Sage Therapeutics, Inc.
Form 10-Q
August 14, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

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

For the quarterly period ended June 30, 2014

OR

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

For the transition period from _____ to _____

Commission file number: 001-36544

Sage Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**27-4486580**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

215 First Street

Cambridge, Massachusetts 02142

(Address of principal executive office) (Zip Code)

Registrant s telephone number, including area code:

(617) 229-8380

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

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 (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

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

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

As of August 1, 2014, there were 25,711,926 shares of the registrant s Common Stock, $0.001 par value per share, outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as may, will, should, expects, intends, plans, anticipates, estimates, predicts, potential, continue or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the accuracy of our estimates regarding expenses, future revenues and capital requirements;
- our plans to develop and commercialize our product candidates, initially as treatments for status epilepticus, refractory status epilepticus and super refractory status epilepticus;
- our ability to complete our ongoing clinical trials and to advance our product candidates into additional clinical trials, including pivotal clinical trials, and successfully complete such clinical trials;
- regulatory developments in the United States and foreign countries;
- the performance of our third-party manufacturers and contract research organizations;
- our ability to obtain and maintain intellectual property protection for our proprietary assets;
- the size of the potential markets for our product candidates and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates for any indication once approved;
- our ability to obtain additional financing;
- the success of competing products that are or become available for the indications that we are pursuing;
- the loss of key scientific or management personnel; and
- other risks and uncertainties, including those listed under Part II, Item 1A. Risk Factors.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and 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, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part II, Item 1A. Risk Factors and elsewhere in this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

Sage Therapeutics, Inc.

INDEX

	Page
PART I FINANCIAL INFORMATION	
Item 1. Financial Statements (Unaudited)	5
Balance Sheets as of June 30,2014 and December 31, 2013	5
Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2014 and 2013	6
Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders Equity (Deficit)	7
Statements of Cash Flows for the six months ended June 30, 2014 and 2013	8
Notes to Financial Statements	9
Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations	17
Item 3. Quantitative and Qualitative Disclosures About Market Risk	27
Item 4. Controls and Procedures	28
PART II OTHER INFORMATION	
Item 1. Legal Proceedings	28
Item 1A. Risk Factors	28
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	58
Item 6. Exhibits	59
Signatures	60

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

Sage Therapeutics, Inc.

Balance Sheets

(in thousands, except share and per share data)

(Unaudited)

	June 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 49,127	$ 8,066
Prepaid expenses and other current assets	2,416	341
Total current assets	51,543	8,407
Property and equipment, net	69	86
Restricted cash	39	39
Total assets	$ 51,651	$ 8,532
Liabilities, Redeemable Convertible Preferred Stock and Stockholders Deficit		
Current liabilities:		
Accounts payable	$ 1,862	$ 1,988
Accrued expenses	2,069	327
Total current liabilities	3,931	2,315
Other liabilities:	40	44
Total liabilities	3,971	2,359
Redeemable convertible preferred stock (Series A, B and C), $0.0001 par value; 56,723,905 and 37,750,000 shares authorized at June 30, 2014 and December 31, 2013, respectively; 56,723,904 and 37,750,000 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively; liquidation preference of $96,615 and $40,663 at June 30, 2014 and December 31, 2013, respectively	92,472	37,709
Stockholders deficit:		
Common stock, $0.0001 par value; 70,623,905 and 66,000,000 shares authorized at June 30, 2014 and December 31, 2013, respectively; 1,714,248 and 1,622,761 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively		
Additional paid-in capital		139

Accumulated deficit	(44,792)	(31,675)
Total stockholders deficit	(44,792)	(31,536)
Total liabilities, redeemable convertible preferred stock and stockholders deficit	$ 51,651	$ 8,532

The accompanying notes are an integral part of these financial statements.

Sage Therapeutics, Inc.

Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Operating expenses:				
Research and development	$ 4,381	$ 3,854	$ 8,554	$ 6,437
General and administrative	1,807	801	3,424	1,607
Total operating expenses	6,188	4,655	11,978	8,044
Loss from operations	(6,188)	(4,655)	(11,978)	(8,044)
Interest income (expense), net	1		1	
Other income (expense), net	(5)		(5)	
Net loss and comprehensive loss	(6,192)	(4,655)	(11,982)	(8,044)
Accretion of redeemable convertible preferred stock to redemption value	(1,577)		(1,903)	
Net loss attributable to common stockholders	$ (7,769)	$ (4,655)	$ (13,885)	$ (8,044)
Net loss per share attributable to common stockholders basic and diluted	$ (4.57)	$ (3.18)	$ (8.28)	$ (5.58)
Weighted average number of common shares used in net loss per share attributable to common stockholders basic and diluted	1,700,517	1,464,419	1,676,864	1,442,774

The accompanying notes are an integral part of these financial statements.

Sage Therapeutics, Inc.

Statement of Changes in Redeemable Convertible Preferred Stock and Stockholders Deficit

(in thousands, except share)

(Unaudited)

	Series A, B and C Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balances at December 31, 2013	37,750,000	$ 37,709	1,622,761	$	$ 139	$ (31,675)	$ (31,536)
Issuance of Series B Preferred stock, net of issuance costs of $30	9,999,999	14,970					
Issuance of Series C Preferred Stock, net of issuance costs of $110	8,973,905	37,890					
Issuance of common stock from exercise of stock options			3,968		2		2
Vesting of restricted stock			71,647		5		5
Issuance of common stock in payment of consultant fees			15,872		127		127
Stock-based compensation expense					495		495
Accretion of redeemable convertible preferred stock to redemption value		1,903			(768)	(1,135)	(1,903)
Net loss						(11,982)	(11,982)
Balances at June 30, 2014	56,723,904	$ 92,472	1,714,248	$	$	$ (44,792)	$ (44,792)

The accompanying notes are an integral part of these financial statements.

Sage Therapeutics, Inc.

Statements of Cash Flows

(in thousands)

(Unaudited)

	Six Months Ended June 30,	
	2014	**2013**
Cash flows from operating activities		
Net loss	$ (11,982)	$ (8,044)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	495	12
Licensing or consulting fees paid in common stock	127	
Depreciation and amortization	22	23
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	(435)	(33)
Accounts payable	(385)	525
Accrued expenses and other	1,269	211
Net cash used in operating activities	(10,889)	(7,306)
Cash flows from investing activities		
Purchase of property and equipment	(5)	(3)
Net cash used in investing activities	(5)	(3)
Cash flows from financing activities		
Proceeds from the issuance of Series A preferred stock, net of issuance costs		4,995
Proceeds from the issuance of Series B preferred stock, net of issuance costs	14,970	
Proceeds from the issuance of Series C preferred stock, net of issuance costs	37,890	
Proceeds from the issuance of common stock and restricted stock	2	35
Payment of offering costs	(907)	
Net cash provided by financing activities	51,955	5,030
Net increase (decrease) in cash and cash equivalents	41,061	(2,279)
Cash and cash equivalents at beginning of period	8,066	2,802
Cash and cash equivalents at end of period	$ 49,127	$ 523
Supplemental disclosure of non-cash investing and financing activities		
Accretion of redeemable convertible preferred stock to redemption value	$ 1,903	$
Deferred initial public offering costs included in accounts payable or accrued expenses	$ 733	$

The accompanying notes are an integral part of these financial statements.

8

SAGE THERAPEUTICS, INC.

Notes to Financial Statements

(Amounts in thousands, except share and per share data)

(Unaudited)

1. Nature of the Business

Sage Therapeutics, Inc. (Sage or the Company) is a clinical-stage biopharmaceutical company committed to developing and commercializing novel medicines to treat life-threatening, rare central nervous system (CNS) disorders, where there are inadequate or no approved existing therapies. The Company is targeting CNS indications where patient populations are easily identified, acute treatment is typically initiated in the hospital setting, clinical endpoints are well-defined, and development pathways are feasible. This focus allows the Company to make highly informed decisions when advancing its product candidates through the development process. The Company s initial product candidates are aimed at treating different stages of status epilepticus, a life-threatening condition in which the brain is in a state of persistent seizure.

The Company was incorporated under the laws of the state of Delaware on April 16, 2010 and commenced operations on January 19, 2011 as Sterogen Biopharma, Inc. On September 13, 2011, the Company changed its name to Sage Therapeutics, Inc. under its second Amended and Restated Certificate of Incorporation.

The Company is subject to risks and uncertainties common to early-stage companies in the biotech industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, and ability to secure additional capital to fund operations.

2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited interim financial statements of the Company included herein have been prepared, pursuant to the rules and regulations of the Securities and Exchange Commission (the SEC). Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted from this report, as is permitted by such rules and regulations. Accordingly, these consolidated financial statements should be read in conjunction with the financial statements as of and for the year ended December 31, 2013 and the three months ended March 31, 2014 and notes thereto, included in the Company s prospectus filed with the SEC pursuant to Rule 424(b)(4) on July 18, 2014 (the Prospectus).

The unaudited interim financial statements have been prepared on the same basis as the audited consolidated financial statements. In the opinion of the Company s management, the accompanying unaudited interim consolidated financial statements contain all adjustments which are necessary to present fairly the Company s financial position as of June 30, 2014, the results of its operations for the three and six months ended June 30, 2014 and 2013 and its cash flows for the six months ended June 30, 2014 and 2013. Such adjustments are of a normal and recurring nature. The results for the six months ended June 30, 2014 are not necessarily indicative of the results for the year ending December 31, 2014, or for any future period.

On July 23, 2014, the Company completed the sale of 5,750,000 shares of its common stock in its initial public offering (the IPO), at a price to the public of $18.00 per share, resulting in net proceeds to the Company of $94.0 million after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company. In preparation for the IPO, the Company s board of directors and stockholders approved a 1-for-3.15 reverse stock split of the Company s common stock effective July 2, 2014. All share and per share amounts in the unaudited financial statements contained herein and notes thereto have been retroactively adjusted, where necessary, to give effect to this reverse stock split. In connection with the closing of the IPO, all of the Company s outstanding redeemable convertible

preferred stock automatically converted into shares of common stock as of July 23, 2014, resulting in the issuance by the Company of an additional 18,007,575 shares of common stock. The significant increase in shares outstanding in July 2014 is expected to impact the year-over-year comparability of the Company s net loss per share calculations over the next year.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Fair Value Measurements

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three categories:

- Level 1 — Quoted market prices in active markets for identical assets or liabilities. At June 30, 2014 (unaudited) and December 31, 2013, the Company s Level 1 assets consisted of a money market fund totaling $49,548 and $8,024, respectively.
- Level 2 — Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. At June 30, 2014 (unaudited) and December 31, 2013, the Company had no Level 2 assets or liabilities.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. At June 30, 2014 (unaudited) and December 31, 2013, the Company had no Level 3 assets or liabilities.

The Company s financial instruments generally consist of cash equivalents, accounts payable and accrued expenses. The carrying amounts for the applicable financial instruments reported in the balance sheets approximate their fair values at June 30, 2014 (unaudited).

Deferred Offering Costs

The Company capitalizes certain legal, accounting and other third-party fees that are directly associated with in-process equity financings as other assets until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering. As of June 30, 2014 (unaudited), the Company recorded $1,640 of deferred offering costs, included in prepaid expenses and other current assets in the accompanying consolidated balance sheet, in contemplation of its July 2014 IPO. The Company did not record any deferred offering costs as of December 31, 2013.

Recently Issued Accounting Pronouncements

In June 2014, the FASB issued guidance that removes all incremental reporting requirements for development stage entities, including the requirement to report inception-to-date information in the statements of income, cash flows, and shareholders equity. The Company elected to early adopt this guidance for the period ended June 30, 2014. The adoption of this guidance resulted in decreased financial statement disclosures, but did not impact the Company s financial condition, results of operations or cash flows.

There have been no other material changes to the significant accounting policies previously disclosed in the Company s Prospectus.

3. Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2014	December 31, 2013
Employee related expenses	$ 674	$ 49
Development & clinical costs	686	57
Professional services	210	190
Initial public offering costs	474	
Other accrued expenses	25	31
Total accrued expenses	$ 2,069	$ 327

4. Stock-Based Compensation

The Company maintains the 2011 Stock Option and Incentive Plan (the 2011 Stock Option Plan) which provides for the grant of restricted stock awards, incentive stock options and non-statutory stock options to purchase up to 3,142,857 shares of the Company s common stock to employees, officers, directors and consultants of the Company. At June 30, 2014, there were 648,952 shares available for future issuance under the 2011 Stock Option Plan.

