Sage Therapeutics, Inc. Form 10-Q November 06, 2015 <u>Table of Contents</u>

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

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

For the quarterly period ended September 30, 2015

OR

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

For the transition period from ______ to _____

Commission file number: 001-36544

Sage Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of 27-4486580 (I.R.S. Employer

incorporation or organization)

Identification No.)

215 First Street

Cambridge, Massachusetts 02142

(Address of principal executive office) (Zip Code)

Registrant s telephone number, including area code: (617) 299-8380

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 x No "

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (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 November 1, 2015, there were 28,862,471 shares of the registrant s Common Stock, \$0.0001 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:

our estimates regarding expenses, the potential for future revenues and capital requirements;

our plans to develop and commercialize our product candidates in the CNS disorders we discuss in this Quarterly Report and potentially in other indications;

our plans with respect to filing for regulatory approval for our product candidates, if clinical trial development is successful, and the potential to obtain such approval and to commercialize any product, if approved

our ability to complete our ongoing nonclinical studies and 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 expected 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;

the level of costs we may incur in connection with our activities, and our ability to obtain additional financing when needed;

the potential for success of competing products that are or become available for the indications that we are pursuing;

the potential risk of 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 and with respect 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 described 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, the general business environment, 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 information, market data 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, in some cases applying assumptions that may, in the future, not prove to have been accurate.

Sage Therapeutics, Inc.

INDEX

Page

PART I FINANCIAL INFORMATION

| Item 1. | Financial Statements (Unaudited) | 4 |
|----------|--|----|
| | Consolidated Balance Sheets as of September 30, 2015 and December 31, 2014 | 4 |
| | Consolidated Statements of Operations and Comprehensive Loss for the three and nine months | |
| | ended September 30, 2015 and 2014 | 5 |
| | Consolidated Statements of Cash Flows for the nine months ended September 30, 2015 and | |
| | <u>2014</u> | 6 |
| | Notes to Consolidated Financial Statements | 7 |
| Item 2. | Management s Discussion and Analysis of Financial Condition and Results of Operations | 15 |
| Item 3. | Quantitative and Qualitative Disclosures About Market Risk | 28 |
| Item 4. | Controls and Procedures | 28 |
| | PART II OTHER INFORMATION | |
| Item 1. | Legal Proceedings | 29 |
| Item 1A. | Risk Factors | 29 |
| Item 2. | Unregistered Sales of Equity Securities and Use of Proceeds | 59 |
| Item 6. | Exhibits | 60 |
| | Signatures | 61 |

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

Sage Therapeutics, Inc. and Subsidiaries

Consolidated Balance Sheets

(in thousands, except share and per share data)

(Unaudited)

| AssetsCurrent assets:Cash and cash equivalents\$ 204,877Prepaid expenses and other current assets2,604Total current assets207,481Property and equipment, net249Restricted cash39Deferred tax assets641Total assets\$ 208,410Liabilities and Stockholders Equity\$ 3,246Accounts payable\$ 3,246Accounts payable\$ 4,404Deferred tax liabilities641Total current liabilities641Total current liabilities10,291Other liabilities15Total liabilities10,306Commitments and contingencies (Note 4)Stockholders equity: | \$ 127,766 1,056 128,822 |
|---|--------------------------------|
| Cash and cash equivalents\$ 204,877Prepaid expenses and other current assets2,604Total current assets207,481Property and equipment, net249Restricted cash39Deferred tax assets641Total assets\$ 208,410Liabilities and Stockholders Equity\$ 3,246Accounts payable\$ 3,246Accrued expenses6,404Deferred tax liabilities641Total current liabilities641Total current liabilities10,291Other liabilities15Total liabilities10,306Commitments and contingencies (Note 4)5 | 1,056 |
| Prepaid expenses and other current assets2,604Total current assets207,481Property and equipment, net249Restricted cash39Deferred tax assets641Total assets\$ 208,410Liabilities and Stockholders EquityCurrent liabilities:3,246Accounts payable\$ 3,246Accrued expenses6,404Deferred tax liabilities641Total current liabilities641Total current liabilities10,291Other liabilities15Total liabilities10,306Commitments and contingencies (Note 4)5 | 1,056 |
| Total current assets207,481Property and equipment, net249Restricted cash39Deferred tax assets641Total assets\$ 208,410Liabilities and Stockholders EquityCurrent liabilities:Accounts payable\$ 3,246Accrued expenses6,404Deferred tax liabilities641Total current liabilities641Total current liabilities10,291Other liabilities15Total liabilities10,306Commitments and contingencies (Note 4) | · |
| Property and equipment, net249Restricted cash39Deferred tax assets641Total assets\$208,410\$Liabilities and Stockholders Equity Current liabilities: Accounts payableAccounts payable\$3,246Accrued expenses6,404Deferred tax liabilities641Total current liabilities10,291Other liabilities15Total liabilities10,306Commitments and contingencies (Note 4)10,201 | 128,822 |
| Restricted cash39Deferred tax assets641Total assets\$ 208,410Liabilities and Stockholders Equity Current liabilities: Accounts payableAccounts payable\$ 3,246Accrued expenses6,404Deferred tax liabilities641Total current liabilities10,291Other liabilities15Total liabilities10,306Commitments and contingencies (Note 4)10 | |
| Deferred tax assets641Total assets\$ 208,410Liabilities and Stockholders EquityCurrent liabilities: | 163 |
| Total assets\$208,410Liabilities and StockholdersEquityCurrent liabilities: Accounts payable\$3,246Accrued expenses6,404Deferred tax liabilities641Total current liabilities10,291Other liabilities15Total liabilities10,306Commitments and contingencies (Note 4)5 | 39 |
| Liabilities and StockholdersEquityCurrent liabilities:Accounts payable\$ 3,246Accrued expenses6,404Deferred tax liabilities641Total current liabilities10,291Other liabilities15Total liabilities10,306Commitments and contingencies (Note 4)10 | 641 |
| Current liabilities:Accounts payable\$ 3,246Accrued expenses6,404Deferred tax liabilities641Total current liabilities10,291Other liabilities15Total liabilities10,306Commitments and contingencies (Note 4)10 | \$ 129,665 |
| Accrued expenses6,404Deferred tax liabilities641Total current liabilities10,291Other liabilities15Total liabilities10,306Commitments and contingencies (Note 4)10 | |
| Deferred tax liabilities641Total current liabilities10,291Other liabilities15Total liabilities10,306Commitments and contingencies (Note 4)10 | \$ 2,429 |
| Total current liabilities10,291Other liabilities15Total liabilities10,306Commitments and contingencies (Note 4)10 | 4,687 |
| Other liabilities15Total liabilities10,306Commitments and contingencies (Note 4)10 | 641 |
| Total liabilities10,306Commitments and contingencies (Note 4) | 7,757 |
| Commitments and contingencies (Note 4) | 23 |
| | 7,780 |
| Preferred stock, \$0.0001 par value; 5,000,000 shares authorized at September 30, 2015 and December 31, 2014, respectively; no shares issued or outstanding at September 30, 2015 and December 31, 2014, respectively Common stock, \$0.0001 par value; 120,000,000 shares authorized at | |
| September 30, 2015 and December 31, 2014, respectively; 28,788,885 and25,621,791 shares issued and outstanding at September 30, 2015 andDecember 31, 2014, respectively3 | 3 |

