidated Financial Statements

As of June 30, 2015 and for the

Six Months Ended June 30, 2015 and 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. On November 12, 2013, Sonkei Pharmaceuticals, Inc. ("Sonkei"), a biopharmaceutical company focused on the development of an experimental drug for the treatment of depression and an affiliated company through certain common ownership, was merged into Cyrenaic with Cyrenaic being the surviving company. Subsequent to the merger, Cyrenaic changed its name to Minerva Neurosciences, Inc. The Company is a clinical-stage biopharmaceutical company focused on the development and commercialization of a portfolio of product candidates to treat central nervous system ("CNS") diseases.

On February 11, 2014, the Company acquired Mind-NRG (discussed further in Note 3 — Business Acquisition). 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, Janssen Pharmaceutica N.V. ("Janssen"), granted the Company an exclusive license, in certain territories, under certain patent and patent applications to sell products containing any orexin 2 compound, controlled by the licensor and claimed in a licensor patent right, as an active ingredient, or MIN-202, for any use in humans. The license became effective on July 7, 2014 at the closing of the IPO and the payment of the $22.0 million license fee was made at that date.

Going Concern

The Company has limited capital resources and has incurred recurring operating losses and negative cash flows from operations since inception. As of June 30, 2015, the Company has an accumulated deficit of approximately $87.4 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.

In January 2015, the Company entered into a loan and security agreement and drew down on $10.0 million in term loans. In March 2015, the Company closed the sale of 6,281,661 shares of common stock and warrants to purchase an equal number of shares of common stock in a private placement resulting in net proceeds to the Company of $28.5 million after deducting placement fees and issuance costs. The Company believes that based on its operating plan, cash on hand at June 30, 2015 and the proceeds from the term loans and the private placement in March 2015 will be

sufficient to fund the Company's operations into the fourth quarter of 2016.

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

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

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation

The interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim reporting and the requirements of the Securities and Exchange Commission ("SEC") in accordance with Regulation S-X, Rule 10-01. Under those rules, certain footnotes and financial information that are normally required for annual financial statements can be condensed or omitted. In the opinion of the Company's management, the accompanying financial statements contain all adjustments (consisting of items of a normal and recurring nature) necessary to present fairly the financial position as of June 30, 2015 and the results of operations for the three and six months ended June 30, 2015 and 2014 and cash flows for the six months ended June 30, 2015 and 2014. The results of operations for the three and six months ended June 30, 2015, are not necessarily indicative of the results to be expected for the full year. When preparing financial statements in conformity with GAAP, management must make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates. The consolidated balance sheet as of December 31, 2014 was derived from the audited annual financial statements. The accompanying unaudited condensed consolidated financial statements and notes thereto should be read in conjunction with the audited financial statements for the years ended December 31, 2014 and 2013 included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2014 filed with the SEC on March 26, 2015.

Consolidation

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

Significant risks and uncertainties

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

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

Use of estimates

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

could differ from those estimates.

Cash and Cash Equivalents

Cash equivalents include short-term, highly-liquid instruments, consisting of money market accounts and short-term investments with original maturities of less than 90 days. The majority of cash and cash equivalents are maintained with major financial institutions in North America. Deposits with these financial institutions may exceed the amount of insurance provided on such deposits; however, these deposits may be redeemed upon demand and, therefore, bear minimal risk.

Marketable Securities

Marketable securities consists of corporate debt securities maturing in fifteen months or less. Based on the Company's intentions regarding its marketable securities, all marketable securities are classified as held-to-maturity and are carried under the amortized cost approach. As of June 30, 2015, remaining maturities of marketable securities ranged from November 2015 to September 2016, with a weighted average remaining maturity of approximately 10 months. The following table provides the amortized cost basis, aggregate fair value, unrealized losses (there were no unrealized gains) and the net carrying value of investments in held-to-maturity securities as of June 30, 2015:

	June 30, 2015			
	Amortized Cost	Aggregate Fair Value	Unrealized Losses	Net Carrying Value
	(in thousands)			
Marketable securities:				
Corporate bonds - current	$13,651	$ 13,632	$ 19	$ 13,651
Corporate bonds - noncurrent	9,444	9,413	31	9,444
Marketable securities	$23,095	$ 23,045	$ 50	$ 23,095

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 employee salaries and benefits, fees paid to consultants and various entities that perform certain research and testing on behalf of the Company. We determine our expenses related to clinical studies based on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual accordingly. The expenses for some trials may be recognized on a straight-line basis if the expected costs are expected to be incurred ratably during the period. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the condensed consolidated financial statements as prepaid or accrued expenses.

In July 2014, the Company paid a $22.0 million license fee, which has been included as a component of research and development expense since the licensed rights were not deemed to have an alternative future use. The Company accounts for the co-development and license agreement pursuant to which the license fee was paid as a joint risk-sharing collaboration in accordance with ASC 808, Collaboration Arrangements. Costs between the Company and the licensor with respect to each party's share of development costs that have been incurred pursuant to the joint development plan are recorded within research and development expense or general and administrative expense, as applicable, in the accompanying condensed consolidated financial statements due to the joint risk-sharing nature of the activities. The Company has included $1.1 million in accrued collaborative expenses as of June 30, 2015 related to this agreement.

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

The amounts capitalized are being accounted for as indefinite-lived intangible assets, subject to impairment testing, until completion or abandonment of research and development efforts associated with the project. An IPR&D asset is considered abandoned when it ceases to be used (that is, when research and development efforts associated with the asset have ceased, and there are no plans to sell or license the asset or derive defensive value from the asset). At that point, the asset is considered to be disposed of and is written off. Upon successful completion of each project, the Company will make a determination about the then remaining useful life of the intangible asset and begin

amortization. The Company tests its indefinite-lived intangibles, IPR&D assets, for impairment annually on November 30 and more frequently if events or changes in circumstances indicate that it is more likely than not that the asset is impaired. When testing indefinite-lived intangibles for impairment, the Company may assess qualitative factors for its indefinite-lived intangibles to determine whether it is more likely than not (that is, a likelihood of more than 50 percent) that the asset is impaired. Alternatively, the Company may bypass this qualitative assessment for some or all of its indefinite-lived intangibles and perform the quantitative impairment test that compares the fair value of the indefinite- lived intangible asset with the asset's carrying amount. There was no impairment of IPR&D for the three and six months ended June 30, 2015 and 2014.

Stock-based compensation

The Company recognizes compensation cost relating to stock-based payment transactions in operating results using a fair-value measurement method, in accordance with ASC Topic 718 Compensation-Stock Compensation. ASC-718 requires all stock-based payments to employees, including grants of employee stock options, to be recognized in operating results as compensation expense based on fair value over the requisite service period of the awards. The Company determines the fair value of stock-based awards using the Black-Scholes option-pricing model which uses both historical and current market data to estimate fair value. The method incorporates various assumptions such as the risk-free interest rate, expected volatility, expected dividend yield, expected forfeiture rate and expected life of the options.

