Axovant Sciences Ltd.
Form 10-K
June 06, 2016
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended March 31, 2016
or
o 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 001-37418

Axovant Sciences Ltd.
(Exact name of registrant as specified in its charter)

Bermuda	Not Applicable
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
Clarendon House - 2 Church Street Hamilton HM 11 Bermuda	Not Applicable
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: +1 (441) 824-8100

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

Title of each Class	Name of each exchange on which registered
Common Stock, $0.00001 par value	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark whether the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No ý
Indicate by check mark whether the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes o No ý

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 ý No o

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ý

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

Large accelerated filer o Accelerated filer o

Non-accelerated filer x (Do not check if a smaller reporting company) Smaller reporting company o

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

The aggregate market value of voting Common Stock held by non-affiliates of the registrant on second fiscal quarter ended September 30, 2015 was approximately $312,018,000 based on the last reported sale price of the Common Stock on The New York Stock Exchange Global Select Market on September 30, 2015 of $12.92 per share.

The number of shares outstanding of the Registrant’s common shares, $0.00001 par value per share, on June 3, 2016, was 99,150,000.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended March 31, 2016. With the exception of the portions of the 2016 Proxy Statement expressly incorporated into this Annual Report on Form 10-K by reference, such document shall not be deemed filed as part of this Form 10-K.

Portions of the proxy statement are incorporated herein by reference into the following parts of this Annual Report on Form 10-K:

Part III, Item 10. Directors, Executive Officers and Corporate Governance;

Part III, Item 11. Executive Compensation;

Part III, Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters;

Part III, Item 13. Certain Relationships and Related Transactions, and Director Independence; and

Part III, Item 14. Principal Accounting Fees and Services.

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AXOVANT SCIENCES LTD.

ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED MARCH 31, 2016

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PART I.

All brand names or trademarks appearing in this report are the property of their respective owners. Unless the context requires otherwise, references in this report to "Axovant" the "Company," "we," "us," and "our" refer to Axovant Sciences Ltd and its subsidiaries.

Item 1. Business

General

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements are often identified by the use of words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "project," "will," "would" or the negative or plural of these words or similar exp or variations. Such forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, and those discussed in the section titled "Risk Factors," set forth in Part I, Item 1A of this Annual Report on Form 10-K and in our other filings with the SEC. You should not rely upon forward-looking statements as predictions of future events. Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Overview of Our Company

We are a clinical-stage biopharmaceutical company focused on acquiring, developing and commercializing novel therapeutics for the treatment of dementia. We intend to develop a pipeline of product candidates to comprehensively address the cognitive, functional and behavioral aspects of dementia and related neurological disorders. Our vision is to become the leading company focused on the treatment of dementia by addressing all forms and aspects of the disease. Our near-term focus is to develop our lead product candidate, intepirdine, previously referred to as RVT-101, a selective 5-HT_6 receptor antagonist, for the treatment of Alzheimer's disease and dementia with Lewy bodies, or DLB, and to develop nelotanserin, our second product candidate, a potent and highly selective 5-HT_{2A} receptor inverse agonist, for the treatment of visual hallucinations in patients with Lewy body dementia and REM behavior disorder, or RBD, in patients with DLB. In the long-term, we intend to develop a broader pipeline of product candidates to comprehensively address the cognitive, behavioral and functional aspects of dementia.

We were founded in October 2014 as a wholly-owned subsidiary of Roivant Sciences Ltd., or RSL, a company focused on the acquisition, development and commercialization of late-stage product candidates that are non-strategic, deprioritized or under-resourced at other biopharmaceutical companies, with the intent of reducing the time and cost of the drug development process. Our operations to date have consisted of organizing and staffing our company, raising capital, acquiring our product candidates and preparing for and advancing our product candidates intepirdine and nelotanserin into clinical development.

In June 2015, we completed our initial public offering, or IPO, from which we raised proceeds of $334.5 million, net of underwriting discounts and issuance costs. We are a "controlled company" within the meaning of the corporate governance rules of the New York Stock Exchange, or the NYSE. RSL owns, in the aggregate, approximately 75.6% of our outstanding common shares. To date, we have not generated any revenue, and we recorded net losses of $133.1 million and $21.0 million for the year ended March 31, 2016 and for the period from October 31, 2014 (date of inception) to March 31, 2015, respectively.

