Sage Therapeutics, Inc.
Form 10-Q
August 07, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2018

OR

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

Commission file number: 001-36544

Sage Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

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

215 First Street

Cambridge, Massachusetts 02142

(Address of principal executive office) (Zip Code)

Registrant's telephone number, including area code: (617) 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 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 No

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

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

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

As of August 1, 2018, there were 46,664,296 shares of the registrant's common stock, $0.0001 par value per share, outstanding.

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q, or Quarterly Report, 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 are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may”, “will”, “should”, “expects”, “intends”, “plans”, “anticipates”, “beli “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 plans to develop and commercialize our product candidates in the central nervous system, or CNS, disorders we discuss in this Quarterly Report, and potentially in other indications;
- our expectations as to the sufficiency of the data generated from the clinical trials and non-clinical studies of our proprietary intravenous, or IV, formulation of brexanolone to support approval by the U.S. Food and Drug Administration, or FDA, of our new drug application, or NDA, for brexanolone IV in the treatment of postpartum depression, or PPD, and the potential timing of such a decision;
- our expectations as to the timing of a potential launch of brexanolone IV in the U.S. as a treatment for PPD, if our NDA is approved by the FDA; our views as to our future readiness for such a launch; and our plans with respect to the size, readiness and focus of our field force and possible sites of care for administration of brexanolone IV, including supervised home infusion;
- our expectations as to the sufficiency of our planned development program for SAGE-217 in major depressive disorder and PPD, if successful, to expedite our development of SAGE-217, and to support filing of an NDA with the FDA and potential approval in such indications;
- our expectations with respect to the anticipated development pathway and regulatory approval requirements for our product candidates outside the United States, including the potential for filing of a marketing authorization application in the European Union, or EU, and our related plans and expectations, including plans for continuing to build our organization in the EU, and the potential for entering into future collaborations and other types of contractual relationships, if appropriate, for accomplishing our strategic objectives;
- our views as to the anticipated rate and degree of market acceptance, and expectations regarding pricing and the potential scope, level and availability of reimbursement, of brexanolone IV and our other product candidates in any indication and country, if approved
- our ability, within the expected time-frames, to initiate clinical trials and non-clinical studies of existing or future product candidates, including pivotal clinical trials, and to successfully complete and announce the results of ongoing or future clinical trials;
- our estimates regarding expenses, use of cash, timing of future cash needs, and capital requirements;
- our expectations as to the potential to achieve future revenues;
- our expectations with respect to the availability of supplies of our product candidates, and the expected performance of our third-party manufacturers;
- our ability to obtain and maintain intellectual property protection for our proprietary assets and other forms of exclusivity relevant to our business;
- the estimated number of patients in indications of interest to us; the size of the potential markets for our product candidates; the potential for our product candidates in those markets, if approved; and our ability to serve those markets;
- the level of costs we may incur in connection with our activities, the possible timing and sources of future financings, and our ability to obtain additional financing when needed to fund future operations;

- the potential for success of competing products that are or become available for the indications that we are pursuing or may pursue in the future;
- 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 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. 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.

We may from time to time provide estimates, projections and other information concerning our industry, the general business environment, and the markets for certain diseases, including estimates regarding the potential size of those markets and the estimated 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, circumstances or numbers, including actual disease prevalence rates and market size, may differ materially from the information reflected in this Quarterly Report. Unless otherwise expressly stated, we obtained this industry, business information, market data, prevalence information 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 our own assumptions and analysis that may, in the future, prove not to have been accurate.

Sage Therapeutics, Inc.

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements
Sage Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

(in thousands, except share and per share data)

(Unaudited)

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$325,830	$306,235
Marketable securities	766,603	212,613
Prepaid expenses and other current assets	12,958	6,227
Receivable from collaborator	18,378	—
Total current assets	1,123,769	525,075
Property and equipment, net	4,445	4,013
Restricted cash	1,269	849
Total assets	$1,129,483	$529,937
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$8,338	$9,350
Accrued expenses	39,581	42,601
Total current liabilities	47,919	51,951
Other liabilities	3,801	2,511
Total liabilities	51,720	54,462
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, $0.0001 par value per share; 5,000,000 shares authorized at June 30, 2018 and December 31, 2017; no shares issued or outstanding at June 30, 2018 and December 31, 2017	—	—
Common stock, $0.0001 par value per share; 120,000,000 shares authorized at June 30, 2018 and December 31, 2017; 46,605,353 and 42,003,894 shares issued at June 30, 2018 and December 31, 2017, respectively; 46,603,839 and 42,002,934 shares outstanding at June 30, 2018 and	5	5

December 31, 2017, respectively		
Treasury stock, at cost, 1,514 and 960 shares		
at June 30, 2018 and December 31, 2017, respectively	(211)	(113)
Additional paid-in capital	1,760,137	1,066,059
Accumulated deficit	(682,023)	(590,447)
Accumulated other comprehensive loss	(145)	(29)
Total stockholders' equity	1,077,763	475,475
Total liabilities and stockholders' equity	$1,129,483	$529,937

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

Sage Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2018	2017	2018	2017
Collaboration revenue	$90,000	$—	$90,000	$—
Operating expenses:				
Research and development	68,980	55,900	118,250	101,100
General and administrative	43,167	14,954	72,016	27,234
Total operating expenses	112,147	70,854	190,266	128,334
Loss from operations	(22,147)	(70,854)	(100,266)	(128,334)
Interest income, net	5,137	672	8,666	1,379
Other expense, net	32	(20)	24	(24)
Net loss	$(16,978)	$(70,202)	$(91,576)	$(126,979)
Net loss per share—basic and diluted	$(0.36)	$(1.88)	$(2.02)	$(3.40)
Weighted average number of common shares outstanding—basic and diluted	46,541,716	37,361,129	45,439,666	37,315,393
Comprehensive loss:				
Net loss	$(16,978)	$(70,202)	$(91,576)	$(126,979)
Other comprehensive items:				
Unrealized gain (loss) on marketable securities	40	14	(116)	35
Total other comprehensive gain (loss)	40	14	(116)	35
Total comprehensive loss	$(16,938)	$(70,188)	$(91,692)	$(126,944)

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

Sage Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

(in thousands)

(Unaudited)