Grants to non-employees are accounted for in accordance with ASC Topic 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 stock-based awards granted to non-employees similar to the way fair value of awards are determined for employees except that certain assumptions used in the Black-Scholes option-pricing model, such as expected life of the option, may be different and the fair value of each unvested award is adjusted at the end of each period for any change in fair value from the previous valuation until the award vests.

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. During the periods when the Company earns net income, diluted loss per share would reflect the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that shared in the earnings of the entity. The Company had a net loss in all periods presented thus the inclusion of stock options and warrants would be anti-dilutive to net loss per share.

Business combinations

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

Goodwill

The Company tests its goodwill for impairment annually, or whenever events or changes in circumstances indicate an impairment may have occurred, by comparing its reporting unit's carrying value to its implied fair value. Impairment may result from, among other things, deterioration in the performance of the acquired business, adverse market conditions, adverse changes in applicable laws or regulations and a variety of other circumstances. If the Company determines that an impairment has occurred, it is required to record a write-down of the carrying value and charge the impairment as an operating expense in the period the determination is made. In evaluating the recoverability of the carrying value of goodwill the Company must make assumptions regarding estimated future cash flows and other factors to determine the fair value of the acquired assets. Changes in strategy or market conditions could significantly impact those judgments in the future and require an adjustment to the recorded balances. The Company tests its goodwill for impairment annually at November 30 and more frequently if events or changes in circumstances indicate that it is more likely than not that the asset is impaired. There was no impairment of goodwill for the three and six months ended June 30, 2015 and 2014.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") and are adopted by the Company as of the specified effective date. The Company believes that the impact of recently issued but not yet adopted accounting pronouncements will not have a material impact on the condensed consolidated financial position, condensed consolidated results of operations, and condensed consolidated cash flows, or do not apply to the Company.

In April 2015, the FASB issued ASU 2015-03, which simplifies the presentation of debt issuance costs. The Company has elected early adoption of this guidance and recorded its debt issuance costs associated with the Term Loans as a direct reduction to the face amount of the loans.

NOTE 3 — BUSINESS ACQUISITION

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 consisted of 1,481,583 shares of the Company's common stock

with an estimated fair value of $11.17 per share, or approximately $16.5 million. The Company acquired 100% of the share capital of Mind-NRG largely to obtain the intellectual property estate that underpins Mind-NRG's lead product candidate, 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. Identifying the fair value of the tangible and intangible assets and liabilities acquired required the use of estimates by management and were based upon currently available data, as noted below.

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

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

The Company allocated the excess of purchase price over the identifiable intangible and net tangible assets to goodwill. The goodwill recorded recognizes the value of the overall development program, including 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 was allocated to assets acquired and liabilities assumed based on estimated fair values as follows:

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

IPR&D, an indefinite-lived asset, has been 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. In 2014, the Company corrected the deferred tax rate used to record a deferred tax liability at acquisition date by recording at $0.1 million reduction in deferred tax liability with a corresponding increase to goodwill.

NOTE 4 — ACCRUED EXPENSES

Accrued expenses and other liabilities consist of the following:

	June 30, 2015	December 31, 2014
Accrued bonus	$ 300,000	$ 327,960
Research and development costs and other accrued expenses	349,582	422,821
Accrued severance	212,500	636,033
Professional fees	-	54,350
Primomed research funding (1)	107,491	127,209
Interest payable	58,750	-
Accrued excise and franchise taxes	-	76,885
Vacation pay	54,212	-
	$ 1,082,535	$ 1,645,258

(1) Under the terms of a research agreement with Primomed, the Company received grant funds that will be used to offset certain costs under the MIN-301 development program.

NOTE 5 — NET LOSS PER SHARE OF COMMON STOCK

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Net loss	$(6,610,134)	$(19,365,662)	$(12,703,381)	$(22,304,080)
Weighted average shares of common stock outstanding	24,721,143	7,604,503	22,083,539	7,255,648
Net loss per share of common stock – basic and diluted	$(0.27)	$(2.55)	$(0.58)	$(3.07)

The following securities outstanding at June 30, 2015 and 2014 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,	
	2015	2014
Common stock options	2,905,336	2,141,807
Warrants	6,322,451	-

NOTE 6 — LICENSE AGREEMENTS

The Company has entered into a license agreement with Mitsubishi Tanabe Pharma Corporation ("MTPC") dated as of August 30, 2007, as amended (the "License Agreement"). Under the terms of the License Agreement, the Company acquired an exclusive license to the compound known as CYR-101 (subsequently renamed MIN-101) and other compounds with a similar structure and intended purpose and other data included within the valid claims of certain patents licensed to the Company under the License Agreement. The license is for world-wide rights, excluding certain Asian countries such as China, Japan, India and South Korea. The Company will pay a tiered royalty for net sales of product by it or any of its affiliates or sub-licensees containing the licensed compound equal to a percentage ranging from the high single digits to the low teens depending on net sales of products under the License Agreement. The initial $1.0 million licensing fee paid in 2007 was expensed as research and development expense, as was an additional payment of $0.5 million in 2008 upon the onset of a Phase IIa study. The Company made a $0.5 million extension payment in 2010 which was expensed as part of research and development expense. The Company was also required to make milestone payments upon the achievement of certain development and commercial milestones, potentially up to $57.5 million for MIN-101 and up to $59.5 million for additional products.

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.

In connection with the merger of Sonkei in November 2013, the Company has a second license agreement with MTPC dated September 1, 2008, as amended. Under the terms of the agreement, the Company has an exclusive license to the compound known as SON-117 (subsequently renamed MIN-117) and other data included within the valid claims of certain patents licensed to the Company under the agreement. The license is for world-wide rights other than certain countries in Asia, including China, Japan, India and South Korea. Under the agreement, the Company will pay a tiered royalty for net sales of product by it or any of its affiliates or sub-licensees containing the licensed compound ranging from the high single digits to the low teens depending on net sales of products. Through the date of the agreement, as amended, the Company was required to make payments up to $57.5 million upon the achievement of certain commercial milestones.

In January 2014, the Company renegotiated the structure of the license for MIN-117 such that the Company is required to make 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 was required to initiate by the end of April 2015 a Phase IIa or Phase IIb study with MIN-117 in patients suffering major mood disorders where initiation is defined as first patient enrolled in the study.

In April 2015, the Company amended the diligence milestone obligation under the license agreement for MIN-117 to extend the deadline to begin enrollment in a Phase IIa or Phase IIb study with MIN-117 in patients suffering major mood disorders from April 30, 2015 to June 30, 2015. As consideration for the two-month extension, the Company paid MTPC and expensed $80,000 in May 2015. The Company met the enrollment milestone obligation in June 2015.

The Company did not make any other license payments under the agreements for the six months ended June 30, 2015 or 2014.