| Additional paid-in capital | 330,879 | 188,727 |
|---|---------------|---------------|
| Accumulated deficit | (132,778) | (66,845) |
| Total stockholders equity | 198,104 | 121,885 |
| Total liabilities and stockholders equity | \$ 208,410 | \$ 129,665 |

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

Sage Therapeutics, Inc. and Subsidiaries

Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

(Unaudited)

| | Thre | e Months End 2015 | ded | September 30, 2014 | Nine | Months Ende 2015 | ed Se | ptember 30, 2014 |
|--|------|----------------------|-----|-----------------------|------|---------------------|-------|---------------------|
| Operating expenses: | | | | | | | | |
| Research and development | \$ | 17,478 | \$ | 6,601 | \$ | 48,981 | \$ | 15,155 |
| General and administrative | | 6,604 | | 2,869 | | 17,057 | | 6,294 |
| Total operating expenses | | 24,082 | | 9,470 | | 66,038 | | 21,449 |
| Loss from operations | | (24,082) | | (9,470) | | (66,038) | | (21,449) |
| Interest income, net | | 53 | | 3 | | 115 | | 4 |
| Other expense, net | | (6) | | (1) | | (10) | | (5) |
| Net loss and comprehensive loss Accretion of redeemable convertible preferred stock to redemption value Net loss attributable to common | | (24,035) | | (9,468) (391) | | (65,933) | | (21,450) (2,294) |
| stockholders | \$ | (24,035) | \$ | (9,859) | \$ | (65,933) | \$ | (23,744) |
| Net loss per share attributable to common stockholders basic and diluted | \$ | (0.84) | \$ | (0.50) | \$ | (2.40) | \$ | (3.08) |
| Weighted average number of common shares used in net loss per share attributable to common stockholders basic and diluted | | 28,737,743 | | 19,581,624 | | 27,430,275 | | 7,711,038 |

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

Sage Therapeutics, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

(in thousands)

(Unaudited)

| | Nine Mont Septem 2015 | |
|---|-----------------------------|-------------|
| Cash flows from operating activities | | |
| Net loss | \$ (65,933) | \$ (21,450) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation expense | 11,154 | 1,186 |
| Non-cash licensing and consulting fees | 1,211 | 127 |
| Depreciation | 83 | 35 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | (1,548) | (722) |
| Accounts payable | 808 | (6) |
| Accrued expenses and other liabilities | 1,661 | 2,455 |
| Net cash used in operating activities | (52,564) | (18,375) |
| Cash flows from investing activities | | |
| Purchase of property and equipment | (160) | (83) |
| Net cash used in investing activities | (160) | (83) |
| Cash flows from financing activities | | |
| 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 stock option exercises and employee stock purchase plan issuances | 663 | 39 |
| Payment of offering costs | (548) | (2,035) |
| Proceeds from public offering of common stock, net of commissions and underwriting discounts | 129,720 | 96,255 |
| Net cash provided by financing activities | 129,835 | 147,119 |
| | 77,111 | 128,661 |
| Net increase in cash and cash equivalents Cash and cash equivalents at beginning of period | 127,766 | 8,066 |
| Cash and cash equivalents at beginning of period | 127,700 | 8,000 |
| Cash and cash equivalents at end of period | \$ 204,877 | \$ 136,727 |
| Supplemental disclosure of non-cash financing activities | | |
| Accretion of redeemable convertible preferred stock to redemption value | \$ | \$ 2,294 |

| Public offering costs included in accounts payable or accrued expenses | \$ | 4 | \$ 246 |
|---|-------------|-------|--------------|
| Conversion of preferred stock to common stock | \$ | | \$ 92,863 |
| The accompanying notes are an integral part of these consolidated finan | cial statem | ents. | |

SAGE THERAPEUTICS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

(Unaudited)

1. Nature of Operations

Sage Therapeutics, Inc. (Sage or the Company) is a clinical-stage biopharmaceutical company committed to developing and commercializing novel medicines to treat life-altering 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, 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 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 companies in the biotech industry, including, but not limited to, the risks associated with developing product candidates at each stage of nonclinical and clinical development; the challenges associated with gaining regulatory approval of such product candidates; the potential for development by third parties of new technological innovations that may compete with the Company s products; the dependence on key personnel; the challenges of protecting proprietary technology; the need to comply with government regulations; the high costs of drug development; and the uncertainty of being able to secure additional capital when needed to fund operations.