	Six months ended June 30,	
	2018	2017
Cash flows from operating activities		
Net loss	$(91,576)	$(126,979)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	44,845	15,558
Premium on marketable securities	(75)	—
Amortization of premium (discount) on marketable securities	(4,154)	5
Depreciation	493	260
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(25,091)	(93)
Accounts payable	(903)	(6,768)
Accrued expenses and other liabilities	(2,245)	3,731
Net cash used in operating activities	(78,706)	(114,286)
Cash flows from investing activities		
Proceeds from sales and maturities of marketable securities	263,460	110,436
Purchases of marketable securities	(813,337)	(33,922)
Purchases of property and equipment	(1,054)	(321)
Net cash provided by (used in) investing activities	(550,931)	76,193
Cash flows from financing activities		
Proceeds from stock option exercises and employee stock purchase plan issuances	19,402	3,311
Payment of employee tax obligations related to vesting of restricted stock units	(904)	—
Payments of offering costs	(340)	—
Proceeds from public offerings of common stock, net of commissions and underwriting discounts	631,494	—
Net cash provided by financing activities	649,652	3,311
Net increase (decrease) in cash, cash equivalents and restricted cash	20,015	(34,782)
Cash, cash equivalents and restricted cash at beginning of period	307,084	169,081
Cash, cash equivalents and restricted cash at end of period	$327,099	$134,299
Supplemental disclosure of non-cash investing and financing activities		
Purchases of property and equipment included in accounts payable	$10	$—

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

SAGE THERAPEUTICS, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Nature of the Business

Sage Therapeutics, Inc. ("Sage" or the "Company") is a clinical-stage biopharmaceutical company committed to developing and commercializing novel medicines to treat life-altering central nervous system ("CNS") disorders, where there are no approved therapies or existing therapies are inadequate. The Company has a portfolio of product candidates with a current focus on modulating two critical CNS receptor systems, GABA and NMDA. The GABA receptor family, which is recognized as the major inhibitory neurotransmitter in the CNS, mediates downstream neurologic and bodily function via activation of $GABA_A$ receptors. The NMDA-type receptors of the glutamate receptor system are a major excitatory receptor system in the CNS. Dysfunction in these systems is implicated in a broad range of CNS disorders. The Company is targeting CNS indications where patient populations are easily identified, clinical endpoints are well-defined, and development pathways are feasible.

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.

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 non-clinical and clinical development; the challenges associated with gaining regulatory approval of such product candidates; the risks associated with commercializing pharmaceutical products, if approved for marketing and sale; 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.

Under Accounting Standards Update, or ASU, 2014-15, Presentation of Financial Statements—Going Concern (Subtopic 205-40), or ASC 205-40, the Company has the responsibility to evaluate whether conditions and/or events raise substantial doubt about its ability to meet its future financial obligations as they become due within one year after the date that the financial statements are issued. The Company has incurred losses and negative cash flows from operations since its inception. As of June 30, 2018, the Company had an accumulated deficit of $682.0 million. From its inception through June 30, 2018, the Company received net proceeds of $1.6 billion from the sales of redeemable convertible preferred stock, the issuance of convertible notes, and the sales of common stock in its initial public offering ("IPO") in July 2014 and follow-on public offerings in April 2015, January 2016, September 2016, November 2017 and February 2018. Until such time, if ever, as the Company can generate substantial product revenue and achieve profitability, the Company expects to finance its cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other sources of funding. If the Company is unable to raise additional funds through equity or debt financings when needed, the Company may be required to delay, limit, reduce or terminate product development or future commercialization efforts or grant rights to develop and market products or product candidates that the Company would otherwise prefer to develop and market itself. The Company expects that, based on its current operating plans, the Company's existing cash, cash equivalents and marketable securities will be sufficient to fund its current planned operations for at least the next twelve months from the issuance of these unaudited interim condensed consolidated financial statements.

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2. Summary of Significant Accounting Policies

The following is a summary of significant accounting policies followed in the preparation of these unaudited condensed consolidated financial statements.

Basis of Presentation

The unaudited interim condensed 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 ("GAAP") have been condensed or omitted from this report, as is permitted by such rules and regulations. Accordingly, these unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements as of and for the year ended December 31, 2017, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

The unaudited interim condensed 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 condensed consolidated financial statements contain all adjustments, consisting of only normal recurring adjustments, necessary for a fair statement of its financial position as of June 30, 2018, its results of operations and comprehensive loss for the three and six months ended June 30, 2018 and 2017, and its cash flows for the three and six months ended June 30, 2018 and 2017. The consolidated balance sheet at December 31, 2017 was derived from audited financial statements, but does not include all disclosures required by GAAP. The results for the three and six months ended June 30, 2018 are not necessarily indicative of the results for the year ending December 31, 2018, or for any future period.

Principles of Consolidation

The unaudited interim condensed 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, 2017. Intercompany accounts and transactions have been eliminated.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and 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.

Research and Development

Research and development expenses are comprised of costs incurred in performing research and development activities, including salaries and benefits, overhead costs, depreciation, contract services and other related costs. Research and development costs are expensed to operations as the related obligation is incurred.

The Company has entered into various research and development contracts with research institutions and other companies both inside and outside of the United States. These agreements are generally cancelable, and related costs

are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the estimates made by the Company. The historical accrual estimates made by the Company have not been materially different from the actual costs.

Stock-Based Compensation

The Company recognizes compensation expense for stock-based awards, including grants of stock options and restricted stock, made to employees and non-employee directors based on the estimated fair value on the date of grant, over the requisite service period.

The Company recognizes compensation expense for stock-based awards granted to non-employee consultants based on the fair value of the award on each date on which the awards vest. Compensation expense is recognized over the vesting period, provided that services are rendered by such non-employee consultants during that time. At the end of each financial reporting period, the fair value of unvested options is re-measured using the then-current fair value of the Company's common stock and updated assumptions in the Black-Scholes option-pricing model; and the fair value of restricted stock awards is re-measured using the then-current fair value of the Company's common stock.

For awards that vest upon achievement of a performance condition, the Company recognizes compensation expense when achievement of the performance condition is met or during the period from which meeting the condition is deemed probable until the expected date of meeting the performance condition.

The fair value of each option grant is estimated using the Black-Scholes option-pricing model. Through December 31, 2015, the Company lacked sufficient Company-specific historical and implied volatility information, and as a result, the Company used the volatility of a group of publicly-traded peer companies in the Black-Scholes calculations. Beginning in 2016, the Company estimated its expected volatility using a weighted average of the historical volatility of publicly-traded peer companies and the volatility of its common stock and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its traded stock price for the duration of the expected term. The expected term of the Company's options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options, while the expected term of its options granted to consultants and non-employee directors has been determined based on the contractual term of the options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The Company also applies a forfeiture rate in order to calculate stock-based compensation expense. Expected forfeitures are based on the historical experience of the Company and management's expectations of future forfeitures. To the extent actual forfeitures differ from the estimates, the difference is recorded as a cumulative adjustment in the period in which the estimates are revised. The Company recognizes stock-based compensation expense for only the portion of awards that are expected to vest.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. As of June 30, 2018, cash equivalents were comprised of cash equivalents and money market funds. As of December 31, 2017, cash equivalents were comprised of cash equivalents, money market funds and overnight reverse repurchase agreements.