NOTE 7 — DEBT

Loan and Security Agreement

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

The Company drew down the initial term loans in the aggregate principal amount of $10 million (the “Term A Loans”), on January 16, 2015. The Term A Loans bear interest at a fixed rate of 7.05% per annum. On or prior to March 31, 2016, the Company may borrow additional term loans or Term B Loans, together with the Term A Loans, (the “Term Loans”), in the aggregate principal amount up to $5 million, subject to the satisfaction of certain borrowing conditions, including its achievement of primary endpoints on its Phase IIa trials for its MIN-117 and MIN-202 programs. The Term B Loans will bear interest at a fixed rate per annum of the greater of (i) 7.05% or (ii) the sum of (a) the prime rate reported in The Wall Street Journal three (3) business days prior to the funding date of the Term B Loans, plus (b) 3.80%.

The Company paid a facility fee of $75,000 for access to the Term Loans and will be required to pay a final payment of 4.45% (or, if the interest-only period is extended as described below, 5.10%) of the total amount borrowed, which has been included as a component of the debt discount and is amortized to interest expense over the term of the

loans. The Term A Loans and debt discount are as follows:

	June 30, 2015
Term A Loans	$ 10,000,000
Less: debt discount and financing costs	(215,781)
Less: current portion	(1,087,420)
Long-term portion	$ 8,696,799

For the three and six months ended June 30, 2015, the Company recognized interest expense of $0.3 million and $0.5 million, respectively, related to the Term A Loans, including $0.1 million and $0.1 million, respectively, related to the debt discount.

Through February 1, 2016, the Company is obligated only to make monthly interest payments on the outstanding principal balance on the Term A Loans, followed by 30 months of equal principal and interest payments. If the Company raises at least $30.0 million in capital (including at least $20.0 million from the sale of equity securities) and completes the first dosing of its Phase I/II clinical trial for MIN-117 prior to December 31, 2015, the interest-only period will be extended an additional six months and the repayment period will be reduced by six months. The Term Loans mature on August 1, 2018. The Company may prepay all, but not less than all, of the

loaned amount upon 30 days' advance notice to the Lenders, provided that the Company will be obligated to pay a prepayment fee equal to (i) 3% of the outstanding balance, if the loan is prepaid within 24 months of the funding date, (ii) 2% of the outstanding balance, if the loan is prepaid between 24 and 36 months of the funding date and (iii) 1% of the outstanding balance, if the loan is prepaid thereafter (each, a "Prepayment Fee"). The expected repayment of the $10.0 million Term A loan principal is as follows:

2015	$-
2016	3,140,089
2017	4,019,155
2018	2,840,756
Total Term A Loans	$10,000,000

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

Upon the occurrence of certain events, including but not limited to the Company's failure to satisfy its payment obligations under the Loan Agreement, the breach of certain of its other covenants under the Loan Agreement, or the occurrence of a material adverse change, the Lenders will have the right, among other remedies, to declare all principal and interest immediately due and payable, and will have the right to receive the final payment fee and, if the payment of principal and interest is due prior to maturity, the applicable Prepayment Fee.

Under the Loan Agreement, the Company agreed to issue the Lenders warrants to purchase shares of its common stock upon its draw of each tranche of the Term Loans. The aggregate number of shares of common stock issuable upon exercise of the warrants is equal to 2.25% of the amount drawn of such tranche, divided by the average closing price per share of the Company's common stock reported on the NASDAQ Global Market for the 10 consecutive trading days prior to the applicable draw. On January 16, 2015, upon the draw of the Term A Loans, the Company issued to the Lenders warrants to purchase 40,790 shares of common stock at a per share exercise price of $5.516. The warrants were immediately exercisable upon issuance, and other than in connection with certain mergers or acquisitions, will expire on the ten-year anniversary of the date of issuance. The fair value of the warrants was estimated at $0.2 million using a Black-Scholes model and assuming: (i) expected volatility of 100.8%, (ii) risk free interest rate of 1.83%, (iii) an expected life of 10 years and (iv) no dividend payments. The fair value of the warrants was included as a discount to the Term A Loans and also as a component of additional paid-in capital at June 30, 2015.

NOTE 8 — CO-DEVELOPMENT AND LICENSE AGREEMENT

On February 12, 2014, the Company signed a co-development and license agreement with Janssen and Janssen Research & Development, LLC ("JJDC"), subject to the completion of an IPO and the payment of a $22.0 million license fee. Under the agreement, the licensor granted the Company an exclusive license, with the right to sublicense, in the European Union, Switzerland, Liechtenstein, Iceland and Norway, referred to as the Minerva Territory, under

(i) certain patent and patent applications to sell products containing any orexin 2 compound, controlled by the licensor and claimed in a licensor patent right as an active ingredient and (ii) MIN-202 for any use in humans. In addition, upon regulatory approval in the Minerva Territory (and earlier if certain default events occur), the Company will have rights to manufacture MIN-202. The Company has granted to the licensor an exclusive license, with the right to sublicense, under all patent rights and know-how controlled by the Company related to MIN-202 to sell MIN-202 outside the Minerva Territory. In consideration of the licenses granted on July 7, 2014, the Company made a license fee payment of $22.0 million, which was included as a component of research and development expense in 2014. The Company will pay a quarterly royalty percentage in the high single digits on aggregate net sales for MIN-202 products sold by the Company, its affiliates and sublicensees in the European Union. The licensor will pay a quarterly royalty percentage to the Company in the high single digits on aggregate net sales for MIN-202 products sold by the licensor outside the European Union. In accordance with the development agreement, the Company will pay 40% of MIN-202 development costs related to the joint development of any MIN-202 products. However, the Company's share of aggregate development costs shall not exceed (i) $5.0 million for the period beginning from the effective date of the license and ending following the completion of certain Phase Ib clinical trials and animal toxicology studies, and (ii) $24.0 million for the period beginning from the effective date of the license and ending following the completion of certain Phase II clinical trials. The licensor has a right to opt out at the end of certain development milestones, with the first milestone being the completion of a single day Phase I clinical trial in patients with Major Depressive Disorder ("MDD"). Upon opt out, the licensor will not have to fund further development of MIN-202 and the Minerva Territory will be expanded to also include all of North America. The Company would then owe the licensor a reduced royalty in the mid-single digits for all sales in the Minerva Territory. The Company has the right to terminate the license following certain development milestones, the first being completion of a certain Phase Ib clinical trial in patients with insomnia and certain toxicology studies in animals. If the Company terminates the license within

45 days of this milestone, the Company must pay a termination fee equal to $3.0 million. If the Company terminates the license at any time following the last development milestone involving a certain Phase IIb clinical trial, the Company will be entitled to a royalty in the mid-single digits from sales of MIN-202 by the licensor. The licensor may also terminate the agreement for the Company's material breach or certain insolvency events, including if the Company is unable to fund its portion of the development costs.

