Sage Therapeutics, Inc.
Form 10-Q
May 02, 2019

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 March 31, 2019

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 every Interactive Data File required to be submitted 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 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	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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	SAGE	The Nasdaq Global Market

As of April 25, 2019, there were 51,147,698 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 expectations as to the timing of anticipated commercial launch of our lead product, ZULRESSO™ (brexanolone) injection, in the U.S. as a treatment for postpartum depression, or PPD, including our expectations as to the timing of completion of controlled substance scheduling of brexanolone by the U.S. Drug Enforcement Administration and incorporation of the scheduling into our labeling and other product information approved by the U.S. Food and Drug Administration, or FDA;
- our views as to our readiness for commercial launch of ZULRESSO in the U.S. as a treatment for PPD, including our plans with respect to the focus and activities of our field force, the nature of our planned marketing, market access and patient support activities, and our expected pricing of ZULRESSO and related assumptions;
- our views as to potential future results of our commercialization efforts in the U.S. with respect to ZULRESSO, including our expectations with respect to: availability of sites of care for administration of ZULRESSO willing to be certified under the Risk Evaluation and Mitigation Strategy (REMS) program to which ZULRESSO is subject; the scope, level and availability of reimbursement and the nature of any limitations imposed by payors; and the level of market acceptance of ZULRESSO as a treatment for PPD by healthcare settings, prescribers and women suffering from PPD.
- our expectations as to the sufficiency of our planned development program for SAGE-217 in major depressive disorder and PPD, if successful, to support filing of a New Drug Application, or NDA, with the FDA; our statements regarding the potential for approval of SAGE-217 in such indications in the U.S.; and our view of the potential product profile, market impact, market size and opportunity for SAGE-217, if successfully developed and approved.
- our plans to develop and commercialize our other product candidates in the central nervous system, or CNS, disorders we discuss in this Quarterly Report, and potentially in other indications and our view of the potential product profile and treatment paradigm impact for such product candidates, if successfully developed and 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 plans and potential outcomes with respect to other research and development activities and our business development efforts;
- our plans and expectations with respect to the potential development of any product or product candidate for markets outside the U.S.;
- our estimates regarding expenses, use of cash and projected cash on hand at any given timepoint, 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 ZULRESSO and 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 with diseases or disorders of interest to us; the size of the potential market for ZULRESSO in PPD and for our product candidates in the indications we are studying or plan to study; the potential for ZULRESSO and current or future product candidates, if successfully developed and approved, in the markets for which they are 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 PPD or any of the indications that we are pursuing or may pursue in the future with our product candidates;
- 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 business and 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)

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$342,295	$190,943
Marketable securities	1,008,956	731,833
Prepaid expenses and other current assets	20,281	21,919
Total current assets	1,371,532	944,695
Property and equipment, net	6,513	5,643
Restricted cash	2,367	2,367
Right of use operating asset	38,124	—
Other long-term assets	4,378	—
Total assets	$1,422,914	$952,705
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$13,556	$34,036
Accrued expenses	47,651	51,994
Other current liabilities	7,169	—
Total current liabilities	68,376	86,030
Long-term lease operating liability, net of current portion	34,528	—
Other long-term liabilities	476	3,704
Total liabilities	103,380	89,734
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, $0.0001 par value per share; 5,000,000 shares authorized at March 31, 2019 and December 31, 2018; no shares issued or outstanding at March 31, 2019 and December 31, 2018	—	—
Common stock, $0.0001 par value per share; 120,000,000 shares authorized at March 31, 2019 and December 31, 2018; 51,037,205 and 46,891,296 shares issued at March 31, 2019 and December 31, 2018; 51,034,172 and	5	5

46,888,263 shares outstanding at March 31, 2019 and December 31, 2018		
Treasury stock, at cost, 3,033 shares at March 31, 2019 and December 31, 2018	(400)	(211)
Additional paid-in capital	2,446,770	1,827,021
Accumulated deficit	(1,126,735)	(963,329)
Accumulated other comprehensive loss	(106)	(515)
Total stockholders' equity	1,319,534	862,971
Total liabilities and stockholders' equity	$1,422,914	$952,705

