Akebia Therapeutics, Inc.
Form 10-Q
May 05, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2016

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 001-36352

AKEBIA THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation or Organization)	20-8756903 (I.R.S. Employer Identification No.)
245 First Street, Suite 1100, Cambridge, MA (Address of Principal Executive Offices)	02142 (Zip Code)

(617) 871-2098

(Registrant's Telephone Number, Including Area Code)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site if any, every Interactive Date File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨	Smaller reporting company ¨

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding at April 30, 2016
Common Stock, $0.00001 par value	37,976,705

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that are being made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, or PSLRA, with the intention of obtaining the benefits of the "safe harbor" provisions of the PSLRA. Forward-looking statements involve risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "target," "will," "would," or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the projected timing of (1) commencement of the INNO$_2$VATE clinical program, our Phase 3 development program in dialysis patients with anemia related to chronic kidney disease (CKD), (2) submission of an NDA for vadadustat, and (3) commencement of Phase 1 clinical studies of AKB-6899;
- our enrollment plans for the PRO$_2$TECT and INNO$_2$VATE clinical programs;
- our plans to seek a geographic collaboration for the development and commercialization of vadadustat outside the United States;
- our development plans with respect to vadadustat and AKB-6899;
- the timing or likelihood of regulatory filings and approvals, including any required post-marketing testing or any labeling and other restrictions;
- our plans to commercialize vadadustat, if it is approved;
- the implementation of our business model and strategic plans for our business, product candidates and technology;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our competitive position;
- our intellectual property position;
- developments and projections relating to our competitors and our industry;
- our estimates regarding expenses (including those associated with the PRO$_2$TECT and INNO$_2$VATE clinical programs), future revenue, capital requirements and needs for additional financing; and
- other risks and uncertainties, including those listed under Part II, Item 1A. Risk Factors.

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

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

NOTE REGARDING STOCK SPLIT

Unless otherwise indicated, all information in these condensed consolidated financial statements gives retrospective effect to the 1.75-for-1 stock split of the Company's common stock (the Stock Split) that was effected on March 6, 2014, as well as any other stock-splits in historical periods.

Akebia Therapeutics, Inc.

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PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

AKEBIA THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets

(Unaudited)

(in thousands, except share and per share data)

	March 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$43,439	$49,778
Available for sale securities	173,586	88,676
Prepaid expenses and other current assets	2,505	2,563
Total current assets	219,530	141,017
Property and equipment, net	629	540
Deferred offering costs	—	102
Other assets	1,281	1,281
Total assets	$221,440	$142,940
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$2,415	$2,313
Accrued expenses	10,994	9,555
Total current liabilities	13,409	11,868
Deferred rent, net of current portion	257	69
Deferred revenue, net of current portion	40,000	—
Other non-current liabilities	12	5
Total liabilities	53,678	11,942
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock $0.00001 par value, 25,000,000 shares authorized at March 31, 2016 and December 31, 2015; 0 shares issued and outstanding at March 31, 2016 and December 31, 2015	—	—
Common stock: $0.00001 par value; 175,000,000 shares authorized at March 31, 2016 and December 31, 2015; 37,946,010 and 30,662,218 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	—	—
Additional paid-in capital	355,138	292,783

Treasury stock, at cost, 8,463 shares	(162)	(162)
Accumulated other comprehensive loss	(27)	(234)
Accumulated deficit	(187,187)	(161,389)
Total stockholders' equity	167,762	130,998
Total liabilities and stockholders' equity	$221,440	$142,940

See accompanying notes to unaudited condensed consolidated financial statements.

