UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): November 2, 2017

Sage Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

DELAWARE	001-36544	27-4486580
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

215 First Street Cambridge, MA	02142
(Address of principal executive offices)	(Zip Code)

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

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition

On November 2, 2017, Sage Therapeutics, Inc. announced its financial results for the quarter ended September 30, 2017. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K. Also on November 2, 2017, Sage Therapeutics, Inc. hosted a conference call to discuss, among other matters, its financial results for the quarter ended September 30, 2017. A transcript of this conference call is attached as Exhibit 99.2 to this Report on Form 8-K.

The information in this Report on Form 8-K and the exhibits attached hereto are intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Sage Therapeutics, Inc. on November 2, 2017, furnished herewith.
99.2	Transcript of conference call hosted by Sage Therapeutics, Inc. on November 2, 2017

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 hereunto duly authorized.

Date: November 7, 2017

SAGE THERAPEUTICS, INC.

By: /s/ Anne Marie Cook
Anne Marie Cook
Senior Vice President, General Counsel

Exhibit 99.1

Sage Therapeutics Announces Third Quarter 2017 Financial Results and Provides Pipeline Update

Enrollment completed in both Phase 3 trials of brexanolone in postpartum depression and in the Phase 2 placebo-controlled trial of SAGE-217 in major depressive disorder

Activity in open-label Parkinson's disease trial and essential tremor trial supports further clinical development

A Phase 1 single ascending dose study for first NMDA program, SAGE-718, successfully completed

Conference call today at 8:00 AM ET

CAMBRIDGE, Mass., November 2, 2017 — Sage Therapeutics, Inc. (NASDAQ: SAGE), a clinical-stage biopharmaceutical company developing novel medicines to treat life-altering central nervous system (CNS) disorders, today reported business highlights and financial results for the third quarter ended September 30, 2017.

"We are on the verge of important data readouts as we move into the last quarter of 2017, and as we continue to make progress in executing on our R&D strategy," said Jeff Jonas, M.D., Chief Executive Officer of Sage. "Sage has focused on understanding the underlying mechanisms of CNS disorders and developing novel treatments that may address current treatment gaps. We are pleased that our open-label data in Parkinson's disease and essential tremor demonstrate potential for further development. The upcoming months have the potential to be transformational for Sage as we seek to bring new treatments to patients impacted by life-altering CNS disorders."

Pipeline Updates:

Sage is advancing a portfolio of novel CNS product candidates targeting the GABA and NMDA receptor systems. Dysfunction in these systems is known to be at the core of numerous psychiatric and neurological disorders. Sage is pursuing a data-driven approach to CNS drug development by employing efficient human proof-of-concept methodology studies both to uncover activity signals and to help understand future trial design, before investing in larger clinical programs.

"Enrollment in our Phase 3 PPD trials and in our Phase 2 placebo-controlled MDD study is complete, and we are excited by the potential opportunity to change patients' options for treatment of these disorders," said Steve Kanes, M.D., Ph.D., Chief Medical Officer of Sage. "In addition to data readouts in PPD and MDD, our Phase 2 open-label methodology studies in movement disorders allow us to follow clinical data and take a deliberate and disciplined approach to designing the next Phase 2 studies."

- Brexanolone in Postpartum Depression:
  - Sage is currently developing brexanolone in a Phase 3 clinical program as an acute interventional treatment for postpartum depression (PPD), consisting of separate multi-center, double-blind, placebo-controlled, randomized trials in severe PPD patients (202B) and in moderate PPD patients (202C), collectively known as the Hummingbird Study.
  - Sage recently completed enrollment in its Phase 3 Hummingbird clinical program, and currently expects top-line results from the Phase 3 clinical trials of brexanolone in PPD to be the company's next data readout.

- SAGE-217 in Major Depressive Disorder:
  - Sage is currently conducting a multi-center, double-blind, placebo-controlled, randomized Phase 2 clinical trial of SAGE-217 in major depressive disorder (MDD).
  - Sage recently completed enrollment in the study, and expects to report top-line results in 4Q 2017.

- SAGE-217 in Postpartum Depression:
  - Sage is currently conducting a multi-center, double-blind, placebo-controlled, randomized Phase 2 clinical trial of SAGE-217 in severe PPD.
  - Completion of enrollment for the Phase 2 trial is expected in 4Q 2017 with top-line results expected in 1Q 2018.

- SAGE-217 in Parkinson's Disease:
  - Sage today announced top-line results from an open-label Phase 2 clinical trial of SAGE-217 in patients with tremor-predominant Parkinson's disease.
  - Part B of the exploratory study evaluated SAGE-217 as an adjunctive treatment for seven days in 14 tremor-predominant Parkinson's disease patients who were on stable doses of anti-Parkinsonian agents.
  - SAGE-217 improved tremor symptoms, as assessed by the MDS-UPDRS - Part II/III tremor score, by a mean change of 7.7 points (40.0%) by Day 8 from a mean baseline score of 19.1 points, which was the primary efficacy endpoint in the Part B study.
  - Additional secondary efficacy endpoints were consistent with the primary efficacy endpoint. SAGE-217 improved overall Parkinson's disease motor symptoms, as assessed by the MDS-UPDRS Part III motor score, by a mean change of 18.6 points (36.3%) by Day 8 from a mean baseline score of 52.4 points.
  - SAGE-217 also improved symptoms of sleep dysfunction in five patients with clear sleep dysfunction at baseline, as assessed by the Parkinson's Disease Sleep Scale (PDSS-2) score, by a mean change of 12.2 points (41.2%) by Day 8 from a mean baseline score of 29.8 points.

- Administration of SAGE-217 in the evening was generally well-tolerated with no serious adverse events or discontinuations reported. The most common adverse events were dizziness, sedation, and somnolence, each occurring in two patients.
- Sage believes the results from this open-label Phase 2 trial support further clinical development, and that the data from this study will provide guidance on methodology, dosing, and design for a future placebo-controlled Phase 2 clinical trial in Parkinson's disease.

- SAGE-217 in Essential Tremor:
  - Sage is currently conducting Part C of an exploratory Phase 2 clinical trial of SAGE-217 in essential tremor.
  - Part A was an open-label trial with morning dosing of SAGE-217 for 7 days. Part A enrolled 16 patients diagnosed with essential tremor, defined as visible and persistent bilateral postural tremor and kinetic tremor, involving hands and forearms, with a duration greater than 5 years prior to screening. Part C is an open-label clinical trial that was initiated to study higher doses and extended evening dosing of SAGE-217. As a result of the change in design, enrollment in Parts A and B of the trial was discontinued prior to completion. The Part A data are summarized below.
  - In Part A, SAGE-217 improved tremor symptoms, as assessed by the TETRAS upper limb combined kinetic score, by at least 30% on Day 7 in 8/12 patients (67%) who received SAGE-217 oral capsule in the study for 7 days, which was the pre-established success criteria for moving to the next part of the study.
  - Administration of SAGE-217 in the morning was generally well-tolerated. The most common adverse events were somnolence, dizziness, and sedation. There were no serious adverse events reported in the 14 patients receiving SAGE-217 oral capsule. There was one serious adverse event (confusion) reported in one of the two patients who received oral solution.
  - Top-line results from Part C of the SAGE-217 essential tremor study are expected in 4Q 2017.