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Our Product Pipeline

The following table summarizes the status of our development programs:

Compound	Clinical Indication	Development Stage	Global Commercial Rights
Intepirdine (RVT-101)			
	Mild-to-Moderate Alzheimer's disease	Phase 3 (MINDSET Study)	Axovant Sciences Ltd.
	Dementia with Lewy Bodies (DLB)	Phase 2b (HEADWAY-DLB Study)	Axovant Sciences Ltd.
Nelotanserin			
	Visual Hallucinations in Lewy Body Dementia	Phase 2	Axovant Sciences Ltd.
	REM Behavior Disorder (RBD) in DLB	Phase 2	Axovant Sciences Ltd.

Intepirdine (RVT-101)

Overview

Our lead product candidate intepirdine (RVT-101) is currently being developed for the treatment of mild-to-moderate Alzheimer’s disease and DLB. The United States Adopted Names Council and World Health Organization have recently adopted intepirdine as the unique nonproprietary, or generic, name for RVT-101. We acquired the worldwide rights to intepirdine from Glaxo Group Limited and GlaxoSmithKline Intellectual Property Development Limited, collectively GSK, under an asset purchase agreement entered into in December 2014, or the GSK Agreement.

Mechanism of Action

Intepirdine is an orally administered potent antagonist of the 5-HT_6 receptor. By antagonizing the 5-HT_6 receptor, intepirdine promotes the release of key neurotransmitters including acetylcholine. These neurotransmitters are believed to be critical for alertness, memory, thought and judgment, which are the key components of cognition and function that are impaired in patients with dementia.

We believe that intepirdine's action as a 5-HT_6 receptor antagonist supports its use in combination with cholinesterase inhibitors. While cholinesterase inhibitors help prevent the breakdown of acetylcholine, 5-HT_6 receptor antagonists promote the release of acetylcholine. Therefore, when used in combination with one another, we believe that 5-HT_6 receptor antagonists and cholinesterase inhibitors may increase the concentration of acetylcholine through complementary mechanisms. 5-HT_6 receptors are primarily localized to the central nervous system, or CNS, particularly in regions of the brain that modulate cognition. Because 5-HT_6 receptor antagonists do not have activity outside the CNS, we believe they should not significantly increase levels of acetylcholine outside of the CNS, and therefore should not exacerbate the peripheral side effects that are commonly associated with cholinesterase inhibitors.

Intepirdine for the Treatment of Alzheimer’s Disease

Medical Need

Alzheimer’s disease, the most common form of dementia, is a progressive neurodegenerative disorder that results in significant impairments in cognition, function and behavior. According to the Alzheimer’s Association, Alzheimer’s disease affects approximately 5.3 million people in the United States. It is estimated that between 70% and 90% of Alzheimer’s disease patients age 65 and older are classified as having mild-to-moderate Alzheimer’s disease. No new chemical entity has been approved by the FDA for the treatment of Alzheimer’s disease since 2003.

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Clinical Development

We plan to develop intepirdine for use in combination with donepezil. Donepezil, a generic drug also marketed under the trade name Aricept by Eisai Co., Ltd. and Pfizer, Inc., is the most commonly used cholinesterase inhibitor. Cholinesterase inhibitors are the current standard of care for the treatment of Alzheimer's disease, and the only class of drugs approved by the FDA for the treatment of patients with mild Alzheimer's disease. Based on preclinical and clinical data collected to date, we believe intepirdine, when used in combination with donepezil, works additively or synergistically to increase the concentration of acetylcholine, potentially leading to improved cognition and function in patients with Alzheimer's disease.

We believe intepirdine has the potential to be a best-in-class 5-HT_6 receptor antagonist for the treatment of Alzheimer's disease based on its safety, tolerability and efficacy profile for up to 48 weeks, as observed in a 684-subject, randomized, placebo-controlled Phase 2b trial conducted by GSK. We believe this is significant, in part, because currently marketed Alzheimer's disease drugs were approved on efficacy data of 28 weeks or less. Furthermore, we believe intepirdine has a number of favorable properties as a product candidate for Alzheimer's disease, including once daily dosing, a low potential for drug interactions, and an ability to be administered with or without food.