Terms of restricted stock awards and stock option agreements, including vesting requirements, are determined by the Board of Directors, subject to the provisions of the 2011 Stock Option Plan. Options and restricted stock awards granted by the Company generally vest based on the grantee s continued service with the Company during a specified period following grant. Awards generally vest ratably over four years, with 25% cliff vesting at the one-year anniversary for new employee awards. During 2013, the Company also granted a pool of option awards which vest ratably over one year. All awards are exercisable from the date of grant for a period of ten years. The stock-based compensation expense recognized during the three and six months ended June 30, 2014 and 2013 was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Stock compensation expense:				
Research and development	$ 153	$ 8	$ 259	$ 12
General and administrative	182		236	
	$ 335	$ 8	$ 495	$ 12

For stock option awards, the fair value of the options is estimated at the grant date using the Black-Scholes option-pricing model, taking into account the terms and conditions upon which options are granted. The fair value of the options is amortized on a straight-line basis over the requisite service period of the awards. The weighted average grant date fair value per share relating to outstanding stock options granted under the 2011 Stock Option Plan during the three and six months ended June 30, 2014 was $9.61 and $8.90, respectively.

The fair value of each option granted to employees and directors during the three and six months ended June 30, 2014 under the 2011 Stock Option Plan has been calculated on the date of grant using the following weighted average assumptions:

	Three Months Ended June 30, 2014	Six Months Ended June 30, 2014
Expected dividend yield	0.00%	0.00%
Expected volatility	102.15%	100.88
Risk free interest rate	1.82%	1.90%
Expected term	6.06 years	6.02 years

Expected dividend yield: The Company has not paid and does not anticipate paying any dividends in the foreseeable future.

Risk-free interest rate: The Company determined the risk-free interest rate by using a weighted average equivalent to the expected term based on the U.S. Treasury yield curve in effect as of the date of grant.

Expected volatility: As the Company had been operating as a private company, there is not sufficient historical volatility for the expected term of the options. Therefore, the Company used an average historical share price volatility based on an analysis of reported data for a peer group of comparable companies.

Expected term (in years): Expected term represents the period that the Company s share option grants are expected to be outstanding. As the Company had been operating as a private company, there is not sufficient historical share data to calculate the expected term of the options. Therefore, the Company elected to utilize the simplified method to value share option grants issued to employees. Under this approach, the weighted average expected life is presumed to be

the average of the vesting term and the contractual term of the option.

Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from estimates. The Company estimates forfeitures based on historical termination behavior. For the three and six months ended June 30, 2014, a forfeiture rate of 10% was applied.

For options granted to nonemployees, the expected life of the option used is ten years, which is the contractual term of each such option. All other assumptions used to calculate the grant date fair value are generally consistent with the assumptions used for options granted to employees.

The table below summarizes activity related to stock options:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Life (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2013	1,203,481	$ 0.51	9.60	$ 1,038
Granted	680,940	6.77		
Exercised	(3,968)	0.44		
Forfeited	(20,634)	1.35		
Outstanding as of June 30, 2014	1,859,819	$ 2.78	9.35	$ 28,281
Vested or expected to vest as of June 30, 2014	1,617,115	$ 2.66	9.33	$ 24,783
Exercisable as of June 30, 2014	80,201	$ 1.09	9.11	$ 1,355

As of June 30, 2014, the Company had unrecognized stock-based compensation expense related to its unvested stock option awards of $4,953, which is expected to be recognized over the remaining weighted average vesting period of 3.36 years. The total fair value of shares vested for the six months ended June 30, 2014 was $219. During the six months ended June 30, 2014, stock option exercises resulted in proceeds of $2. The intrinsic value of stock options exercised during the six months ended June 30, 2014 was $30.

Restricted Stock Awards

During the six months ended June 30, 2014, the Company granted restricted stock awards to certain officers, employees, directors, and consultants of the Company. During the three and six months ended June 30, 2014, the Company recorded $33 and $55, respectively, of stock-based compensation expense related to its restricted stock.

The table below summarizes activity relating to restricted stock:

	Shares	Weighted Average Grant Date Fair Value
Unvested restricted common stock as of December 31, 2013	315,718	$
Issued		
Vested	(71,647)	
Forfeited		
Repurchased	(6,778)	
Unvested restricted common stock as of June 30, 2014	237,293	

As of June 30, 2014, the Company had unrecognized stock-based compensation expense related to its unvested restricted stock awards of $239, which is expected to be recognized over the remaining weighted average vesting period of 1.64 years.

Unvested shares are subject to repurchase by the Company, at the issuance price, upon the employee s termination at the Company s sole discretion. In the six months ended June 30, 2014, the Company repurchased 6,778 shares of restricted common stock issued to employees with a value of less than $1 in conjunction with the employees termination from the Company.

5. Net Loss Per Share

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders for the three and six months ended June 30, 2014 and 2013:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Numerator:				
Net loss attributable to common stockholders	$ (7,769)	$ (4,655)	$ (13,885)	$ (8,044)
Denominator:				
Weighted average common shares outstanding basic	1,700,517	1,464,419	1,676,864	1,442,774
Dilutive effect of common share equivalents resulting from common share options and preferred common shares (as converted)				
Weighted average common shares outstanding diluted	1,700,517	1,464,419	1,676,864	1,442,774
Net loss per share attributable to common stockholders basic and diluted	$ (4.57)	$ (3.18)	$ (8.28)	$ (5.58)

The following common stock equivalents, presented on a weighted average basis, were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been anti-dilutive:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Options to purchase common stock	1,595,481		1,595,481	
Restricted stock	235,247	274,798	235,265	274,795
Convertible preferred stock (as converted to common stock)	18,007,575	6,349,204	16,572,562	5,855,143
	19,838,303	6,624,002	18,403,308	6,129,938

6. Income Taxes

The Company did not record a federal or state income tax benefit for the Company s losses for the six months ended June 30, 2014 and 2013 due to the Company s conclusion that a valuation allowance is required.

7. Related Party Transactions

Since inception, the Company has received consulting and management services from Third Rock Ventures LLC, which through its affiliates, has a controlling interest in the Company and owns Series A, B and C preferred stock and common stock at June 30, 2014. The Company paid Third Rock Ventures LLC $99 and $190 for these services during the three months ended June 30, 2014 and 2013, respectively. The Company paid Third Rock Ventures LLC $224 and $403 for these services during the six months ended June 30, 2014 and 2013, respectively. The Company owed to Third Rock Ventures LLC $31 at June 30, 2014. This amount is included in Accounts Payable.

8. Subsequent Events

2014 Stock Option Plan

On July 2, 2014, the Company s stockholders approved the 2014 Stock Option and Incentive Plan (the 2014 Stock Option Plan), which became effective upon the completion of the IPO. The 2014 Stock Option Plan replaced the 2011 Stock Option Plan. Any options or awards outstanding under the Company s 2011 Stock Option Plan remained outstanding and effective. The 2014 Stock Option Plan provides for the grant of stock options, stock appreciation rights, restricted stock, restricted stock units, unrestricted stock, performance-share awards and cash-based awards. The number of shares initially reserved for issuance under the 2014 Stock Option Plan is the sum of (i) 1,143,000 shares of common stock and (ii) the number of shares under the 2011 Stock Option Plan that are not needed to fulfill the Company s obligations for awards issued under the 2011 Stock Option Plan as a result of forfeiture, expiration, cancellation, termination or net issuances of awards thereunder. The number of shares of common stock that may be issued under the 2014 Stock Option Plan is also subject to increase on the first day of each fiscal year by up to 4% of the Company s issued and outstanding shares of common stock on the immediately preceding December 31.

2014 Employee Stock Purchase Plan

On July 2, 2014, the Company s stockholders approved the 2014 Employee Stock Purchase Plan. A total of 282,000 shares of common stock were initially authorized for issuance under this plan. The 2014 Employee Stock Purchase Plan became effective upon the completion of the IPO.

Initial Public Offering

On July 23, 2014, the Company completed the sale of 5,750,000 shares of its common stock in its IPO, at a price to the public of $18.00 per share, resulting in net proceeds to the Company of $94.0 million after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company.

In preparation for the IPO, the Company s board of directors and stockholders approved a 1-for-3.15 reverse stock split of the Company s common stock effective July 2, 2014. All share and per share amounts in the unaudited consolidated financial statements contained herein and notes thereto have been retroactively adjusted, where necessary, to give effect to this reverse stock split. In connection with the closing of the IPO, all of the Company s outstanding redeemable convertible preferred stock automatically converted into shares of common stock as of July 23, 2014, resulting in the issuance by the Company of an additional 18,007,575 shares of common stock.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in our final prospectus for our initial public offering filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the Securities Act), with the Securities and Exchange Commission (the SEC) on July 18, 2014 (the Prospectus).

Our actual results and timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forward-looking statements. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report, they may not be predictive of results or developments in future periods.

The following information and any forward-looking statements should be considered in light of factors discussed elsewhere in the Quarterly Report on Form 10-Q, including those risks identified under Part II, Item 1A. Risk Factors.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company committed to developing and commercializing novel medicines to treat life-threatening, rare central nervous system, or CNS, disorders, where there are inadequate or no approved existing therapies. We are targeting CNS indications where patient populations are easily identified, acute treatment is typically initiated in the hospital setting, clinical endpoints are well-defined, and development pathways are feasible. This focus allows us to make highly informed decisions when advancing our product candidates through the development process. Our initial product candidates are aimed at treating different stages of status epilepticus, or SE, a life-threatening condition in which the brain is in a state of persistent seizure.

The lead product candidate in our SE program, SAGE-547, is an intravenous, or IV, agent in Phase 1/2 clinical development as an adjunctive therapy, a therapy combined with current therapeutic approaches, for the treatment of super-refractory SE, or SRSE. The current standard of care for SRSE is empiric, and there are no therapies at present that have been specifically approved for this indication. We thus believe there is a significant unmet medical need for SAGE-547.

SE is diagnosed when a patient has a seizure lasting longer than five minutes, and is associated with substantial morbidity and mortality. We estimate that in the United States each year there are up to 150,000 cases of SE, of which 30,000 SE patients die. We estimate that there are 35,000 patients with SE in the United States that are hospitalized in the intensive care unit, or ICU, each year. An SE patient is first treated with benzodiazepines, or BDZs, and if no response then treated with other, second-line, anti-seizure drugs. If the seizure persists after second-line therapy the patient is diagnosed as having refractory SE, or RSE, admitted to the ICU and placed into a medically induced coma. Currently, there are no therapies that have been specifically approved for refractory SE, or RSE; however, physicians typically use anesthetic agents to induce the coma and stop the seizure immediately. After a period of 24 hours, an attempt is made to wean the patient from the anesthetic agents to evaluate whether or not the seizure condition has

resolved. Unfortunately, not all patients respond to weaning attempts, in which case the patient must be maintained in the medically induced coma. At this point, the patient is diagnosed as having SRSE.

We have compiled evidence which we believe supports the safety and activity of SAGE-547 for treatment of SRSE. Six patients have been treated with SAGE-547 by independent centers under emergency-use Investigational New Drug Applications, or INDs. Five of these patients treated with SAGE-547 achieved resolution of SRSE either during the course of or soon after SAGE-547 treatment. The one patient that did not achieve resolution of SRSE during the course of or soon after SAGE-547 treatment had low plasma exposures of SAGE-547. On October 30, 2013, we filed an IND for SAGE-547 for the treatment of SRSE with the U.S. Food and Drug Administration, or FDA, and we received notification allowing us to proceed with our Phase 1/2 clinical trial of SAGE-547

on November 27, 2013. We commenced our Phase 1/2 clinical trial to study safety, tolerability and efficacy of SAGE-547 in adult patients with SRSE in January 2014. This clinical trial is an open-label study in at least ten patients diagnosed with SRSE. As of August 8, 2014, there are 10 active study sites in the United States, and we plan to open up to 10 additional study sites in the United States to achieve full enrollment of this clinical trial. As previously reported in the Prospectus, four patients have been enrolled in this trial and treated with SAGE-547 with the remainder of enrollment expected during the second half of 2014. While data collection in and data review from these patients is ongoing, all four patients met the key efficacy endpoint, in that each was successfully weaned off his or her anesthetic agent while SAGE-547 was being administered. Three of these patients were subsequently weaned off SAGE-547 without reinstating general anesthesia, while one patient experienced recurrence of SE upon withdrawal of SAGE-547 requiring reinstitution of general anesthesia. Of the three patients that have completed the three-week follow up period, one patient was discharged to a rehabilitation facility to continue recovery, one remained hospitalized to continue to be treated for severe ongoing medical conditions, and one experienced recurrence of SE. We believe this data provides preliminary evidence of the pharmacological effect of SAGE-547. We plan to report data from this Phase 1/2 clinical trial in the second half of 2014. In April 2014, the FDA granted us orphan drug designation for SAGE-547 as a treatment for SE. In July, we announced that the FDA granted fast track designation for the SAGE-547 development program. Fast track designation is intended to facilitate the review of drug candidates that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs.