The Company included the $22.0 million license fee payment as a component of research and development expense since the licensed rights were not deemed to have an alternative future use. The Company accounts for the co-development and license agreement as a joint risk-sharing collaboration in accordance with ASC 808, Collaboration Arrangements. Payments between the Company and the licensor with respect to each party's share of MIN-202 development costs that have been incurred pursuant to the joint development plan are recorded within research and development expense or general and administrative expense, as applicable, in the accompanying consolidated statements of operations due to the joint risk-sharing nature of the activities. The Company has included $1.1 million and $1.2 million in accrued collaborative expenses as of June 30, 2015 and December 31, 2014, respectively. The Company paid $2.7 million during the six months ended June 30, 2015 under this agreement.

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

NOTE 9 — STOCKHOLDERS' EQUITY

Private Placement of Common Stock and Warrants

On March 18, 2015, pursuant to a securities purchase agreement with certain accredited investors dated March 13, 2015, the Company sold in a private placement 6,281,661 shares of the Company's common stock at a price per share of $4.81 and warrants to purchase up to an aggregate of 6,281,661 shares of common stock at a purchase price of $0.125 per warrant share, with an initial exercise price of $5.772 per share, resulting in gross proceeds of approximately $31.0 million. The warrants will expire on March 18, 2017, two years after the date on which they were initially issued. The Company incurred $2.5 million for placement agent fees and transaction costs which have been included as a component of additional paid-in capital, resulting in net proceeds of $28.5 million.

In connection with the private placement, the Company also entered into a registration rights agreement (the "Registration Rights Agreement"), dated March 13, 2015 with certain accredited investors. Pursuant to the terms of the Registration Rights Agreement, the Company was obligated to prepare and file with the SEC a registration statement to register for resale the 6,281,661 shares of its common stock issued in the private placement and the 6,281,661 shares of its common stock issuable upon exercise of the warrants on or prior to May 2, 2015. The Company filed a resale registration statement on Form S-1 the SEC on April 30, 2015. The Company filed a post-effective amendment to the Form S-1 to convert the filing to a Form S-3 on July 2, 2015. If registration statements are not maintained effective, the Company could be subject to penalties of up to 10.0% of proceeds received in the private placement.

Term Loan Warrants

In connection with the Loan Agreement, the Company issued the Lenders warrants to purchase shares of its common stock upon its draw of each tranche of the Term Loans. The aggregate number of shares of common stock issuable upon exercise of the warrants is equal to 2.25% of the amount drawn of such tranche, divided by the average closing

price per share of the Company's common stock reported on the NASDAQ Global Market for the 10 consecutive trading days prior to the applicable draw. Upon the draw of the Term A Loans, the Company issued the Lenders warrants to purchase 40,790 shares of common stock at a per share exercise price of $5.516. The warrants are immediately exercisable upon issuance, and other than in connection with certain mergers or acquisitions, will expire on the ten-year anniversary of the date of issuance. The fair value of the warrants was estimated at $0.2 million using a Black-Scholes model and assuming: (i) expected volatility of 100.8%, (ii) risk free interest rate of 1.83%, (iii) an expected life of 10 years and (iv) no dividend payments. The fair value of the warrants was included as a discount to the Term A Loans and also as a component of additional paid-in capital at June 30, 2015.

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 January 1, 2015, in accordance with the terms of the Plan, the total shares authorized for issuance under the plan increased by 737,579 to 4,281,333. This increase represents 4% of the total shares outstanding calculated as of the end of the most recent fiscal year. The exercise price per share shall not be less than the fair value of the

Company's underlying common stock on the grant date and no option may have a term in excess of ten years. Stock option activity under the Plan is as follows:

	Stock Options	Weighted-Average Exercise Price
Outstanding January 1, 2015	2,076,558	$ 6.64
Granted	848,778	$ 5.18
Forfeited	(20,000)	$ 6.26
Outstanding June 30, 2015	2,905,336	$ 6.22
Exercisable June 30, 2015	1,412,527	$ 6.79
Available for future grant	1,375,997	

The Company granted 848,778 and 1,495,048 stock options during the six months ended June 30, 2015 and 2014 that had a weighted average exercise price of $5.18 and $6.00, respectively. The Company uses the Black Scholes model to estimate the fair value of stock options granted. For stock options granted during the six months ended June 30, 2015 and 2014, the Company utilized the following assumptions:

	June 30, 2015	June 30, 2014
Expected term (years)	5.5-6.25	6.25
Risk free interest rate	1.27 - 1.80%	1.94%
Volatility	74-110%	113%
Dividend yield	0%	0%
Weighted average grant date fair value per share of common stock	$ 4.21	$5.11

The Company recognized stock-based compensation expense for the six months ended June 30, 2015 and 2014 of $0.9 million and $14.8 million, respectively. The weighted average grant-date fair value of stock options outstanding on June 30, 2015 was $5.19 per share. Total unrecognized compensation costs related to non-vested awards at June 30, 2015 was approximately $6.6 million and is expected to be recognized within future operating results over a period of 3.19 years. At June 30, 2015, the weighted average contractual term of the options outstanding is approximately 9.2 years. The intrinsic value of outstanding stock options at June 30, 2015 was $0.5 million.

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

NOTE 11 — COMMITMENTS

In September 2014, the Company entered into a lease agreement for 4,043 square feet of office space in Waltham, MA. The term of the lease is approximately 2 years, and the Company is required to make monthly rental payments commencing December 2014. Estimated annual rent payable under this operating lease is approximately $0.1 million per year in each of the two years.

NOTE 12 — RELATED PARTY TRANSACTIONS

An investor previously provided accounting and other services to the Company during 2014. For the three and six months ended June 30, 2014, the expense recognized in operating results in connection with these services was $15,000 and $35,000, respectively.

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

NOTE 13 — SUBSEQUENT EVENTS

Stock Option Grants

On July 1, 2015, in accordance with the terms of the Plan, the Company granted 200,000 options to purchase common stock to two new employees with a vesting term of four years. On July 1, 2015, the Company also granted 25,000 options to one new member of the Board of Directors with a vesting term of three years pursuant to the Company's Non-Employee Director Compensation Plan. All grants have an exercise price equal to the closing price of the stock on the date of grant of $5.60 per common share.

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

You should read the following discussion of our financial condition and results of operations in conjunction with our condensed consolidated financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q and with our annual audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2014 as filed with the Securities and Exchange Commission on March 26, 2015.

Historical Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of a portfolio of product candidates to treat patients suffering from central nervous system, or CNS, diseases. Leveraging our deep 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 candidate is MIN-101, a compound for the potential treatment of patients with schizophrenia. In addition, our portfolio includes MIN-202, a compound we are co-developing with Janssen Pharmaceuticals ("Janssen"), for the treatment of patients suffering from primary and comorbid insomnia; MIN-117, a compound we are developing for the treatment of patients suffering from major depressive disorder, or MDD; 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 ("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. ("Sonkei"), a clinical-stage biopharmaceutical company and, in February 2014, we acquired Mind-NRG, a pre-clinical-stage biopharmaceutical company. We refer to these transactions as the Sonkei Merger and Mind-NRG Acquisition, respectively. Sonkei licensed MIN-117 from MTPC in 2008 with the rights to develop, sell and import MIN-117 globally, excluding most of Asia. With the acquisition of Mind-NRG, we obtained exclusive rights to develop and commercialize MIN-301. We have also entered into a co-development and license agreement with Janssen Pharmaceutica NV ("Janssen"), for the exclusive rights to develop and commercialize MIN-202 in the European Union, subject to royalty payments to Janssen, and royalty rights for any sales outside the European Union.