Marketable securities

Marketable securities consist of investments with original maturities greater than 90 days. The Company considers its investment portfolio of investments to be available-for-sale. Accordingly, these investments are recorded at fair value, which is based on quoted market prices. Unrealized gains and losses are reported as a component of accumulated

other comprehensive items in stockholders' equity. Realized gains and losses and declines in value judged to be other than temporary are included as a component of other expense, net, based on the specific identification method. When determining whether a decline in value is other than temporary, the Company considers several factors, including whether the Company has the intent to sell the security, and whether it is more likely than not that the Company will be required to sell the security prior to recovery of its amortized cost basis. Marketable securities that have remaining contractual

maturities of one year or less are classified as short term. No declines in value were deemed to be other than temporary during the three and six months ended June 30, 2018 and 2017.

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 classified and disclosed in one of the following three categories:

Level 1 —Quoted market prices in active markets for identical assets or liabilities.

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.

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.

The Company's cash equivalents and marketable securities at June 30, 2018 and December 31, 2017 were carried at fair value, determined according to the fair value hierarchy; see Footnote 3, Fair Value Measurements herein.

The carrying amounts reflected in the unaudited condensed consolidated balance sheets for accounts payable and accrued expenses approximate their fair values due to their short-term maturities at June 30, 2018 and December 31, 2017, respectively.

Revenue Recognition

Effective January 1, 2017, the Company adopted Accounting Standards Codification ("ASC"), Topic 606, Revenue from Contracts with Customers ("Topic 606"). This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as collaboration arrangements and leases. Prior to the three months ended June 30, 2018, the Company did not have any revenue-generating arrangements and therefore there was no transition impact from the adoption of Topic 606.

Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction

price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration to which it is entitled in exchange for the goods or services it transfers to a customer.

Once a contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. The Company assesses if these options provide a material right to the customer and if so, they are considered performance obligations. The exercise of a material right may be accounted for as a contract modification or as a continuation of the contract for accounting purposes.

The Company assesses whether each promised good or service is distinct for the purpose of identifying the performance obligations in the contract. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such are separable from the other aspects of the contractual relationship. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the

customer (that is, the good or service is capable of being distinct) and (ii) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract). In assessing whether a promised good or service is distinct in the evaluation of a collaboration arrangement subject to Topic 606, the Company considers factors such as the research, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. The Company also considers the intended benefit of the contract in assessing whether a promised good or service is separately identifiable from other promises in the contract. If a promised good or service is not distinct, the Company is required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

The transaction price is then determined and allocated to the identified performance obligations in proportion to their standalone selling prices ("SSP") on a relative SSP basis. SSP is determined at contract inception and is not updated to reflect changes between contract inception and when the performance obligations are satisfied. Determining the SSP for performance obligations requires significant judgment. In developing the SSP for a performance obligation, the Company considers applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs. In certain circumstances, the Company may apply the residual method to determine the SSP of a good or service if the standalone selling price is considered highly variable or uncertain. The Company validates the SSP for performance obligations by evaluating whether changes in the key assumptions used to determine the SSP will have a significant effect on the allocation of arrangement consideration between multiple performance obligations.

If the consideration promised in a contract includes a variable amount, the Company estimates the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to a customer. The Company determines the amount of variable consideration by using the expected value method or the most likely amount method. The Company includes the unconstrained amount of estimated variable consideration in the transaction price. The amount included in the transaction price is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

If an arrangement includes development and regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

In determining the transaction price, the Company adjusts consideration for the effects of the time value of money if the timing of payments provides the Company with a significant benefit of financing. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period

between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less. The Company assessed its revenue-generating arrangement in order to determine whether a significant financing component exists and concluded that a significant financing component does not exist in the arrangement. For arrangements with licenses of intellectual property that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes royalty revenue and sales-based milestones at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied at a point in time or over time, and if over time this is based on the use of an output or input method.

Recently Issued Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (“FASB”) issued ASU No. 2016-02, Leases, which will replace the existing guidance in ASC 840, “Leases.” The updated standard aims to increase transparency and comparability among organizations by requiring lessees to recognize leased assets and leased liabilities on the consolidated balance sheets and requiring disclosure of key information about leasing arrangements. The standard will be effective on January 1, 2019, with early adoption permitted. The Company is in the process of evaluating the impact that this new guidance will have on its consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, which introduces a new methodology for accounting for credit losses on financial instruments, including available-for-sale debt securities. The guidance establishes a new "expected loss model" that requires entities to estimate current expected credit losses on financial instruments by using all practical and relevant information. Any expected credit losses are to be reflected as allowances rather than reductions in the amortized cost of available-for-sale debt securities. Early adoption is permitted for annual periods beginning after December 15, 2018, and interim periods therein. The Company is in the process of evaluating the impact that this new guidance will have on its consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. The standard reduces the diversity in practice in how certain cash receipts and cash payments are presented and classified in the statements of cash flows. The Company adopted the standard on the required effective date of January 1, 2018. This guidance did not have a significant impact on the Company’s consolidated financial statements and related disclosures.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash that changes the presentation of restricted cash and cash equivalents in the statements of cash flows. Restricted cash and restricted cash equivalents will be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statements of cash flows. The Company adopted this standard during the first quarter of 2018. Restricted cash is now included as a component of cash, cash equivalents, and restricted cash on the Company’s unaudited condensed consolidated statements of cash flows. Restricted cash balances are classified as non-current unless, under the terms of the applicable agreements, the funds will be released from restrictions within one year from the balance sheet date. The inclusion of restricted cash increased the beginning balances of the unaudited condensed consolidated statements of cash flows by $0.8 million and $0.6 million, respectively, and the ending balances by $1.3 million and $0.8 million, respectively, for the six months ended June 30, 2018 and 2017.

In May 2017, the FASB issued ASU No. 2017-09, Compensation—Stock Compensation (Topic 718) — Scope of Modification Accounting, which applies to entities that change the terms or conditions of a share-based payment award. The amendments in this standard include guidance on determining whether changes to the terms and conditions of share-based payment awards require an entity to apply modification accounting under Topic 718 unless all of the following conditions are met: (1) the fair value of the modified award is the same as the fair value of the original award immediately before the original award is modified, and if the modification does not affect any of the inputs to the valuation technique that the entity uses to value the award, then the entity is not required to estimate the value immediately before and after the modification; (2) the vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified; and (3) the classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. The Company adopted the standard on the required effective date of January 1, 2018. This guidance did not have a significant impact on the Company’s

consolidated financial statements and related disclosures.