Prior to our acquisition of intepirdine in December 2014, GSK conducted 13 clinical trials for intepirdine involving over 1,250 individuals, which included healthy subjects as well as subjects with mild-to-moderate Alzheimer's disease. Since our acquisition of intepirdine, we have completed additional studies and increased the number of individuals treated with the product candidate to more than 1,300. In the Phase 2b clinical trial of 684-subjects with mild-to-moderate Alzheimer's disease, subjects who received 35 mg intepirdine in combination with donepezil achieved a 1.50 point benefit (p-value = 0.013) versus the donepezil-only group at 24 weeks following treatment initiation as measured by the Alzheimer's Disease Assessment Scale-cognitive, or ADAS-cog, subscale (pre-specified co-primary endpoint). Statistically significant improvements in cognition were also observed at 12 and 48 weeks following initiation of treatment, compared to subjects who received donepezil alone. In addition, subjects who received 35 mg intepirdine in combination with donepezil achieved a 2.00 point (p-value = 0.024) benefit versus the donepezil-only group at 24 weeks following initiation of treatment as measured by the Alzheimer's Disease Cooperative Study Activities of Daily Living, or ADCS-ADL scale, a commonly used scale evaluating a subject's ability to perform a list of daily activities.The ADCS-ADL scale is evaluated based on information obtained from the subject's caregiver. Statistically significant improvements of activities of daily living were also observed at 12 and 36 weeks following the initiation of treatment, compared to subjects who received donepezil alone. We believe these results on the ADCS-ADL scale are particularly noteworthy in light of the fact that the decline in the ability of patients to perform activities essential to daily living places a significant burden on caregivers and the healthcare system.

GSK’s other pre-specified co-primary endpoint in the 684-patient Phase 2b trial was Clinical Dementia Rating Sum of Boxes, or CDR-SB, a composite scale with certain components that evaluate cognition and other components that assess function, at 24 weeks following treatment. While the 35 mg intepirdine dose group achieved statistically significant improvement in the CDR-SB at 12 weeks and was numerically superior at 24 weeks and further time points, the benefits at 24 weeks and beyond were not statistically significant. No Alzheimer's disease drugs have ever been approved on the basis of CDR-SB as a primary endpoint. We believe that the ADAS-cog and ADCS-ADL represent more appropriate endpoints to meet the FDA’s guidance to show effect on independent measures of cognition and function, and we have chosen these as co-primary endpoints for our ongoing trial in patients with mild-to-moderate Alzheimer's disease, the MINDSET study. This choice of ADAS-cog and ADCS-ADL as co-primary endpoints for the MINDSET study was confirmed by our Special Protocol Assessment, or SPA, agreement with the FDA.

Intepirdine was observed to be well-tolerated by subjects in all 15 clinical trials conducted to date. In the 684-subject Phase 2b adjunctive therapy study the proportion of subjects who experienced drug-related adverse events was lower in the group that received 35 mg intepirdine with donepezil than in the group that received placebo with donepezil, at

24 weeks (6% versus 9%) and 48 weeks (7% versus 13%). There were no drug-related serious adverse events in the intepirdine groups at 24 or 48 weeks, and there was one drug-related serious adverse event in the placebo group (aphasia) at 24 weeks. Falls were less frequent in both the 35 mg intepirdine group (2%) and the 15 mg intepirdine group (2%) compared to the placebo group (6%). There were no notable differences between the intepirdine and placebo groups in vital sign changes, electrocardiogram changes or significant changes in laboratory parameters, and there was no evidence of significant liver toxicity.