- SAGE-324:
  - Sage is currently evaluating a series of novel $GABA_A$ receptor modulators in pre-clinical development, including SAGE-324, a novel, orally-active next-generation positive allosteric modulator of synaptic and extrasynaptic $GABA_A$ receptors.
  - SAGE-324 is currently in IND-enabling studies, and is intended to be developed with a focus on orphan epilepsies and indications involving GABA hypofunction.

- SAGE-718:
  - Sage is also developing novel compounds that target the NMDA receptor. The first product candidate selected for development from this program is SAGE-718, a novel, oral, first-in-class oxysterol-based positive allosteric modulator of the NMDA receptor. Positive modulation of NMDA receptors may have potential in the treatment of a range of neurological disorders associated with a variety of cognitive, neurological and behavioral symptoms.

- Sage today announced that it recently completed a Phase 1 single-ascending dose study of SAGE-718 in healthy volunteers. The primary objectives of the study were to assess the safety, tolerability, and pharmacokinetics of SAGE-718.
- SAGE-718 was well-tolerated with no serious adverse events reported in the single ascending dose study.
- SAGE-718 was administered as an oral solution in four double-blind placebo-controlled cohorts (randomized 6:2) enrolling a total of 32 healthy volunteers. The pharmacokinetics of SAGE-718 were highly predictable with low variability.
- Based on these results, Sage plans to initiate a Phase 1 multiple ascending dose trial along with further dose finding studies. Sage is also investigating the effects of SAGE-718 on pharmacodynamic biomarkers.

Expected Near-Term Clinical Milestones

- **Top-Line Data Readouts:**
  - Phase 3 Hummingbird Study (202B) of brexanolone in severe PPD (4Q 2017)
  - Phase 3 Hummingbird Study (202C) of brexanolone in moderate PPD (4Q 2017)
  - Phase 2 trial of SAGE-217 in MDD (4Q 2017)
  - Part C of Phase 2 trial of SAGE-217 in essential tremor (4Q 2017)
  - Phase 2 trial of SAGE-217 in PPD (1Q 2018)
  - Phase 1 multiple ascending dose trial of SAGE-718 (2H 2018)

Financial Results for the Third Quarter of 2017

- **Cash Position:** Cash, cash equivalents, and marketable securities as of September 30, 2017 were $243.5 million, compared with $397.5 million at December 31, 2016.
- **R&D Expenses:** Research and development expenses were $58.3 million, including $5.4 million of non-cash stock-based compensation expense, in the third quarter of 2017, compared to $29.1 million, including $2.5 million of non-cash stock-based compensation expense, for the same period of 2016. The increase in R&D expense was primarily due to the Phase 3 clinical development of brexanolone and CMC work in preparation for a potential filing for regulatory approval, the ongoing Phase 2 development of SAGE-217, ongoing early-stage R&D programs and discovery efforts focused on identifying new development candidates and additional indications of interest, and investments in R&D headcount to support the growth in Sage's pipeline and operations.
- **G&A Expenses:** General and administrative expenses were $16.1 million, including $4.3 million of non-cash stock-based compensation expense, in the third quarter of 2017, compared to $9.0 million, including $2.2 million of non-cash stock-based compensation expense, for the same period of 2016. The increase in G&A expenses

was primarily due to the increase in personnel-related expenses, professional fees to support expanding operations, costs related to continued preparations for a potential commercial launch, and facilities-related costs to support expanding operations.

- **Net Loss:** Net loss was $73.7 million for the third quarter of 2017, compared to a net loss of $37.8 million for the same period of 2016.

Conference Call Information

Sage will host a conference call and webcast today at 8:00 AM ET to discuss its third quarter financial results and recent corporate updates. The live webcast can be accessed on the investor page of Sage's website at investor.sagerx.com. The conference call can be accessed by dialing 1-866-450-8683 (toll-free domestic) or 1-281-542-4847 (international) and using the conference ID 94558257. A replay of the webcast will be available on Sage's website approximately two hours after the completion of the event and will be archived for up to 30 days.

About Sage Therapeutics

Sage Therapeutics is a clinical-stage biopharmaceutical company committed to developing novel medicines to transform the lives of patients with life-altering central nervous system (CNS) disorders. Sage has a portfolio of novel product candidates targeting critical CNS receptor systems, GABA and NMDA. Sage's lead program, a proprietary IV formulation of brexanolone (SAGE-547), is in Phase 3 clinical development for postpartum depression. Sage is developing its next generation modulators, including SAGE-217 and SAGE-718, in various CNS disorders. For more information, please visit www.sagerx.com.

Forward-Looking Statements

Various statements in this release concern Sage's future expectations, plans and prospects, including without limitation: our expectations regarding development of our product candidates and their potential in the treatment of various CNS disorders; our clinical development plans with respect to clinical development of our product candidates and the anticipated timing of activities; the anticipated availability and announcement of data and results from clinical trials; our plans for evaluation of new indications and new compounds; our expectations regarding a potential regulatory filing and future commercial launch of our proprietary IV formulation of brexanolone, if successfully developed and approved; and the potential for transformative events and our success as a multi-product company. These forward-looking statements are neither promises nor guarantees of future performance, and are subject to a variety of risks and uncertainties, many of which are beyond our control, which could cause actual results to differ materially from those contemplated in these forward-looking statements, including the risks that: we may not be able to successfully demonstrate the efficacy and safety of our product candidates at each stage of clinical development; success in earlier stage clinical trials or in our non-clinical studies may not be repeated or observed in ongoing or future studies involving the same compound or other product candidates; ongoing and future clinical results and preclinical data may not be positive or support further development of product candidates or may not be sufficient to file for or gain regulatory approval to launch and commercialize any product; decisions or actions of regulatory agencies may affect the initiation, timing, progress and cost of clinical trials, and our ability to proceed with further clinical studies of a product candidate or to obtain marketing approval or may result in restrictions in an approved indication or the need for additional clinical trials, including the risk that regulatory authorities may, despite prior advice, decide that the clinical and non-clinical data from our development programs are not sufficient to support approval; the internal and external costs required for our activities, and to build our organization in connection with such activities, and the resulting use of cash, may be higher than expected, or we may conduct additional clinical trials or pre-clinical studies, or engage

in new activities, requiring additional expenditures and using cash more quickly than anticipated; and we may encounter technical and other unexpected hurdles in the development and manufacture of our products which may delay our timing or increase our expenses and use of cash, as well as those risks more fully discussed in the section entitled "Risk Factors" in our most recent Quarterly Report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent our views only as of today, and should not be relied upon as representing our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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Sage Therapeutics, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(in thousands)
(Unaudited)