AKEBIA THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(in thousands, except share and per share data)

	Three months ended	
	March 31, 2016	March 31, 2015
Operating expenses:		
Research and development	$20,235	$6,664
General and administrative	5,811	4,232
Total operating expenses	26,046	10,896
Operating loss	(26,046)	(10,896)
Other income (expense):		
Interest income (expense), net	234	96
Other income	14	105
Net loss	$(25,798)	$(10,695)
Net loss per share applicable to common stockholders—basic and diluted	$(0.70)	$(0.53)
Weighted-average number of common shares used in net loss per share applicable to common stockholders—basic and diluted	36,873,594	20,030,129
Comprehensive loss:		
Net loss	$(25,798)	$(10,695)
Other comprehensive loss - unrealized loss on securities	(26)	(8)
Comprehensive loss	$(25,824)	$(10,703)

See accompanying notes to unaudited condensed consolidated financial statements.

AKEBIA THERAPEUTICS, INC.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(in thousands)

	Three months ended	
	March 31, 2016	March 31, 2015
Operating activities:		
Net loss	$(25,798)	$(10,695)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	32	19
Amortization of premium/discount on investments	144	135
Stock-based compensation expense	1,251	1,128
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	58	(801)
Accounts payable	102	2,308
Accrued expenses	1,457	(411)
Deferred revenue	40,000	—
Other liabilities	188	(30)
Net cash provided by (used in) operating activities	17,434	(8,347)
Investing activities:		
Purchase of equipment	(109)	(200)
Proceeds from maturities of available for sale securities	15,314	9,585
Purchases of available for sale securities	(100,160)	(5,980)
Net cash (used in) provided by investing activities	(84,955)	3,405
Financing activities:		
Proceeds from the issuance of common stock, net of issuance costs	61,166	—
Proceeds from sale of stock under employee stock purchase plan	—	50
Proceeds from the exercise of stock options	19	—
Payments on capital lease obligations	(3)	(1)
Net cash provided by financing activities	61,182	49
Decrease in cash and cash equivalents	(6,339)	(4,893)
Cash and cash equivalents at beginning of period	49,778	32,780
Cash and cash equivalents at end of period	$43,439	$27,887
Non-cash financing activities:		
Unpaid follow-on offering costs	$20	$55
Assets acquired under capital lease	$-	$12

See accompanying notes to unaudited condensed consolidated financial statements

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Akebia Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

March 31, 2016

1. Nature of Organization and Operations

Incorporated in Delaware in 2007, Akebia Therapeutics, Inc. (Akebia, or the Company) is a biopharmaceutical company focused on the development of novel proprietary therapeutics based on hypoxia inducible factor, or HIF, biology and the commercialization of these products for patients with serious unmet medical needs. HIF is the primary regulator of the production of red blood cells, or RBCs, in the body and a potentially novel mechanism for the treatment of anemia secondary to chronic kidney disease, or CKD. Pharmacologic modulation of the HIF pathway may also have broader therapeutic applications in acute renal failure, organ protection, ischemia-reperfusion injury, cancer, ophthalmology, and inflammatory diseases. The Company's lead product candidate, vadadustat, formerly known as AKB-6548, is being developed as a once-daily, oral therapy for the anemia of chronic kidney disease. We have successfully completed Phase 2 development demonstrating that vadadustat can safely and predictably raise hemoglobin levels in patients with anemia related to CKD.

The Company's operations to date have been limited to organizing and staffing the Company, business planning, raising capital, acquiring and developing its technology, identifying potential product candidates and undertaking preclinical and clinical studies. The Company has not generated any product revenue to date, nor is there any assurance of any future product revenue. The Company's product candidates are subject to long development cycles and there is no assurance the Company will be able to successfully develop, obtain regulatory approval for or market its product candidates.

The Company is subject to a number of risks including, but not limited to, the need to obtain adequate additional funding including the resources necessary to fund its recently commenced global Phase 3 development of vadadustat, in dialysis and non-dialysis patients. In December 2015, the Company began dosing patients in its Phase 3 vadadustat program in non-dialysis patients with anemia related to CKD, PRO_2TECT, after obtaining feedback from United States and European regulatory authorities regarding the design of the program. The Company also expects to initiate its Phase 3 vadadustat program in dialysis-dependent CKD patients, $INNO_2VATE$, in 2016, anticipating full enrollment by early 2018. The Company has engaged a clinical research organization for the PRO_2TECT and $INNO_2VATE$ programs. The Company expects the cost of the Phase 3 program to be in the range of $80,000 to $85,000 per patient and it plans to enroll approximately 3,100 patients in PRO_2TECT and approximately 2,600 patients in $INNO_2VATE$.