The Company has incurred losses and negative cash flows from operations since its inception. As of September 30, 2015, the Company had an accumulated deficit of \$132.8 million. From its inception through September 30, 2015, the Company has raised aggregate net proceeds of \$90.6 million from the issuance of Series A, Series B and Series C redeemable convertible preferred stock. In July 2014, the Company raised net proceeds of \$94.0 million from the sale of common stock in its initial public offering, (IPO). In April 2015, the Company raised net proceeds of \$129.1 million from the sale of common stock in a follow-on underwritten public offering. Based on its current operating plans, the Company believes its cash and cash equivalents balance of \$204.9 million as of September 30, 2015 will be sufficient to fund its anticipated level of operations through mid-2017.

2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited interim consolidated 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 audited consolidated financial statements as of and for the year ended December 31, 2014.

The unaudited interim consolidated 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 September 30, 2015, the results of its operations and comprehensive loss for the three and nine months ended September 30, 2015 and 2014, and its cash flows for the nine months ended September 30, 2015 and 2014. Such adjustments are of a normal and recurring nature. The results for the three and nine months ended September 30, 2015 are not indicative of the results for the year ending December 31, 2015, 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 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 offering costs paid by the Company. The shares began trading on the Nasdaq Global Market on July 18, 2014.

In connection with preparing 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. The significant increase in common stock outstanding in July 2014 will impact the year-over-year comparability of the Company s net loss per share calculations through the end of 2015.

On April 20, 2015, the Company completed the sale of 2,628,571 shares of common stock in its underwritten public offering of its common stock at a price to the public of \$52.50 per share, resulting in net proceeds to the Company of \$129.1 million after deducting underwriting discounts and commissions and offering costs paid by the Company.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries as disclosed in Note 2, Summary of Significant Accounting Policies, within the Notes to Consolidated Financial Statements accompanying its Annual Report on Form 10-K for the fiscal year ended December 31, 2014, as amended. Intercompany accounts and transactions have been eliminated.

Recently Issued Accounting Pronouncements

In May 2014, the FASB issued guidance that outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry specific guidance. The guidance is based on the principle that an entity should recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The guidance also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to fulfill a contract. Entities have the option of using either a full retrospective or a modified retrospective approach for the adoption of the new standard. The guidance becomes effective for the Company in the year ending December 31, 2018, and the Company could early adopt the standard for the year ending December 31, 2017. The Company is currently assessing the method of adoption and the impact of this new accounting guidance will have on its consolidated financial statements and footnote disclosures.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements Going Concern (Subtopic 205-40). The new guidance addresses management s responsibility to evaluate whether there is substantial doubt about an entity s ability to continue as a going concern and to provide related footnote disclosures. Management s evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued. The standard will be effective for the first interim period within annual reporting periods beginning after December 15, 2016. Early adoption is permitted. The Company is evaluating the effect that this guidance will have on its consolidated financial statements.

Use of Estimates

The preparation of consolidated 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 consolidated 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 September 30, 2015 and December 31, 2014, the Company s Level 1 assets consisted of money market funds totaling \$204.9 million and \$127.8 million, 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 September 30, 2015 and December 31, 2014, 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 September 30, 2015 and December 31, 2014, 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 September 30, 2015 and December 31, 2014.

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 IPO in July 2014, \$2.3 million of these costs were recorded in stockholders equity as a reduction of additional paid-in capital generated as a result of the IPO. After consummation of the public offering of common stock in April 2015, \$0.6 million of these costs were recorded in stockholders equity as a reduction of additional paid-in capital generated as a result of the offering.

Segment Data

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company s singular focus is on advancing medicines to treat CNS disorders, where there are inadequate or no approved existing therapies. All tangible assets are held within the United States.

3. Accrued Expenses

Accrued expenses consist of the following (amounts in thousands):

| | Septem | ber 30, 2015 | Decem | ber 31, 2014 |
|---------------------------|--------|--------------|-------|--------------|
| Development costs | \$ | 4,096 | \$ | 2,788 |
| Employee-related expenses | | 1,545 | | 1,279 |
| Professional services | | 756 | | 574 |
| Other accrued expenses | | 7 | | 46 |
| | \$ | 6,404 | \$ | 4,687 |

4. Commitments and contingencies

CyDex License Agreement

In September 2015, the Company and CyDex Pharmaceuticals, Inc. (CyDex) amended and restated their existing commercial license agreement. Under the terms of the commercial license agreement as amended and restated, CyDex has granted to the Company an exclusive license to CyDex s Captisol drug formulation technology and related intellectual property for the manufacture of pharmaceutical products incorporating the Company s compounds known as SAGE-547 and SAGE-689, and the development and commercialization of the resulting products in the treatment, prevention or diagnosis of any disease or symptom in humans or animals other than (i) the ocular treatment of any disease or condition with a formulation, including a hormone; (ii) topical ocular treatment of inflammatory conditions; (iii) treatment and prophylaxis of fungal infections in humans; and (iv) any ocular treatment for retinal degeneration.

As consideration for the inclusion of SAGE-689 in the license granted by CyDex, the Company paid a milestone to CyDex of \$0.1 million, which was recorded as research and development expense in the three months ended September 30, 2015 in connection with execution of the amended and restated license agreement.

The Company is obligated to make milestone payments under the amended and restated license agreement with CyDex based on the achievement of clinical development and regulatory milestones in the amount of \$0.8 million in clinical milestones and \$3.8 million in regulatory milestones for each of the first two fields with respect to SAGE-547; \$1.3 million in clinical milestones and \$8.5 million in regulatory milestones for each of the third and fourth fields with respect to SAGE-547; and \$0.8 million in clinical milestones and \$1.8 million in regulatory milestones for one field with respect to SAGE-689.

In March 2015, a clinical development milestone was met for the SAGE-547 program under the license agreement with CyDex, and accordingly, the Company recorded research and development expense for the three months ended March 31, 2015 of \$0.3 million.