In June 2018, the FASB issued ASU 2018-07, Compensation—Stock Compensation (Topic 718) – Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-07"), which aligns the accounting for share-based payment awards issued to employees and non-employees. Under the new guidance, the existing guidance regarding employees will apply to share-based transactions with non-employees, as long as the transaction is not effectively a form of financing, with the exception of specific guidance related to the attribution of compensation cost. The cost of non-employee awards will continue to be recorded as if the grantor had paid cash for the goods or services. In addition, the contractual term will be able to be used in lieu of an expected term in the option-pricing model for non-employee awards. The amendments in

the new guidance are effective for public entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, including in interim periods, but no earlier than an entity's adoption of Accounting Standards Codification 606. The Company is in the process of evaluating the impact that this new guidance will have on its consolidated financial statements.

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company's consolidated financial statements upon adoption.

3. Fair Value Measurements

The Company's cash equivalents are classified within Level 1 of the fair value hierarchy. The Company's investments in marketable securities are classified within Level 2 of the fair value hierarchy.

The fair values of the Company's marketable securities are based on prices obtained from independent pricing sources. Consistent with the fair value hierarchy described above, securities with validated quotes from pricing services are reflected within Level 2, as they are primarily based on observable pricing for similar assets or other market observable inputs. Typical inputs used by these pricing services include, but are not limited to, reported trades, benchmark yields, issuer spreads, bids, offers or estimates of cash flow, prepayment spreads and default rates.

The following tables summarize the Company's money market funds and marketable securities as of June 30, 2018 and December 31, 2017.

	June 30, 2018			
	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	(in thousands)			
Cash equivalents:				
Cash equivalents	$325,830	$325,830	$ —	$ —
Total cash equivalents	325,830	325,830	—	—
Marketable securities:				
U.S. government securities	225,335	—	225,335	—
U.S. corporate bonds	110,363	—	110,363	—
International corporate bonds	26,503	—	26,503	—
U.S. commercial paper	211,144	—	211,144	—
International commercial paper	193,258	—	193,258	—
Total marketable securities	766,603	—	766,603	—
Total cash equivalents and marketable securities	$1,092,433	$325,830	$ 766,603	$ —

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	December 31, 2017			
	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	(in thousands)			
Cash equivalents:				
Cash equivalents	$306,235	$306,235	$—	$—
Total cash equivalents	306,235	306,235	—	—
Marketable securities:				
U.S. government securities	49,606	—	49,606	—
U.S. corporate bonds	48,959	—	48,959	—
U.S. commercial paper	65,583	—	65,583	—
International commercial paper	48,465	—	48,465	—
Total marketable securities	212,613	—	212,613	—
Total cash equivalents and marketable securities	$518,848	$306,235	$212,613	$—

During the six months ended June 30, 2018 and 2017, there were no transfers among the Level 1, Level 2 and Level 3 categories.

Marketable Securities

The following tables summarize the gross unrealized gains and losses of the Company’s marketable securities as of June 30, 2018 and December 31, 2017:

	June 30, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
Assets:				
U.S. government securities	$225,363	$ 5	$ (33)	$225,335
U.S. corporate bonds	110,454	1	(92)	110,363
International corporate bonds	26,518	—	(15)	26,503
U.S. commercial paper	211,150	—	(6)	211,144
International commercial paper	193,263	—	(5)	193,258
	$766,748	$ 6	$ (151)	$766,603

	December 31, 2017		
		Gross Unrealized	Gross Unrealized

	Amortized Cost	Gains	Losses	Fair Value
	(in thousands)			
Assets:				
U.S. government securities	$49,612	$ —	$ (6)	$49,606
U.S. corporate bonds	48,982	2	(25)	48,959
U.S. commercial paper	65,583	—	—	65,583
International commercial paper	48,465	—	—	48,465
	$212,642	$ 2	$ (31)	$212,613

As of June 30, 2018, all marketable securities held by the Company had remaining contractual maturities of one year or less.

There have been no impairments of the Company’s assets measured and carried at fair value during the six months ended June 30, 2018 and the year ended December 31, 2017.

4. Balance Sheet Components
Property and Equipment, net

Property and equipment, net, consists of the following:

	June 30, 2018	December 31, 2017
	(in thousands)	
Computer hardware and software	$1,476	$ 1,090
Furniture and equipment	936	1,029
Leasehold improvements	3,599	2,967
	6,011	5,086
Less: Accumulated depreciation	(1,566)	(1,073)
	$4,445	$ 4,013

Depreciation expense for the three months ended June 30, 2018 and 2017 was $0.2 million and $0.1 million, respectively. Depreciation expense for the six months ended June 30, 2018 and 2017 was $0.5 million and $0.3 million, respectively.

The useful life for computer hardware and software is 3 years, furniture and equipment is 5 years and leasehold improvements is the lesser of the useful life or the term of the respective lease.

Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2018	December 31, 2017
	(in thousands)	
Development costs	$23,679	$ 23,473
Employee-related expenses	9,250	15,838
Professional services	6,195	3,166
Other accrued expenses	457	124
	$39,581	$ 42,601

5. Commitments and Contingencies
Operating Leases

The Company leases office space in two multi-tenant buildings in Cambridge, Massachusetts, consisting, as of March 31, 2018, of 54,943 square feet in one building under an operating lease that expires on August 15, 2024 and 19,805 square feet in the second building under an operating lease that will expire on February 28, 2022.

In April 2018, the Company entered into the First Amendment to the lease for office space in the second building. The Company increased the amount of square feet of office space from 19,805 square feet to 40,419 square feet, an increase of 20,614 square feet, consisting of (i) 13,481 square feet beginning on August 1, 2018, and (ii) 7,133 square feet beginning on October 1, 2018. The term for this additional space will expire on August 31, 2024. Additionally, the term of the existing lease will be extended from February 28, 2022 until August 31, 2024.

In May 2018, the Company entered into a lease for office space in a multi-tenant building in Raleigh, North Carolina. The amount of square feet of office space is 15,525 square feet and the lease period will begin on September 1, 2018. The term for this space will expire on November 30, 2024.

Future minimum lease payments under non-cancelable operating leases are as follows at June 30, 2018:

Years Ending December 31,	(in thousands)
2018	$ 2,867
2019	6,657
2020	6,784
2021	6,913
2022	7,106
Thereafter	12,189
	$ 42,516

License Agreements

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 brexanolone and the Company’s compound known as 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 of June 30, 2018, the Company paid to CyDex $1.0 million for licensing fees, which was recorded as research and development expense.