We have not received regulatory approvals to sell any of our product candidates, and we have not generated any revenue from the sales or license of our product candidates. We have incurred significant operating losses since inception. We 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.

On March 18, 2015, pursuant to a securities purchase agreement with certain accredited investors dated March 13, 2015, we sold in a private placement 6,281,661 shares of our common stock at a price per share of $4.81 and warrants to purchase up to an aggregate of 6,281,661 shares of common stock at a purchase price of $0.125 per warrant share, with an initial exercise price of $5.772 per share. We received net proceeds of approximately $28.5 million, after deducting placement agent fees and issuance costs. The warrants will expire on March 18, 2017, two years after the date on which they were initially issued. All of the shares of common stock and warrant shares issued and sold were registered under the Securities Act of 1933, as amended, or the Securities Act, pursuant to a registration statement on Form S-1, which we filed with the Securities and Exchange Commission, on April 30, 2015 (File No. 333-203737).

On January 16, 2015, we entered into a Loan and Security Agreement with Oxford Finance LLC, or Oxford, and Silicon Valley Bank, or SVB, providing for term loans in an aggregate principal amount of up to $15 million, in two tranches. We drew down the initial term loans, or the Term A Loans, in the aggregate principal amount of $10 million on January 16, 2015. The Term A Loans bear interest at a fixed rate of 7.05% per annum. On or prior to March 31, 2016, we may borrow additional term loans, or the Term B loans, in the aggregate principal amount up to $5 million,

subject to the satisfaction of certain borrowing conditions, including achievement of the primary endpoints on our Phase IIa trials for our MIN-117 and MIN-202 programs. The Term B Loans will bear interest at a fixed rate per annum of the greater of (i) 7.05% or (ii) the sum of (a) the prime rate reported in The Wall Street Journal three (3) business days prior to the funding date of the Term B Loans, plus (b) 3.80%.

On July 7, 2014, we closed our initial public offering, in which we issued and sold 5,454,545 shares of common stock at a public offering price of $6.00 per share, for aggregate gross proceeds to us of $32.7 million. All of the shares issued and sold in our initial public offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-195169), which was declared effective by the SEC on June 30, 2014. Net proceeds to us from the offering were approximately $28.2 million, after deducting the underwriting discount and transaction expenses of approximately $3.1 million. Following our initial public offering, on July 29, 2014, we closed the sale of an over-allotment of 160,993 shares of our common stock at a price of $6.00 per share, resulting in net proceeds to us of approximately $0.9 million, after deducting the underwriting discount of approximately $0.1 million.

Clinical Update

MIN-101

Enrollment is ongoing in our Phase IIb clinical trial of MIN-101 in Europe. Approximately 40 clinical sites have been initiated in six countries, and patient enrollment is expected to continue through the end of 2015. The primary study objective is an evaluation of the efficacy of MIN-101 compared to placebo in improving the negative symptoms of schizophrenia. Topline results for the core 12-week evaluation period are expected in the second quarter of 2016. The trial is being conducted in stable subjects with schizophrenia suffering from predominantly negative symptoms. We are evaluating two doses of MIN-101 (32mg and 64mg) versus placebo, in a double-blind design in 234 subjects. The primary efficacy endpoint is the change from baseline of negative symptoms after three months of drug administration, as measured from the baseline by the Positive and Negative Symptom Scale, or PANSS. We plan to also investigate the effects on positive symptoms and overall symptoms of schizophrenia measured by PANSS and the Clinical Global Impression rating scales, as well as the effects of MIN-101 on sleep, cognition, anxiety and mood, and clinical and biological safety and drug plasma levels. Patients who experience improved symptomatology during the first three months will be offered the opportunity to enter into an extension phase of six months, which we expect will provide additional long term safety and efficacy data.

MIN-117

In April 2015, we amended the diligence milestone obligation under the license agreement for MIN-117 to extend the deadline to begin enrollment in a Phase IIa or Phase IIb study with MIN-117 in patients suffering major mood disorders from April 30, 2015 to June 30, 2015. We extended the deadline in order to amend the protocol previously approved by the Latvian regulatory authorities for the double blinded placebo controlled Phase IIa study to request an additional patient study arm to evaluate a 2.5mg dose of MIN-117. As consideration for the two-month extension, we paid MTPC $80,000 in May 2015. We met the enrollment milestone obligation in June 2015.

The amended study is expected to include a total 80 patients, of whom 20 will receive a 0.5mg dose of MIN-117, 20 will receive a 2.5mg dose of MIN-117, 20 will receive a 20mg dose of paroxetine and 20 will receive a placebo. The primary endpoint of the trial will be the efficacy of MIN-117 versus placebo in reducing depressive symptoms. We have dosed the first patient in the Phase IIa study and expect topline results to be available in the first half of 2016.

MIN-202

In January 2015, we announced results from a double-blind, placebo-controlled, randomized, 4-way crossover single dose study with MIN-202 in 20 male and female subjects with MDD and insomnia completed by Janssen in Europe. The primary endpoint in this study was the effect of MIN-202 (dosed PM) on latency to persistent sleep, LPS. Certain additional endpoints were evaluated by polysomnography or PSG. Preliminary results demonstrated a statistically significant effect on LPS of all three doses tested (10, 20, and 40mg). Treatment with MIN-202 also resulted in prolonged total sleep duration by approximately 45 minutes. This study was performed using a suspension formulation. MIN-202 was found to be safe and well-tolerated in this study.

In January 2015, we also announced results from a double-blind, placebo-controlled, randomized, multiple ascending dose study in sequential cohorts of male and female healthy subjects completed by Janssen in Europe. MIN-202 was administered in the morning at dose levels ranging from 5mg to 60mg for 10 days. A dose level as low as 5mg of MIN-202 elicits sedation while dose levels ≥ 20mg induce (daytime) somnolence. The MIN-202 plasma exposure is dose proportional from 5mg to 20mg. At higher doses, the exposure is less than dose proportional. This study was

performed using a suspension formulation and MIN-202 was found to be safe and well-tolerated. Pharmacodynamic assessments were incorporated into the clinical study to evaluate the effect of MIN-202 on alertness via PK/PD modeling.

Janssen also recently completed a bioavailability, food effects, safety and tolerability of a solid dosage formulation of MIN-202 in the United States in healthy male subjects. To support planned Phase Ib and Phase II activities, a solid dose formulation has been evaluated. The results of the study showed that similar absorption profiles were observed for both formulations thereby qualifying the solid dose to support further clinical studies. Janssen has dosed the first patient in a European Phase Ib study in adjunctive treatment of major depressive disorder and has opened an Investigational New Drug Application ("IND") for this indication in the U.S. In addition, we expect that Janssen will initiate a Phase IIa study with MIN-202 in insomnia disorder within the next few months. Data readouts for both trials are expected in the first half of 2016.