The Company is also subject to a number of risks including the need to obtain adequate additional funding, possible failure of preclinical testing or clinical trials, the need to obtain marketing approval for its product candidates, the development of new technological innovations by competitors, the need to successfully commercialize and gain market acceptance of any of the Company's products that are approved and the ability to protect its proprietary technology. If the Company does not successfully commercialize any of its products, it will be unable to generate product revenue or achieve profitability.

Through 2015 we have raised approximately $187.4 million of net proceeds from three underwritten public offerings, including our Initial Public Offering, or IPO. In January 2016, we completed a follow-on public offering whereby we sold 7,250,000 shares of common stock at a price of $9.00 per share. The aggregate net proceeds received by us from the offering were approximately $61.0 million, net of underwriting discounts and commissions and estimated offering expenses payable by us.

In December 2015, we entered into a collaboration agreement with Mitsubishi Tanabe to develop and commercialize vadadustat in Japan and certain other countries in Asia for total milestone payments of up to $350.0 million, including up to $100.0 million in upfront and development payments, of which $40.0 million was received in January 2016. If Japanese patients are not included in either the global Phase 3 PRO_2TECT or $INNO_2VATE$ programs, $20.0 million of the $40.0 million received would be used to fund further local development of vadadustat in Japan or be refunded to Mitsubishi. In addition, we will receive tiered double-digit royalty payments on sales of vadadustat.

The Company believes that it can continue as a going concern as the Company ended the first quarter of 2016 with cash, cash equivalents and available for sale securities of $217.0 million and expects its cash resources to fund its current operating plan through at least the second quarter of 2017. There can be no assurance, however, that the current operating plan will be achieved in the timeframe anticipated by the Company, or that its cash resources will fund the Company's operating plan for the period anticipated by the Company or that additional funding will be available on terms acceptable to the Company, or at all.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Akebia Therapeutics Securities Corporation and Akebia Europe Limited. All intercompany balances and transactions have been eliminated in consolidation. These condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP. Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification (ASC) and Accounting Standards Update (ASU) of the Financial Accounting Standards Board (FASB).

In the quarter ended December 31, 2015, the Company identified and corrected an error in the historical classification of certain operating costs between research and development and general and administrative expenses. The Company concluded the effect of this classification error was not material to its consolidated financial statements for any prior period. The classification correction had no effect on the Company's current or historical total operating expenses or net loss.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year. These interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements as of and for the year ended December 31, 2015, and the notes thereto, which are included in the Company's Annual Report on Form 10-K (File No. 001-36352), which was filed with the Securities and Exchange Commission (SEC) on March 14, 2015.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard-setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In March 2016, the FASB issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting, as part of its Simplification Initiative. The areas for simplification in this update involve several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. Some of the areas for simplification apply only to nonpublic entities. The amendments in ASU 2016-09 are effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. Early application is permitted for all entities. The Company is currently evaluating the impact of this new standard on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which supersedes the existing guidance for lease accounting, Leases (Topic 840). ASU 2016-02 requires lessees to recognize leases on their balance sheets, and leaves lessor accounting largely unchanged. The amendments in this ASU are effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. Early application is permitted for all entities. ASU 2016-02 requires a modified retrospective approach for all leases existing at, or entered into after, the date of initial application, with an option to elect to use certain transition relief. The Company is currently evaluating the impact of this new standard on its consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, which requires management of public and private companies to evaluate whether there is substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. Management's evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued. If conditions or events raise substantial doubt about an entity's ability to continue as a going concern, and substantial doubt is not alleviated after consideration of management's plans, an entity should include a statement in the footnotes indicating that there is substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. The new standard is effective for annual periods ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. If this standard had been adopted as of March 31, 2016 and applied to these financial statements, the Company believes that there would be no significant impact to its disclosure. However, the Company faces certain risks and uncertainties as further described in Note 1, "Nature of Organization and Operations" that could affect this conclusion.