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 up to $0.8 million in clinical milestones and up to $3.8 million in regulatory milestones for each of the first two fields with respect to brexanolone; up to $1.3 million in clinical milestones and up to $8.5 million in regulatory milestones for each of the third and fourth fields with respect to brexanolone; and up to $0.8 million in clinical milestones and up to $1.8 million in regulatory milestones for one field with respect to SAGE-689. As of June 30, 2018, the Company recorded research and development expense and made cash payments of $2.3 million related to these clinical development and regulatory milestones.

For the three and six months ended June 30, 2018, the Company recorded research and development expense and made cash payments of $0.8 million related to regulatory milestones for the brexanolone program under the license agreement with CyDex. For the three and six months ended June 30, 2017, the Company did not record any expense or make any milestone payments related to clinical development or regulatory milestones for the brexanolone program under the license agreement with CyDex.

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 under which 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 postpartum 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. As of December 31, 2015, the Company paid to The Regents of the University of California clinical development milestones of $0.1 million and will be required to pay royalties of less than 1% on net sales for a period of fifteen years following the sale of the first product developed using the data and materials. 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 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 payments of $15,000 for annual maintenance fees 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, of which none have been paid to date. Following the first sale, 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. As of June 30, 2018, the Company recorded research and development expense and made cash payments of $0.3 million related to these regulatory and sales milestones.

For the three and six months ended June 30, 2018, the Company recorded research and development expense and made cash payments of $0.2 million related to regulatory milestones under the license agreements with The Regents of the University of California. For the three and six months ended June 30, 2017, the Company did not record any expense or make any milestone or royalty payments under either license agreement with The Regents of the University of California.

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 of $0.1 million was recorded as research and development expense in 2013. As of June 30, 2018, the Company recorded research and development expense and made a cash payment of $50,000 related to these clinical and development milestones.

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.

For the three and six months ended June 30, 2018 and 2017, the Company did not record any expense or make any milestone payments under the license agreement with Washington University.

Consulting Agreement

In January 2014, the Company entered into a consulting agreement with a non-employee 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. As of June 30, 2018, the Company

recorded research and development expense of $1.8 million, comprised of $0.5 million in cash and $1.3 million related to the issuance of 39,681 shares of the Company's common stock, related to the achievement of these milestones.

For the three and six months ended June 30, 2018 and 2017, the Company did not record any expense or make any milestone payments under the consulting agreement with the non-employee advisor.

6. Collaboration Agreement

Effective June 12, 2018, the Company entered into a strategic collaboration with Shionogi & Co., Ltd., (“Shionogi”) for the clinical development and commercialization of SAGE-217 for the treatment of major depressive disorder (“MDD”) and other indications in Japan, Taiwan and South Korea.

Under the terms of the agreement, Shionogi will be responsible for all clinical development, regulatory filings and commercialization of SAGE-217 for MDD, and potentially other indications, in Japan, Taiwan and South Korea. Shionogi is required to make an upfront payment to the Company of $90.0 million, and the Company will be eligible to receive additional payments of up to $485.0 million if certain regulatory and commercial milestones are achieved by Shionogi. The potential future milestone payments include up to $70.0 million for the achievement of specified regulatory milestones, up to $30.0 million for the achievement of specified commercialization milestones, and up to $385.0 million for the achievement of specified net sales milestones. Due to the uncertainty of pharmaceutical development and the high historical failure rates generally associated with drug development, we may not receive any additional milestone payments or any royalty payments from Shionogi. The Company will receive tiered royalties on sales of SAGE-217 in Japan, Taiwan and South Korea, if development efforts are successful, with tiers averaging in the low to mid-twenty percent range, subject to other terms of the agreement. Shionogi has also granted to the Company certain rights to co-promote SAGE-217 in Japan across all indications. The Company maintains exclusive rights to develop and commercialize SAGE-217 outside of Japan, Taiwan and South Korea. The upfront cash payment and any payments for milestones and royalties are non-refundable, non-creditable and not subject to set-off.

The Company concluded that Shionogi meets the definition to be accounted for as a customer since the Company is delivering intellectual property and know-how rights for the SAGE-217 program in support of territories in which the parties are not jointly sharing the risks and rewards. In addition, the Company determined that the Shionogi collaboration met the requirements to be accounted for as a contract, including that it is probable that the Company will collect the consideration related to the up-front payment to which the Company is entitled in exchange for the goods or services that will be delivered to Shionogi.

In determining the appropriate amount of revenue to be recognized under ASC 606, the Company performed the following steps: (i) identified the promised goods or services in the contract; (ii) determined whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measured the transaction price, including the constraint on variable consideration; (iv) allocated the transaction price to the performance obligations; and (v) recognized revenue when (or as) the Company satisfies each performance obligation.

The Company determined that, pursuant to the new revenue standard, the performance obligations included the license to SAGE-217, supply of certain clinical materials and manufacturing supply of the active pharmaceutical ingredient (“API”). The performance obligation related to the license to SAGE-217 was determined to be distinct from other

performance obligations and therefore was a standalone performance obligation for which control was transferred upon signing. The obligation to provide certain clinical materials was determined to be a separate performance obligation. The agreement related to supplying API was determined to be an option for Shionogi to purchase, rather than a firm obligation since no minimum amount or quantities are specified and, therefore, was not considered a performance obligation within the main agreement. Given this fact pattern, the Company has concluded the agreement has two performance obligations.

The Company completed the evaluation of the standalone selling prices of each of the performance obligations and determined that the standalone selling price of the license performance obligation was $90.0 million. The Company recognized the transaction price allocated to the license performance obligation of $90.0 million as revenue during the quarter upon delivery of the license to the customer and resulting ability of the customer to use and benefit from the license. The remaining transaction price related to the performance obligation for the supply of certain clinical material is not significant. The potential milestone payments that the Company is eligible to receive were excluded from the transaction price, as all milestone amounts were fully constrained based on the probability of achievement. The Company

will reevaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and, if necessary, adjust its estimate of the transaction price. As of June 30, 2018, the Company received $71.6 million of the $90.0 million upfront license payment and had a receivable from collaborator on the balance sheet for the remaining $18.4 million.

7. Sale of Equity Securities

On November 17, 2017, the Company completed the sale of 4,058,822 shares of its common stock in an underwritten public offering at a price to the public of $85.00 per share, resulting in net proceeds of $325.8 million after deducting commissions and underwriting discounts and offering costs paid by the Company.

On February 13, 2018, the Company completed the sale of 4,032,012 shares of its common stock in an underwritten public offering at a price to the public of $164.00 per share, resulting in net proceeds of $631.2 million after deducting commissions and underwriting discounts and offering costs both paid and payable by the Company.