In April 2015, an additional clinical development milestone for the SAGE-547 program was met under the license agreement with CyDex, and accordingly, the Company recorded research and development expense for the three months ended June 30, 2015 of \$0.5 million.

The Company will also be required to pay royalties to CyDex on sales of SAGE-547 and SAGE-689, if successfully developed, in the low single digits based on levels of net sales. The Company and CyDex are also parties to a supply agreement which was amended in September 2015 to cover the supply of CyDex s Captisol for use in the manufacture of products incorporating SAGE-689. Under the amended supply agreement with CyDex, the Company is required to purchase all of its requirements for Captisol with respect to SAGE-547 and SAGE-689 from CyDex, and CyDex is required to supply the Company with Captisol for such purposes, subject to certain limitations.

Washington University License Agreement

In November 2013, the Company entered into a license agreement with Washington University whereby the Company was granted exclusive, worldwide rights to develop and commercialize a novel set of neuroactive steroids developed by Washington University. In exchange for development and commercialization rights, the Company paid an upfront, non-refundable payment of \$50,000 and is required to pay an annual license maintenance fee of \$15,000 on each subsequent anniversary date, until the first Phase 2 clinical trial for a licensed product is initiated. The Company is obligated to make milestone payments to Washington University based on achievement of clinical development and regulatory milestones of up to \$0.7 million and \$0.5 million, respectively. Additionally, the Company fulfilled its obligation to issue to Washington University 47,619 shares of common stock on December 13, 2013. The fair value of these shares totaling \$0.1 million was recorded as research and development expense in 2013.

The Company is obligated to pay royalties to Washington University at rates in the low single digits on net sales of licensed products covered under patent rights and royalties at rates in the low single digits on net sales of licensed products not covered under patent rights. Additionally, the Company has the right to sublicense and is required to make payments at varying percentages of sublicensing revenue received, initially in the mid-teens and descending to the mid-single digits over time.

In September 2015, a regulatory milestone was met for one of the programs. Accordingly, the Company recorded research and development expenses for the three months ended September 30, 2015 of \$50,000.

University of California License Agreements

In October 2013, the Company entered into a non-exclusive license agreement with The Regents of the University of California whereby the Company was granted a non-exclusive license to certain clinical data and clinical material for use in the development and commercialization of biopharmaceutical products in the licensed field, including status epilepticus and post-partum depression. In May 2014, the license agreement was amended to add the treatment of essential tremor to the licensed field of use, materials and milestone fee provisions of the agreement.

The Company will be required to pay to The Regents of the University of California clinical development milestones of up to \$0.1 million and pay royalties of less than 1% on net sales for a period of fifteen years following the sale of the first commercial product.

The license will terminate on the earlier to occur of (i) 27 years after the effective date or (ii) 15 years after the last-derived product is first commercially sold.

In March 2015, a clinical development milestone was met. Accordingly, the Company recorded research and development expenses for the three months ended March 31, 2015 totaling \$0.1 million.

In June 2015, an additional clinical development milestone was met. Accordingly, the Company recorded research and development expenses for the three months ended June 30, 2015 totaling \$25,000.

In September 2015, an additional clinical development milestone was met. Accordingly, the Company recorded research and development expenses for the three months ended September 30, 2015 totaling \$25,000. In June 2015, the Company entered into an exclusive license agreement with The Regents of the University of California whereby the Company was granted an exclusive license to certain patent rights related to the use of allopregnanolone to treat various diseases. In exchange for such license, the Company paid an upfront payment of \$50,000 and will make annual maintenance fees of \$15,000 until the calendar year following the first sale, if any, of a licensed product. The Company is obligated to make milestone payments following the achievement of specified regulatory and sales milestones of up to \$0.7 million and \$2.0 million in the aggregate, respectively. Following the first sale, if any, of a licensed, if any, of a licensed product, the Company is obligated to pay royalties at a low single digit percentage of net sales, if any, of licensed products, subject to specified minimum annual royalty amounts. Unless terminated by operation of law or by acts of the parties under the terms of the agreement, the license agreement will terminate when the last-to-expire patents or last-to-be abandoned patent applications expire, whichever is later.

Consulting Agreement

In January 2014, the Company entered into a consulting agreement with a nonemployee advisor whereby the Company is obligated to make cash payments of up to \$2.0 million and to issue up to 126,984 shares of common stock upon attainment of certain clinical development and regulatory milestones.

In January and March 2014, the first clinical development milestones for each of two programs included in the consulting agreement were met. Accordingly, the Company recorded research and development expense for the year ended December 31, 2014 of \$0.2 million, comprised of \$50,000 in cash and \$0.1 million related to the issuance of 15,872 shares of the Company s common stock.

In March 2015, the second clinical development milestone for one of the programs included in the consulting agreement was met. Accordingly, the Company recorded research and development expense for the three months ended March 31, 2015 of \$0.6 million, comprised of \$0.2 million in cash and \$0.4 million related to the issuance of 7,936 shares of the Company s common stock.

In April 2015, the third clinical development milestone for one of the programs included in the consulting agreement was met. Accordingly, the Company recorded research and development expense for the three months ended June 30, 2015 of \$1.1 million, comprised of \$0.3 million in cash and \$0.8 million related to the issuance of 15,873 shares of the Company s common stock.

5. Stock-Based Compensation

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 provides for the grant of restricted stock awards, incentive stock options, non-statutory stock options, among others. The 2014 Stock Option Plan replaced the Company s 2011 Stock Option and Grant Plan (the 2011 Stock Option Plan). The Company will grant no further stock options or other awards under the 2011 Stock Option Plan. Any options or awards outstanding under the 2011 Stock Option Plan remained outstanding and effective. As of September 30, 2015, the total number of shares reserved under the 2014 Stock Option Plan and the 2011 Stock Option Plan was 3,868,298 and the Company had 997,486 shares available for future issuance under the 2014 Stock Option Plan.