	September 30, 2017	December 31, 2016
Assets		
Current Assets:		
Cash and cash equivalents	$ 134,916	$ 168,517
Marketable securities	108,535	228,962
Prepaid expenses and other current assets	4,892	5,100
Total current assets	248,343	402,579
Property and equipment and other long-term assets	2,742	1,952
Total assets	$ 251,085	$ 404,531
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 13,030	$ 12,817
Accrued expenses	36,807	22,352
Total current liabilities	49,837	35,169
Other liabilities	1,196	845
Total liabilities	51,033	36,014
Total stockholders' equity	200,052	368,517
Total liabilities and stockholders' equity	$ 251,085	$ 404,531

Sage Therapeutics, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	$ 58,286	$ 29,075	$ 159,386	$ 78,752
General and administrative	16,087	8,989	43,320	25,033
Total operating expenses	74,373	38,064	202,706	103,785
Loss from operations	(74,373)	(38,064)	(202,706)	(103,785)
Interest income, net	677	275	2,056	717
Other expense, net	(23)	(7)	(48)	(18)
Net loss	$ (73,719)	$ (37,796)	$ (200,698)	$ (103,086)
Net loss per share - basic and diluted	$ (1.97)	$ (1.15)	$ (5.37)	$ (3.20)
Weighted average shares outstanding - basic and diluted	37,470,912	32,975,897	37,367,802	32,218,204

Exhibit 99.2

THOMSON REUTERS STREETEVENTS

EDITED TRANSCRIPT

SAGE - Q3 2017 SAGE Therapeutics Inc Earnings Call

EVENT DATE/TIME: NOVEMBER 02, 2017 / 12:00PM GMT

CORPORATE PARTICIPANTS

Jeffrey M. Jonas *Sage Therapeutics, Inc. - CEO, President & Director*

Kimi E. Iguchi *Sage Therapeutics, Inc. - CFO & Treasurer*

Paul Cox

Stephen J. Kanes *Sage Therapeutics, Inc. - Chief Medical Officer*

CONFERENCE CALL PARTICIPANTS

Adam Anderson Walsh *Stifel, Nicolaus & Company, Incorporated, Research Division - MD and Senior Analyst*

Brian Corey Abrahams *RBC Capital Markets, LLC, Research Division - Senior Analyst*

Cory William Kasimov *JP Morgan Chase & Co, Research Division - Senior Biotechnology Analyst*

Danielle Catherine Brill *Needham & Company, LLC, Research Division - Senior Analyst*

Gary Jay Nachman *BMO Capital Markets Equity Research - Analyst*

Laura K. Chico *Robert W. Baird & Co. Incorporated, Research Division - Healthcare Research Analyst*

Ritu Subhalaksmi Baral *Cowen and Company, LLC, Research Division - MD and Senior Biotechnology Analyst*

Salveen Richter

Tazeen Ahmad *BofA Merrill Lynch, Research Division - VP*

Timothy Francis Lugo *William Blair & Company L.L.C., Research Division - Co-Group Head of Biopharma Equity Research*

PRESENTATION

Operator

Good morning and welcome to Sage Therapeutics Third Quarter 2017 Financial Results Conference Call. (Operator Instructions) This call is being webcast live on the Investors & Media section of Sage's website at sagerx.com. This call is the property of Sage Therapeutics and recording, reproduction or transmission of this call without the express written consent of Sage Therapeutics is strictly prohibited. Please note that this call is being recorded.

I would now like to introduce Paul Cox, Head of Investor Relations at Sage.

Paul Cox

Good morning. This morning we issued a press release with our third quarter 2017 financial results along with recent company highlights, upcoming milestones and progress on our corporate strategy. The press release and the presentation slides used on this call can be found on the Investors & Media section of our website at sagerx.com.

On Slide 2 of the presentation is the agenda for today's call. We will begin the call with prepared remarks by Dr. Jeff Jonas, our Chief Executive Officer; Dr. Steve Kanes, our Chief Medical Officer; and Kimi Iguchi, our Chief Financial Officer.

On Slide 3 is the safe harbor statement. During today's call, we will make forward-looking statements, including statements about our expectations, plans and timelines for clinical development, reporting of clinical trial results and planned regulatory activities, the potential success of our development efforts and product candidates including the potential for approval and future commercial launch, our financial projections and expectations regarding other upcoming events. Actual results may differ materially. The risks and other factors that could cause actual results to differ are discussed in today's press release and in the risk factors section of our most recent quarterly report on Form 10-Q filed with the Securities and Exchange Commission and other reports filed with the SEC. Any forward-looking statements represent our views as of today only. We may update these statements in the future, but we disclaim any obligation to do so. I would now like to turn the call over to Jeff.

Jeffrey M. Jonas - *Sage Therapeutics, Inc. - CEO, President & Director*

Thanks, Paul. Good morning everyone and welcome to our call. Please turn to Slide 4 for our current development pipeline. We continue to make progress on our company building mission to position Sage for long-term success as a multi-product neuroscience drug company. Our vision has been to create a company with the capabilities to deliver differentiated medicines utilizing innovative approaches to research and development combined with the corporate dedication to making people's lives better. Throughout our 6-year history, we've explored innovative methods of drug discovery and development as well as clinical trial design in the pursuit of novel treatments for central nervous system disorders that may address gaps in the efficacy and safety profile of current therapies.

While our Phase III program to develop the first ever evidence based treatment for SRSE was not successful, we are now on the verge of important data readouts as we move into the final months of 2017 and continue making progress as we execute on our R&D strategy. So we have several important progress updates across our pipeline today.

On Slide 5 regarding our most advanced program, our proprietary IV formulation of brexanolone in postpartum depression or PPD, we recently completed enrollment in both placebo-controlled Phase III PPD's clinical trials. And we currently expect that top line results from both of these trials will be our next data readout this quarter.

On Slide 6, we also completed enrollment in a placebo-controlled Phase II clinical trial of SAGE-217 in major depressive disorder or MDD. We expect to report top line results from this trial in this quarter as well. In our other mood disorder program, SAGE- 217, we are currently conducting a placebo-controlled Phase II clinical trial of SAGE-217 in severe PPD. We currently expect completion of enrollment for this trial this quarter with top line results expected in the first quarter of 2018.

Turning now to our movement disorder programs on SAGE-217. We are pleased to report activity with SAGE-217 in both our open-label Parkinson's disease trial and our open-label essential tremor trial. These results demonstrate our R&D approach of conducting open-label methodology studies to inform future clinical trial design by generating data that can potentially better define endpoints and appropriately target the right patient population. This is seen in our Parkinson's program, where our data led us to focus on the tremor predominant population. Overall, we believe our results in Parkinson's and essential tremor support further clinical development. Steve will review these data in more detail later on the call.