8. Stock-Based Compensation

Restricted Stock Units

During the six months ended June 30, 2017, the Company granted 32,500 restricted stock units to certain employees of the Company. The Company did not grant restricted stock units prior to January 1, 2017. These restricted stock units vest ratably over two years, with cliff vesting of 50% at both the one-year and two-year anniversary of the grant, which was in February 2018 and will be in February 2019, respectively.

During the three months ended March 31, 2018, the Company granted 33,600 performance restricted stock units to certain employees of the Company. These performance restricted stock units will vest upon the achievement of a certain regulatory milestone, in some cases upon meeting the milestone and, in other cases, on the first anniversary of meeting the milestone.

During the three months ended June 30, 2018, the Company granted 37,800 performance restricted stock units to certain employees of the Company. These performance restricted stock units will vest upon the achievement of a certain commercial milestone.

The fair value of restricted stock units that vested during the six months ended June 30, 2018 was $2.6 million. No restricted stock units vested during the six months ended June 30, 2017 and during the three months ended June 30, 2018.

The table below summarizes activity relating to restricted stock:

	Shares
Outstanding as of December 31, 2017	29,100
Granted	71,400
Vested	(14,550)
Forfeited	(900)
Outstanding as of June 30, 2018	85,050

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Stock Option Plans

On July 2, 2014, the stockholders of the Company approved the 2014 Stock Option and Incentive Plan (the "2014 Stock Option Plan"), which became effective immediately prior to the completion of the Company's IPO. The 2014 Stock Option Plan provides for the grant of restricted stock awards, restricted stock units, incentive stock options and non-statutory stock options. The 2014 Stock Option Plan replaced the Company's 2011 Stock Option and Grant Plan (the "2011 Stock Option Plan"). The Company no longer grants 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.

On December 15, 2016, the Board of Directors of the Company approved the 2016 Inducement Equity Plan (the "2016 Stock Option Plan"). The 2016 Stock Option Plan provides for the grant of equity awards to individuals who have not previously been an employee or a non-employee director of the Company to induce them to accept employment and to provide them with a proprietary interest in the Company.

As of June 30, 2018, the total number of shares reserved under all equity plans is 9,030,623, and 1,589,715 shares were available for future issuance under such plans.

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 outstanding shares of common stock as of the last day of the prior year. On January 1, 2018, 1,680,117 shares of common stock, representing 4% of the Company's outstanding shares of common stock as of December 31, 2017, were added to the 2014 Stock Option Plan.

During the three months ended March 31, 2018 and 2017, the Company granted 323,753 and 449,208 options, respectively, to employees to purchase shares of common stock that contain performance-based vesting criteria, primarily related to the achievement of certain clinical and regulatory development milestones related to 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, which consider the inherent risk and uncertainty regarding the future outcomes of the milestones.

During the three months ended June 30, 2018 and 2017, the Company granted 200,250 and no options, respectively, to employees to purchase shares of common stock that contain performance-based vesting criteria, related to the achievement of certain clinical development, regulatory development and commercial milestones related to 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, which consider the inherent risk and uncertainty regarding the future outcomes of the milestones.

During the three months ended June 30, 2018, a performance milestone was achieved under a stock option granted to a consultant. The milestone was related to the consummation of a licensing or corporate partnering arrangement. During the three months ended June 30, 2018, the Company recognized stock-based compensation expense related to this milestone of $6.9 million.

During the six months ended June 30, 2018 and 2017, the achievement of the milestones that had not been met that are the criteria for vesting of performance-based stock options was considered not probable, and therefore no expense has been recognized related to these awards for the six months ended June 30, 2018 and 2017.

Stock-based compensation expense for stock options, restricted stock units and the employee stock purchase plan recognized during the three and six months ended June 30, 2018 and 2017 was as follows:

	Three months ended June 30,		Six months ended June 30,	
	2018	2017	2018	2017
	(in thousands)			
Research and development	$12,095	$5,245	$20,994	$8,840
General and administrative	16,933	4,105	23,851	6,718
	$29,028	$9,350	$44,845	$15,558

Stock-based compensation expense by award type recognized during the three and six months ended June 30, 2018 and 2017 was as follows:

	Three months ended June 30,		Six months ended June 30,	
	2018	2017	2018	2017
	(in thousands)			
Stock options	$28,627	$9,119	$44,007	$15,152
Restricted stock units	155	167	324	267
Employee stock purchase plan	246	64	514	139
	$29,028	$9,350	$44,845	$15,558

The weighted average grant date fair value per share relating to outstanding stock options granted under the Company's stock option plans during the six months ended June 30, 2018 and 2017 was $114.72 and $39.62, respectively.

The table below summarizes activity related to stock options:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2017	5,586,593	$ 43.58	8.09	$ 676,717
Granted	2,313,844	171.26		
Exercised	(490,050)	36.37		
Forfeited	(54,529)	74.88		
Outstanding as of June 30, 2018	7,355,858	$ 83.99	8.26	$ 575,909
Exercisable as of June 30, 2018	2,439,246	$ 34.23	6.89	$ 298,310

At June 30, 2018, the Company had unrecognized stock-based compensation expense related to its unvested service-based stock option awards of $274.5 million, which is expected to be recognized over the remaining weighted average vesting period of 3.04 years. The intrinsic value of stock options exercised during the six months ended June 30, 2018 and 2017 was $64.4 million and $10.0 million, respectively.

At June 30, 2018, 1,148,686 performance-based stock options were both outstanding and unvested, and the total unrecognized stock-based compensation expense related to those awards was $58.8 million.