The 2014 Stock Option Plan provides for an annual increase, to be added 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. On January 1, 2015, 773,779 shares of common stock, representing 3% of the Company s issued and outstanding shares of common stock as of December 31, 2014, were added to the 2014 Stock Option Plan. Such shares are included in the equity plan totals specified in the paragraph above.

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. As of September 30, 2015, 3,852 shares of common stock have been issued under this plan. During the nine months ended September 30, 2015, issuances of common stock under the Employee Stock Purchase Plan resulted in proceeds to the Company of \$0.1 million.

Stock-Based Compensation

Terms of restricted stock awards and stock option agreements, including vesting requirements, are determined by the Compensation Committee of the Company s Board of Directors or the Board of Directors, subject to the provisions of the applicable stock option plan. Options and restricted stock awards granted by the Company generally vest based on the continued service of the grantee with the Company during a specified period following the grant. Awards generally vest ratably over four years, with a 25% cliff vesting at the one year anniversary.

During the nine months ended September 30, 2015, the Company granted 497,100 options to employees to purchase shares of common stock that contain performance-based vesting criteria, primarily related to achievement of certain clinical and regulatory development milestones related to the Company s product candidates. Recognition of stock-based compensation expense associated with these performance-based stock options commences when the performance condition is considered probable of achievement, using management s best estimates. During the quarter ended June 30, 2015, the achievement of one milestone was considered probable and that milestone was achieved during the quarter ended September 30, 2015. The related expense was recognized over the estimated service period. This milestone represents 35% of the performance-based grants that were made during the nine months ended September 30, 2015. The achievement of the remaining milestones was deemed to be not probable as of September 30, 2015, and therefore no expense has been recognized related to these awards. During the three and nine months ended September 30, 2015, the Company recognized stock-based compensation expense of \$1.4 million and \$4.8 million, respectively, related to stock options with performance-based vesting criteria. During the three and nine months ended September 30, 2014, the Company recognized no stock-based compensation expense related to stock options with performance-based vesting criteria.

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 nine months ended September 30, 2015 and 2014 was as follows (amounts in thousands):

| | Three Months Ended September Nine Months Ended September 3 | | | | | | | |
|-----------------------------|--|-------|----|-----|----|--------|----|-------|
| | | 2015 | 2 | 014 | | 2015 | | 2014 |
| Stock compensation expense: | | | | | | | | |
| Research and development | \$ | 1,472 | \$ | 294 | \$ | 4,293 | \$ | 553 |
| General and administrative | | 2,935 | | 396 | | 6,861 | | 633 |
| | | | | | | | | |
| | \$ | 4,407 | \$ | 690 | \$ | 11,154 | \$ | 1,186 |

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 exercise price per share relating to outstanding stock options granted under the Company s stock option plans during the nine months ended September 30, 2015 and 2014 was \$45.27 and \$9.08, respectively. The weighted average Black-Scholes value per share relating to outstanding stock options granted under the Company s stock option plans during the nine months ended September 30, 2015 was \$33.44.

The fair value of each option granted to employees and directors during the three and nine months ended September 30, 2015 and 2014 under the Company s stock option plans has been calculated on the date of grant using the following weighted average assumptions:

Black-Scholes Assumptions:

| | Three Months Ended September 30Nine Months Ended September 30, | | | | | | | | |
|-------------------------|--|------------|------------|------------|--|--|--|--|--|
| | 2015 | 2014 | 2015 | 2014 | | | | | |
| Expected dividend yield | 0% | 0% | 0% | 0% | | | | | |
| Expected volatility | 86.59% | 100.43% | 91.03% | 101.07% | | | | | |
| Risk free interest rate | 1.80% | 1.99% | 1.57% | 1.90% | | | | | |
| Expected term | 6.08 years | 5.96 years | 6.03 years | 6.01 years | | | | | |

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:

| | Weighted-Average Weighted-Averag R emaining | | | | | | |
|--|---|----|-------|------------|----|--------|--|
| | Exercise Life Aggregate Intrins | | | | | | |
| | Shares | | Price | (in years) | | Value | |
| Outstanding as of December 31, 2014 | 1,996,615 | \$ | 7.01 | 8.98 | \$ | 59,362 | |
| Granted | 1,369,807 | | 45.27 | | | | |
| Exercised | (411,349) | | 1.30 | | | 28,184 | |
| Forfeited | (84,261) | | 26.31 | | | 1,644 | |
| Outstanding as of September 30, 2015 | 2,870,812 | \$ | 25.52 | 8.86 | \$ | 55,937 | |
| Vested or expected to vest as of September 30, 2015 | 2,236,739 | \$ | 23.58 | 8.78 | \$ | 48,431 | |
| Exercisable as of September 30, 2015 | 565,941 | \$ | 14.74 | 8.56 | \$ | 15,607 | |

As of September 30, 2015, the Company had unrecognized stock-based compensation expense related to its unvested stock option awards of \$29.6 million, which is expected to be recognized over the remaining weighted average vesting period of 3.08 years. The total fair value of shares vested for the nine months ended September 30, 2015 and 2014 was \$7.3 million and \$0.6 million, respectively. During the nine months ended September 30, 2015 and 2014, stock option exercises resulted in proceeds of \$0.5 million and \$39,379, respectively. The intrinsic value of stock options exercised during the nine months ended September 30, 2015 and 2014 was \$28.2 million and \$2.4 million, respectively.

Restricted Stock Awards

The Company has granted restricted stock awards to certain officers, employees, directors, and consultants of the Company. During the three months ended September 30, 2015 and 2014, the Company recorded \$0.1 million of stock-based compensation expense related to its restricted stock. During the nine months ended September 30, 2015 and 2014, the Company recorded \$0.2 million and \$0.1 million, respectively, of stock-based compensation expense related to its restricted stock.