MIN-301

In January 2015, we announced results from a non-human primate study showing that treatment with an analog of MIN-301 resulted in improvements in a range of symptoms associated with a Parkinson's disease model in primates. The results confirmed the beneficial effects of MIN-301 in non-primate preclinical models. The next planned steps in this program involving our compound based on an investigational extra-cellular domain of neuregulin-1 beta1 to treat Parkinson's disease are the filing of an IND in the U.S. or an Investigational Medicinal Product Dossier (IMPD) in Europe in 2016, and pending acceptance by regulatory authorities, the initiation of Phase I clinical testing thereafter.

Financial Overview

Presentation

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

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

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

In the future, we expect research and development expense to consist of the items described above as well as expense incurred in performing research and development activities, including compensation and benefits for full-time research and development employees and facilities expenses. These costs may also include non-cash stock-based compensation expense as part of our compensation strategy to attract and retain qualified staff. We expect research and development expense to be our largest category of operating expense and to increase as we continue our planned pre-clinical and clinical trials for our product candidates.

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

General and Administrative Expense. General and administrative expenses consist principally of costs for functions in executive, finance, legal, auditing and taxes. Our general and administrative expenses include salaries, bonuses, facility and information system costs and professional fees for auditing, accounting, consulting and legal services. General and administrative costs also include non-cash stock-based compensation expense as part of our compensation strategy to attract and retain qualified staff. We expect general and administrative expenses to be higher in 2015 versus the prior year in order to support our operations as a public reporting company, including increased

payroll, consulting, legal and compliance, accounting, insurance and investor relations costs.

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

Interest Expense (Income), Net. Interest expense consists of amortization of discounts and premiums on our marketable securities and interest incurred under our current and former debt obligations, including our outstanding Term A loans with SVB and Oxford, our former 8.0% convertible promissory notes and our former 8% working capital loans. Interest income consists of interest earned on our cash, cash equivalents and marketable securities.

During the period ended June 30, 2015, interest expense was related primarily to our Term A loans with SVB and Oxford. Interest expense during the period ended June 30, 2014 is primarily related to our former 8.0% convertible promissory notes and working

capital loans, which were repaid in conjunction with our IPO in July 2014. The convertible promissory notes contained a beneficial conversion feature, for which we recorded a debt discount of approximately $2.0 million. The discount was amortized to interest expense using the effective interest method through the notes' maturity date of June 30, 2014.

Results of Operations

Comparison of Three Months Ended June 30, 2015 versus June 30, 2014

Research and Development Expenses

Total research and development expenses were $4.5 million for the three months ended June 30, 2015 compared to $14.6 million for the same period in 2014, a decrease in total expense of $10.1 million. Research and development expense in the three months ended June 30, 2015 and 2014 included non-cash stock-based compensation expenses of $0.2 million and $13.0 million, respectively. The decrease in stock-based compensation expense was primarily due to the vesting of 926,604 shares of common stock and 441,973 options to purchase common stock that were issued and fully vested during the second quarter of 2014. Excluding stock-based compensation, total research and development expense related to drug development programs for the three months ended June 30, 2015 and 2014 was $4.3 million and $1.6 million, respectively, an increase of $2.7 million. This increase in research and development expense primarily reflect increased expenses related to our Phase IIb clinical trial of MIN-101, our Phase IIa clinical trial of MIN-117 and the recent MIN-202 Phase I clinical trials.

General and Administrative Expenses

Total general and administrative expenses were $1.8 million for the three months ended June 30, 2015 compared to $3.1 million for the same period in 2014, a decrease of approximately $1.3 million. General and administrative expense in the three months ended June 30, 2015 and 2014 included non-cash stock-based compensation expenses of $0.4 million and $1.5 million, respectively. The decrease in stock-based compensation expense was primarily due to 97,143 options to purchase common stock that were issued and fully vested during the second quarter of 2014. Excluding stock-based compensation, general and administrative expense for the three months ended June 30, 2015 and 2014 was $1.4 million and $1.6 million, respectively.

Foreign Exchange (Losses) Gains

Foreign exchange loss was $29 thousand for the three months ended June 30, 2015 compared to a gain of $11 thousand for the same period in 2014, a decrease of $40 thousand. The loss was primarily due to certain expenses of Mind-NRG and clinical activities denominated in Euros, with more negative currency movements in 2015.

Interest Expense/(Income), Net

Interest expense/(income) was $0.2 million for the three months ended June 30, 2015 compared to $1.7 million for the same period in 2014, a decrease of $1.5 million. The decrease was primarily due to higher interest expense incurred in 2014 under our convertible promissory notes and the beneficial conversion feature. These convertible promissory notes and accrued interest were converted into 352,000 common shares in July 2014.

Comparison of Six Months Ended June 30, 2015 versus June 30, 2014

Research and Development Expenses

Total research and development expenses were $8.4 million for the six months ended June 30, 2015 compared to $15.1 million for the same period in 2014, a decrease in total expense of $6.7 million. Research and development

expense in the six months ended June 30, 2015 and 2014 included non-cash stock-based compensation expenses of $0.2 million and $13.0 million, respectively. The decrease in stock-based compensation expense was primarily due to the vesting of 926,604 shares of common stock and 441,973 options to purchase common stock that were issued and fully vested during the second quarter of 2014. Excluding stock-based compensation, total research and development expense related to drug development programs for the six months ended June 30, 2015 and 2014 was $8.2 million and $2.1 million, respectively, an increase of $6.1 million. This increase in research and development expense primarily reflect increased expenses related to our Phase IIb clinical trial of MIN-101, our Phase IIa clinical trial of MIN-117 and the recent MIN-202 Phase I clinical trials.

General and Administrative Expenses

Total general and administrative expenses were $3.8 million for the six months ended June 30, 2015 compared to $5.1 million for the same period in 2014, a decrease of approximately $1.3 million. General and administrative expense in the six months ended June 30,

2015 and 2014 included non-cash stock-based compensation expenses of $0.6 million and $1.9 million, respectively. The decrease in stock-based compensation expense of $1.3 million was primarily due to 97,143 options to purchase common stock that were issued and fully vested during the second quarter of 2014 and the cancellation in November 2014 of 519,671 options to purchase common stock that had been outstanding during the prior year period. Excluding stock-based compensation, general and administrative expense for the six months ended June 30, 2015 and 2014 was $3.2 in both periods.

Foreign Exchange (Losses) Gains

Foreign exchange losses were $13 thousand for the six months ended June 30, 2015 compared to a gain of $4 thousand for the same period in 2014, a decrease of $17 thousand. The decrease was primarily due to certain expenses of Mind-NRG and clinical activities denominated in Euros, with more negative currency movements in 2015.