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 March 31,	
	2019	2018
Collaboration revenue	$465	$—
Operating expenses:		
Research and development	86,398	49,270
General and administrative	83,919	28,849
Total operating expenses	170,317	78,119
Loss from operations	(169,852)	(78,119)
Interest income, net	6,442	3,529
Other income (expense), net	4	(8)
Net loss	$(163,406)	$(74,598)
Net loss per share—basic and diluted	$(3.37)	$(1.68)
Weighted average number of common shares outstanding—basic and diluted	48,491,834	44,325,371
Comprehensive loss:		
Net loss	$(163,406)	$(74,598)
Other comprehensive items:		
Unrealized gain (loss) on marketable securities	409	(156)
Total other comprehensive gain (loss)	409	(156)
Total comprehensive loss	$(162,997)	$(74,754)

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)

	Three Months Ended March 31,	
	2019	2018
Cash flows from operating activities		
Net loss	$(163,406)	$(74,598)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	44,116	15,817
Premium on marketable securities	(739)	(4)
Amortization of discount on marketable securities	(2,322)	(1,348)
Depreciation	415	247
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,637	(5,348)
Other long-term assets	(1,378)	—
Right of use operating asset	2,942	—
Operating lease liabilities	(2,500)	—
Accounts payable	(20,507)	(877)
Accrued expenses and other liabilities	(8,192)	(12,460)
Net cash used in operating activities	(149,934)	(78,571)
Cash flows from investing activities		
Proceeds from sales and maturities of marketable securities	307,263	81,960
Purchases of marketable securities	(580,916)	(394,109)
Purchases of property and equipment	(1,257)	(652)
Net cash used in investing activities	(274,910)	(312,801)
Cash flows from financing activities		
Proceeds from stock option exercises and employee stock purchase plan issuances	15,681	12,757
Payment of employee tax obligations related to vesting of restricted stock units	(692)	(904)
Payments of offering costs	(70)	(235)
Proceeds from public offerings of common stock, net of commissions and underwriting discounts	561,277	631,494
Net cash provided by financing activities	576,196	643,112
Net increase in cash, cash equivalents and restricted cash	151,352	251,740
Cash, cash equivalents and restricted cash at beginning of period	193,310	307,084

Cash, cash equivalents and restricted cash at end of period	$344,662	$558,824
Supplemental disclosure of non-cash investing and financing activities		
Purchases of property and equipment included in accounts payable	$78	$15
Public offering costs included in accrued expenses	$259	$105

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

Sage Therapeutics, Inc. and Subsidiaries

Consolidated Statements of Changes in Stockholders' Equity

(in thousands, except share data)

(Unaudited)

	Common Stock		Treasury Stock		Additional Paid-in	Accumulated Other Comprehensive Income	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	(Loss)	Deficit	Equity
Balances at December 31, 2017	42,002,934	$ 5	960	$ (113)	$ 1,066,059	$ (29)	$ (590,447)	$ 475,475
Issuance of common stock from exercise of stock options	402,227	—	—	—	11,728	—	—	11,728
Issuance of common stock under employee stock purchase plan	11,683	—	—	—	1,127	—	—	1,127
Purchase of treasury stock	—	—	554	(98)	—	—	—	(98)
Stock-based compensation expense	—	—	—	—	15,549	—	—	15,549
Public offering of common stock, net of offering costs	4,032,012	—	—	—	631,153	—	—	631,153
Unrealized loss on available-for-sale securities	—	—	—	—	—	(156)	—	(156)
Vesting of restricted stock units, net of employee tax obligations	9,442	—	—	—	(904)	—	—	(904)
Net loss	—	—	—	—	—	—	(74,598)	(74,598)
Balances at March 31, 2018	46,458,298	$ 5	1,514	$ (211)	$ 1,724,712	$ (185)	$ (665,045)	$ 1,059,276
Balances at December 31, 2018	46,888,263	$ 5	3,033	$ (211)	$ 1,827,021	$ (515)	$ (963,329)	$ 862,971
	287,659	—	—	—	14,072	—	—	14,072