The table below summarizes activity relating to restricted stock:

| | Shares |
|--------------------------------------|----------|
| Outstanding as of December 31, 2014 | 170,832 |
| Issued | |
| Vested | (99,513) |
| Forfeited | |
| Repurchased | |
| | |
| Outstanding as of September 30, 2015 | 71,319 |

As of September 30, 2015 and 2014, the Company had unrecognized stock-based compensation expense related to its unvested restricted stock awards of \$0.1 million and \$0.4 million, respectively, which is expected to be recognized over the remaining weighted average vesting period of 0.49 years and 1.39 years, respectively

Unvested shares are subject to repurchase by the Company, at the issuance price, upon the employee s termination at the Company s sole discretion. No shares of restricted stock were repurchased in the nine months ended September 30, 2015.

6. Net Loss Per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows for the three and nine months ended September 30, 2015 and 2014 (in thousands, except share and per share data):

| | Thre | e Months End | led | September N | dņe | Months Ende | ed S | September 3 |
|--|------|--------------|-----|-------------|-----|-------------|------|-------------|
| | | 2015 | | 2014 | | 2015 | | 2014 |
| Basic net loss per share attributable to |) | | | | | | | |
| common stockholders: | | | | | | | | |
| Numerator: | | | | | | | | |
| Net loss | \$ | (24,035) | \$ | (9,859) | \$ | (65,933) | \$ | (23,744) |
| | | | | | | | | |
| Denominator: | | | | | | | | |
| Weighted average common shares | | | | | | | | |
| outstanding basic and diluted | | 28,737,743 | | 19,581,624 | | 27,430,275 | | 7,711,038 |
| - | | | | | | | | |
| | \$ | (0.84) | \$ | (0.50) | \$ | (2.40) | \$ | (3.08) |

Net loss per share attributable to common stockholders basic and diluted

The following common stock equivalents outstanding as of September 30, 2015 and 2014 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 September Mine Months Ended September 30, | | | | |
|----------------------------------|--|-----------|-----------|-----------|--|
| | 2015 | 2014 | 2015 | 2014 | |
| Options to purchase common stock | 2,510,900 | 1,580,223 | 2,510,900 | 1,580,223 | |
| Employee Stock Purchase Plan | 2,803 | | 2,803 | | |
| Restricted stock | 71,319 | 202,986 | 71,319 | 202,986 | |
| | | | | | |
| | 2,585,022 | 1,783,209 | 2,585,022 | 1,783,209 | |

7. Income Taxes

The Company did not record a federal or state income tax benefit for the Company s losses for the three and nine months ended September 30, 2015 and 2014 due to the Company s conclusion that a valuation allowance is required.

8. Subsequent Event

In October 2015, the Company entered into a Third Amendment to Lease, effective as of September 9, 2015, and a Fourth Amendment to Lease, effective as of October 27, 2015, with ARE-MA Region No. 38 (Landlord) under which the Company increased the amount of rented space under the lease for its 215 First Street, Cambridge, MA offices and extended the term through February, 2022. The increase in future expected payments under these amendments total \$6.6 million.

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 consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q (Quarterly Report) and the Annual Report on Form 10-K, as amended (Annual Report) and the audited financial information and the notes thereto.

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 developments in 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 developments in 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 this Quarterly Report, 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-altering, 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, clinical endpoints are well-defined and development pathways are feasible.

Our initial product candidates are summarized in the table below.

The lead product candidate in our status epilepticus (SE) program, SAGE-547, is an intravenous, or IV, agent in Phase 3 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. Over the course of 2014, the U.S. Food and Drug Administration, or FDA, granted us orphan drug designation for SAGE-547 in the treatment of SE including SRSE, and Fast Track designation for our investigational new drug application for SAGE-547 as a treatment for SRSE. On April 2, 2015, we announced that, at an End-of-Phase 2 meeting with the FDA, general agreement was reached on the design and key elements for our Phase 3 clinical program for SAGE-547 for the treatment of SRSE, and in August 2015, we reached agreement with the FDA under a Special Protocol Assessment for the Phase 3 clinical trial. In the third quarter of 2015, we initiated the STATUS Trial (SAGE-547 Treatment as Adjunctive Therapy Utilized in Status Epilepticus), a global, randomized, double-blind, placebo-controlled Phase 3 clinical trial to evaluate SAGE-547 as a treatment for patients with SRSE. On August 17, 2015, we reported we had treated the first patient enrolled in our Phase 3 STATUS Trial. If successful, we believe the results from this Phase 3 clinical trial, together with other clinical data obtained from the SAGE-547 development program and results of completed and ongoing non-clinical studies, could form the basis of a New Drug Application, or NDA, submission for SAGE-547. On May 14, 2015, we reported final results from our Phase 1/2 clinical trial of SAGE-547 in SRSE.

SAGE-547 demonstrated robust activity with 77% of 22 evaluable patients meeting the key efficacy endpoint of being successfully weaned off their anesthetic agents while SAGE-547 was being administered. In addition, 77% of the total evaluable patients were successfully weaned off SAGE-547 without recurrence of SRSE in the 24 hour period following treatment. SAGE-547 also demonstrated favorable tolerability and a benefit-risk profile supporting further development for this acutely ill patient population. Overall, 64% of patients experienced at least one serious adverse event, though none were drug-related as determined by the Safety Review Committee. Independent of treatment response, six patient deaths occurred within the study period, all driven by underlying medical conditions.

We have also used SAGE-547 in proof-of-concept clinical trials to explore potential uses of $GABA_A$ receptor modulators to treat essential tremor, a debilitating neurological disorder that causes involuntary, rhythmic shaking with no known cause, and post-partum depression, or PPD, a distinct and readily identified depressive disorder that affects certain women following childbirth.