Interest (Income)/Expense, Net

Interest expense was $0.5 million for the six months ended June 30, 2015 compared to $2.0 million for the same period in 2014, a decrease of $1.5 million. The decrease was primarily due to higher interest expense incurred in 2014 under our convertible promissory notes and the beneficial conversion feature. These convertible promissory notes and accrued interest were converted into 352,000 common shares in July 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, 2015, we had an accumulated deficit of approximately $87.4 million. We anticipate that we will continue to incur net losses for the foreseeable future as we continue the development and potential commercialization of our product candidates and to support our operations as a public company. At June 30, 2015, we had approximately $44.8 million in cash, cash equivalents (current and non-current) and marketable securities. We believe that our cash, cash equivalents and marketable securities will be sufficient to fund our operations into the fourth quarter of 2016.

Sources of Funds

Private Placement

On March 18, 2015, pursuant to a securities purchase agreement with certain accredited investors dated March 13, 2015, we sold in a private placement 6,281,661 shares of our common stock at a price per share of $4.81 and warrants to purchase up to an aggregate of 6,281,661 shares of our common stock at a purchase price of $0.125 per warrant share, with an initial exercise price of $5.772 per share for gross proceeds of approximately $31.0 million and net proceeds of approximately $28.5 million. The warrants will expire on March 18, 2017, two years after the date on which they were initially issued.

Term Loans

On January 16, 2015, we entered into a Loan and Security Agreement with Oxford and SVB, providing for term loans to us in an aggregate principal amount of up to $15 million, in two tranches. We drew down the initial term loans in the aggregate principal amount of $10 million, which we refer to as the Term A Loans, on January 16, 2015. The Term A Loans bears interest at a fixed rate of 7.05% per annum. On or prior to March 31, 2016, we may borrow additional term loans, which we refer to as the Term B Loans, in the aggregate principal amount up to $5 million, subject to the satisfaction of certain borrowing conditions, including our achievement of primary endpoints on our Phase IIa trials for our MIN-117 and MIN-202 programs. The Term B Loans will bear interest at a fixed rate per

annum of the greater of (i) 7.05% or (ii) the sum of (a) the prime rate reported in The Wall Street Journal three (3) business days prior to the funding date of the Term B Loans, plus (b) 3.80%.

Uses of Funds

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

We anticipate that we will need substantial additional funding in connection with our continuing operations and to fund Phase III clinical trials of our lead product candidates.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or other third party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third party funding, commercialization, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. There can be no assurance that such additional funding, if available, can be obtained on terms acceptable to us. If we are unable to obtain additional financing, future operations would need to be scaled back or discontinued. Based on our current operating plan, existing cash, the proceeds from our term loan and the March 2015 private placement, we expect to be able to fund our operations into the fourth quarter of 2016.

Under our collaboration agreement with Janssen for MIN-202, we have paid a total of $2.7 million during the six months ended June 30, 2015. We have included an additional $1.1 million in accrued collaborative expenses as of June 30, 2015 and have reached our maximum contribution to program costs for the remainder of 2015, in accordance with the terms of the agreement.

Under our $10.0 million Term A Loan, we expect to make principal repayments of approximately $3.1 million in 2016, $4.0 million in 2017 and $2.9 million in 2018, in accordance with the terms of the agreement.

Cash Flows

The table below summarizes our significant sources and uses of cash for the six months ended June 30, 2015 and 2014:

	Six months Ended June 31,	
	2015	2014
	(dollars in millions)	
Net cash provided by (used in):		
Operating activities	$ (11.9)	$ (3.8)
Investing activities	(23.2)	1.2
Financing activities	38.3	1.3
Net increase in cash	$ 3.2	$ (1.3)

Net Cash Used in Operating Activities

Net cash used in operating activities of approximately $11.9 million during the six months ended June 30, 2015 was primarily due to our net loss of $12.7 million and a $0.8 million decrease in accounts payable and accrued expenses, partially offset by stock-based compensation expense of $0.9 million, amortization of investments and debt discount

of $0.2 million, and a $0.4 million decrease in prepaid expenses.

Net cash used in operating activities of $3.8 million during the six months ended June 30, 2014 was primarily due 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 Provided by Investing Activities

Net cash used in investing activities of approximately $23.2 million during the six months ended June 30, 2015 was primarily due to the purchase of marketable securities of $23.2 million.

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 $38.3 million during the six months ended June 30, 2015 was primarily due to proceeds from the January 2015 Term Loans of $10.0 million and net proceeds from our March 2015 private placement.

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

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Estimates

In our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, our most critical accounting policies and estimates upon which our financial status depends were identified as those relating to stock-based compensation; net operating losses and tax credit carryforwards; and impairment of long-lived assets. We reviewed our policies and determined that those policies remain our most critical accounting policies for the six months ended June 30, 2015.

Recent Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Market risk represents the risk of loss that may affect us due to adverse changes in financial market prices and rates. Our market risk exposure is primarily related to fluctuations in interest rates.

Interest rate exposure

As of June 30, 2015, we had $23.1 million of marketable debt securities, which consisted primarily of corporate bonds, with fixed interest rates. These securities have a weighted-average remaining maturity of 10 months. Due to the overall short-term remaining maturities of our marketable debt securities, our interest rate exposure is not significant. Our Term A loans have fixed interest rates and therefore are not subject to interest rate sensitivity.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2015. Based on the evaluation of our disclosure controls and procedures as of June 30, 2015, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no other changes in internal control over financial reporting during the Company's latest fiscal quarter that would have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

This Quarterly Report on Form 10-Q contains forward-looking information based on our current expectations. Because our actual results may differ materially from any forward-looking statements that we make or that are made on our behalf, this section includes a discussion of important factors that could affect our actual future results, including, but not limited to, our capital resources, the progress and timing of our clinical programs, the safety and efficacy of our product candidates, risks associated with regulatory filings, risks associated with determinations made by regulatory agencies, the potential clinical benefits and market potential of our product candidates, commercial market estimates, future development efforts, patent protection, effects of healthcare reform, reliance on third parties, and other risks set forth below. The risk factors set forth below with an asterisk (*) next to the title are new risk factors or risk factors containing changes, which may be material, from the risk factors previously disclosed in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, as filed with the SEC.

Risks Related to Our Financial Position and Capital Requirements

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

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

We are not profitable and have incurred losses in each period since our inception in 2007. For the six months ended June 30, 2015 and 2014, we reported net losses of $12.7 million and $22.3 million, respectively. As of June 30, 2015, we had an accumulated deficit of $87.4 million.

We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates. If any of our product candidates fail in clinical trials or do not gain regulatory approval, or if any of our product candidates, if approved, fail to achieve market acceptance, we may never generate revenue or become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our

ability to generate revenues. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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

Our operations and the historic operations of Sonkei and Mind-NRG have consumed substantial amounts of cash since inception. We expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance our product candidates into clinical trials.