We are also pleased to have successfully completed a Phase I single ascending dose study for our first NMDA program SAGE-718, which is an oxysterol-based positive allosteric modulator of the NMDA receptor. This first-in-class compound is an example of how we are focused on understanding the underlying mechanisms of CNS disorders and developing novel treatments that may address current treatment gaps. Steve will also cover these results in more detail.

The upcoming months have the potential to be transformational for Sage as we seek to bring new CNS treatments to patients. Kimi will discuss more on our company building progress as we prepare for a near-term potential commercial launch of brexanolone in PPD if the results of our Phase III clinical trial support an NDA filing and approval.

And now I'd like to turn the call over to Steve.

Stephen J. Kanes - *Sage Therapeutics, Inc. - Chief Medical Officer*

Good morning. I'd like to provide more detail on the results of our 3 clinical programs that were released this morning. Please turn to Slide 7 for our top line results from the Part B open label portion of a Phase II clinical trial of SAGE-217 in patients with tremor predominant Parkinson's disease. Note that our Phase II open label methodology studies in movement disorders allow us to follow the clinical data and take a deliberate and disciplined approach to designing any future Phase II studies.

Part B of the exploratory study evaluated SAGE-217 as an adjunctive treatment for 7 days in 14 tremor predominant Parkinson's disease patients who are on stable doses of anti-Parkinsonian agents. SAGE-217 improved tremor symptoms as assessed by the MDS-UPDRS Part II/III tremor score by a mean change of 7.7 points or 40% by day 8 from a mean baseline of 19.1 points, which was the primary efficacy endpoint in the Part B study. Additional secondary efficacy endpoints were consistent with the primary efficacy endpoint including improved overall Parkinson's disease motor symptoms and improved symptoms of sleep dysfunction in 5 patients with clear sleep dysfunction at baseline. These data are provided in more detail in our press release this morning.

Administration of SAGE-217 in the evening was generally well tolerated with no serious adverse events or discontinuations reported. The most common adverse events were dizziness, sedation and somnolence, each occurring in 2 patients. We believe that these data support further clinical development and we'll use these data to provide guidance on methodology, dosing and design for a future placebo-controlled Phase II clinical trial in Parkinson's disease.

Please turn to Slide 8 for our top line results from Part A of an exploratory Phase II clinical trial of SAGE-217 in essential tremor. Sage is currently conducting Part C of an exploratory Phase II clinical trial of SAGE-217 in essential tremor. Part A was an open-label trial with morning dosing of SAGE-217 for 7 days. Part A enrolled 16 patients diagnosed with essential tremor defined as visible and persistent bilateral postural tremor and kinetic tremor involving hands and forearms with a duration of greater than 5 years prior to screening. Part C is an open label clinical trial that was initiated to study higher doses and extended evening dosing of SAGE-217.

As a result of the change in design enrollment in Parts A and B of the trial was discontinued prior to completion. In Part A, SAGE-217 improved tremor symptoms as assessed by the TETRAS upper limb combined kinetic score by at least 30% on day 7 in 8 of 12 or 67% of patients who received SAGE-217 oral capsules for 7 days in the study. This was the pre-defined success criteria for moving into the next part of the trial.

The administration of SAGE-217 in the morning was generally well tolerated. The most common adverse events were somnolence, dizziness and sedation. There were no serious adverse events recorded in the 14 patients receiving SAGE-217 oral capsule. There was 1 serious adverse event, confusion, reported in 1 of the 2 patients receiving oral solution. Top line results from Part C of the SAGE-217 essential tremor study are expected in the fourth quarter of 2017. As Jeff mentioned, we also announced that we recently completed a Phase I single ascending dose study of SAGE-718 in healthy volunteers.

Please turn to Slide 9. The primary objectives of the study were to assess the safety, tolerability and pharmacokinetics of SAGE-718. SAGE-718 was well tolerated with no serious adverse events reported in the single ascending dose study. SAGE-718 was administered as an oral solution in 4 double blind placebo-controlled cohorts, randomized 6:2, enrolling a total of 32 healthy volunteers. The pharmacokinetics of SAGE-718 were highly predictable with low variability. Based on these results, we plan to initiate a Phase I multiple ascending dose trial along with further dose finding studies. Sage is also investigating the effects of SAGE-718 on pharmacodynamic biomarkers.

Positive modulation of NMDA receptors may have potential in the treatment of a range of neurologic disorders associated with a variety of cognitive neurological and behavioral symptoms. We are pleased with this progress across our pipeline and look forward to sharing the results of our Phase III PPD trials and our Phase II MDD trial this quarter.

With that I'll now turn the call over to Kimi to discuss over financial results.

Kimi E. Iguchi - *Sage Therapeutics, Inc. - CFO & Treasurer*

Thanks, Steve. Let me start with a quick summary of our financial results for the third quarter and then provide an overview of our financial guidance.

On Slide 10, we have a summary of our financial results for the third quarter. Research and development expenses were $58.3 million in the third quarter compared to $29.1 million for the same period of 2016. General and administrative expenses were $16.1 million in the third quarter, compared to $9 million for the same period of 2016. We reported a net loss in the third quarter of $73.7 million, compared to a net loss of $37.8 million for the same period of 2016. We ended the third quarter with $243.5 million in cash, cash equivalents and marketable securities.

The increase in R&D spending in the quarter was primarily due to our continued efforts in advancing our portfolio and expanding our team to execute against our goals. These include the Phase III development of brexanolone in the completed PPD and SRSE programs and CMC work in preparation for a potential regulatory filing in PPD, the ongoing Phase II development of SAGE-217 in both mood and movement disorders, the R&D work associated with evolving the earlier pipeline programs including Phase I development of SAGE-718 and IND-enabling studies of SAGE-324, the discovery efforts focused on identifying new development candidates and additional indications of interest and finally investments in R&D headcount to support the growth in Sage's pipeline and operation.

The increase in G&A expenses was primarily due to the increase in personnel related expenses, professional fees and facilities to support expanding the team and operations as well as continued preparations for a potential commercial launch. We're encouraged by our progress in preparation for commercial readiness across the entire organization. We have the key leadership in place in the commercial, technical operations and quality groups.

Our brexanolone supply chain readiness activities are on track for a commercial launch timeline. Our brexanolone clinical supply chain is active in the safety stock and replace. Our commercial manufacturing process is developed and scale-up has been completed. And we're making progress in understanding the payer landscape for PPD, conducting health economics research, developing our go-to-market model and investing in disease, awareness and education. We are pleased with our progress to-date and believe we are financially well positioned as we head into the remainder of the year with numerous clinical milestones expected. We plan to update our financial guidance following the remainder of these upcoming milestones, which will have a significant impact on our spending plans over the next year. Each of these milestones and data readouts, which you can see on Slide 11 has a potential to further our efforts to develop innovative treatments and we look forward to updating you on the progress in the coming months.