On June 9, 2015, we reported top-line data from our proof-of-concept open-label clinical trial of SAGE-547 in PPD that indicated a statistically significant improvement from baseline in depression in four women within 24 hours after administration of intravenous SAGE-547. During the SAGE-547 treatment period, all four patients rapidly achieved remission, as measured by the Hamilton Rating Scale for Depression, or HAM-D, and improved from a mean HAM-D score of 26.5 at baseline to a mean HAM-D score of 1.8 at the end of the 60-hour treatment period. All four patients also demonstrated consistent improvement as measured by the Clinical Global Impression-Improvement, or CGI-I scale. SAGE-547 was well-tolerated in all patients treated with no serious adverse events observed on therapy or during the 30-day follow-up period, and no discontinuations due to adverse events. A total of 14 adverse events were reported in four patients. In November 2015, we initiated a multi-center, placebo-controlled, proof-of-concept study of SAGE-547 in severe PPD patients. We plan to enroll 32 patients in the trial.

On September 3, 2015, we announced results from a successful proof-of-concept clinical trial of SAGE-547 to evaluate the GABA_A mechanism of action as a treatment for essential tremor. In a randomized, double-blind, placebo-controlled, crossover trial of 25 patients affected by essential tremor, where patients were exposed to the target steady state dose of SAGE-547 for only two hours, several clinician-rated and accelerometer-rated measures showed significant reductions in tremor. These changes included a significant reduction in accelerometer-measured upper limb kinetic tremor (p=0.046) which is one of the major manifestations of tremor impacting morbidity. Overall clinician ratings of large tremor motions, as well as smaller movements such as writing and spiral drawing, also showed improvement (p=0.056). In addition, SAGE-547 demonstrated a clinically meaningful reduction of tremor amplitude as measured by accelerometer (at least a 30% reduction from baseline) in 33% of patients, compared with 16% of patients in the placebo arm. In this phase of the trial, anti-tremor activity of SAGE-547 was observed at non-sedating doses, and peak anti-tremor activity correlated with steady state SAGE-547 levels. The time points showing the greatest reductions in tremor corresponded to peak plasma measurements. Seventeen of these patients were exposed to higher doses of SAGE-547 in an open-label extension with 44% demonstrating at least a 30% reduction in tremor amplitude from baseline. The most common adverse events at higher doses were fatigue and dizziness. Hypotension led to discontinuation of one patient. No serious adverse events were observed on therapy or during the 30-day follow-up period.

Our next-generation product candidates, SAGE-217 and SAGE-689, utilize similar mechanistic pathways as SAGE-547 and are designed to have pharmaceutical properties which optimize both their non-clinical profiles and potential clinical profiles for the treatment of different stages of status epilepticus, as well as other seizure and non-seizure disorders. On October 3, 2015, we announced the initial dosing in a Phase 1 single ascending dose trial evaluating SAGE-217 in healthy volunteers, and, if the Phase 1 clinical trial is successful, we plan to advance development of SAGE-217 as an oral therapy for orphan epilepsies, such as Dravet syndrome and Rett syndrome, and in certain non-seizure indications such as essential tremor. SAGE-689 is in non-clinical development. In November

2015, we announced that commencement of our Phase 1 clinical trial of SAGE-689 has been delayed to respond to a request from the FDA for additional non-clinical study data.

We are also studying novel compounds that target the NMDA receptor, a critical excitability receptor system implicated in a broad range of CNS disorders. The first product candidate selected for development for this program is known as SAGE-718. The Company plans to begin non-clinical studies of SAGE-718, with an initial development focus on two rare conditions, Smith-Lemli-Opitz Syndrome and Anti-NMDA Receptor Encephalitis.

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 and conducting non-clinical studies and clinical trials 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 our common stock and redeemable convertible preferred stock; the issuance of convertible notes and through proceeds from our initial public offering of common stock, or IPO, and a follow-on offering of common stock that was completed in April 2015.

We have not generated any revenue to date. We have incurred net losses in each year since our inception, and we have an accumulated deficit of \$132.8 million as of September 30, 2015. Our net losses were \$65.9 million and \$36.1 million for the nine months ended September 30, 2015 and the year ended December 31, 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 3 clinical trial for SAGE-547 in SRSE and additional clinical and non-clinical studies of SAGE-547 required for a new drug application (NDA), advancing regulatory activities focused on potential filing of the NDA, and initial preparations for a potential commercial launch;

continue to advance our efforts to establish proof of principle of the potential for use of GABA_A receptor modulators in PPD;

complete the Phase 1 clinical trial of SAGE-217 in healthy volunteers, and if successful, advance development of SAGE-217 as an oral therapy for orphan epilepsies such as Dravet syndrome and Rett syndrome, and in certain non-seizure indications such as essential tremor;

advance development of SAGE-689 as an adjunctive second-line therapy for the treatment of SE, including conducting additional non-clinical studies;

advance our early-stage novel allosteric modulator for NMDA into non-clinical studies;

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

seek regulatory approvals for our product candidates that successfully complete clinical development;

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

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 September 30, 2015, will enable us to fund our operating expenses and capital expenditure requirements, based on our current operating plan, through mid-2017. See Liquidity and Capital Resources.

Financial Operations Overview

Operating Expenses

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

Research and Development Expenses

Research and development expenses, which consist primarily 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 trial 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 clinical trials 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-217 and SAGE-689 and 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 contract manufacturing organizations, or 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:

Nine Months Ended September 30, Inc

Increase

| | 2015 | 2014 | (De | ecrease) |
|---|----------|--------------|-----|----------|
| | | (in thousand | s) | |
| SAGE-547 | \$26,654 | \$ 5,148 | \$ | 21,506 |
| SAGE-217 | 3,386 | 1,950 | | 1,436 |
| SAGE-689 | 2,643 | 2,607 | | 36 |
| Other research and development programs | 6,987 | 1,328 | | 5,659 |
| Unallocated expenses | 9,311 | 4,122 | | 5,189 |
| | | | | |
| Total research and development expenses | \$48,981 | \$15,155 | \$ | 33,826 |

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 continue or initiate clinical trials and non-clinical studies 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. The duration, costs, and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

the scope, size, 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 and non-clinical study results;

decisions by regulatory authorities related to our product candidates;

uncertainties in clinical trial enrollment rate or design;

significant and changing government regulation; and

the timing and receipt of any regulatory approvals, if any.