9. Net Loss Per Share

Basic and diluted net loss per share was calculated as follows for the three and six months ended June 30, 2018 and 2017:

	Three months ended June 30,		Six months ended June 30,	
	2018	2017	2018	2017
Basic net loss per share:				
Numerator:				
Net loss (in thousands)	$(16,978)	$(70,202)	$(91,576)	$(126,979)
Denominator:				
Weighted average common stock outstanding—basic	46,541,716	37,361,129	45,439,666	37,315,393
Dilutive effect of shares of common stock equivalents resulting from common stock options and restricted stock units	—	—	—	—
Weighted average common stock outstanding—diluted	46,541,716	37,361,129	45,439,666	37,315,393
Net loss per share—basic and diluted	$(0.36)	$(1.88)	$(2.02)	$(3.40)

The following common stock equivalents outstanding as of June 30, 2018 and 2017 were excluded from the computation of diluted net loss per share for the periods presented because including them would have been anti-dilutive:

	Three months ended June 30,		Six months ended June 30,	
	2018	2017	2018	2017
Stock options	6,207,172	5,313,821	6,207,172	5,313,821
Restricted stock units	13,950	30,400	13,950	30,400
Employee stock purchase plan	8,004	8,697	8,004	8,697
	6,229,126	5,352,918	6,229,126	5,352,918

Stock options and restricted stock units that are outstanding and contain performance-based vesting criteria for which the performance conditions have not been met are excluded from the calculation of common stock equivalents outstanding.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q, or Quarterly Report, and the audited financial statements and related notes contained in our Annual Report on Form 10-K for the year ended December 31, 2017, or Annual Report. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. 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 our business and the industry in which we operate, may differ materially from the results discussed or projected in the forward-looking statements contained in this Quarterly Report. We discuss risks and other factors that we believe could cause or contribute to these potential differences elsewhere in this report, including under Item 1A. "Risk Factors" and under "Cautionary Note Regarding Forward-Looking Statements" in this Quarterly Report. In addition, even if our results of operations, financial condition and liquidity, and the developments in our business and 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. 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 Securities and Exchange Commission, or 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 no approved therapies or existing therapies are inadequate. We have a portfolio of product candidates with a current focus on modulating two critical CNS receptor systems, GABA and NMDA. The GABA receptor family, which is recognized as the major inhibitory neurotransmitter in the CNS, mediates downstream neurologic and bodily function via activation of $GABA_A$ receptors. The NMDA-type receptors of the glutamate receptor system are a major excitatory receptor system in the CNS. Dysfunction in these systems is implicated in a broad range of CNS disorders. We are targeting CNS indications where patient populations are easily identified, clinical endpoints are well-defined, and development pathways are feasible.

The following table summarizes the status of our development programs as of the date of this Quarterly Report.

Our lead product candidate, brexanolone (USAN) for intravenous, or IV, use, is a proprietary formulation of allopregnanolone, a naturally occurring neuroactive steroid that acts as a positive allosteric modulator of $GABA_A$ receptors. We are developing brexanolone IV as a treatment for postpartum depression, or PPD. PPD is a common biological complication of childbirth, and is characterized by significant depressive symptoms that typically commence during the third trimester of pregnancy or in the months following childbirth. In November 2017, we announced positive results from two blinded, placebo-controlled Phase 3 clinical trials of brexanolone IV in PPD. We submitted a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, in April, 2018 seeking approval to market and sell brexanolone IV as a treatment for PPD in the U.S. The NDA is under review by the FDA. The FDA granted the NDA Priority Review status and assigned a Prescription Drug User Fee Act (PDUFA) target date of December 19, 2018. The FDA is currently planning to hold an advisory committee meeting on November 2, 2018 to discuss the brexanolone IV application, and has conditionally accepted the proprietary name ZULRESSO™ for our product. We have also received Breakthrough Therapy designation from the FDA in the U.S. and PRIority MEdicines, or PRIME, designation from the European Medicines Agency, or EMA, in the European Union, or EU, for brexanolone IV as a potential treatment for PPD. We expect to receive scientific advice from the EMA in the second half of 2018 regarding the potential regulatory pathway for a marketing authorization application, or MAA, filing in the EU. We continue to prepare for a potential commercial launch of brexanolone IV for the treatment of PPD in the U.S. in the first half of 2019, if our NDA is approved.

Our most advanced next-generation product candidate is SAGE-217, a novel neuroactive steroid that, like brexanolone, is a positive allosteric modulator of $GABA_A$ receptors, targeting both synaptic and extrasynaptic $GABA_A$ receptors. We are currently developing SAGE-217 as a potential treatment for major depressive disorder, or MDD, PPD, bipolar depression, and sleep disorders. The FDA has granted SAGE-217 breakthrough therapy designation in the treatment of MDD. In June 2018, we announced our expedited development plan for SAGE-217 in depression following a breakthrough therapy meeting with the FDA. This development plan is intended, if successful, to support a potential filing for approval of SAGE-217 in the U.S. for the episodic treatment of MDD and in the treatment of PPD. The planned expedited development program for SAGE-217 includes one additional placebo-controlled Phase 3 clinical trial in patients with MDD in which we plan to study two weeks of 20mg or 30mg SAGE-217 treatment compared to placebo in 450 patients with MDD, with four weeks of additional follow-up. The program also includes the ongoing placebo-controlled clinical trial in PPD, now designated a pivotal trial, in which we expect to enroll 140 women with PPD. The

planned expedited development program for SAGE-217 in MDD and PPD also includes an open-label study in which approximately 300 patients with MDD treated with SAGE-217 will be followed for six months and 100 patients would be followed for a year after initial treatment and episodic retreatment as needed, to evaluate the potential of episodic treatment for recurrent or new major depressive episodes and provide additional safety data. We plan to initiate the placebo-controlled Phase 3 clinical trial of SAGE-217 in MDD and to announce top-line data from the placebo-controlled pivotal trial of SAGE-217 in PPD during the fourth quarter of 2018. As part of the SAGE-217 mood disorder program, we also plan to initiate in the fourth quarter of 2018 a Phase 2 open-label trial evaluating four weeks of SAGE-217 treatment in up to 30 patients with bipolar I/II disorder with a current major depressive episode. The trial is intended to evaluate the safety and tolerability of SAGE-217 as the primary endpoint and to study secondary endpoints, including efficacy in improving depressive symptoms and sleep. If the results of the trial are positive and warrant moving forward, we then plan to conduct a randomized, placebo-controlled trial in this indication.

In addition to our mood disorder program, we also plan to study SAGE-217 in the treatment of sleep disorders. We plan to initiate a placebo-controlled polysomnography trial of SAGE-217 in patients with MDD who have co-morbid insomnia in the fourth quarter of 2018, and also plan to seek feedback from the FDA in the second half of 2018 on a potential development plan for SAGE-217 in the treatment of sleep disorders. We may also explore the development of SAGE-217 in other indications. In addition to SAGE-217, we have a portfolio of other novel compounds that target $GABA_A$ receptors, including SAGE-324 and SAGE-689, which are at earlier stages of development with a focus on both acute and chronic CNS disorders.

Our second area of focus is the development of novel compounds that target the NMDA receptor. The first product candidate selected for development from this program is SAGE-718, an oxysterol-based positive allosteric modulator of the NMDA receptor. Our initial areas of focus for development of SAGE-718 will be indications involving NMDA receptor hypofunction. Examples of these potential areas for future evaluation include certain types, aspects or subpopulations of a number of diseases such as depression, Alzheimer’s disease, attention deficit hyperactivity disorder, schizophrenia, Huntington’s disease, and neuropathic pain. We completed a Phase 1 single ascending dose trial of SAGE-718 in 2017. A Phase 1 multiple ascending dose trial is ongoing.