SAGE-689 and SAGE-217, two additional product candidates in our SE program, are currently in IND-enabling toxicology and safety pharmacology testing. SAGE-689 is being developed as an adjunctive second-line therapy for the treatment of SE, and SAGE-217 is being developed as both an IV monotherapy for the treatment of RSE, and as an orally delivered maintenance therapeutic to prevent recurrent seizures in patients whose SE, RSE or SRSE has resolved.

We anticipate that SAGE-217 may also have the potential for use in a broader range of seizure conditions beyond maintenance therapy, including orphan genetic seizure disorders, such as Rett syndrome and Dravet syndrome. In addition, we believe related molecules from our portfolio may be useful in the treatment of a variety of neurological and psychiatric disorders, including, for example, fragile X syndrome, anxiety and tremor. With respect to our near-term SE programs, we plan to file an IND for SAGE-689 in the second half of 2014 and to begin a Phase 1 clinical trial thereafter. We are currently conducting IND-enabling studies of SAGE-217, with a plan to file an IND in the first half of 2015.

Since our inception in April 2010, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, identifying and developing our product candidates, preparing to conduct clinical studies of our product candidates, providing general and administrative support for these operations and protecting our intellectual property. We have funded our operations to date through sales of redeemable convertible preferred stock and, to a lesser extent, the issuance of convertible notes. From our inception through June 30, 2014, we had received net proceeds of $90.7 million from such transactions. On July 23, 2014, we completed the sale of 5,750,000 shares of our common stock in an initial public offering, or IPO, at a price to the public of $18.00 per share, resulting in net proceeds of $94.0 million after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We are an early-stage company and have not generated any revenue. We have incurred net losses in each year since our inception, and we have a deficit accumulated $44.8 million as of June 30, 2014. Our net losses were $9.6 million and $18.3 million for the years ended December 31, 2012 and 2013, respectively, and $12.0 million for the six months ended June 30, 2014. These losses have resulted principally from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. We expect to incur significant expenses and increasing operating losses for the foreseeable future.

We expect that our expenses will increase substantially in connection with our ongoing activities, as we:

- advance clinical development of SAGE-547, our lead product candidate in our SE program, including completing the Phase 1/2 clinical trial currently underway and commencing other clinical trials thereafter;

- advance development of SAGE-689, the first follow-on product candidate in our SE program, including filing an Investigational New Drug Application, or IND, in the second half of 2014 and conducting a Phase 1 clinical trial thereafter;

- advance development of SAGE-217, the second follow-on product candidate in our SE program, including completing the IND-enabling toxicology and safety pharmacology testing currently underway;

continue our research and development efforts for other drug candidates in the treatment of CNS disorders;

continue to engage contract manufacturing organizations, or CMOs, to manufacture our clinical study materials and to develop large-scale manufacturing capabilities;

seek regulatory approvals for our product candidates;

add personnel, including personnel to support our product development and future commercialization;

add operational, financial and management information systems;

maintain, leverage and expand our intellectual property portfolio; and

operate as a public company.

As a result, we will need additional financing to support our continuing operations. Until such time that we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity or debt financings or other sources, which may include collaborations with third parties. Arrangements with collaborators or others may require us to relinquish rights to certain of our technologies or product candidates. In addition, we may never successfully complete development of any of our product candidates, obtain adequate patent protection for our technology, obtain necessary regulatory approval for our product candidates or achieve commercial viability for any approved product candidates. Adequate additional financing may not be available to us on acceptable terms, or at all. Our inability to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenue to achieve profitability, and we may never do so.

We expect that our existing cash and cash equivalents as of June 30, 2014, along with proceeds from our initial public offering which closed on July 23, 2014, will enable us to fund our operating expenses and capital expenditures requirements for at least the next 12 months. See Liquidity and Capital Resources.

Financial Operations Overview

Revenue

We have not generated any revenue from product sales since our inception and do not expect to generate any revenue from the sale of products in the near future. If our development efforts result in clinical success and regulatory approval or collaboration agreements with third parties for our product candidates, we may generate revenue from those product candidates.

Operating Expenses

Our operating expenses since inception have consisted of research and development activities and general and administrative costs.

Research and Development Expenses

Research and development expenses, which consist of costs associated with our product research and development efforts, are expensed as incurred. Research and development expenses consist primarily of:

- personnel costs, including salaries, related benefits, stock-based compensation and related travel expenses for employees engaged in scientific research and development functions;

expenses incurred under agreements with contract research organizations, or CROs, and investigative sites that conduct our non-clinical studies and clinical trials;

expenses associated with manufacturing clinical study materials and developing external manufacturing capabilities;

costs of outside consultants, including their fees, stock-based compensation and related travel expenses;

other expenses related to our non-clinical studies and expenses related to our regulatory activities; and

payments made under our third-party licensing agreements.

Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and our clinical sites.

We have been developing SAGE-547, SAGE-689 and SAGE-217 and are focusing on other research and development programs related to exploratory efforts, target validation, and lead optimization for our earlier-validated programs. Our direct research and development expenses are tracked on a program-by-program basis and consist primarily of external costs, such as fees paid to investigators, central laboratories, CROs and CMOs in connection with our non-clinical studies and clinical trials; third-party license fees related to our product candidates; fees paid to outside consultants who perform work on our programs; and costs related to manufacturing or purchasing clinical trial materials. We do not allocate employee related costs and other indirect costs to specific research and development programs because these costs are deployed across multiple product programs under research and development and, as such, are separately classified as unallocated research and development expenses.

The following table summarizes our research and development expenses by program:

	Six Months Ended June 30,		
	2014	2013	Change
	(in thousands)		
SAGE-547	$ 2,614	$ 1,240	$ 1,374
SAGE-689	1,766	1,697	69
SAGE-217	1,392		1,392
Other research and development programs	259	2,116	(1,857)
Unallocated expenses	2,523	1,384	1,139
Total research and development expenses	$ 8,554	$ 6,437	$ 2,117

Research and development activities are central to our business. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will continue to increase in the foreseeable future as we initiate clinical trials for certain product candidates and pursue later stages of clinical development of our product candidates.

We cannot determine with certainty the duration and completion costs of the current or future clinical trials of our product candidates or if, when, or to what extent we will generate revenue from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs, and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- the scope, rate of progress, and expense of our ongoing as well as any additional non-clinical studies, clinical trials and other research and development activities;

future clinical trial results;

uncertainties in clinical trial enrollment rate or design;

significant and changing government regulation; and

the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, consisting of salaries, related benefits, stock-based compensation and related travel expenses of our executive, finance, business and corporate development and other administrative functions. General and administrative expenses also include facilities, information technology and other expenses, including rent, depreciation, maintenance of facilities, insurance and supplies; and professional fees for auditing, tax and legal services, including legal expenses to pursue patent protection of our intellectual property.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support the expected growth in our research and development activities and the potential commercialization of our product candidates. We also anticipate increased expenses associated with being a public company, including costs related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, and investor relations costs. Additionally, if and when we believe that a regulatory approval of the first product candidate appears likely, we anticipate an increase in payroll and related expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidates.

Other Income (Expense)

Interest income (expense), net. Interest income (expense), net consists of interest earned on our cash and cash equivalents and interest expense on prior debt. Our interest income has not been significant due to low interest earned on invested balances. We anticipate that our interest income will increase in the future due to increased balances from the net proceeds of our IPO. During the six months ended June 30, 2014 and 2013, interest income (expense) was not material.

Other income (expense), net. Other income (expense), net consists of the realized and unrealized net gains and losses from foreign currency-denominated vendor payables. During the six months ended June 30, 2014 and 2013, other income (expense) was not material.

Results of Operations

Comparison of Three Months Ended June 30, 2014 and 2013

The following table summarizes our results of operations for the three months ended June 30, 2014 and 2013:

	Three Months Ended June 30,		
	2014	2013	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 4,381	$ 3,854	$ 527
General and administration	1,807	801	1,006
Total operating expenses	6,188	4,655	1,533
Loss from operations	(6,188)	(4,655)	(1,533)
Interest income (expense), net	1		1
Other income (expense), net	(5)		(5)
Net loss	$ (6,192)	$ (4,655)	$ (1,537)

Research and development expenses

	Three Months Ended June 30,		
	2014	2013	Change
	(in thousands)		
SAGE-547	$ 1,441	$ 841	$ 600
SAGE-689	905	904	1
SAGE-217	706		706
Other research and development programs	3	1,345	(1,342)
Direct research and development expenses	3,055	3,090	(35)
Personnel related expenses	1,178	602	576
Other expenses	148	162	(14)
Total research and development expenses	$ 4,381	$ 3,854	$ 527

Research and development expenses for the three months ended June 30, 2014 were $4.4 million compared to $3.9 million for the three months ended June 30, 2013. The increase of $0.5 million period over period was primarily due to the following:

- an increase of $0.6 million in expenses of our SAGE-547 program, consisting of expenses related to the completion of toxicology studies and the external clinical and drug supply costs associated with our

ongoing Phase 1/2 clinical trial of SAGE-547;

an increase of $0.7 million of expenses of our SAGE-217 program with advancement of lead optimization program into IND-enabling non-clinical development;

a net decrease $1.3 million in expenses of our other research and development programs reflecting portfolio priorities and timing of investment in certain research programs; and

an increase of $0.6 million in unallocated personnel-related R&D spending reflecting the effects of hiring additional, full-time employees during 2013 and the first quarter of 2014 to support advancement of development programs.

General and administrative expenses

	Three Months Ended June 30,		
	2014	2013	Change
	(in thousands)		
Personnel related	$ 827	$ 296	$ 531
Professional fees	693	295	398
Facilities	87	81	6
Other	200	129	71
Total general and administrative expenses	$ 1,807	$ 801	$ 1,006

General and administrative expenses for the three months ended June 30, 2014 were $1.8 million, compared to $0.8 million for the three months ended June 30, 2013. The increase of $1 million in general and administrative expenses was primarily due to $0.5 million increase in personnel related costs including salary and bonus increases of $0.4 million due to the effects of hiring additional, full-time employees during 2013 to support corporate operations, finance and business development activities as well as an increase in stock compensation expense. The increase period over period in general and administrative expenses was also due to a $0.4 million increase in professional fees incurred primarily in connection with preparation for our planned IPO and professional fees to support the requirements of being a public company.

Other income (expense), net

Interest income (expense), net and other income (expense), net was in insignificant for the three months ended June 30, 2014 and 2013.

Comparison of Six Months Ended June 30, 2014 and 2013

The following table summarizes our results of operations for the six months ended June 30, 2014 and 2013:

	Six Months Ended June 30,		
	2014	2013	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 8,554	$ 6,437	$ 2,117
General and administration	3,424	1,607	1,817
Total operating expenses	11,978	8,044	3,934
Loss from operations	(11,978)	(8,044)	(3,934)
Interest income (expense), net	1		1
Other income (expense), net	(5)		(5)
Net loss	$ (11,982)	$ (8,044)	$ (3,938)

23

Research and development expenses

	Six Months Ended June 30,		
	2014	2013	Change
	(in thousands)		
SAGE-547	$ 2,614	$ 1,240	$ 1,374
SAGE-689	1,766	1,697	69
SAGE-217	1,392		1,392
Other research and development programs	259	2,116	(1,857)
Direct research and development expenses	6,031	5,053	978
Personnel related expenses	2,293	1,152	1,141
Other expenses	230	232	(2)
Total research and development expenses	$ 8,554	$ 6,437	$ 2,117

Research and development expenses for the six months ended June 30, 2014 were $8.6 million, compared to $6.4 million for the six months ended June 30, 2013. The increase of $2.1 million period over period was primarily due to the following:

an increase of $1.4 million in expenses of our SAGE-547 program. We initiated the Phase 1/2 clinical trial of SAGE-547 in SRSE in early 2014;

an increase of $1.4 million in expenses of our SAGE-217 program with advancement of the lead optimization program into IND-enabling non-clinical development (e.g. toxicology and chemistry, manufacturing and controls, or CMC studies);

a net decrease $1.8 million in expenses of our other research and development programs reflecting focus on advancing SAGE-689 and SAGE-217 into IND-enabling non-clinical development, portfolio priorities, and timing of investment in certain research programs; and

an increase of $1.1 million in employee related spending to support the growth in our research and development activities, reflecting the effects of hiring additional, full-time employees during 2014.

General and administrative expenses

	Six Months Ended June 30,		
	2014	2013	Change
	(in thousands)		
Personnel related	$ 1,454	$ 612	$ 842

Professional fees	1,430	594	836
Facilities	185	158	27
Other	355	243	112
Total general and administrative expenses	$ 3,424	$ 1,607	$ 1,817

General and administrative expenses for the six months ended June 30, 2013 were $1.6 million, compared to $3.4 million for the six months ended June 30, 2014. The increase of $1.8 million in general and administrative expenses was primarily due to increased personnel related costs of $0.8 million, which were principally due to employee salary and bonus increases of $0.7 million, including the effects of hiring additional, full-time employees during 2014 to support corporate operations, finance and business development activities. The increase period over period in general and administrative expenses was also due to a $0.8 million increase in professional fees Incurred primarily in connection with preparation for our planned IPO and professional fees to support the requirements of being a public company.