Issuance of common stock from exercise of stock options								
Issuance of common stock under employee stock purchase plan	16,398	—	—	—	1,799	—	—	1,799
Purchase of treasury stock	—	—	—	(189)	—	—	—	(189)
Stock-based compensation expense	—	—	—	—	43,622	—	—	43,622
Public offering of common stock, net of offering costs	3,833,334	—	—	—	560,948	—	—	560,948
Unrealized gain on available-for-sale securities	—	—	—	—	—	409	—	409
Vesting of restricted stock units, net of employee tax obligations	8,518	—	—	—	(692)	—	—	(692)
Net loss	—	—	—	—	—	—	(163,406)	(163,406)
Balances at March 31, 2019	51,034,172	$ 5	3,033	$ (400)	$ 2,446,770	$ (106)	$ (1,126,735)	$ 1,319,534

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 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's lead product, ZULRESSO™ (brexanolone) injection, was approved by the U.S. Food and Drug Administration ("FDA") in March 2019, for the treatment of postpartum depression ("PPD") in adults. The Company expects to make ZULRESSO commercially available in the U.S. in late June 2019, after completion of controlled substance scheduling of brexanolone by the U.S. Drug Enforcement Administration ("DEA") and incorporation of the scheduling into the Company's FDA-approved label and other product information. The Company has a portfolio of other 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 and pharmaceutical industries, 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 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 ("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 March 31, 2019, the Company had an accumulated deficit of $1.1 billion. From its inception through March 31, 2019, the Company received net proceeds of $2.2 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, February 2018, and February 2019. 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. At some point after that time, the Company will require additional financing to fund its future operations.

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, 2018, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

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 March 31, 2019, its results of operations and comprehensive loss for the three months ended March 31, 2019 and 2018, and its cash flows for the three months ended March 31, 2019 and 2018. The consolidated balance sheet at December 31, 2018 was derived from audited financial statements, but does not include all disclosures required by GAAP. The results for the three months ended March 31, 2019 are not necessarily indicative of the results for the year ending December 31, 2019, 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, 2018. 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 U.S. 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.

Effective January 1, 2019, the Company recognizes compensation expense for stock-based awards, including grants of stock options and restricted stock, made to non-employee consultants based on the estimated fair value on the date of grant, over the requisite service period. Through December 31, 2018, the Company recognized compensation expense for stock-based awards granted to non-employee consultants based on the fair value of the awards on each date on which the awards vest. Compensation expense was recognized over the vesting period, provided that services were rendered by such non-employee consultants during that time. At the end of each financial reporting period, the fair value of unvested options was re-measured using the then-current fair value of the common stock of the Company and updated assumptions in the Black-Scholes option-pricing model.

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 options granted to employees and non-employee directors by the Company has been determined utilizing the “simplified” method for awards that qualify as “plain-vanilla” options. Through December 31, 2018, the expected term of its options granted to non-employee consultants has been determined based on the contractual term of the options, and effective January 1, 2019, the “simplified” method is used. 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 90 days or less at the date of purchase to be cash equivalents. As of March 31, 2019 and December 31, 2018, cash equivalents were comprised of cash equivalents and money market funds.

Marketable securities

Marketable securities consist of investments with original maturities greater than 90 days. The Company has classified its investments with maturities beyond one year as short-term, based on their highly liquid nature and because such marketable securities represent the investment of cash that is available for current operations. 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. No declines in value were deemed to be other than temporary during the three months ended March 31, 2019 and 2018.

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 March 31, 2019 and December 31, 2018 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 March 31, 2019 and December 31, 2018, 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, when the Company recorded its initial revenue under Topic 606, 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.

Intangible assets

The Company had no intangible assets as of December 31, 2018. As a result of the approval by the FDA of the New Drug Application for ZULRESSO in March 2019, the Company was required to pay to CyDex Pharmaceuticals, Inc. ("CyDex") and The Regents of the University of California milestone payments of $3.0 million and $0.5 million, respectively. At March 31, 2019, the amount of these milestones were capitalized as an intangible asset, and no amounts had been amortized.