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In October 2015, we commenced a global, multi-center, double-blind, placebo-controlled confirmatory Phase 3 clinical study of intepirdine for the treatment of patients with mild-to-moderate Alzheimer's disease (the MINDSET study). The MINDSET study is evaluating the safety, tolerability and efficacy of intepirdine over a 24-week period and compares 35 mg, once-daily oral doses of intepirdine to placebo in approximately 1,150 patients with mild-to-moderate Alzheimer's disease on a background of stable donepezil therapy. The primary endpoints are improvements in ADAS-cog and ADCS-ADL scores, which have been used as endpoints supporting regulatory approval of currently-marketed Alzheimer's disease treatments in the United States and Europe. Subjects completing the MINDSET study will be eligible to enroll in a 12-month, open-label extension in which other medications for the treatment of Alzheimer's disease, including memantine and other cholinesterase inhibitors, may be administered in combination with intepirdine. We have received a SPA agreement from the FDA for the MINDSET study. The SPA agreement states that the design and planned analysis of this study adequately address the objectives necessary to support an application for marketing approval. The MINDSET study seeks to confirm the results of the prior 684-subject Phase 2b adjunctive therapy study conducted by GSK. We expect to report results from our MINDSET study in calendar year 2017. If the results of MINDSET study are favorable, we plan to seek regulatory approval and commercialize intepirdine.

Intepirdine for the Treatment of Dementia with Lewy Bodies

Medical Need

In addition to evaluating intepirdine for patients with mild-to-moderate Alzheimer's disease, we are also developing intepirdine to address other forms of dementia, such as dementia with Lewy bodies, or DLB. DLB, a subset of Lewy body dementia, is a progressive neurodegenerative disorder which is pathologically characterized by the aggregation of alpha-synuclein and other proteins in the brain, known as Lewy bodies, causing disruption in cognition, function and behavior. DLB is the second most prevalent cause of neurodegenerative dementia in elderly patients. It has been estimated that DLB affects approximately 1.1 million people in the United States.

In addition to suffering from deficits and fluctuations in cognition, DLB patients often suffer from visual hallucinations, parkinsonism, sensitivity to neuroleptic (antipsychotic) medications and REM behavior disorder, or RBD, a condition in which patients physically act out their dreams.

DLB patients are often treated off-label with cholinesterase inhibitors. Cholinergic neurotransmission is thought to be even more dysfunctional in DLB than in Alzheimer's disease. This suggests that neurotransmitter-targeted therapies that work by increasing the inter-synaptic concentration of acetylcholine, much like intepirdine in Alzheimer's disease, may also be effective in improving cognition and function in DLB patients. While cholinesterase inhibitors are not approved by the FDA or EMA for the treatment of DLB, donepezil was approved in September 2014 in Japan for this indication. We believe that the addition of a 5-HT_6 receptor antagonist, such as intepirdine, may help improve cognition in DLB patients by promoting the synaptic release of acetylcholine. In addition, intepirdine has antagonist activity against the 5-HT_{2A} receptor, which has been implicated in the pathophysiology of visual hallucinations and other behavioral disturbances affecting patients with DLB. We believe that intepirdine has the potential to be the first drug approved by the FDA and EMA for the treatment of DLB.

Clinical Development

Following the FDA's acceptance of our Investigational New Drug, or IND, application in December 2015, we began a Phase 2b clinical trial of intepirdine, called the HEADWAY-DLB study, in patients with DLB in the first quarter of calendar year 2016. In addition to the 35 mg dose of intepirdine that is being studied in the MINDSET study we will utilize a 70 mg dose of intepirdine in this trial, which we believe could have greater activity against the 5-HT_{2A} receptor to potentially address visual hallucinations and behavioral disturbances in this patient population. This decision is supported by a safety and food effect study testing the 70 mg dose completed by Axovant in 2015. We expect to report results from this trial in calendar year 2017. If the results of the HEADWAY-DLB study are

favorable, we believe that it, in combination with data from our studies in Alzheimer's disease, could serve as the basis for seeking approval of intepirdine for DLB.

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Nelotanserin

Overview

In October 2015, we acquired from our parent company RSL the global rights, title, interest and obligations in and to nelotanserin, a potent and highly selective 5-HT_{2A} receptor inverse agonist. Initially, we intend to develop nelotanserin to address visual hallucinations in patients with Lewy body dementia and RBD in patients with DLB. Nelotanserin has been evaluated in seven clinical studies to date with nearly 800 human subjects exposed to the drug candidate and has been observed to be well tolerated.