Other income (expense), net

Interest income (expense), net and other income (expense), net was insignificant for the three months ended June 30, 2014 and 2013.

Liquidity and Capital Resources

Since our inception in April 2010, we have not generated any revenue and have incurred recurring net losses. As of June 30, 2014, we had an accumulated deficit of $44.8 million. We have funded our operations since inception primarily through sales of redeemable convertible preferred stock and, to a lesser extent, the issuance of convertible notes. From our inception through June 30, 2014, we have received net proceeds of $90.7 million from such transactions. On July 23, 2014, we completed the sale of 5,750,000 shares of common stock in our IPO, at a price to the public of $18.00 per share, resulting in net proceeds of $94.0 million after deducting underwriting discounts and commissions and estimated offering expense payable by us.

As of June 30, 2014, excluding the proceeds from the IPO we had cash and cash equivalents totaling $49.1 million. We invest our cash equivalents in money market accounts in order to preserve principal.

The following table summarizes our sources and uses of cash for each of the periods presented:

	Six Months Ended June 30,	
	2014	2013
	(in thousands)	
Cash used in operating activities	$ (10,889)	$ (7,306)
Cash used in investing activities	(5)	(3)
Cash provided by financing activities	51,955	5,030
Net increase (decrease) in cash and cash equivalents	$ 41,061	$ (2,279)

Net cash used in operating activities

Operating activities used $10.9 million of cash in the six months ended June 30, 2014. The cash flow used in operating activities resulted primarily from our net loss of $12.0 million for the period and cash used for changes in our operating assets and liabilities of $0.5 million, offset by non-cash charges of $0.7 million. Our net loss was primarily attributable to research and development activities related to our lead programs in development and our general and administrative expenses, as we had no revenue in the period. Our net non-cash charges during the six months ended June 30, 2014 primarily consisted of stock-based compensation expenses of $0.5 million and non-cash licensing fees paid in shares of our common stock of $0.1 million. Net cash used in changes in our operating assets

and liabilities consisted of a decrease in prepaid expenses and other current assets of $0.4 million, a decrease in accounts payable of $0.4 million and an increase in accrued expenses and other liabilities of $1.3 million. Our prepaid expenses and other current assets, accounts payable and accrued expense balances were affected by the timing of vendor invoicing and payments.

During the six months ended June 30, 2013, operating activities used $7.3 million of cash, primarily resulting from our net loss of $8.0 million, partially offset by cash provided by changes in our operating assets and liabilities of $0.7 million. Our net loss was primarily attributed to research and development activities related to our lead programs in development and our general and

administrative expenses. Net cash provided by changes in our operating assets and liabilities for the six months ended June 30, 2013 consisted primarily of increases in accounts payable and accrued expenses totaling $0.7 million. Our prepaid expenses and other current assets, accounts payable and accrued expense balances were affected by the timing of vendor invoicing and payments.

Net cash used in investing activities

During the six months ended June 30, 2014, we used $5,000 of cash for purchases of property and equipment.

During the six months ended June 30, 2013, we used $3,000 of cash for purchases of property and equipment.

Net cash provided by financing activities

During the six months ended June 30, 2014 and 2013, net cash provided by financing activities was $52 million and $0.5 million, respectively. Net cash provided by financing activities in the six months ended June 30, 2014 consisted of $52.9 million from the issuance of Series B and Series C redeemable convertible preferred stock and from the exercise of stock options, offset by the payment of fees incurred in connection with our planned IPO of $0.9 million. Net cash provided by financing activities in the six months ended June 30, 2013 consisted of $5 million from the issuance of Series A redeemable convertible preferred stock and from the exercise of stock options.

Operating Capital Requirements

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize one of our current or future product candidates. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products. We 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 and manufacturing. Accordingly, we anticipate that we will need substantial additional funding in connection with our continuing operations.

Based on our current operating plan, we expect that our existing cash and cash equivalents as of June 30, 2014, together with net proceeds from our IPO which closed on July 23, 2014, will enable us to fund our operating expenses and capital expenditures requirements for at least the next 12 months. In that time, we expect that our expenses will increase substantially as we fund Phase 1/2 clinical development of SAGE-547, fund IND-enabling activities and Phase 1 clinical development of SAGE-689, fund IND-enabling activities for SAGE-217, fund new and ongoing research and development activities and working capital and other general corporate purposes. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development and commercialization of our product candidates.

Our future capital requirements will depend on many factors, including:

- the costs, timing and outcome of regulatory reviews and approvals;

the ability of our product candidates to progress through clinical development successfully;

the initiation, progress, timings, costs and results of non-clinical studies and clinical trials for our other programs and potential product candidates;

the number and characteristics of the product candidate we pursue;

the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;

the extent to which we acquire or in-license other products and technologies; and

our ability to establish any future collaboration arrangements on favorable terms, if at all.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, 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 interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. 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 and may require the issuance of warrants, which could potentially dilute your ownership interest. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or research programs or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

There have been no material changes to our contractual obligations and commitments from those described under Management s Discussion and Analysis of Financial Condition and Results of Operations included in our Prospectus filed by us with the SEC on July 18, 2014.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under Securities and Exchange Commission rules, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

Application of Critical Accounting Policies

We have prepared our financial statements in accordance with U.S. generally accepted accounting principles. Our preparation of these financial statements requires us to make estimates, assumptions, and judgments that affect the reported amounts of assets, liabilities, expenses, and related disclosures at the date of the financial statements, as well as revenue and expenses recorded during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies from those described in Management s Discussion and Analysis of Financial Condition and Results of Operations included in our Prospectus.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

Interest Rate Fluctuation Risk

Our cash and cash equivalents as of June 30, 2014 consisted of cash and money market accounts. The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significantly increasing risk. Our primary exposure to market risk is interest income sensitivity, which is affected by

changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operation.

Foreign Currency Exchange Risk

Foreign currency transaction exposure results primarily from transactions with our contract research organizations and other providers related to our non-clinical studies and clinical trials that are denominated in currencies other than the U.S. dollar, primarily the Euro and the Swiss Franc. Any transaction gains or losses that result from currency fluctuations are recorded in other income (expense), net in our statement of operations. $5,000 and $0 foreign currency transaction gains or losses were recorded for the six months ended June 30, 2014 and 2013.

Currently, we do not have any significant foreign currency exposures, and at this time, we do not hedge our foreign currency risk.

Item 4. Management s Evaluation of our Disclosure Controls and Procedures

Management s Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC s rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

As of June 30, 2014, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of June 30, 2014, our disclosure controls and procedures were effective at the reasonable assurance level.

We continue to review and document our disclosure controls and procedures, including our internal controls and procedures for financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

Changes in Internal Control Over Financial Reporting

During the three months ended June 30, 2014, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1. Legal Proceedings

As of the date of this filing, we were not party to any legal matters or claims. In the future, we may become party to legal matters and claims arising in the ordinary course of business, the resolution of which we do not anticipate would have a material adverse impact on our financial position, results of operations or cash flows.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q and in our other public filings before making an investment decision. Our business, prospects, financial condition, or operating results could be harmed by any of

these risks, as well as other risks not currently known to us or that we currently consider immaterial. If any such risks or uncertainties actually occur, our business, financial condition or operating results could differ materially from the plans, projections and other forward-looking statements included in the section titled Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this report and in our other public filings. The trading price of our common stock could decline due to any of these risks, and as a result, you may lose all or part of your investment.

Risks Related to Product Development, Regulatory Approval and Commercialization

We depend heavily on the success of the product candidates within our status epilepticus, or SE, program, of which SAGE-547 is in Phase 1/2 clinical development and SAGE-689 and SAGE-217 are in non-clinical development. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, any of our product candidates.

We currently have no drug products for sale and may never be able to develop marketable drug products. Our business depends heavily on the successful non-clinical and clinical development, regulatory approval and commercialization of the product candidates in our lead program in SE, of which only one product candidate, SAGE-547, is in Phase 1/2 clinical development for the treatment of super-refractory SE, or SRSE, and our other product candidates, SAGE-689 and SAGE-217, are in non-clinical development. SAGE-547 will require substantial additional clinical development, testing and regulatory approval before we are permitted to commence its commercialization. Our other product candidates, including SAGE-689 and SAGE-217, are still in non-clinical development stages. The non-clinical studies and clinical trials of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through non-clinical studies and clinical trials that the product candidate is safe and effective for use in each target indication. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. This process can take many years and may include post-marketing studies and surveillance, which will require the expenditure of substantial resources. Of the large number of drugs in development in the United States, only a small percentage will successfully complete the U.S. Food and Drug Administration, or FDA, regulatory approval process and will be commercialized. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development and non-clinical studies and clinical trials, we cannot assure you that any of our product candidates will be successfully developed or commercialized.

We are not permitted to market our product candidates in the United States until we receive approval of a New Drug Application, or an NDA, from the FDA, or in any foreign countries until we receive the requisite approval from such countries. We have initiated a Phase 1/2 clinical trial to study safety, tolerability and efficacy of SAGE-547 in patients with SRSE. If our Phase 1/2 clinical trial of SAGE-547 is successful, we expect that the FDA will require us to complete at least one pivotal trial in order to submit an NDA for SAGE-547 as a treatment for SRSE patients. However, the FDA may require that we conduct additional pivotal trials before we can submit an NDA for SAGE-547. We have had only limited feedback from the FDA on the design of our ongoing Phase 1/2 clinical trial of SAGE-547 and on what would be required in a pivotal clinical trial of SAGE-547. Before beginning our pivotal trial for SAGE-547, the FDA will need to accept the results of our long-term toxicity studies in two animal species, which we submitted to the FDA in the second quarter of 2014. The FDA may require that we conduct additional toxicity studies and may also require us to conduct additional non-clinical studies before submitting an NDA for SAGE-547.

Both SAGE-689 and SAGE-217 are in non-clinical development and have yet to begin the clinical development process. We plan to file an Investigational New Drug Application, or IND, for SAGE-689 in the second half of 2014 and to begin a Phase 1 clinical trial thereafter.

Obtaining approval of an NDA is a complex, lengthy, expensive and uncertain process, and the FDA may delay, limit or deny approval of any of our product candidates for many reasons, including, among others:

- we may not be able to demonstrate that our product candidates are safe and effective in treating SE, refractory SE, or RSE, or SRSE, as applicable, to the satisfaction of the FDA;

the results of our non-clinical studies and clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval;

the FDA may disagree with the number, design, size, conduct or implementation of our non-clinical studies and clinical trials;

the FDA may require that we conduct additional non-clinical studies and clinical trials;

the FDA or the applicable foreign regulatory agency may not approve the formulation, labeling or specifications of any of our product candidates;

the contract research organizations, or CROs, that we retain to conduct our non-clinical studies and clinical trials may take actions outside of our control that materially adversely impact our non-clinical studies and clinical trials;

the FDA may find the data from non-clinical studies and clinical trials insufficient to demonstrate that our product candidates clinical and other benefits outweigh their safety risks;

the FDA may disagree with our interpretation of data from our non-clinical studies and clinical trials;

the FDA may not accept data generated at our non-clinical studies and clinical trial sites;

if our NDA, if and when submitted, is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional non-clinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;

the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval or post-approval;

the FDA or the applicable foreign regulatory agency may determine that the manufacturing processes or facilities of third-party manufacturers with which we contract do not conform to applicable requirements, including current Good Manufacturing Practices, or cGMPs; or

the FDA or applicable foreign regulatory agency may change its approval policies or adopt new regulations.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market our product candidates. Any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects.

A Fast Track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.

We have obtained Fast Track designation for SAGE-547, and we may do so for other product candidates as well. If a product is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for the FDA Fast Track designation. The FDA has broad discretion whether or not to grant this designation, and even if we believe our product candidates are eligible for this designation, we cannot be sure that the review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development programs.

The number of patients suffering from SE, RSE and SRSE is small or has not been established with precision. If the actual number of patients with SE, RSE and SRSE is smaller than we anticipate, we may encounter difficulties in enrolling patients in our clinical trials, thereby delaying or preventing development of our product candidates, and if any of our product candidates are approved, we believe our revenue and ability to achieve profitability would be materially adversely affected.

There is no precise method of establishing actual number of patients with SE, RSE or SRSE in any geography over any time period. Moreover, SE, RSE and SRSE are acute episode conditions. If we are not able to identify patients at the time of SE, RSE or SRSE onset, we will have difficulty completing our clinical trials. We estimate that the annual incidence of SE, RSE and SRSE in the United States is up to 150,000, 35,000 and 25,000 patients, respectively. If the actual number of patients with SE, RSE or SRSE is lower than we believe, we may experience difficulty in enrolling patients in our clinical trials, thereby delaying development of our product candidates. Further, if any of our product candidates are approved, the markets for our product candidates for these indications would be smaller than we anticipate, which could limit our ability to achieve profitability.