As of June 30, 2015, we had cash, cash equivalents and marketable securities (current and non-current) of $44.8 million. We believe that our existing cash and cash equivalents, together with amounts drawn or available under our credit facility with Oxford Finance LLC and Silicon Valley Bank and the net proceeds from our private placement of common stock and warrants to purchase common

stock, which was completed in March 2015, will fund our projected operating requirements into the fourth quarter of 2016. In particular, we expect these funds will allow us to complete our Phase IIb trial for MIN-101, our Phase IIa trial for MIN-117, our portion of the funding for the Phase IIa trial in primary insomnia for MIN-202 with Janssen, our portion of the funding for the Phase Ib trial in comorbid insomnia for MIN-202 with Janssen and additional pre-clinical development for MIN-301. However, circumstances may cause us to consume capital more rapidly than we currently anticipate. In any event, we will require significant additional capital to fund future clinical trials of our product candidates, and to obtain regulatory approval for, and to commercialize, our product candidates.

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

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

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

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

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

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

As of December 31, 2014, we had approximately $26.4 million of Federal NOL carryforwards. These Federal NOL carryforwards will begin to expire at various dates beginning in 2027, if not utilized. We plan to use our operating losses to offset any potential future taxable income generated from operations or collaborations. To the extent we generate taxable income, we plan to use our existing NOL carryforwards and future losses to offset income that would otherwise be taxable. However, under the Tax Reform Act of 1986, the amount of benefits from our NOL carryforwards may be impaired or limited if we incur a cumulative ownership change of more than 50%, as interpreted by the U.S. Internal Revenue Service, over a three year period. We have not performed a detailed analysis to determine whether an ownership change occurred upon consummation of the merger between us and Sonkei, upon the acquisition of Mind-NRG or our initial public offering or the concurrent private placements. However, as a result of these transactions, it is likely that an ownership change has occurred. Therefore, it is likely that some or all of our existing NOL carryforwards would be limited by

the provisions of Section 382 of the United States Internal Revenue Code of 1986, as amended. Further, state NOL carryforwards may be similarly limited. We had approximately $21.4 million of state net operating carryforwards at December 31, 2014. It is also possible that future changes in ownership, including as a result of subsequent sales of securities by us or our stockholders, could similarly limit our ability to utilize NOL carryforwards. It is possible that all of our existing NOL carryforwards have been or will be disallowed. Any such disallowances may result in greater tax liabilities than we would incur in the absence of such a limitation and any increased liabilities could adversely affect our business, results of operations, financial condition and cash flow.

Risks Related to Our Business and Industry

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

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

We currently hold no Investigational New Drug, or IND, approvals in the United States (other than the IND held by Janssen, our co-development partner for MIN-202), and as a result do not intend to initiate human clinical trials of our product candidates in the United States (other than the clinical trial being initiated in the United States by Janssen, our co-development partner for MIN-202) until 2015 or later. Whether regulatory approval will be granted is unpredictable and depends upon numerous factors, including the substantial discretion of the regulatory authorities. Moreover, the filing of a marketing application, including a New Drug Application, or NDA, requires a payment of a significant user fee upon submission. The filing of marketing applications for our product candidates may be delayed due to our lack of financial resources to pay such user fee.

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

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

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

regulatory approval, even if we expend substantial time and resources seeking such approval.

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

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

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

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

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

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

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

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

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

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

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

- difficulties obtaining regulatory approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;
- delays in reaching or failure to reach agreement on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- deviations from the trial protocol by clinical trial sites and investigators, or failing to conduct the trial in accordance with regulatory requirements;
- failure of our third parties, such as CROs, to satisfy their contractual duties or meet expected deadlines;
- insufficient or inadequate supply or quantity of product material for use in trials due to delays in the importation and manufacture of clinical supply, including delays in the testing, validation, and delivery of the clinical supply of the investigational drug to the clinical trial sites;
- delays in identification and auditing of central or other laboratories and the transfer and validation of assays or tests to be used;
- delays in having subjects complete participation in a trial or return for post-treatment follow-up;
- difficulties obtaining IRB or ethics committee approval to conduct a trial at a prospective site, or complying with conditions imposed by IRBs or ethics committees;
- challenges recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including competition from other programs for the treatment of similar conditions;
- severe or unexpected drug-related adverse events experienced by subjects in a clinical trial;
- difficulty retaining subjects who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, which are common among schizophrenia and MDD subjects who we require for our clinical trials of two of our product candidates, MIN-101 and MIN-117;
- delays in adding new investigators and clinical sites;
- withdrawal of clinical trial sites from clinical trials;
- lack of adequate funding; and
- clinical holds or termination imposed by the European Union national regulatory authorities, the FDA or IRBs or ethics committees.

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

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

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

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

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

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

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

·the size and nature of the subject population;
·the number and location of clinical sites we enroll;
·competition with other companies for clinical sites or subjects;

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

We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials in Europe and, we expect, eventually in the United States and, while we have agreements governing their committed activities, we have limited influence over their actual performance. We may also experience difficulties enrolling subjects for our clinical trials relating to MIN-101 and MIN-117 due to the mental health of the subjects that we will need to enroll. For instance, according to Datamonitor, roughly one-third of purported schizophrenia patients may not receive an accurate diagnosis, with negative symptoms more difficult to recognize. The patient discontinuation rate for current schizophrenia drugs is also high. For instance, 66 out of 99 subjects ceased to participate in the Phase IIa clinical trial of MIN-101. As a result, the process of finding, diagnosing and retaining subjects throughout a clinical trial targeting the negative symptoms of schizophrenia or MDD may prove difficult and costly.

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

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive pre-clinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication, and failures can occur at any stage of testing. Clinical trials often fail to demonstrate safety and efficacy of the product candidate studied for the target indication. For instance, our clinical studies of MIN-101 and MIN-117 did not show statistically significant differences favorable to the investigational products between the treatment and comparator groups on all the studies' primary, secondary and/or exploratory endpoints. While these studies were not powered for statistical significance, regulatory authorities may find that the studies do not support, in combination with other studies, approval of our product candidates for the target indication. In addition, our product candidates may be associated with undesirable side effects or have characteristics that are unexpected, which may result in abandoning their development or regulatory authorities restricting or denying marketing approval. For instance, prior clinical studies indicated that MIN-101 and MIN-117 may cause adverse events, including, but not limited to, dizziness, vital sign changes, central nervous system events, cardiac events, including prolongation of the QT/QTc interval, and gastrointestinal events. Most product candidates that commence clinical trials are never approved by the applicable regulatory authorities.

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

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

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

Because we have limited financial and management resources, we focus on a limited number of research programs and product candidates. For instance, at the present time we are prioritizing the clinical trials and development of the most advanced of our product candidates, MIN-101. As a result, we may forego or delay pursuit of opportunities with

other product candidates, including MIN-117, MIN-202 and MIN-301, or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

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

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our product candidates demonstrate safety and efficacy in clinical trials, the regulatory agencies may not complete

their review processes in a timely manner, or we may not be able to obtain marketing approval from the relevant regulatory agencies. Additional delays may result if the EMA, FDA, an FDA Advisory Committee, or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials and the review process.

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

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

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

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

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