Over the last 6 years, as we push from an early to late stage R&D company, the team has worked tirelessly to support our strategy of having disciplined spending and gating a certain investment to specific milestones.

This approach has allowed us the flexibility to pursue our strategic and operational goals and I want to thank the entire Sage team as we head towards additional data readouts before the end of the year.

With that, we'd like to now open the call for Q&A. Please limit yourself to 2 questions each so that we can leave enough time to get to everyone. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And our first question comes from Salveen Richter of Goldman Sachs.

Salveen Richter

So as it relates to Parkinson's disease, with the mean change of 7.7 points that you saw from the baseline score, just wondering if you could put that in context for us of what that fundamentally means on a clinical relevant scale.

Stephen J. Kanes - *Sage Therapeutics, Inc. - Chief Medical Officer*

Yes, this is Steve. That change represents a clinical meaningful change. These are patients that are on current standard of care, which means that these tremors which can be quite substantial aren't touched at all by the treatment that they are taking. So 40% improvement on the scale represents a real clinical meaningful improvement. Yes, the other thing I should point out here is that this was seen with dosing in only 7 days. And from our perspective, the most important part of this is that this is a clear signal. It's one that we'd be interested in following up on.

Salveen Richter

And then just with postpartum depression, you have 2 programs reading out with 217 and brexanolone. Could you just frame for us, if these 2 programs are to be successful how are you going to position these drugs in the market?

Jeffrey M. Jonas - *Sage Therapeutics, Inc. - CEO, President & Director*

This is Jeff. With respect to the 2 drugs you are talking about, 547 and 217 I am assuming, the approach has always been in our hands to consider 547 obviously the near-term opportunity for these patients where there is no currently available therapy. And we view this as well as establishing potentially, if the studies are positive, a commercial footprint that would — where 217 could be a follow-on agent. At this time, it's probably premature to speculate until we see what kind of data we get from both of these programs about what sort of positioning we might be able to achieve with both of these agents. I guess, I would just simply point out that if that were your case — that would be the case, it would be a very high quality problem for us to confront.

Operator

Our next question comes from Paul Matteis with Leerink.

Unidentified Analyst

This is [Geoffrey Lynn] on for Paul Matties. I guess the first question is, do you expect the moderate PPD study to have a slightly elevated placebo rate? And what have you done to mitigate that? And what kind of strategy do you have if only the severe study succeeds but the moderate fails?

Jeffrey M. Jonas - *Sage Therapeutics, Inc. - CEO, President & Director*

The placebo rate, as you know, has been a daunting issue throughout the course of all central nervous system development. What we did here is, again as you know, that people have tried various maneuvers with limited success. So our approach has always been, I think, rather straightforward which is to, first, look at a population that can be clearly identified. And we think we've done that with the PPD cases. And then secondly to make sure that the patients we enroll are the appropriate patients. And we — I think we've done that as well. We do look at each patient as they enroll. In addition, the way we saw it in — remember, we had a pretty clear data chain moving up into this and in each case we saw pretty clear robust responses. And in the controlled study we also saw a very — not a very — sort of a low to moderate response rate. I would point out that in any cyclic disorder, we shouldn't talk about any activity in the placebo on as placebo response, because we know that some patients will simply spontaneously [remiss]. So we think that what we've done is to find the right patients. We think we have a very clear end point. And finally recall that in these studies the patients are being treated for weeks and weeks, which is what people typically see where you see these placebo rates in major depressive disorder studies they are being treated for a matter of hours. So we think in as much as one can attenuate a placebo response, we will do that. But again, we just have to wait for the data. With respect to your second question, I think it's premature to speculate. I think we'll just wait to see what the data look like before we look at different scenarios.

Unidentified Analyst

And one quick one, if you don't mind. Just a follow-on for the earlier question on the PD data. Is there any other options for it? I guess tremor is, I guess, predominant PD. And can you help us contextualize that data — the data we see to that — to these options, if any?

Jeffrey M. Jonas - *Sage Therapeutics, Inc. - CEO, President & Director*

The patients who are — were included in the trial were specifically identified for having ongoing tremor despite the available treatment which is levodopa/carbidopa. So in fact there really aren't any treatments that are specifically targeting this. And we think this is an important signal, one that they represent an entry into an entirely different way of addressing ongoing symptoms of patients with Parkinson's disease.

Operator

And our next question comes from Tazeen Ahmad of Bank of America.

Tazeen Ahmad - *BofA Merrill Lynch, Research Division - VP*

I wanted to ask you, Jeff, on your program in insomnia. I know it's early, but based on what you know so far how could you be distinguished from the other products on the market? And then I have another follow-up.

Jeffrey M. Jonas - *Sage Therapeutics, Inc. - CEO, President & Director*

Thanks for the question. What we know from animal data is that this mechanism may have some unique features in terms of induction of healthy sleep. However, it's never been studied systematically because no one has ever had an oral agent like this that can actually effectively drug this -the extrasynaptic receptor with such high potency. This is part of our experimental medicine program. And by nature, it's still experimental and exploratory. But our hope would be that if we can show induction of sleep without alterations of architecture in theory this could have some advantages over current benzodiazepine related GABA — synaptic GABA agents where you do see things like sleep rebound, tachyphylaxis and excessive sedation. So this is one of the first — that's one of the goals of looking at this. Importantly, we know anecdotally, so we don't know, we hear anecdotally that we do see sleep improvement in patients taking 217 at night. Steve just pointed out those data in the patient with Parkinson's who have preexisting sleep disturbance. So it's important across all of our programs to understand how this mechanism impacts sleep architecture and performance in the morning. So there's a lot of important data we learn from this, whether or not this ends up being a potential treatment for insomnia. So, again, stay tuned, we will have those data likely in the first quarter.

Tazeen Ahmad - *BofA Merrill Lynch, Research Division - VP*

Can you just remind us how many patients you are expecting to release data for?

Jeffrey M. Jonas - *Sage Therapeutics, Inc. - CEO, President & Director*

So this study has a series of cohorts. And it is a sleep lab study in a sleep model (inaudible) sleep model. So it's going to be reasonably sized at about 40 to 50 patients. And depending on what the findings are we will be exploring different dosing regimens and potentially patient cohorts.

Tazeen Ahmad - *BofA Merrill Lynch, Research Division - VP*

Okay. Presumably if that goes well, would you expand out into a larger Phase II or would you want to do anymore work on early stage?

Jeffrey M. Jonas - *Sage Therapeutics, Inc. - CEO, President & Director*

I think it's too soon to speculate. But I think it's fair to note that sleep lab studies are [good]. Sleep is one of those areas where sleep lab studies can be very predictive to the types of programs and responses you will see in larger trials.

Operator

And our next question comes from Laura Chico of Raymond James.