In May 2014, the FASB issued a new revenue recognition standard which amends revenue recognition principles and provides a single, comprehensive set of criteria for revenue recognition within and across all industries. The new standard provides a five step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also requires enhanced disclosures pertaining to revenue recognition in both interim and annual periods. In August 2015, the FASB deferred the

effective date of the new revenue standard from January 1, 2017 to January 1, 2018. Early adoption is permitted any time after the original effective date, which for us is January 1, 2017. The standard allows for adoption using a full retrospective method or a modified retrospective method. The Company is currently evaluating the timing, method of adoption and the expected impact that the standard could have on our consolidated financial statements and related disclosures.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment, which is the business of developing and commercializing proprietary therapeutics based on HIF biology.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including: expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management must select an amount that falls within that range of reasonable estimates. Estimates are used in the following areas, among others: prepaid and accrued research and development expense, stock-based compensation expense, accrued expenses and income taxes.

Prior to the IPO, the Company utilized significant estimates and assumptions in determining the fair value of its common stock. The Company granted stock options at exercise prices not less than the fair market value of its common stock as determined by the Board of Directors contemporaneously at the date such grants were made, with input from management. Prior to the Company’s IPO in March 2014, the fair value of common stock at the grant date was adjusted in connection with the Company’s retrospective fair value assessment for financial reporting purposes. Accordingly, the Board of Directors determined the estimated fair value of the Company’s common stock based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector and the prices at which the Company sold shares of preferred stock, the superior rights and preferences of securities senior to the Company’s common stock at the time and the likelihood of achieving a liquidity event, such as an IPO or sale of the Company.

Cash and Cash Equivalents

Cash and cash equivalents consist of all cash on hand, deposits and funds invested in available-for-sale securities with original maturities of three months or less at the time of purchase. At March 31, 2016, the Company’s cash is primarily in money market funds. The Company may maintain balances with its banks in excess of federally insured limits.

Investments

Management determines the appropriate classification of securities at the time of purchase and reevaluates such designation as of each balance sheet date. Currently, the Company classifies all securities as available-for-sale which are included in current assets as they are intended to fund current operations. The Company carries available-for-sale securities at fair value. The Company conducts periodic reviews to identify and evaluate each investment that has an unrealized loss, in accordance with the meaning of other-than-temporary impairment and its application to certain investments. When assessing whether a decline in the fair value of a security is other-than-temporary, the Company considers the fair market value of the security, the duration of the security's decline, and prospects for the underlying business. Based on these considerations, the Company did not identify any other-than-temporary unrealized losses at March 31, 2016. Unrealized losses on available-for-sale securities that are determined to be temporary, and not related to credit loss, are recorded in accumulated other comprehensive loss, a component of stockholders' equity. The amortized cost of debt securities in this category reflects amortization of premiums and accretion of discounts to maturity computed under the effective interest method. The Company includes this amortization in the caption "Interest income, net" within the Consolidated Statements of Operations and Comprehensive Loss. The Company also includes in net investment income, realized gains and losses and declines in value determined to be other than temporary. The Company bases the cost of securities sold upon the specific identification method, and includes interest and dividends on securities in interest income.

Revenue Recognition

To date, the Company has not generated any revenue from the sales of products or other means. For the foreseeable future, the Company expects substantially all of its revenues will be generated from its collaboration with Mitsubishi Tanabe (see Note 9) and any other collaborations the Company may enter into.