We expect to continue our focus on allosteric modulation of the $GABA_A$ and NMDA receptor systems in the brain. The $GABA_A$ and NMDA receptor systems are broadly accepted as impacting many psychiatric and neurological disorders, spanning disorders of mood, seizure, cognition, anxiety, sleep, pain, and movement, among others. We believe that we may have the opportunity to develop molecules from our internal portfolio with the goal of addressing a number of these disorders in the future. Our ability to identify and develop such novel CNS therapies is enabled by our proprietary chemistry platform that is centered, as a starting point, on knowledge of the chemical scaffolds of certain endogenous neuroactive steroids. We believe our knowledge of the chemistry and activity of allosteric modulators allows us to efficiently design molecules with different characteristics. This diversity enables us to regulate important properties such as half-life, brain penetration and receptor pharmacology to develop product candidates that may have the potential for better selectivity, increased tolerability, and fewer off-target side effects than either current CNS therapies or previous therapies which have failed in development.

We have not generated any revenue to date from the sale of products. All of our revenue to date has been derived from a strategic collaboration we entered into in the second quarter of 2018 with Shionogi & Co., Ltd., or Shionogi, for the clinical development and commercialization of SAGE-217 in Japan, Taiwan and South Korea. We have incurred net losses in each year since our inception, and we have an accumulated deficit of $682.0 million as of June 30, 2018. Our net losses were $91.6 million for the six months ended June 30, 2018 and $270.1 million for the year ended December 31, 2017. 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 regulatory activities focused on the review process with respect to the NDA we submitted to the FDA seeking approval of brexanolone IV in PPD in the U.S.;
- continue preparations for a potential future commercial launch of brexanolone IV in PPD in the U.S., if approved;
- complete the ongoing clinical trial of SAGE-217 in PPD, and advance SAGE-217 further in development in MDD, bipolar depression, and sleep disorders;
- continue to advance SAGE-718, our early-stage novel allosteric modulator for NMDA, including continuing the ongoing Phase 1 clinical program;
- continue Phase 1 clinical studies of SAGE-324 with potential future focus on epileptiform disorders, Parkinson's disease, essential tremor and other indications involving GABA hypofunction;
- continue our research and development efforts to evaluate the potential for our product candidates in the treatment of additional indications or in new formulations, and to identify new drug candidates in the treatment of CNS disorders;
- continue regulatory and other activities focused on potential pathways for advancing our lead product candidates in the EU, subject to feedback from the EMA, including obtaining scientific advice on the potential regulatory pathway for an MAA filing as part of planned discussions with the EMA regarding brexanolone IV;
- seek regulatory approvals for any product candidates that successfully complete clinical development;
- complete validation work and other supply chain activities related to brexanolone IV to be ready for commercial supply if our NDA is approved; refine and scale-up the manufacturing process for SAGE-217 for planned late stage clinical trials; improve the manufacturing process for our other product candidates; and manufacture clinical supplies as development progresses;
- add personnel, including personnel to support our product development and future commercialization efforts and potential expansion of EU activities, and incur increases in stock-based compensation expense related to existing and new personnel with respect to both service-based and performance-based awards;
- evaluate market opportunities for our product candidates, including brexanolone IV in PPD, in other global markets;
- add operational, financial and management information systems; and
- maintain, leverage and expand our intellectual property portfolio.

As a result, we will need additional financing in the future 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 equity or debt financings or other sources, which may include collaborations with third parties. We may never successfully complete development of any of our product candidates; obtain adequate patent protection or other exclusivity for our product candidates; obtain necessary regulatory approval for our product candidates; or achieve commercial viability for any approved product. 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 on our ability to pursue our business strategy. Arrangements with collaborators or others may require us to relinquish

rights to certain of our technologies or product candidates. We will need to generate significant revenue to achieve profitability, and we may never do so.

We expect that our existing cash, cash equivalents and marketable securities as of June 30, 2018 will enable us to fund our operating expenses and capital expenditure requirements, based on our current operating plan, into 2020. See "—Liquidity and Capital Resources".

Financial Operations Overview

Revenue

We have not generated any revenue from product sales since our inception. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we successfully develop, obtain regulatory approval of and commercialize one of our current or future product candidates. All of our revenue to date has been derived from our collaboration with Shionogi. If we enter into additional collaboration agreements with third parties for our product candidates, we may generate revenue from those product candidates. We expect that revenue, if any, we generate under collaboration agreements will fluctuate from quarter to quarter as a result of the timing and amount of license fees, research and development services and related reimbursements, payments for clinical materials or manufacturing services, and milestone and other payments.

Operating Expenses

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

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, benefits, stock-based compensation and travel expenses, for employees engaged in research and development functions;
- expenses incurred under agreements with contract research organizations, or CROs, and sites that conduct our non-clinical studies and clinical trials;
- expenses associated with manufacturing materials for use in clinical trials and developing external manufacturing capabilities;
- costs of outside consultants engaged in research and development activities, including their fees, stock-based compensation and 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 license 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 our product candidates and focusing on other research and development programs, including exploratory efforts to identify new compounds, target validation for identified compounds 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; and fees paid to outside consultants who perform work on our programs. 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.

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 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, if approved for marketing and sale. 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 clinical trials, non-clinical studies, 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 receipt and timing of 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 for regulatory approval, or if we experience significant delays in enrollment in any of our clinical trials or need to enroll additional patients, 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, including salaries, benefits, stock-based compensation and travel expenses for our executive, finance, business, commercial, corporate development and other administrative functions. General and administrative expenses also include expenses incurred under agreements with third parties relating to evaluation, planning and preparation for a potential commercial launch; facilities and other related 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, including payroll and related expenses, will increase in the future as we continue to increase our headcount to support the expected growth in our business, expand our operations and organizational capabilities and prepare for the potential commercialization of brexanolone IV, if approved, and our other product candidates, if successfully developed. We also anticipate increased expenses associated with general operations, including costs related to audit, tax and legal services, director and officer insurance premiums, and investor relations costs.

Results of Operations

Comparison of the Three Months Ended June 30, 2018 and 2017

The following table summarizes our results of operations for the three months ended June 30, 2018 and 2017:

	Three Months Ended		
	June 30, 2018	2017	Increase (Decrease)
	(in thousands)		
Collaboration revenue	$90,000	$-	$ 90,000
Operating expenses:			
Research and development	68,980	55,900	13,080
General and administrative	43,167	14,954	28,213
Total operating expenses	112,147		