Laura K. Chico - *Robert W. Baird & Co. Incorporated, Research Division - Healthcare Research Analyst*

Congrats on completing enrollment in Hummingbird. You mentioned, Jeff, PPD timing for Q1 ['17] has shifted out to 1Q '18. I'm just curious what's your confidence in hitting that target? And I guess also if you could perhaps speak to enrollment demand and kind of the pace and just how has that compared to your expectations? And have you learned anything, I guess, about the market opportunity that surprised you so far?

Jeffrey M. Jonas - *Sage Therapeutics, Inc. - CEO, President & Director*

(technical difficulty) (inaudible) finish enrolling the Phase III. So of course that — that was our first step and most important priority for 547. And with that completed, we turn the sights over to the 217 program and those are enrolling quite well now. And — so in terms of interest, the interest is very, very high. We saw that both in the 547 program as well as in the 217 program. So that — so, again that's how we — that's sort of the base with the story there. The demand as I mentioned I think it's always risky to look at clinical trial as a surrogate for demand. But if one wants to do that in this particular instance, there has been, as I mentioned just a minute ago, a large amount of interest both in the 547 Phase III, and again we completed with that, and with the 217. And we're very confident that we'll be able to report out in the first quarter.

Laura K. Chico - *Robert W. Baird & Co. Incorporated, Research Division - Healthcare Research Analyst*

That's very helpful. I guess one follow-up. In terms of 217 assuming success in the MDD study, you'll be advancing to larger trials likely. Can you just remind us where you are at in the manufacturing process with 217, I guess, and what would be your current capacity to supply for later stage trials?

Stephen J. Kanes - *Sage Therapeutics, Inc. - Chief Medical Officer*

One thing that we are doing from our programs is making sure that all of the enrollment programs sort of match in time. So we are very confident that we have the ability to deliver on the Phase II into Phase III from a manufacturing capability. Remember, one of the things that's happened this year is that we've been able to begin manufacturing what we think is the appropriate solid oral dosing formulation. So all of the trials that we are reporting on right now are with a capsule that's given once a day in the evening.

Jeffrey M. Jonas - *Sage Therapeutics, Inc. - CEO, President & Director*

Yes, this is Jeff. That was Steve, just to make sure no one is confused. But I think the short answer is that we're very comfortable we have adequate clinical supplies for all our planned programs.

Operator

And our next question comes from Ritu Baral of Cowen.

Ritu Subhalaksmi Baral - *Cowen and Company, LLC, Research Division - MD and Senior Biotechnology Analyst*

You mentioned some payer outreach that you guys have already started for PPD. Can you tell us, at least top line, what this outreach has yielded so far? I guess, how the payers look at this condition as far as price, cost benefit and also duration of disease? I mean, do they consider this was treating for 6 months, is this sort of a longer-term disease? And I have a follow-up after that.

Jeffrey M. Jonas - *Sage Therapeutics, Inc. - CEO, President & Director*

So we are involved with payers here and overseas in a number of constituencies and that's true. I think, again, probably early days — not early days, the probably premature [to except to] talk in detail about this. What I can tell you is that there is a great deal of interest across the board in a treatment regimen that might not require chronic therapy. And in particular that may — that may deliver a rapid onset of action with durability which of course is our target profile. I think we'll have to wait to see the data, which I think will be the most — you know this. When you go out, we talk about a target product profile. We do have early data that we've shown people, but I think the proof is going to be in pudding. And when we turn over the cards now and in the first quarter with the oral, I think we'll get a much better sense of — about that. It is important to remember this is an innovator product. There really aren't any particular analogs that look like this drug and potentially could do. So you're looking at a completely different model of treating both PPD and MDD that's unique in the space. And so I think that there is a learning curve, but we are very encouraged with what we're getting back.

Ritu Subhalaksmi Baral - *Cowen and Company, LLC, Research Division - MD and Senior Biotechnology Analyst*

As far as just for brexanolone [and the Hummingbird], I mean do they look at PPD completely differently than they look at MDD or are they — are there different overlaps in the payer side?

Jeffrey M. Jonas - *Sage Therapeutics, Inc. - CEO, President & Director*

We are very careful to define PPD quite rigorously in the way [we've been] defining it. I think there is a larger heuristic question that you're asking, which I don't want to go off topic. But is — and how — what is the relationship of MDD and PPD, we don't know that yet. But I can say that we have great — there is a good deal of specificity with respect to the idea that PPD is a unique problem, it's unique issue for the patient, it's has a unique patient journey, and uniquely affects the families as well. So that's well accepted and we're not seeing any push-back from that.

Ritu Subhalaksmi Baral - *Cowen and Company, LLC, Research Division - MD and Senior Biotechnology Analyst*

Okay. And then just moving on to 718 quickly. Steve you mentioned that in the next trials you'd be looking at some important biomarkers. Can you tell us what biomarkers are of most interest to you guys? And if you were designed like a Phase II program around those biomarkers, what sort of duration a Phase II program would be looking at to a meaningful data?

Stephen J. Kanes - *Sage Therapeutics, Inc. - Chief Medical Officer*

Well, I'll answer it first and then I'll turn it over to Jeff. We've always used EEG as a way of understanding the utility of our drugs to ensure that they're getting into the brain. And that's something that spans across all of our programs. We've shared that — the various points both with brexanolone with SAGE-217, and we're looking to see other ways to adopt that into the 718 program as well.

Jeffrey M. Jonas - *Sage Therapeutics, Inc. - CEO, President & Director*

Yes, I mean we have a number of potential biomarkers. I think we're not going to disclose them at this time. I think there are 2 points to make here. One is that we're looking for activity in the CNS. And with the GABA side, it's very easy to demonstrate the high potency of our molecules. On the side of NMDA, these are novel molecules that's really ever been tested before. So we have a number of approaches we're looking at. It's important

to emphasize though that things such as receptor occupancy while they are useful or not a surrogate for clinical and physiologic activity and that's what we'll be looking at before we move forward into Phase II. We have a distinct program that is quite deliberate at this point, but I think that's all we can say now. We've been very pleased that we're through the single ascending dose phase with a novel mechanism that's never been drugged before and I think (inaudible) we'll leave it at that.

Operator

And our next question comes from Cory Kasimov of JPMorgan.

Cory William Kasimov - *JP Morgan Chase & Co, Research Division - Senior Biotechnology Analyst*

I guess my first one is similar to the earlier question on Parkinson's. Can you put the essential tremor data in the context with what you believe is clinically meaningful given the single-arm nature of the study and maybe talk about the go/no-go hurdle as you look towards Part C? And then I've one follow-up.

Jeffrey M. Jonas - *Sage Therapeutics, Inc. - CEO, President & Director*

Essential tremor is something that we've been working on now for many years. Our first look at essential tremor actually was with brexanolone where we saw very similar changes, about a 40% improvement overall in essential tremor score and that was a placebo-controlled study. So this program is really based on our first placebo-controlled data from several years ago. What we were looking for in SAGE-217 initially was to see similar effect as we plan for a placebo-controlled follow on. And part of what we're doing in Part C is to see how we can maximize that effect. And that's something that we would be looking for when we release those results.