The Company will recognize revenue in accordance with ASC Topic 605, Revenue Recognition (ASC 605). Accordingly, revenue will be recognized for each unit of accounting when all of the following criteria are met:

- Persuasive evidence of an arrangement exists;
- Delivery has occurred or services have been rendered;
- The seller's price to the buyer is fixed or determinable; and
- Collectability is reasonably assured.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified in current liabilities. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

The Company evaluates multiple element arrangements based on the guidance in ASC Topic 605 25, Revenue Recognition Multiple Element Arrangements (ASC 605 25). Pursuant to the guidance in ASC 605 25, the Company evaluates multiple element arrangements to determine (1) the deliverables included in the arrangement and (2) whether the individual deliverables represent separate units of accounting or whether they must be accounted for as a combined unit of accounting. This evaluation involves subjective determinations and requires the Company to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. Deliverables are considered separate units of accounting provided that the delivered item has value to the customer on a standalone basis and, if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in the Company's control. In assessing whether an item has standalone value, the Company considers factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the collaboration partner can use a deliverable for its intended purpose without the receipt of the remaining deliverable, whether the value of the deliverable is dependent on the undelivered item and whether there are other vendors that can provide the undelivered items.

The consideration received under the arrangement that is fixed or determinable is then allocated among the separate units of accounting using the relative selling price method. The Company determines the estimated selling price for units of accounting within each arrangement using vendor specific objective evidence (VSOE) of selling price, if available, third party evidence (TPE) of selling price if VSOE is not available, or best estimate of selling price (BESP) if neither VSOE nor TPE is available. Determining the BESP for a unit of accounting requires significant judgment. In developing the BESP for a unit of accounting, 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. The Company validates the BESP for units of accounting by evaluating whether changes in the key assumptions used to determine the BESP will have a significant effect on the allocation of arrangement consideration between multiple units of accounting.

The Company will recognize arrangement consideration allocated to each unit of accounting when all of the revenue recognition criteria in ASC 605 are satisfied for that particular unit of accounting. In the event that a deliverable does not represent a separate unit of accounting, the Company will recognize revenue from the combined unit of accounting over the Company's contractual or estimated performance period for the undelivered elements, which is

typically the term of the Company's research and development obligations. If there is no discernible pattern of performance or objectively measurable performance measures do not exist, then the Company will recognize revenue under the arrangement on a straight line basis over the period the Company is expected to complete its performance obligations. Conversely, if the pattern of performance in which the service is provided to the customer can be determined and objectively measurable performance measures exist, then the Company recognizes revenue under the arrangement using the proportional performance method. Revenue to be recognized is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the straight line method or proportional performance method, as applicable, as of the period ending date.

At the inception of an arrangement that includes milestone payments, the Company evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether: (1) the consideration is commensurate with either the Company's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from its performance to achieve the milestone, (2) the

consideration relates solely to past performance and (3) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone and the level of effort and investment required to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether a milestone satisfies all of the criteria required to conclude that a milestone is substantive. Milestones that are not considered substantive are recognized as earned if there are no remaining performance obligations or over the remaining period of performance, assuming all other revenue recognition criteria are met.

Options are considered substantive if, at the inception of the arrangement, the Company is at risk as to whether the collaboration partner will choose to exercise the option. Factors that the Company considers in evaluating whether an option is substantive include the cost to exercise the option, the overall objective of the arrangement, the benefit the collaborator might obtain from the arrangement without exercising the option and the likelihood the option will be exercised. When an option is considered substantive, the Company does not consider the option or item underlying the option to be a deliverable at the inception of the arrangement and the associated option fees are not included in allocable consideration, assuming the option is not priced at a significant and incremental discount. Conversely, when an option is not considered substantive, the Company would consider the option, including other deliverables contingent upon the exercise of the option, to be a deliverable at the inception of the arrangement and a corresponding amount would be included in allocable arrangement consideration. In addition, if the price of the option includes a significant incremental discount, the discount would be included as a deliverable at the inception of the arrangement.

The Company will recognize royalty revenue in the period of sale of the related product(s), based on the underlying contract terms, provided that the reported sales are reliably measurable and the Company has no remaining performance obligations, assuming all other revenue recognition criteria are met.

Patents

Costs incurred in connection with the application for and issuance of patents are expensed as incurred.