Mechanism of Action

Nelotanserin is a potent and highly selective inverse agonist of the 5-HT_{2A} receptor which has the effect of reducing the activity of the 5-HT_{2A} receptor. The 5-HT_{2A} receptor has been linked to neuropsychiatric disturbances including visual hallucinations and sleep disturbances. In in vitro studies, nelotanserin did not antagonize the dopamine D_2 receptor. Antagonism of the D_2 receptor in Lewy body dementia patients can lead to severe side effects including increased parkinsonism, worsening of cognition, heavy sedation, and symptoms resembling neuroleptic malignant syndrome which can be fatal.

Nelotanserin for Visual Hallucinations in Lewy Body Dementia

Medical Need

Lewy body dementia includes two similar conditions, DLB and Parkinson's disease dementia, or PDD. There is significant overlap in the pathology and clinical presentation of both conditions; however, the primary difference generally depends on the timing of the onset of cognitive decline relative to the onset of movement-related symptoms. In DLB, the cognitive decline typically occurs before or within one year of the onset of movement disorder symptoms. In PDD, movement disorder symptoms typically precede cognitive decline by more than one year. The Lewy Body Dementia Association estimates that there are 1.4 million patients with Lewy body dementia in the United States. Lewy body dementia patients suffer from frequent visual hallucinations, which are often treated with off-label atypical antipsychotic medications such as quetiapine. Use of atypical antipsychotic medications, which have activity against the dopamine D_2 receptor, can lead to increased or possibly irreversible parkinsonism in Lewy body dementia patients and a life threatening side-effect resembling neuroleptic malignant syndrome. We believe that there is a need for new therapeutic options that can reduce visual hallucinations in Lewy body dementia patients without risk of these severe side effects.

Clinical Development

In January 2016 we initiated a double-blind, randomized, placebo-controlled, cross-over Phase 2 clinical study of nelotanserin in DLB and PDD patients suffering from visual hallucinations. We expect to receive results from this pilot study in the second half of calendar year 2016.

Nelotanserin for REM Behavior Disorder (RBD) in Dementia with Lewy Bodies (DLB)

Medical Need

RBD is a common clinical feature of DLB, and is a condition in which patients physically act out their dreams, impacting their quality of life and endangering themselves and their bed partners. While off-label treatment of RBD with benzodiazepines is common, this class of drugs is associated with concerning side effects in patients with dementia, including sedation, worsening of cognition and increased risk of falls. We believe that there is a need for new therapeutic options that can reduce the frequency of RBD without sedating patients or worsening cognition in patients with dementia.

Clinical Development

In March 2016 we initiated a four-week double-blind, randomized, placebo-controlled Phase 2 study in patients with DLB suffering from RBD. This study will utilize objective measures of efficacy as assessed in a sleep-lab setting. We have designed this study to potentially serve as a pivotal trial in support of an application for regulatory approval, and we expect to receive results in calendar year 2017.

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Our Key Agreements

Asset Purchase Agreement with GlaxoSmithKline for Intepirdine

In December 2014, we acquired the worldwide rights to intepirdine from GSK. Under the GSK Agreement, we made an upfront payment of $5.0 million and will make an additional $5.0 million payment in June 2016. We are obligated to pay GSK $35.0 million, $25.0 million and $10.0 million upon the receipt of marketing approval of intepirdine in the United States, the European Union and Japan, respectively, as well as an additional payment of $85.0 million for the first calendar year in which we achieve global net sales of $1.2 billion for intepirdine. We are obligated to pay a fixed 12.5% royalty based on net sales of intepirdine, subject to reduction on account of expiration of patent and regulatory exclusivity or upon generic entry.

Our royalty obligations with respect to the GSK Agreement will end, on a product-by-product and country-by-country basis, on the latest of: (1) expiration of the last valid claim of the assigned patents covering the manufacture, use or composition of such product in such country; (2) expiration of regulatory exclusivity for such product in such country; or (3) 12 years from the first commercial sale of such product in such country, or if such country is one of the five major European countries listed in the GSK Agreement, then 12 years from the first commercial sale of such product in at least three such major European countries.

Our royalty payment obligations and milestone payment obligations under the GSK Agreement may be reduced by a portion of royalty payments, and in some cases other payments, made to third parties for rights to certain U.S. patents, in each case subject to a maximum reduction.