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 expenses incurred under agreements with third parties relating to initial commercial evaluation and planning, facilities and other expenses, including rent, depreciation, maintenance of facilities, insurance and supplies; and professional fees for audit, 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 business and the potential commercialization of our product candidates. We also anticipate increased expenses associated with being a public company and general operations, 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, we anticipate an increase in payroll and related expenses as we continue to build our organizational capabilities and as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidates, if approved.

Interest Income, net and Other Expense, net

Interest income, net, and other expense, net, were insignificant for the nine months ended September 30, 2015 and 2014.

Results of Operations

Comparison of Three Months Ended September 30, 2015 and 2014

The following table summarizes our results of operations for the three months ended September 30, 2015 and 2014:

| Three M | Ionths | |
|---------|--------------|------------|
| Enc | led | |
| Septem | Increase | |
| 2015 | 2014 | (Decrease) |
| | (in thousand | ds) |

Operating expenses:

| Research and development | \$ 17,478 | \$ 6,601 | \$ 10,877 |
|----------------------------|-------------|------------|-------------|
| General and administration | 6,604 | 2,869 | 3,735 |
| | | | |
| Total operating expenses | 24,082 | 9,470 | 14,612 |
| Loss from operations | (24,082) | (9,470) | (14,612) |
| Interest income, net | 53 | 3 | 50 |
| Other expense, net | (6) | (1) | (5) |
| | | | |
| Net loss | \$ (24,035) | \$ (9,468) | \$ (14,567) |

Research and development expenses

| | Three Months | | т. | |
|---|----------------------------------|---------|------------------------|--------|
| | Ended September 30, 2015 2014 | | Increase (Decrease) | |
| | (in thousands) | | | |
| SAGE-547 | \$ 9,891 | \$2,533 | \$ | 7,358 |
| SAGE-217 | 1,048 | 558 | | 490 |
| SAGE-689 | 521 | 841 | | (320) |
| Other research and development programs | 2,864 | 1,068 | | 1,796 |
| Unallocated expenses | 3,154 | 1,601 | | 1,553 |
| Total research and development expenses | \$ 17,478 | \$6,601 | \$ | 10,877 |

Research and development expenses for the three months ended September 30, 2015 and 2014 were \$17.5 million and \$6.6 million, respectively. The increase of \$10.9 million period over period was primarily due to the following:

an increase of \$7.4 million in expenses associated with our SAGE-547 program, due to the advancement of the program in clinical development, including commencement of activities for Phase 3, an increase in work related to chemistry, manufacturing and controls, or CMC, and toxicology. Expenses related to payments made as a result of development milestones met by consultants and licensors were \$0.2 million in the three months ended September 30, 2015, and no such costs were incurred in the three months ended September 30, 2014;

an increase of \$0.5 million in expenses of our SAGE-217 program with advancement of the lead optimization program into IND-enabling non-clinical development activities (e.g., toxicology studies, process development, and drug substance manufacturing), filing of the IND and preparation for the Phase 1 clinical trial initiated in October 2015;

a decrease of \$0.3 million in expenses of our SAGE-689 program, due to the timing of IND-enabling non-clinical development activities (e.g., toxicology studies, process development, and drug substance manufacturing), offset by an increase in costs associated with filing of the IND;

an increase of \$1.8 million in expenses of our other research and development programs and discovery efforts for our next clinical candidates and back-up programs; and

an increase of \$1.6 million in employee-related expenses, including an increase of \$1.2 million of non-cash stock-based compensation expense and the effects of hiring additional

full-time employees to support the growth in our activities. The amount of non-cash stock-based compensation related to the achievement of performance-based vesting criteria was \$0.6 million for the three months ended September 30, 2015.

General and administrative expenses

| | | Three Months Ended September 30, | | Increase | |
|---|---------|-------------------------------------|----|------------|--|
| | 2015 | 1 , | | (Decrease) | |
| | | (in thousands) | | | |
| Personnel-related | \$4,237 | \$1,178 | \$ | 3,059 | |
| Professional fees | 1,572 | 1,221 | | 351 | |
| Facilities | 135 | 90 | | 45 | |
| Other | 660 | 380 | | 280 | |
| Total general and administrative expenses | \$6,604 | \$ 2,869 | \$ | 3,735 | |

General and administrative expenses for the three months ended September 30, 2015 and 2014 were \$6.6 million and \$2.9 million, respectively. The increase of \$3.7 million in general and administrative expenses was primarily due to the \$3.1 million increase in personnel-related costs due to the effects of hiring additional full-time employees to support operations, finance, human resources and early commercial planning activities, including an increase of \$2.5 million in non-cash stock-based compensation expense. The amount of non-cash stock-based compensation related to the achievement of the performance-based vesting criteria was \$0.8 million for the three months ended September 30, 2015. The increase of \$0.4 million in professional fees was associated with being a public company and general operations, including costs related to audit, legal, regulatory and tax-related services, as well as investor relations costs.

Other income (expense), net

Interest income, net, and other expense, net, were insignificant for the three months ended September 30, 2015 and 2014.

Comparison of Nine Months Ended September 30, 2015 and 2014

The following table summarizes our results of operations for the nine months ended September 30, 2015 and 2014:

| | | Nine Months Ended September 30, | |
|----------------------------|-----------|------------------------------------|-----------|
| | 2015 | 2015 2014 | |
| | | (in thousands |) |
| Operating expenses: | | | |
| Research and development | \$ 48,981 | \$ 15,155 | \$ 33,826 |
| General and administration | 17,057 | 6,294 | 10,763 |
| | | | |
| Total operating expenses | 66,038 | 21,449 | 44,589 |
| Loss from operations | (66,038) | (21,449) | (44,589) |
| Interest income, net | 115 | 4 | 111 |
| Other expense, net | | | |