Leases

The Company determines if an arrangement is a lease at contract inception. Operating lease assets represent the Company's right to use an underlying asset for the lease term and operating lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease assets and liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. When determining the lease term, the Company includes options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. The Company uses the implicit interest rate when readily determinable and uses the Company's incremental borrowing rate when the implicit rate is not readily determinable based upon the information available at the commencement date in determining the present value of the lease payments.

The lease payments used to determine the Company's operating lease assets may include lease incentives, stated rent increases and escalation clauses linked to rates of inflation when determinable and are recognized in the Company's operating lease assets in the Company's condensed consolidated balance sheets. In addition, the Company's contracts contain lease and non-lease components. The Company combines lease and non-lease components, which are accounted for together as lease components.

The Company's operating leases are reflected in right of use operating asset, other current liabilities and long-term lease operating liability, net of current portion in the Company's condensed consolidated balance sheets. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. Short-term leases, defined as leases that have a lease term of 12 months or less at the commencement date, are excluded from this treatment and are recognized on a straight-line basis over the term of the lease.

Recently Issued Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-02, Leases, which replaced the existing guidance in ASC 840, "Leases", and in July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842): Targeted Improvements. The new leasing standards generally require lessees to recognize operating and financing lease liabilities and corresponding right-of-use assets on the consolidated balance sheet and to provide enhanced disclosures surrounding the amount, timing and uncertainty of cash flows arising from leasing arrangements. The Company adopted the standards on the required effective date of January 1, 2019 and did not restate comparative periods. Presentation of leases within the consolidated statements of operations and consolidated statements of cash flows is generally consistent with the former lease accounting guidance. The Company elected the package of practical expedients permitted under the transition guidance and as such, the adoption of this ASU did not change the classification of any of the Company's leases. The Company elected to combine lease and non-lease components, elected not to record leases with an initial term of 12 months or less on the balance sheet and will recognize the associated lease payments in the consolidated statements of operations on a straight-line basis over the lease term. On the implementation date, $44.2 million was recognized as total lease liabilities and $41.1 million was recognized as total right-of-use assets on the Company's consolidated balance sheet.

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 adopted the standard on the required effective date of January 1, 2019. 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 Company

adopted the standard on the required effective date of January 1, 2019. This guidance did not have a significant impact on the Company's consolidated financial statements and related disclosures.

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 March 31, 2019 and December 31, 2018.

	March 31, 2019			
	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	$342,295	$342,295	$—	$ —
Total cash equivalents	342,295	342,295	—	—
Marketable securities:				
U.S. government securities	248,155	—	248,155	—
U.S. corporate bonds	386,263	—	386,263	—
International corporate bonds	155,517	—	155,517	—
U.S. commercial paper	108,439	—	108,439	—
International commercial paper	110,582	—	110,582	—
Total marketable securities	1,008,956	—	1,008,956	—
	$1,351,251	$342,295	$1,008,956	$ —

	December 31, 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	$190,943	$190,943	$—	$—
Total cash equivalents	190,943	190,943	—	—
Marketable securities:				
U.S. government securities	220,482	—	220,482	—
U.S. corporate bonds	258,566	—	258,566	—
International corporate bonds	78,468	—	78,468	—
U.S. commercial paper	77,611	—	77,611	—
International commercial paper	96,706	—	96,706	—
Total marketable securities	731,833	—	731,833	—
	$922,776	$190,943	$731,833	$—

During the three months ended March 31, 2019 and 2018, there were no transfers among the Level 1, Level 2 and Level 3 categories.

The following tables summarize the gross unrealized gains and losses of the Company's marketable securities as of March 31, 2019 and December 31, 2018:

	March 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
Assets:				
U.S. government securities	$248,082	$ 86	$ (13)	$248,155
U.S. corporate bonds	386,333	119	(189)	386,263
International corporate bonds	155,571	42	(96)	155,517
U.S. commercial paper	108,487	5	(53)	108,439
International commercial paper	110,589	—	(7)	110,582
	$1,009,062	$ 252	$ (358)	$1,008,956

December 31, 2018

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
Assets:				
U.S. government securities	$220,531	$ 8	$ (57)	$220,482
U.S. corporate bonds	258,876	6	(316)	258,566
International corporate bonds	78,600	—	(132)	78,468
U.S. commercial paper	77,630	8	(27)	77,611
International commercial paper	96,711	8	(13)	96,706
	$732,348	$ 30	$ (545)	$731,833

As of March 31, 2019, all marketable securities, except for 58 bonds with a fair value of $166.2 million that have maturities of between one and two years, held by the Company had remaining contractual maturities of one year or less. As of December 31, 2018, all marketable securities, except for two U.S. corporate bonds, 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 three months ended March 31, 2019 and the year ended December 31, 2018.