Stephen J. Kanes - *Sage Therapeutics, Inc. - Chief Medical Officer*

One other point I'd like to make is that when we started these programs we were using very — in the early stages we were using rather judicious dosing during the day. And what we've learned as we moved forward is one of the advantages of our approach, the sort of methodologic approach of doing open label methodology studies is that we're seeing durable effect by giving the dose at night. Remember these are long half-life drugs. So none of these studies have achieved steady state, especially with the oral. So we expect that in a longer-term study that we ought to expect to see more benefit, which is indicated by the slope of improvement in these open-label studies. The one point I'd like to emphasize still is that these are methodology studies that are meant to inform and define the patient population, which I think we've been very successful now with both Parkinson's and tremor but they are not meant to be [conclusionary]. So we will have to do the controlled studies to replicate these findings. But in as much as that these are designed around giving us methodologic information, they've been very successful. And I think that we're very pleased with what we're seeing so far.

Cory William Kasimov - *JP Morgan Chase & Co, Research Division - Senior Biotechnology Analyst*

And then my follow-up is on the Hummingbird studies. And I'm wondering if you can talk about the relative importance of the longer time points that you're evaluating after 30 days, as compared to the shorter, I believe, it's 3-day primary endpoint, I guess. What's the significance in your mind in the event you were to hit on the primary but only show trends or outright miss on the longer follow-up?

Jeffrey M. Jonas - *Sage Therapeutics, Inc. - CEO, President & Director*

It's probably premature to speculate. And the primary endpoint that we have under the — on the break-through is on the primary. There is obviously an interest in durability and I think we'll just have to see what the data show. I suspect — given the data we've seen we expect durability of response. And to your point, we're just going to have to see what the secondaries look like in this. And as you now, this is true of any drug development program where if the secondaries are out of whack you have a different situation where they are giving you a good finding. But it's important to reiterate the primary endpoint is a 60-hour endpoint and that's what our target is.

Operator

And our next question comes from Brian Abrahams of RBC Capital Markets.

Brian Corey Abrahams - *RBC Capital Markets, LLC, Research Division - Senior Analyst*

I guess a follow-up on the tremor studies. And curious on the PK-PD works that you've done around either Parkinson's or essential tremor. I know in the shorter pilot studies in ET it looks like you've seen efficacy maxing out where 217 or 547 was likely to be at peak plasma concentration. So I am just curious in the 7-day studies whether you saw shifts in activities throughout the data that might correlate to peak 217 exposure? Whether these were starting to even out towards the end of the study? As you approach a steady state, how much intraday variability you saw there?

Stephen J. Kanes - *Sage Therapeutics, Inc. - Chief Medical Officer*

Most important thing is we were seeing in very brief dosing that day by day the improvements continued. In fact over time they actually showed an incremental improvement. That's a signal that we are looking for in these studies and gives us interest in sort of moving on to see, as Jeff has mentioned before, what longer duration dosing would indicate. So while internally we're interested in PK-PD, the most important thing here is that over the course of several days patients continue to improve even at the — even prior to the next day's dosing. So these effects were durable.

Jeffrey M. Jonas - *Sage Therapeutics, Inc. - CEO, President & Director*

One point to make, and I think you've picked this up, the liquid has a more rapid onset, the capsule formulation has a smoother onset which is why we think, again, one of the hypotheses is why the nighttime dosing is giving us nice effect during the day. And just to emphasize what Steve said, we are seeing incremental benefit day by day which suggests that, as you might expect the pharmacokinetics of this type of drug that with longer half-life drugs takes longer to be steady state. So, at least the signal suggests that with longer dosing we can continue to accrue some benefit and we still believe that there may be opportunity for higher doses because the drug has been very well tolerated even with these kind of signals.

Brian Corey Abrahams - *RBC Capital Markets, LLC, Research Division - Senior Analyst*

And then just on PPD, as you've had time now — more time now to digest the SRSE data, you've obviously presented the full details there, just wondering if you had any updated thoughts on brexanolone target engagement or on kind of what — as we get towards the PPD readouts there? And just if you might confirm whether we should expect to see both PPD studies reading out at the same time that will be helpful.

Jeffrey M. Jonas - *Sage Therapeutics, Inc. - CEO, President & Director*

I'll reverse your question. So we anticipate now the first — the next data readout for the company will be both Phase III PPD studies. So let me just say that that will be the next data readout. With respect to your first question, the study with SRSE, this was, as we've said all along, is a very complicated patient population and a very complex study where there were multiple physician decisions along the way prior to getting to the endpoint. It's a very different study than what you are seeing say for example with PPD where you simply — where the design is reasonably straightforward. Steve recently — we recently presented at the Neurocritical Care Society some of the subgroup data that showed that patients with — about 40% of the patients had structural lesions and in that group we saw a data that was reminiscent of the Phase II finds we had initially. With that said, this is a very complicated trial. We're still being into the data. And why that subgroup was active is something we don't know the complete reasoning for that. And so we are still looking at the data and as we learn obviously we'll plan to communicate it.

Operator

And our next question comes from Danielle Brill of Needham.

Danielle Catherine Brill - *Needham & Company, LLC, Research Division - Senior Analyst*

I was just wondering if in the 217 PD tremor trial you looked at depression scores and if so what the impact was?

Stephen J. Kanes - *Sage Therapeutics, Inc. - Chief Medical Officer*

In this trial we did not collect patients who had depression. We were specifically looking for those patients that were tremor-predominant. So we — there is really nothing we can report on that particular front. So there was — it is a really interesting area and one that potentially would be a real utility for patients.

Operator

And our next question comes from Gary Nachman of BMO Capital Markets.

Gary Jay Nachman - *BMO Capital Markets Equity Research - Analyst*

Jeff, if PPD is positive, how soon would you be able to explore change of formulation for a shorter infusion time? Is that still in the works that you think that's important from a commercial standpoint from the work that you guys have started doing in that market?

Jeffrey M. Jonas - *Sage Therapeutics, Inc. - CEO, President & Director*

Well, the old axiom is that if it ain't broke, don't fix it. And I think that if the data — there is no evidence so far from the patients' acceptance that we have any [existing] requirement firstly for a change in the dose regimen. We do have some exploratory work in that Phase III program looking at lower dosing and we may explore other regimens. But so far the data suggest a high level of acceptability for this particular dosing regimen. We are — one of our goals as a company, remember these are — sometimes this is a very complex illness, PPD, in terms of its social dynamics. So our goal is to make sure we can deliver this drug in the setting that's most appropriate for the patients and their family. And it is in that regard, as you know, we are discussing and are in discussions with home infusion companies to look at this. We believe this is a very reasonable pathway. But the bottom line to date has been a very good acceptability with this regimen from the women who are suffering from this and so that's where we're standing with this right now.