Favorable results from the emergency-use cases of SAGE-547 do not ensure that clinical trials will be successful and the results in any future emergency-use cases may not be positive and could adversely impact our clinical development plans.

SAGE-547 has been administered to a small number of patients as part of emergency-use cases, which permitted the administration of SAGE-547 outside of clinical trials. No assurance can be given that positive results observed to date in these emergency-use cases are attributable to SAGE-547, as they were not carried out in the controlled environment of a clinical trial. Further, no assurance can be provided that administration of SAGE-547 to other patients in any future emergency-use cases or otherwise will have positive results. Emergency use is a term that is used to refer to the use of an investigational drug outside of a clinical trial to treat a patient with a serious or immediately life-threatening disease or condition who has no comparable or satisfactory alternative treatment options. Regulators often allow emergency use on a case-by-case basis for an individual patient or for defined groups of patients with similar treatment needs. In the event there are negative results in future emergency-use cases, it could adversely affect or delay our clinical development of SAGE-547.

If serious adverse events or other undesirable side effects are identified during the use of SAGE-547 in emergency-use cases or in investigator sponsored trials of SAGE-547, it may adversely effect our development of SAGE-547 for SRSE.

In addition to use in emergency cases as described above, SAGE-547 is currently being tested in an investigator sponsored clinical trial for the treatment of traumatic brain injury, or TBI, by one of our collaborators. If serious adverse events or other undesirable side effects, or unexpected characteristics of SAGE-547 are observed in emergency-use cases or in investigator sponsored clinical trials of SAGE-547, it may adversely affect or delay our clinical development of SAGE-547, or we may need to abandon its development for SRSE entirely, and the occurrence of these events would have a material adverse effect on our business.

Positive results from early non-clinical studies and clinical trials of our product candidates are not necessarily predictive of the results of later non-clinical studies and clinical trials of our product candidates. If we cannot replicate the positive results from our earlier non-clinical studies and clinical trials of our product candidates in our later non-clinical studies and clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates.

Positive results from our non-clinical studies of our product candidates, and any positive results we may obtain from our early clinical trials of our product candidates, may not necessarily be predictive of the results from required later non-clinical studies and clinical trials. Similarly, even if we are able to complete our planned non-clinical studies or clinical trials of our product candidates according to our current development timeline, the positive results from our non-clinical studies and clinical trials of our product candidates may not be replicated in subsequent non-clinical studies or clinical trial results. For example, although the first four patients treated with SAGE-547 in our Phase 1/2 clinical trial met the key efficacy endpoint and has not yet experienced any severe adverse events related to SAGE-547, future patients enrolled and treated with SAGE-547 in this trial may not have the same outcome. Also, our later-stage clinical trials could differ in significant ways from our ongoing Phase 1/2 clinical trial of SAGE-547, which could cause the outcome of these later-stage trials to differ from our earlier stage clinical trials. For example, these differences may include changes to inclusion and exclusion criteria, efficacy endpoints and statistical design. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, non-clinical findings made while clinical trials were underway or safety or efficacy observations made in non-clinical studies and clinical trials, including previously unreported adverse events. Moreover, non-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in non-clinical studies and clinical trials nonetheless failed to obtain FDA approval. We have not completed any clinical trials for our product candidates yet, and if we fail to produce positive results in our planned non-clinical studies or clinical trials of any of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be materially adversely affected.

Failures or delays in the commencement or completion of our planned clinical trials of our product candidates could result in increased costs to us and could delay, prevent or limit our ability to generate revenue and continue our business.

We have commenced a Phase 1/2 clinical trial of SAGE-547 as a treatment for SRSE and will need to complete at least one additional trial prior to the submission of an NDA for SAGE-547. Successful completion of our clinical trials is a prerequisite to submitting an NDA to the FDA and, consequently, the ultimate approval and commercial marketing of SAGE-547 and our other product candidates. We do not know whether any of our clinical trials will begin or be completed on schedule, if at all, as the commencement and completion of clinical trials can be delayed or prevented for a number of reasons, including, among others:

the FDA may deny permission to proceed with our planned clinical trials or any other clinical trials we may initiate, or may place a clinical trial on hold;

delays in filing or receiving approvals of additional INDs that may be required;

negative results from our ongoing non-clinical studies;

delays in reaching or failing to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical trials, for example delays in the manufacturing of sufficient supply of finished drug product;

difficulties obtaining Institutional Review Board, or IRB, approval to conduct a clinical trial at a prospective site or sites;

challenges in recruiting and enrolling patients to participate in clinical trials, including the small size of the patient population, acute nature of SRSE, the proximity of patients to trial sites, eligibility criteria for the clinical trial, the nature of the clinical trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications

severe or unexpected drug-related side effects experienced by patients in a clinical trial;

delays in validating any endpoints utilized in a clinical trial;

the FDA may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials;

reports from non-clinical or clinical testing of other CNS therapies that raise safety or efficacy concerns; and

difficulties retaining patients who have enrolled in a clinical trial but may be prone to withdraw due to rigors of the clinical trials, lack of efficacy, side effects, personal issues or loss of interest.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRBs at the sites where the IRBs are overseeing a clinical trial, a data and safety monitoring board, or DSMB, overseeing the clinical trial at issue or other regulatory authorities due to a number of factors, including, among others:

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

inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities that reveals deficiencies or violations that require us to undertake corrective action, including the imposition of a clinical hold;

unforeseen safety issues, including any that could be identified in our ongoing non-clinical carcinogenicity studies, adverse side effects or lack of effectiveness;

changes in government regulations or administrative actions;

problems with clinical supply materials; and

lack of adequate funding to continue clinical trials.

Changes in regulatory requirements, FDA guidance or unanticipated events during our non-clinical studies and clinical trials of our product candidates may occur, which may result in changes to non-clinical studies and clinical trial protocols or additional non-clinical studies and clinical trial requirements, which could result in increased costs to us and could delay our development timeline.

Changes in regulatory requirements, FDA guidance or unanticipated events during our non-clinical studies and clinical trials may force us to amend non-clinical studies and clinical trial protocols or the FDA may impose additional non-clinical studies and clinical trial requirements. Amendments or changes to our clinical trial protocols would require resubmission to the FDA and IRBs for review and approval, which may adversely impact the cost, timing or successful completion of clinical trials. Similarly, amendments to our non-clinical studies may adversely impact the cost, timing, or successful completion of those non-clinical studies. If we experience delays completing, or if we terminate, any of our non-clinical studies or clinical trials, or if we are required to conduct additional non-clinical studies or clinical trials, the commercial prospects for our product candidates may be harmed and our ability to generate product revenue will be delayed.

We rely, and expect that we will continue to rely, on third parties to conduct any clinical trials for our product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We do not have the ability to independently conduct clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct clinical trials on our product candidates. We enter into agreements with third-party CROs to provide monitors for and to manage data for our ongoing clinical trials. We rely heavily on these parties for execution of clinical trials for our product candidates and control only certain aspects of their activities. As a result, we have less direct control over the conduct, timing and completion of these clinical trials and the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific requirements and standards, and our reliance on CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with regulations and guidelines, including current Good Clinical Practices, or cGCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces cGCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with cGCPs. In addition, our clinical trials must be conducted with product candidates produced under cGMPs regulations and will require a large number of test patients. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties.

Although we do design our clinical trials for our product candidates, CROs conduct all of the clinical trials. As a result, many important aspects of our drug development programs are outside of our direct control. In addition, the

CROs may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements, but we remain responsible and are subject to enforcement action that may include civil penalties up to and including criminal prosecution for any violations of FDA laws and regulations during the conduct of our clinical trials. If the CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of our product candidates may be delayed or our development program materially and irreversibly harmed. We cannot control the amount and timing of resources these CROs devote to our program or our clinical products. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of our clinical trials and this could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such CROs are associated with may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

We rely completely on third-party suppliers to manufacture our clinical drug supplies for our product candidates, and we intend to rely on third parties to produce non-clinical, clinical and commercial supplies of any future product candidate.

We do not currently have, nor do we plan to acquire, the infrastructure or capability to internally manufacture our clinical drug supply of our product candidates, or any future product candidates, for use in the conduct of our non-clinical studies and clinical trials, and we lack the internal resources and the capability to manufacture any product candidates on a clinical or commercial scale. For example, SAGE-547 used in the emergency-use cases was manufactured at an academic site, the active pharmaceutical ingredient for SAGE-547 for our Phase 1/2 clinical trial was manufactured at an academic site and SAGE-547 as formulated for our Phase 1/2 clinical trial was manufactured at a third-party manufacturer s site. The facilities used by our contract manufacturers to manufacture the active pharmaceutical ingredient and final drug product must complete a pre-approval inspection by the FDA and other comparable foreign regulatory agencies to assess compliance with applicable requirements, including cGMPs, after we submit our NDA or relevant foreign regulatory submission to the applicable regulatory agency.

We do not control the manufacturing process of, and are completely dependent on, our contract manufacturers to comply with cGMPs for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or applicable foreign regulatory agencies, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no direct control over our contract manufacturers ability to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, all of our contract manufacturers are engaged with other companies to supply and/or manufacture materials or products for such companies, which exposes our manufacturers to regulatory risks for the production of such materials and products. As a result, failure to satisfy the regulatory requirements for the production of those materials and products may affect the regulatory clearance of our contract manufacturers facilities generally. If the FDA or an applicable foreign regulatory agency determines now or in the future that these facilities for the manufacture of our product candidates are noncompliant, we may need to find alternative manufacturing facilities, which would adversely impact our ability to develop, obtain regulatory approval for or market our product candidates. Our reliance on contract manufacturers also exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may appropriate our trade secrets or other proprietary information.

We do not have long-term supply agreements in place with our contractors, and each batch of our product candidates is individually contracted under a quality and supply agreement. If we engage new contractors, such contractors must complete an inspection by the FDA and other applicable foreign regulatory agencies. We plan to continue to rely upon contract manufacturers and, potentially, collaboration partners to manufacture commercial quantities of our product candidates, if approved. Our current scale of manufacturing is adequate to support all of our needs for non-clinical studies and clinical trial supplies.

Even if we receive marketing approval for our product candidates in the United States, we may never receive regulatory approval to market our product candidates outside of the United States.

We have not yet selected any markets outside of the United States where we intend to seek regulatory approval to market our product candidates. In order to market any product outside of the United States, however, we must establish and comply with the numerous and varying safety, efficacy and other regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product candidate testing and additional administrative review periods. The time required to obtain approvals in other countries might differ from that required to obtain FDA approval. The marketing approval processes in other countries may implicate all of the risks detailed above regarding FDA approval in the United States as well as other risks. In particular, in many countries outside of the United States, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries. Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in others. Failure to obtain marketing approval in other countries or any delay or other setback in obtaining such approval would impair our ability to market our product candidates in such foreign markets. Any such impairment would reduce the size of our potential market, which could have a material adverse impact on our business, results of operations and prospects.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate any revenue.

We do not currently have an infrastructure for the sales, marketing and distribution of pharmaceutical products. In order to market our product candidates, if approved by the FDA or any other regulatory body, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, or if we are unable to do so on commercially reasonable terms, our business, results of operations, financial condition and prospects will be materially adversely affected.

Even if we receive marketing approval for our product candidates, our product candidates may not achieve broad market acceptance, which would limit the revenue that we generate from their sales.

The commercial success of our product candidates, if approved by the FDA or other applicable regulatory authorities, will depend upon the awareness and acceptance of our product candidates among the medical community, including physicians, patients and healthcare payors. Market acceptance of our product candidates, if approved, will depend on a number of factors, including, among others:

- the efficacy of our product candidates as demonstrated in clinical trials, and, if required by any applicable regulatory authority in connection with the approval for the applicable indications, to provide patients with incremental health benefits, as compared with other available CNS therapies;
- limitations or warnings contained in the labeling approved for our product candidates by the FDA or other applicable regulatory authorities;
- the clinical indications for which our product candidates are approved;
- availability of alternative treatments already approved or expected to be commercially launched in the near future;
- the potential and perceived advantages of our product candidates over current treatment options or alternative treatments, including future alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;

pricing and cost effectiveness;

the effectiveness of our sales and marketing strategies;

our ability to increase awareness of our product candidates through marketing efforts;

our ability to obtain sufficient third-party coverage or reimbursement; or

the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

If our product candidates are approved but do not achieve an adequate level of acceptance by patients, physicians and payers, we may not generate sufficient revenue from our product candidates to become or remain profitable. Before granting reimbursement approval, healthcare payers may require us to demonstrate that our product candidates, in addition to treating these target indications, also provide incremental health benefits to patients. Our efforts to educate the medical community and third-party payers about the benefits of our product candidates may require significant resources and may never be successful.