4. Balance Sheet Components

Property and Equipment, net

Property and equipment, net, consists of the following:

	March 31, 2019	December 31, 2018
	(in thousands)	
Computer hardware and software	$2,286	$ 2,148
Furniture and equipment	1,125	1,002
Leasehold improvements	5,733	4,709
	9,144	7,859
Less: Accumulated depreciation	(2,631)	(2,216)
	$6,513	$ 5,643

Depreciation expense for the three months ended March 31, 2019 and 2018 was $0.4 million and $0.2 million, respectively.

The useful life for computer hardware and software is three years, furniture and equipment is five 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:

	March 31, 2019	December 31, 2018
	(in thousands)	
Development costs	$23,932	$ 21,216

Employee-related expenses	8,676	19,638
Professional services	11,746	10,903
Other accrued expenses	3,297	237
	$47,651	$ 51,994

5. Leases, Commitments and Contingencies

Operating Leases

The Company has leases for office space, vehicles, and certain equipment. All of the leases recorded on the balance sheet are operating leases. The Company's leases have remaining lease terms ranging from less than one year to approximately six years. Some of the leases include options to extend the leases for up to five years and these options were not included for the purpose of determining the right-of-use assets and associated lease liabilities as the Company determined that the renewal of these leases is not reasonably certain so only the original lease term was taken into consideration. The leases do not include any restrictions or covenants that had to be accounted for under the lease guidance.

The Company leases office space in two multi-tenant buildings in Cambridge, Massachusetts, consisting, as of March 31, 2019, of 58,442 square feet in the first building under an operating lease that will expire on August 31, 2024 and 19,805 square feet in the second building under an operating lease that will expire on August 31, 2024.

In April 2018, the Company entered into the First Amendment to the lease for office space in the second multi-tenant building and thereby 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 that began on August 1, 2018, and (ii) 7,133 square feet that began on October 1, 2018. The term for this additional space will expire on August 31, 2024. Additionally, the term of the existing lease was 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 began on September 1, 2018. The term for this space will expire on November 30, 2024.

In October 2018, the Company entered into the Seventh Amendment to the lease for office space in the first building and thereby increased the amount of square feet of office space from 54,943 square feet to 58,442 square feet. The increase of 3,499 square feet began on December 1, 2018. The term for this additional space will expire on August 31, 2024.

In December 2018, the Company entered into a lease in a third multi-tenant building in Cambridge, Massachusetts, for 15,975 square feet of office space which will begin on March 1, 2019. The term for this lease will expire on February 28, 2024.

The following table summarizes the presentation in the Company's condensed consolidated balance sheets of operating leases:

(In thousands)	Balance sheet location	As of March 31, 2019
Assets		
Right of use operating asset	Right of use operating asset	$ 38,124
Liabilities		
Current operating lease liabilities	Other current liabilities	7,149
Long-term operating lease liabilities	Long-term lease operating liability, net of current portion	34,528
Total operating lease liabilities		$ 41,677

The following table summarizes the effect of lease costs in the Company's condensed consolidated statements of operations:

(In thousands)	For the Three Months Ended March 31, 2019
Operating lease cost	$ 2,444

The Company made an accounting policy election not to apply the recognition requirements to short-term leases. The Company recognizes the lease payments for short-term leases in profit or loss on a straight-line basis over the lease term, and variable lease payments in the period in which the obligation for those payments is incurred. For the three months ended March 31, 2019, the Company recorded $0.2 million of expense for its short-term leases.

The minimum lease payments are expected to be as follows:

Years Ending December 31,	(in thousands)
2019 (remaining nine months)	$ 7,513
2020	10,101
2021	9,812
2022	8,694
2023	8,894
Thereafter	