Gary Jay Nachman - *BMO Capital Markets Equity Research - Analyst*

Okay. And could you just remind us in the moderate and severe studies, did you have the same dose for both of those patients, same infusion time everything?

Jeffrey M. Jonas - *Sage Therapeutics, Inc. - CEO, President & Director*

The infusion times are the same and that was done on — that was done purposefully. In the severe program, we did — it was under the thesis that we only change one variable at a time. So in the severe program that is the one we are exploring, a lower dose at 90 nanomolar versus 150, but that's the only change. And in the moderate program it's the standard dose that we used in the Phase II.

Gary Jay Nachman - *BMO Capital Markets Equity Research - Analyst*

And then on 217 for MDD, just if you could tell how many patients did you end up enrolling in the Phase II? What was the expected severity of those patients? Is it across both moderate and severe? And if that study is positive, could you actually move right into Phase III or would you need larger Phase IIs before you do that?

Jeffrey M. Jonas - *Sage Therapeutics, Inc. - CEO, President & Director*

I'm sorry, I am making a list of all your questions here. It is fully enrolled. The target was about 88 to 90. We haven't given our final enrollment figures. We will when we release the data. I think the pathway for this drug if it were to be positive is something that we have to explore given what the data look like. I think it's important to remember that this is a completely novel mechanism. No one has ever really been able to successfully drug this with a potent drug like ours. So I think we — (inaudible) although we're very hopeful about the study, it does have an exploratory Phase II component. We don't know how patients will respond. So we'll have to wait and see what the data look like. Obviously, whether we need to further dose exploration, what the tolerability is, those are all things that are still open questions and that we will learn when we have the data for Phase II.

Gary Jay Nachman - *BMO Capital Markets Equity Research - Analyst*

But it's across both moderate and severe?

Jeffrey M. Jonas - *Sage Therapeutics, Inc. - CEO, President & Director*

No, the MDD program is focused on severe. Again that is if we use the sort of [bromide of] only change one thing at a time. And so — and in antidepressant we're just still focusing on the severe patients. (inaudible) it's a mix between moderate and severe. (inaudible)

Operator

And our next question comes from Adam Walsh with Stifel.

Adam Anderson Walsh - *Stifel, Nicolaus & Company, Incorporated, Research Division - MD and Senior Analyst*

I've got a couple of them here. Just getting back to the earlier question on importance of durability in the brexanolone Phase III PPD study, do you have an internal view on what the minimal durability threshold that you would like to see would be kind of in the context of potential ketamine used in these patients?

Jeffrey M. Jonas - *Sage Therapeutics, Inc. - CEO, President & Director*

This is Jeff. So internally it would be a secret, right. I think we would like — obviously, our hope is to see a level of durability that replicates what we saw in the Phase II program. We think that — remember, this is a — if we show this, this is a piece — this is a piece of fundamental biology. And if the thesis is correct if somehow we're resetting the brain or resetting neural circuitry, we'd like to see some evidence of that in durability. But I -personally, this is me personally, that I think certainly more than a week or 2 is what we hope to see, that would be very practical especially with an acute therapy. But again, our hope, and based on the data we've seen from all of the programs is to see this several weeks out after the dosing.

Adam Anderson Walsh - *Stifel, Nicolaus & Company, Incorporated, Research Division - MD and Senior Analyst*

And then my second question is targeting your internal marketing research efforts. Hopefully we can get something on this. I guess the question from clients quite a bit, do you have any data on the percentage of PPD patients that are currently diagnosed and what percentage of those would be willing to come in for a multi-day infusion?

Jeffrey M. Jonas - *Sage Therapeutics, Inc. - CEO, President & Director*

I'm going to turn some of this over to Steve, but I can just tell you experientially we're seeing no resistance to women coming in. And I will just say this on the call, my favorite comment from someone, I won't say who it is, anyone who thinks that suffering from severe PPD — a women suffering from severe PPD wouldn't want to get better after 60 hours is probably a man. So we've seen that — we've seen no resistance to enrollment of women coming in at all and [we can tell that]. We believe right now in the U.S., our data suggest that there are about 400,000 claims per year for the treatment of postpartum depression in the U.S. The general consensus among experts in the [TL] however is that it is probably under diagnosed and under treated largely because there are no approved therapies specifically for PPD and that there are — and that the therapy that exist are not — are successful but not terribly so. We expect that if you look at the number of live births in the U.S., which is 3 million to 4 million we expect that there are — 3 million to 4 million a year that 10% to 20% of women will be — have a diagnosed affective syndrome surrounding the birth. And so we think it represents a significant area of unmet medical need and significantly under served.

Stephen J. Kanes - *Sage Therapeutics, Inc. - Chief Medical Officer*

One of the things that we hear a lot from the investigators is that patients are reluctant to enter into treatment because the options are so poor. And what we think is so important about what we're doing is if 6 years of treatment really does affect, essentially a very rapid, durable and profound effect in these patients, then that we would certainly change the dynamic for how patients enter into care. So something we're really excited about and we think is, if the data are what we're hoping for, very important for patients.

Operator

And our next question comes from Tim Lugo of William Blair.

Timothy Francis Lugo - *William Blair & Company L.L.C., Research Division - Co-Group Head of Biopharma Equity Research*

I guess going back to brexanolone and 217 for PPD, are the backgrounds of patients, of women who are coming for a 60-hour infusion over several days versus oral outpatient therapy, are those ultimately different? I guess, is that a different disease almost? Is it — what are the baseline criteria differences between those 2 groups of women? And I assume that 400,000 claims data number you mentioned, those are severe PPD patients.

Jeffrey M. Jonas - *Sage Therapeutics, Inc. - CEO, President & Director*

This is Jeff. Those are all patients, not just severe. So that's number one. The demography — we haven't looked at the data yet. All we can say is what the stuff — the information we get from through leaders and people who treat these women is that since there is no therapy, it's premature to understand what the differentiators might be between women who want to come in for an IV versus those who might be interested in oral. So we will have to see what the data look like before we can give you a clear answer on that one.

Operator

Thank you. And that concludes our question-and-answer session for today. I'd like to turn the conference back over to Jeff Jonas for any closing remarks.

Jeffrey M. Jonas - *Sage Therapeutics, Inc. - CEO, President & Director*

First, I'd like to thank everyone for their attention today and your questions and want to thank everyone at Sage for the great work they've done in bringing us to this point [of] all these multiple data readouts. I think all of you know, it's an exciting time for the company. We're potentially on the cusp of becoming [pretty] commercial with several data readouts. Our pipeline is still progressing nicely. So we're looking forward to communicating more of our information over this quarter and I look forward to talking to all of you again. So again, thanks everybody and have a great day.

Operator

Ladies and gentlemen, thank you for participating in today's conference. This does conclude the program and you may all now disconnect. Everyone have a great day.