Our product candidates may cause undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt non-clinical studies and clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If our product candidates receive marketing approval and we or others identify undesirable side effects caused by such product candidates (or any other similar products) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such product candidates;
- regulatory authorities may require the addition of labeling statements, such as a boxed warning or a contraindication;
- we may be required to change the way such product candidate are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such product candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and
- our reputation may suffer.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

Even if we receive marketing approval for our product candidates, we may still face future development and regulatory difficulties.

Even if we receive marketing approval for our product candidates, regulatory authorities may still impose significant restrictions on our product candidates, indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. Our product candidates will also be subject to ongoing FDA requirements governing the labeling, packaging, storage and promotion of the product and record keeping and submission of safety and other post-market information. The FDA has significant post-marketing authority, including, for example, the authority to require labeling changes based on new safety information and to require post-marketing studies or clinical trials to evaluate serious safety risks related to the use of a drug. The FDA also has the authority to require, as part of an NDA or post-approval, the submission of a REMS. Any REMS required by the FDA may lead to increased costs to assure compliance with new post-approval regulatory requirements and potential requirements or restrictions on the sale of approved products, all of which could lead to lower sales volume and revenue.

Manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMPs and other regulations. If we or a regulatory agency discover problems with our product candidates, such as adverse events of unanticipated severity or frequency, or problems with the facility where our product

candidates are manufactured, a regulatory agency may impose restrictions on our product candidates, the manufacturer or us, including requiring withdrawal of our product candidates from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may, among other things:

- issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw marketing approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications submitted by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or request that we initiate a product recall.

Competing therapies could emerge adversely affecting our opportunity to generate revenue from the sale of our product candidates.

The biopharmaceuticals industry is highly competitive. There are many public and private biopharmaceutical companies, universities, governmental agencies and other research organizations actively engaged in the research and development of products that may be similar to our product candidates or address similar markets. It is probable that the number of companies seeking to develop products and therapies similar to our products will increase.

Currently, there are no therapies specifically approved for RSE or SRSE. However, many products approved for other indications, general anesthetics and anti-seizure drugs, are used off-label for various stages of SE therapy. Additionally, though not indicated, acupuncture, hypothermia, and electroconvulsive therapy are sometimes used prior to withdrawal of care for patients with SRSE.

In the field of neuroactive steroids focused on modulation of $GABA_A$ or NMDA receptors, our principal competitor is Marinus Pharmaceuticals, Inc., which is developing a reformulated form of Ganaxolone, a known $GABA_A$ positive allosteric modulator neuroactive steroid, for potential treatment of drug-resistant partial complex seizures and fragile X syndrome.

Many of our potential competitors, alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of treatments and the commercialization of those treatments. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Our commercial opportunity could be

reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

We may seek to establish collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. The terms of any collaborations or other arrangements that we may establish may not be favorable to us.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

In addition, any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

We may not be successful in our efforts to identify or discover additional product candidates or 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.

The success of our business depends primarily upon our ability to identify, develop and commercialize products based on our proprietary chemistry platform. Although some of our product candidates are in non-clinical and clinical development, our research programs may fail to identify other potential product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

Because we have limited financial and management resources, we focus on a limited number of research programs and product candidates and are currently focused on our SE program. As a result, we may forego or delay pursuit of

opportunities with other product candidates 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 drugs. 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 future collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

We are subject to healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any products on the market, once we begin commercializing our products, we may be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers, physicians and others will play a primary role in the recommendation and prescription of our product candidates, if approved. Our future arrangements with third-party payors will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product candidates, if we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

The federal anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid.

The federal False Claims Act imposes criminal and civil penalties, including those from civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government.

The federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

The federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services.

The federal transparency requirements, sometimes referred to as the Sunshine Act, under the Patient Protection and Affordable Care Act, require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children s Health Insurance Program to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests.

Analogous state laws and regulations, such as state anti-kickback and false claims laws and transparency laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry s

voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and drug pricing.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could be costly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines and exclusion from government funded healthcare programs, such as Medicare and Medicaid, any of which could substantially disrupt our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found to have improperly promoted off-label uses, we may become subject to significant liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as SAGE-547, SAGE-689, and SAGE-217, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product s approved labeling. For example, if we receive marketing approval for SAGE-547 as a treatment for SRSE, physicians may nevertheless prescribe SAGE-547 to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Even if approved, reimbursement policies could limit our ability to sell our product candidates.

Market acceptance and sales of our product candidates will depend on reimbursement policies and may be affected by healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels for those medications. Cost containment is a primary concern in the U.S. healthcare industry and elsewhere. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that reimbursement will be available for our product candidates and, if reimbursement is available, the level of such reimbursement. Reimbursement may impact the demand for, or the price of, our product candidates. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates.

In some foreign countries, particularly in Canada and European countries, the pricing of prescription pharmaceuticals is subject to strict governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. To obtain favorable reimbursement for the indications sought or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates with other available therapies. If reimbursement for our product candidates is unavailable in any country in which we seek reimbursement, if it is limited in scope or amount, if it is conditioned upon our completion of additional clinical trials, or if pricing is set at unsatisfactory levels, our operating results could be materially adversely affected.

Even though we have obtained orphan drug designation for SAGE-547 as a treatment for SE, there may be limits to the regulatory exclusivity afforded by such designation.

Even though we have obtained orphan drug designation for SAGE-547 for treatment of SE from the FDA , there are limitations to exclusivity afforded by such designation. In the United States, the company that first obtains FDA approval for a designated orphan drug for the specified rare disease or condition receives orphan drug marketing exclusivity for that drug for a period of seven years. This orphan drug exclusivity prevents the FDA from approving another application, including a full NDA to market the same drug for the same orphan indication, except in very limited circumstances, including when the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. For purposes of small molecule drugs, the FDA defines same drug as a drug that contains the same active moiety and is intended for the same use as the drug in question. To obtain orphan drug exclusivity for a drug that shares the same active moiety as an already approved drug, it must be demonstrated to the FDA that the drug is safer or more effective than the approved orphan designated drug, or that it makes a major contribution to

patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition or if another drug with the same active moiety is determined to be safer, more effective, or represents a major contribution to patient care.

Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability may depend, in part, on our ability to commercialize our product candidates in foreign markets for which we may rely on collaboration with third parties. If we commercialize our product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

our customers ability to obtain reimbursement for our product candidates in foreign markets;

our inability to directly control commercial activities because we are relying on third parties;

the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;

different medical practices and customs in foreign countries affecting acceptance in the marketplace;

import or export licensing requirements;

longer accounts receivable collection times;

longer lead times for shipping;

language barriers for technical training;

reduced protection of intellectual property rights in some foreign countries;

the existence of additional potentially relevant third party intellectual property rights;

foreign currency exchange rate fluctuations; and

the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

Risks Related to Our Intellectual Property Rights

If we are unable to adequately protect our proprietary technology, or obtain and maintain issued patents that are sufficient to protect our product candidates, others could compete against us more directly, which would have a material adverse impact on our business, results of operations, financial condition and prospects.

We strive to protect and enhance the proprietary technologies that we believe are important to our business, including seeking patents intended to cover our products and compositions, their methods of use and any other inventions that are important to the development of our business. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, should they issue, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties. We also rely on know-how, continuing technological

innovation and in-licensing opportunities to develop, strengthen and maintain the proprietary position of our product candidates. Our owned and licensed patent applications relate to SAGE-547, $GABA_A$ receptor modulators, including genus and species claims to SAGE-689 and NMDA receptor modulators.

We currently have no issued patents covering any of our lead product candidates, SAGE-547, SAGE-689, or SAGE-217. We cannot provide any assurances that any of our pending patent applications will mature into issued patents and, if they do, that such patents will include, claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage. For example, the patent applications that may provide coverage for SAGE-547, only cover particular formulations and particular methods of using such formulations to treat seizure conditions, such as SE. As a result, if a patent issues from such patent applications, it would not prevent third-party competitors from creating, making and marketing alternative formulations, that fall outside the scope

of our patent claims or practicing alternative methods. There can be no assurance that any such alternative formulations will not be equally effective as our formulation of SAGE-547. Moreover, other parties have developed technologies that may be related or competitive to our approach, and may have filed or may file patent applications and may have received or may receive patents that may overlap or conflict with our patent applications, either by claiming the same methods or formulations or by claiming subject matter that could dominate our patent position. Such third-party patent positions may limit or even eliminate our ability to obtain patent protection for certain inventories.

The patent positions of biotechnology and pharmaceutical companies, including our patent position, involve complex legal and factual questions, and, therefore, the issuance, scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated, or circumvented. U.S. patents and patent applications may also be subject to interference proceedings, *ex parte* reexamination, or *inter partes* review proceedings, supplemental examination and challenges in district court. Patents may be subjected to opposition, post-grant review, or comparable proceedings lodged in various foreign, both national and regional, patent offices. These proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents, should they issue, that we may own or exclusively license may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize our product candidates.

Furthermore, though a patent, if it were to issue, is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Even if a patent issues and is held to be valid and enforceable, competitors may be able to design around our patents, such as using pre-existing or newly developed technology. Other parties may develop and obtain patent protection for more effective technologies, designs or methods. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, vendors, former employees and current employees. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. If these developments were to occur, they could have a material adverse effect on our sales.

Our ability to enforce our patent rights depends on our ability to detect infringement. It is difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor s or potential competitor s product. Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents, if and when issued, could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents, if and when issued, covering our product candidates are invalidated or found unenforceable, our financial position and results of operations would be materially and adversely impacted. In addition, if a court found that valid, enforceable patents held by third parties covered our product candidates, our financial position and results of operations would also be materially and adversely impacted.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our product candidates or any other products or product candidates;

any of our pending patent applications will issue as patents at all;

we will be able to successfully commercialize our product candidates, if approved, before our relevant patents expire;

we were the first to make the inventions covered by each of our patents and pending patent applications;

we were the first to file patent applications for these inventions;

others will not develop similar or alternative technologies that do not infringe our patents;

others will not use pre-existing technology to effectively compete against us;

any of our patents, if issued, will be found to ultimately be valid and enforceable;

any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;

we will develop additional proprietary technologies or product candidates that are separately patentable; or

that our commercial activities or products will not infringe upon the patents or proprietary rights of others.

We rely upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our product candidates, if approved.

Our success will depend in part on our ability to operate without infringing the intellectual property and proprietary rights of third parties. We cannot assure you that our business, products and methods do not or will not infringe the patents or other intellectual property rights of third parties.

The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may allege that our product candidates or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. As we continue to develop and, if approved, commercialize our current product candidates and future product candidates, competitors may claim that our technology infringes their intellectual property rights as part of business strategies designed to impede our successful commercialization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, third parties may have currently pending patent applications which may later result in issued patents that our product candidates may infringe, or which such third parties claim are infringed by our technologies. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The coverage of patents is subject

to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. Any claim relating to intellectual property infringement that is successfully asserted against us may require us to pay substantial damages, including treble damages and attorney s fees if we are found to be willfully infringing another party s patents, for past use of the asserted intellectual property and royalties and other consideration going forward if we are forced to take a license. In addition, if any such claim were successfully asserted against us and we could not obtain such a license, we may be forced to stop or delay developing, manufacturing, selling or otherwise commercializing our product candidates.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court, or redesign our products. Patent litigation is costly and time-consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, intellectual property litigation or claims could force us to do one or more of the following:

- cease developing, selling or otherwise commercializing our product candidates;
- pay substantial damages for past use of the asserted intellectual property;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all; and
- in the case of trademark claims, redesign, or rename, some or all of our product candidates to avoid infringing the intellectual property rights of third parties, which may not be possible and, even if possible, could be costly and time-consuming.

Any of these risks coming to fruition could have a material adverse effect on our business, results of operations, financial condition and prospects.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We enter into confidentiality and intellectual property assignment agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. For example, even if we have a consulting agreement in place with an academic advisor pursuant to which such academic advisor is required to assign any inventions developed in connection with providing services to us, such academic advisor may not have the right to assign such inventions to us, as it may conflict with his or her obligations to assign all such intellectual property to his or her employing institution.

Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

The U.S. Patent and Trademark Office, or U.S. PTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application,

resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Even if the patent applications we own or license are issued, competitors may infringe these patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid, is unenforceable and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court.

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent, if and when issued, covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the U.S. PTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions, e.g., opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection would have a material adverse impact on our business.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States, assuming that rights are obtained in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. The statutory deadlines for pursuing patent protection in individual foreign jurisdictions are based on the priority date of each of our patent applications. For the patent families related to SAGE-547, SAGE-689 and SAGE-217, as well as for most of the patent families that we own or license, the relevant statutory deadlines have not yet expired. Thus, for each of the patent families that we believe provide coverage for our lead product candidates, we will need to decide whether and where to pursue protection outside the United States.

Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biotechnology. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We are dependent on licensed intellectual property. If we were to lose our rights to licensed intellectual property, we may not be able to continue developing or commercializing our product candidates, if approved. If we breach any of the agreements under which we license the use, development and commercialization rights to our product candidates or technology from third parties or, in certain cases, we fail to meet certain development deadlines, we could lose license rights that are important to our business.

We are a party to a number of license agreements under which we are granted rights to intellectual property that are important to our business and we expect that we may need to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose on us, various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license. Our business could suffer, for example, if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. See Business Licenses for a description of our license agreements, which includes a description of the termination provisions of these agreements.

As we have done previously, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we cannot provide any assurances that third-party patents do not exist that might be enforced against our current product candidates or future products in the absence of such a license. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an

injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;

our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and

the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We have entered into several licenses to support our various programs. We completed an exclusive license agreement with Washington University, or WU, under certain patent families that comprise a variety of small molecule allosteric modulators of $GABA_A$ receptors and for which we have the worldwide right to develop and commercialize. A patent family that discloses and claims SAGE-689 is licensed to us under this agreement. We are obligated to pay WU certain clinical/regulatory milestones and single-digit royalties on products developed from this technology. Termination of our license agreement with WU would have a material adverse impact on our ability to develop and commercialize SAGE-689.

We have also entered into an exclusive license agreement with CyDex Pharmaceuticals, Inc., or CyDex, a wholly owned subsidiary of Ligand Pharmaceuticals, Inc., to use its Captisol technology to develop SAGE-547 for the field of use, which includes all fields for the treatment, prevention or diagnosis of any disease or symptom in humans or animals. We are obligated to pay CyDex certain clinical/regulatory milestones and single-digit royalties on SAGE-547. In addition, we entered into a supply agreement with CyDex, pursuant to which they supply us with Captisol to formulate SAGE-547. Absent an alternative agreement by the parties, our rights under our exclusive license agreement terminate in the event that the supply agreement terminates. Currently, our SAGE-547 product candidate in clinical development is formulated in Captisol. Termination of our license agreement with CyDex would have a material adverse impact on our ability to develop and commercialize SAGE-547 in its current formulation.

We also entered into a non-exclusive license with The Regents of the University of California, or the Regents. Pursuant to this agreement the Regents granted us a non-exclusive, non-transferable license under all personal property rights of the Regents covering the tangible personal property in an IND application package owned by the Regents, or the Data, and a specified quantity of cGMP grade allopregnanolone, or the Material, to (i) use the Data for reference or incorporation in an IND for use of the Material as a treatment of SE, essential tremor and/or post-partum depression and (ii) use the Material or modifications of the Material to develop a pharmaceutical formulation for clinical trials for SE, essential tremor and/or post-partum depression. This agreement requires us to pay milestone payments in connection with the first derived product, which would include SAGE-547, that meets the relevant milestones and we must also pay single-digit royalties for each derived product for a period of 15 years following the first commercial sale of such derived product. Termination of our license agreement with the Regents would have a material adverse impact on our ability to develop and commercialize derived products, which would include SAGE-547.

We may enter into additional license(s) to third-party intellectual property that are necessary or useful to our business. Our current licenses and any future licenses that we may enter into impose various royalty payment, milestone, and other obligations on us. For example, as is the case for the Washington University license, the licensor may retain control over patent prosecution and maintenance under a license agreement, in which case, we may not be able to adequately influence patent prosecution or prevent inadvertent lapses of coverage due to failure to pay maintenance fees. If we fail to comply with any of our obligations under a current or future license agreement, our licensor(s) may allege that we have breached our license agreement and may accordingly seek to terminate our license with them. In addition, future licensor(s) may decide to terminate our license at will. Termination of any of our current or future

licenses could result in our loss of the right to use the licensed intellectual property, which could materially adversely affect our ability to develop and commercialize a product candidate or product, if approved, as well as harm our competitive business position and our business prospects.

In addition, if our licensors fail to abide by the terms of the license, if the licensors fail to prevent infringement by third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms our business could suffer.

Some intellectual property which we have licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as march-in rights, certain reporting requirements, and a preference for U.S. industry. Compliance with such regulations may limit our exclusive rights, subject us to expenditure of resources with respect to reporting requirements, and limit our ability to contract with non-U.S. manufacturers.

Some of the intellectual property rights we have licensed may have been generated through the use of U.S. government funding and may therefore be subject to certain federal regulations. For example, some of the intellectual property rights licensed to us under the license agreements with WU and the Regents may have been generated using U.S. government funds. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole Act. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as march-in rights). The U.S. government also has the right to take title to these inventions if we fail, or the applicable licensor fails, to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. In addition, the U.S. government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us, or the applicable licensor, to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

We currently do not plan to apply for additional U.S. government funding, but if we do, and we discover compounds or drug candidates as a result of such funding, intellectual property rights to such discoveries may be subject to the applicable provisions of the Bayh-Dole Act.

If we do not obtain additional protection under the Hatch-Waxman Amendments and similar foreign legislation by extending the patent terms and obtaining data exclusivity for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of the U.S. patents we own or license may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. For example, we may not be granted an extension if the active ingredient of SAGE-547, allopregnanolone, is used in another drug company s product candidate and that product candidate is the first to obtain FDA approval. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our ability to generate revenues could be materially adversely affected.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation: the Leahy-Smith America Invents Act. The America Invents Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. It is not yet clear what, if any, impact the America Invents Act will have on the operation of our business. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any patents that may issue from our patent applications, all of which could have a material adverse effect on our business and financial condition.

In addition, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. The full impact of these decisions is not yet known. For example, on March 20, 2012 in *Mayo Collaborative Services, DBA Mayo Medical Laboratories, et al. v. Prometheus Laboratories, Inc.*, the Court

held that several claims drawn to measuring drug metabolite levels from patient samples and correlating them to drug doses were not patentable subject matter. The decision appears to impact diagnostics patents that merely apply a law of nature via a series of routine steps and it has created uncertainty around the ability to obtain patent protection for certain inventions. Additionally, on June 13, 2013 in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, the Court held that claims to isolated genomic DNA are not patentable, but claims to complementary DNA molecules are patent eligible because they are not a natural product. The effect of the decision on patents for other isolated natural products is uncertain. However, on March 4, 2014, the U.S. PTO issued a memorandum to patent examiners providing guidance for examining claims that recite laws of nature, natural phenomena or natural products under the Myriad and Prometheus decisions. This guidance did not limit the application of Myriad to DNA but, rather, applied the decision to other natural products.

In addition to increasing uncertainty with regard to our ability to obtain future patents, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on these and other decisions by the U.S. Congress, the federal courts and the U.S. PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce any patents that may issue in the future.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Our employees have been previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We also engage advisors and consultants who are concurrently employed at universities or who perform services for other entities.

Although we are not aware of any claims currently pending against us, we may be subject to claims that we or our employees, advisors or consultants have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third party. We have and may in the future also be subject to claims that an employee, advisor or consultant performed work for us that conflicts with that person s obligations to a third party, such as an employer, and thus, that the third party has an ownership interest in the intellectual property arising out of work performed for us. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money claims, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product candidates, which would materially adversely affect our commercial development efforts.

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology but that is not covered by the claims of patents, should such patents issue from our patent applications;

we might not have been the first to make the inventions covered by a pending patent application that we own;

we might not have been the first to file patent applications covering an invention;

others may independently develop similar or alternative technologies without infringing our intellectual property rights;

pending patent applications that we own or license may not lead to issued patents;

patents, if issued, that we own or license may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;

third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;

we may not be able to obtain and/or maintain necessary or useful licenses on reasonable terms or at all;

third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;

we may not develop or in-license additional proprietary technologies that are patentable; and

the patents of others may have an adverse effect on our business.

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

General Company-Related Risks

We will need to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

As of the date of this filing, we had 25 full-time employees and no part-time employees, and in connection with becoming a public company, we expect to increase our number of employees and the scope of our operations. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

Our future success depends on our ability to retain our President and Chief Executive Officer and to attract, retain and motivate qualified personnel.

We are highly dependent on Dr. Jeffrey M. Jonas, our President and Chief Executive Officer. We have entered into an employment agreement with Dr. Jonas, but he may terminate his employment with us at any time. Although we do not have any reason to believe that we will lose the services of Dr. Jonas in the foreseeable future, the loss of his services might impede the achievement of our research, development and commercialization objectives. We also do not have any key-man life insurance on Dr. Jonas. We rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us and may not be subject to our standard non-compete agreements. Recruiting and retaining qualified scientific personnel and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among

numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific personnel from universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel.

Our employees may engage in misconduct or other improper activities, including violating applicable regulatory standards and requirements or engaging in insider trading, which could significantly harm our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with the regulations of the FDA and applicable non-U.S. regulators, provide accurate information to the FDA and applicable non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report

financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of, including trading on, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may be ineffective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We face potential product liability exposure, and, if claims are brought against us, we may incur substantial liability.

The use of our product candidates in clinical trials and the sale of our product candidates, if approved, exposes us to the risk of product liability claims. Product liability claims might be brought against us by patients, healthcare providers or others selling or otherwise coming into contact with our product candidates. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, including as a result of interactions with alcohol or other drugs, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we become subject to product liability claims and cannot successfully defend ourselves against them, we could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in, among other things:

- withdrawal of patients from our clinical trials;
- substantial monetary awards to patients or other claimants;
- decreased demand for our product candidates or any future product candidates following marketing approval, if obtained;
- damage to our reputation and exposure to adverse publicity;
- increased FDA warnings on product labels;
- litigation costs;
- distraction of management s attention from our primary business;

loss of revenue; and

the inability to successfully commercialize our product candidates or any future product candidates, if approved.

We maintain product liability insurance coverage for our clinical trials with a $10 million annual aggregate coverage limit. Nevertheless, our insurance coverage may be insufficient to reimburse us for any expenses or losses we may suffer. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses, including if insurance coverage becomes increasingly expensive. If and when we obtain marketing approval for our product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may not be able to obtain this product liability insurance on commercially reasonable terms. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. The cost of any product liability litigation or other proceedings, even if resolved in our favor, could be substantial, particularly in light of the size of our business and financial resources. A product liability claim or series of claims brought against us could cause our stock price to decline and, if we are unsuccessful in defending such a claim or claims and the resulting judgments exceed our insurance coverage, our financial condition, business and prospects could be materially adversely affected.

We will incur increased costs as a result of operating as a public company, and our management team will be required to devote substantial time to new compliance initiatives.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the Securities and Exchange Commission and The NASDAQ Stock Market have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

In order to satisfy our obligations as a public company, we will need to hire additional qualified accounting and financial personnel with appropriate public company experience.

As a newly public company, we will need to establish and maintain effective disclosure and financial controls and make changes in our corporate governance practices. We will need to hire additional accounting and financial personnel with appropriate public company experience and technical accounting knowledge, and it may be difficult to recruit and maintain such personnel. Even if we are able to hire appropriate personnel, our existing operating expenses and operations will be impacted by the direct costs of their employment and the indirect consequences related to the diversion of management resources from product development efforts.

Our ability to use our net operating loss carryforwards and certain tax credit carryforwards may be subject to limitation.

As of June 30, 2014, we had federal and state net operating loss carryforwards of $24.0 million and $23.7 million, respectively, which begin to expire in 2031. As of June 30, 2014, we also had federal and state research and development tax credit carryforwards of $0.3 million and $0.2 million, respectively, which begin to expire in 2031 and 2027, respectively. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, changes in our ownership may limit the amount of our net operating loss carryforwards and research and development tax credit carryforwards that could be utilized annually to offset our future taxable income, if any. This limitation would generally apply in the event of a cumulative change in ownership of our company of more than 50% within a three-year period. Any such limitation may significantly reduce our ability to utilize our net operating loss carryforwards and research and development tax credit carryforwards before they expire. The completion of our IPO, together with private placements and other transactions that have occurred since our inception, may trigger such an ownership change pursuant to Section 382. Any such limitation, whether as the result of our IPO, prior private

placements, sales of our common stock by our existing stockholders, could have a material adverse effect on our results of operations in future years. We have not completed a study to assess whether an ownership change for purposes of Section 382 has occurred, or whether there have been multiple ownership changes since our inception, due to the significant costs and complexities associated with such study.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or

prolonged economic downturn, such as the recent global financial crisis, could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Our internal computer systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product candidates development programs.

Despite the implementation of security measures, our internal computer systems and those of our third-party CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed.

We may acquire businesses or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

Risks Related to Our Financial Position and Need for Capital

We are a biopharmaceutical company with a limited operating history and have not generated any revenue from product sales. We have incurred significant operating losses since our inception and anticipate that we will incur

continued losses for the foreseeable future.