Income Taxes

Income taxes are recorded in accordance with ASC Topic 740, Income Taxes (ASC 740), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. As of March 31, 2016 and 2015, the Company does not have any significant uncertain tax positions. The Company recognizes interest and penalties related to uncertain tax positions in income tax expense.

Stock-Based Compensation

The Company accounts for its stock-based compensation awards in accordance with ASC Topic 718, Compensation—Stock Compensation (ASC 718). ASC 718 requires all stock-based payments to employees, including grants of employee stock options, restricted stock, restricted stock units, or RSUs, and modifications to existing stock awards, to be recognized in the statements of operations and comprehensive loss based on their fair values. The Company accounts for stock-based awards to non-employees in accordance with ASC Topic 505-50, Equity-Based Payments to Non-Employees (ASC 505-50), which requires the fair value of the award to be re-measured at fair value until a performance commitment is reached or counterparty performance is complete. The Company's stock-based awards are comprised of stock options, shares of restricted stock and shares of common stock. The Company estimates the fair value of options granted using the Black-Scholes option pricing model. The Company uses the quoted market price of comparable public companies to determine the fair value of restricted stock awards and common stock awards.

The Black-Scholes option pricing model requires the input of certain subjective assumptions, including (a) the expected stock price volatility, (b) the calculation of expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to the lack of company-specific historical and implied volatility data for trading the Company's stock in the public market, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical

volatility is calculated based on a period of time commensurate with the expected term assumption. The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to the Company, including stage of product development and life science industry focus. The Company is in the product development stage with no revenue and the representative group of companies has certain similar characteristics to the Company. The Company believes the group selected has sufficient similar economic and industry characteristics, and includes companies that are most representative of the Company. The Company uses the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, Share-Based Payment, to calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The expected term is applied to the stock option grant group as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior among its employee population. For options granted to non-employees, the Company utilizes the contractual term of the arrangement as the basis for the expected term assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected life of the stock options. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock, which is similar to the Company's peer group.

The Company's stock-based awards are subject to either service- or performance-based vesting conditions. Compensation expense related to awards to employees with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term. Consistent with the guidance in ASC 505- 50, compensation expense related to awards to non-employees with service-based vesting conditions is recognized on a straight-line basis based on the then-current fair value at each financial reporting date prior to the measurement date over the associated service period of the award, which is generally the vesting term. Compensation expense related to awards to employees with performance-based vesting conditions is recognized based on the grant date fair value over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable. Consistent with the guidance in ASC 505-50, compensation expense related to awards to non-employees with performance-based vesting conditions is recognized based on the then-current fair value at each financial reporting date prior to the measurement date over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable.

The Company is also required to estimate forfeitures at the time of grant, and revise those estimates in the subsequent periods if actual forfeitures differ from its estimates. The Company uses historical data to estimate pre-vesting forfeitures and record stock-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from the Company's estimates, the difference is recorded as a cumulative adjustment in the period the estimates were revised. Stock-based compensation expense recognized in the condensed consolidated financial statements is based on awards that are ultimately expected to vest.

Fair Value of Financial Instruments

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. ASC Topic 820, Fair Value Measurements and Disclosures (ASC 820), establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available.

Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation

inputs used in determining the reported fair value of the investments, and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described below:

- Level 1 – Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.
- Level 2 – Valuations based on quoted prices for similar assets or liabilities in markets that are not active, or for which all significant inputs are observable, either directly or indirectly.
- Level 3 – Valuations that require inputs that reflect the Company's own assumptions that are both significant to the fair value measurement and unobservable.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Items measured at fair value on a recurring basis include short-term investments (see Note 4). The carrying amounts of prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values due to their short-term maturities. The rate implicit within the Company's capital lease obligation approximates market interest rates.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Cash and investments are the only financial instruments that potentially subject the Company to concentrations of credit risk. The Company maintains its cash with high quality, accredited financial institutions and, accordingly, such funds are subject to minimal credit risk. The Company has no significant off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.