We are a company with a limited operating history on which to base your investment decision. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We were incorporated in April 2010. Our operations to date have been limited primarily to organizing and staffing our company, raising capital and conducting research and development activities for our product candidates. We have never generated any revenue from product sales. We have not obtained regulatory approvals for any of our product candidates.

We have funded our operations to date through proceeds from sales of redeemable convertible preferred stock and, to a lesser extent, the issuance of convertible notes. On July 23, 2014, we completed the sale of 5,750,000 shares of our common stock in our IPO, at a price to the public of $18.00 per share, resulting in net proceeds of $94.0 million after deducting underwriting discounts and

commissions and estimated offering expenses payable by us. From our inception through June 30, 2014, we had received net proceeds of $90.7 million from such transactions, excluding amounts raised in the IPO. As of June 30, 2014, our cash and cash equivalents were $49.1 million, excluding amounts raised in the IPO. We have incurred significant net losses in each year since our inception, including net losses of $12.0 million for the six months ended June 30, 2014 and $18.3 million and $9.6 million for the years ended December 31, 2013 and 2012, respectively. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders deficit and working capital. We expect our research and development expenses to significantly increase in connection with our clinical trials of our product candidates. In addition, if we obtain marketing approval for our product candidates, we will incur significant sales, marketing and outsourced-manufacturing expenses. Once we are a public company, we will incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from our lead product candidates, SAGE-547, SAGE-689 and SAGE-217, and we do not know when, or if, we will generate any revenue. We do not expect to generate significant revenue unless and until we obtain marketing approval of, and begin to sell, SAGE-547, SAGE-689 or SAGE-217. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- initiate and successfully complete clinical trials that meet their clinical endpoints;
- initiate and successfully complete all safety studies required to obtain U.S. and foreign marketing approval for our product candidates;
- commercialize our product candidates, if approved, by developing a sales force or entering into collaborations with third parties; and
- achieve market acceptance of our product candidates in the medical community and with third-party payors.

Absent our entering into a collaboration or partnership agreement, we expect to incur significant sales and marketing costs as we prepare to commercialize our product candidates. Even if we initiate and successfully complete pivotal clinical trials of our product candidates, and our product candidates are approved for commercial sale, and despite expending these costs, our product candidates may not be a commercially successful drug. We may not achieve profitability soon after generating product sales, if ever. If we are unable to generate product revenue, we will not become profitable and may be unable to continue operations without continued funding.

We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

We are currently advancing our product candidates through non-clinical and clinical development. Developing small molecule products is expensive, and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance our product candidate in clinical trials. Depending on the status of regulatory approval or, if approved, commercialization of our product candidates, as well as the progress we make in selling our product candidates, we may require additional capital to fund operating needs thereafter. We may also need to raise additional funds sooner if we choose to pursue additional indications and/or geographies for our product candidates or otherwise expand more rapidly than we presently anticipate.

As of June 30, 2014, our cash and cash equivalents were $49.1 million, and we received net proceeds of $96.3 million from our IPO , which closed on July 23, 2014. We expect that our existing cash and cash equivalents will be sufficient to fund our current operations for at least the next 12 months. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize, our product candidates. Raising funds in the current economic environment may present additional challenges. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

Any additional fundraising efforts may divert our management from their 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. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidate or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidate or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights.

We may seek additional capital through a combination of private and public equity offerings, debt financings, collaborations and strategic and licensing arrangements. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest in our company will be diluted. In addition, the terms of any such securities may include liquidation or other preferences that materially adversely affect your rights as a stockholder. Debt financing, if available, would increase our fixed payment obligations and 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 collaboration, strategic partnerships and licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, our intellectual property, future revenue streams or grant licenses on terms that are not favorable to us.

Risks Related to Our Common Stock

Market volatility may affect our stock price and the value of your investment.

Our IPO was completed on July 23, 2014, where we sold shares of our common stock at a price of $18.00 per share. There has been a public market for our common stock for only a short period of time. Although our common stock is listed on the NASDAQ Global Market, an active public market for our common stock may not emerge or be sustained.

In addition, the market price of our common stock may fluctuate significantly in response to a number of factors, most of which we cannot control, including, among others:

- plans for, progress of or results from non-clinical studies and clinical trials of our product candidates;

the failure of the FDA to approve our product candidates;

announcements of new products, technologies, commercial relationships, acquisitions or other events by us or our competitors;

the success or failure of other CNS therapies;

regulatory or legal developments in the United States and other countries;

failure of our product candidates, if approved, to achieve commercial success;

fluctuations in stock market prices and trading volumes of similar companies;

general market conditions and overall fluctuations in U.S. equity markets;

variations in our quarterly operating results;

changes in our financial guidance or securities analysts estimates of our financial performance;

changes in accounting principles;

our ability to raise additional capital and the terms on which we can raise it;

sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;

additions or departures of key personnel;

discussion of us or our stock price by the press and by online investor communities; and

other risks and uncertainties described in these risk factors.

We have a significant stockholder, which will limit your ability to influence corporate matters and may give rise to conflicts of interest.

A fund affiliated with Third Rock Ventures, or TRV, is our largest stockholder. As of June 30, 2014, TRV beneficially owned approximately 58.5% of our common stock. Accordingly, TRV exerts and will continue to exert significant influence over us and any action requiring the approval of the holders of our common stock, including the election of directors and amendments to our organizational documents, such as increases in our authorized shares of common stock and approval of significant corporate transactions. Furthermore, the interests of TRV may not always coincide with your interests or the interests of other stockholders and TRV may act in a manner that advances its best interests and not necessarily those of other stockholders, including seeking a premium value for its common stock, which might affect the prevailing market price for our common stock.

Our executive officers, directors, principal stockholders and their affiliates will continue to exercise significant control over our company, which will limit your ability to influence corporate matters and could delay or prevent a change in corporate control.

As of June 30, 2014, existing holdings of our executive officers, directors, principal stockholders and their affiliates, including investment funds affiliated with ARCH Venture Fund VII, L.P., or ARCH, TRV, and entities affiliated with

Fidelity Investment, or Fidelity, represent beneficial ownership, in the aggregate, of approximately 73.0% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and control the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets. These stockholders acquired their shares of common stock for substantially less than the price of the shares of common stock being acquired in the recently completed IPO, and these stockholders may have interests, with respect to their common stock, that are different from those of investors in the recently completed IPO and the concentration of voting power among these stockholders may have an adverse effect on the price of our common stock. In addition, this concentration of ownership might adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;

impeding a merger, consolidation, takeover or other business combination involving us; or

discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale lapse, the market price of our common stock could decline. Based upon the number of shares of common stock, on an as-converted basis, outstanding as of June 30, 2014, upon the completion of our IPO, we had outstanding a total of 24,961,926 shares of common stock. Of these shares, as of the date of this filing, approximately 5,750,000 shares of our common stock, are freely tradable, without restriction, in the public market . The representatives of the underwriters in our IPO, however, may, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

The lock-up agreements pertaining to our IPO will expire 180 days from July 17, 2014. After the lock-up agreements expire, based upon the number of shares of common stock, on an as-converted basis, outstanding as of June 30, 2014, up to an additional 19,961,926 shares of common stock will be eligible for sale in the public market, 73.0% of which shares are held by directors, executive officers and other affiliates and will be subject to certain limitations of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act.

3,930,961 shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

The holders of approximately 18,007,575 shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the market our common stock.

We have broad discretion in how we use the proceeds from our IPO and may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.

We will have considerable discretion in the application of the net proceeds from our recently completed IPO. We intend to use the net proceeds from the offering to fund the costs of our Phase 1/2 clinical development of SAGE-547, to fund the IND-enabling activities and Phase 1 clinical activity for SAGE-689, to fund the IND-enabling activities for SAGE-217 and to fund new and ongoing research and development activities, working capital and other general corporate purposes, which may include funding for the hiring of additional personnel, capital expenditures and the costs of operating as a public company. As a result, investors will be relying upon management s judgment with only limited information about our specific intentions for the use of the balance of the net proceeds from the IPO. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from this offering from the IPO in a manner that does not produce income or that loses value.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, even one that may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may delay or prevent an acquisition of us or a change in our management. These provisions include a classified board of directors, a prohibition on actions by written consent of our stockholders and the ability of our board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or

combine with us. Although we believe these provisions collectively provide for an opportunity to obtain greater value for stockholders by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer rejected by our board were considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

We are an emerging growth company, and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. If we choose not to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, our auditors will not be required to attest to the effectiveness of our internal control over financial reporting. As a result, investors may become less comfortable with the effectiveness of our internal controls and the risk that material weaknesses or other deficiencies in our internal controls go undetected may increase. If we choose to provide reduced disclosures in our periodic reports and proxy statements while we are an emerging growth company, investors would have access to less information and analysis about our executive compensation, which may make it difficult for investors to evaluate our executive compensation practices. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (a) the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering, (b) the last day of the fiscal year in which we have total annual gross revenue of at least $1.0 billion, (c) the date on which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (d) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We do not intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid any cash dividend on our common stock and do not currently intend to do so in the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the foreseeable future. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which you purchased them.

If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our common stock, the price of our common stock could decline.

The trading market for our common stock relies in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts. The price of our common stock could decline if one or more equity analysts downgrade our common stock or if analysts issue other unfavorable commentary or cease publishing reports about us or our business.

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

Unregistered Sales of Equity Securities

During the six months ended June 30, 2014, we issued and sold an aggregate of 3,968 shares of common stock to certain employees and consultants for cash consideration in the aggregate amount of $1,750 upon the exercise of stock options. These issuances were undertaken in reliance upon the exemption from registration requirements of Rule 701 of the Securities Act as offers and sales of securities under compensatory benefit plans and contracts relating to compensation in compliance with Rule 701.

No underwriters were used in the foregoing transactions.

Use of Proceeds from Initial Public Offering of Common Stock

On July 23, 2014, we closed the sale of 5,750,000 shares of common stock to the public (inclusive of 750,000 shares of common stock sold by us pursuant to the full exercise of an overallotment option granted to the underwriters) at a price of $18.00 per share, before underwriting discounts. The offer and sale of the shares in our initial public offering was registered under the Securities Act pursuant to registration statements on Form S-1 (File No. 333- 196849), which was filed with the SEC on June 17, 2014 and amended subsequently and declared effective by the SEC on July 17, 2014. Following the sale of the shares in connection with the closing of our initial public offering, the offering terminated. The offering did not terminate before all the securities registered in the registration statements were sold. JPMorgan Securities Co. and Goldman Sachs & Co. acted as joint book-running managers of the offering, and Canaccord Genuity Inc. and Leerink Partners acted as co-managers of the offering.

We raised approximately $94.0 million in net proceeds after deducting underwriting discounts and commissions and estimated offering expenses payable by us . None of these expenses consisted of direct or indirect payments made by us to directors, officers or persons owning 10% or more of our common stock or to their associates, or to our affiliates. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on July 18, 2014 pursuant to Rule 424(b)(4). We invested the funds received in cash equivalents and other short-term investments in accordance with our investment policy,

Item 6. Exhibits

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which is incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

SAGE THERAPEUTICS, INC.

August 14, 2014

By: /s/ Jeffrey M. Jonas
Jeffrey M. Jonas
Chief Executive Officer

(Principal Executive Officer)

August 14, 2014

By: /s/ Kimi Iguchi
Kimi Iguchi
Chief Financial Officer

(Principal Financial Officer)

EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference to: Filing			
		Form or Schedule	Exhibit No.	Date with SEC	SEC File Number
3.1	Fifth Amended and Restated Certificate of Incorporation of the Registrant.	8-K	3.1	July 23, 2014	001-36544
3.2	Amended and Restated By-Laws of the Registrant.	8-K	3.2	July 23, 2014	001-36544
4.1	Specimen Common Stock Certificate of the Registrant.	S-1/A	4.1	July 8, 2014	333-196849
31.1*	Certification of Principal Executive Officer pursuant to Exchange Act rules 13a-14 or 15d-14.				
31.2*	Certification of Principal Financial Officer pursuant to Exchange Act rules 13a-14 or 15d-14.				
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Exchange Act rules 13a-14(b) or 15d-14(b) and 18 U.S.C. Section 1350.				
101.INS**	XBRL Instance Document.				
101.SCH**	XBRL Taxonomy Extension Schema Document.				
101.CAL**	XBRL Taxonomy Extension Calculation Document.				
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB**	XBRL Taxonomy Extension Labels Linkbase Document.				
101.PRE**	XBRL Taxonomy Extension Presentation Link Document.				

* Filed herewith.

** Attached as Exhibit 101 to this report are documents formatted in XBRL (Extensible Business Reporting Language). Pursuant to Rule 406T of Regulation S-T, the interactive data file is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is otherwise not subject to liability under these sections.

61