Arena Development Agreement for Nelotanserin

In October 2015, we exercised an option to acquire global rights, title, interest and obligations in and to nelotanserin from our parent company RSL. In May 2015, RSL entered into a development, marketing and supply agreement for nelotanserin with Arena Pharmaceuticals, GmbH, or Arena, and we entered into a Waiver and Option Agreement with RSL. Upon the exercise of our option, we assumed RSL's rights and obligations under the development, marketing and supply agreement with Arena, or the Arena Development Agreement. Under the Waiver and Option Agreement, we recorded $5.3 million as research and development expense which was 110% of any payments made to Arena by RSL, and any costs incurred by RSL in connection with the development of nelotanserin. We will be responsible for future contingent payments under the Arena Development Agreement, including up to $4.0 million in potential development milestone payments, up to $37.5 million in potential regulatory milestone payments and up to $60.0 million in potential commercial milestone payments. Under the Arena Development Agreement, we are also obligated to purchase finished drug product under a fixed price equal to 15% of net sales of nelotanserin.

The Arena Development Agreement will remain in effect until terminated: (1) by the parties' mutual agreement; (2) for any reason by us upon 90 days' written notice to Arena; (3) by either party upon written notice for the other party's material breach or insolvency event if such party fails to cure such breach or the insolvency event is not dismissed within the specified cure period; or (4) by Arena if we or our affiliates participate in a challenge to certain Arena patents.

Our Strategy

Our goal is to become the leading biopharmaceutical company focused on the treatment of dementia.

The key elements of our strategy to achieve this goal include the following:

- Rapidly advance intepirdine for the treatment of mild-to-moderate Alzheimer's disease. In October 2015, we commenced a global, multi-center, double-blind, placebo-controlled confirmatory Phase 3 clinical study of intepirdine, in patients on a background of stable donepezil therapy, called MINDSET, for the treatment of mild-to-moderate Alzheimer's disease. We expect to report results from our MINDSET study in calendar year 2017. If the results of our MINDSET study are positive, our goal is to submit a new drug application, or NDA, with the FDA for the regulatory approval and commercialization of intepirdine in the United States by the end of calendar year 2017 followed by a marketing authorization application, or MAA, with the EMA.
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Develop intepirdine for the treatment of DLB. In the first quarter of calendar year 2016, we began a Phase 2b clinical trial of intepirdine, called the HEADWAY-DLB study, in patients with DLB. In addition to the 35 mg dose of intepirdine that is being studied in the MINDSET study, we are evaluating a 70 mg dose of intepirdine in this trial, which we believe could have greater activity against the 5-HT_{2A} receptor which may help address visual hallucinations and behavioral disturbances in this patient population. We expect to report results from the HEADWAY-DLB study in calendar year 2017. If the results of this study are favorable, we believe that those results, in combination with positive MINDSET study results, could serve as the basis for seeking approval of intepirdine in DLB.

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- Develop nelotanserin for the treatment of Lewy Body Dementia. In December 2015, we began a pilot Phase 2 clinical trial of nelotanserin in DLB and PDD patients suffering from visual hallucinations. We also initiated a second Phase 2 study of nelotanserin in DLB patients experiencing RBD.
- Acquire or in-license late-stage product candidates for the treatment of other aspects of dementia in a capital-efficient manner. We intend to identify, acquire, develop and commercialize novel, late-stage product candidates for the treatment of cognitive, functional and behavioral aspects of dementia with mechanisms of action that have previously shown evidence of clinical efficacy and safety. Our targeted approach to acquisition and licensing transactions reflects our goal to be the leading biopharmaceutical company focused on the treatment of dementia. In evaluating product acquisition candidates, we focus on acquisition candidates that are either approved products or late-stage products in development that offer improved solutions to patients and leverage our business infrastructure. In addition, our acquisition strategy has been to acquire global rights for these compounds wherever possible.
- Maximize the commercial potential of our product candidates. We plan to directly commercialize our product candidates in the United States and the European Union. In other markets for which commercialization may be less capital efficient for us, we may selectively pursue strategic collaborations with third parties in order to maximize the commercial potential of our product candidates.

Services Agreement with Roivant Sciences, Inc., or RSI

We and our wholly-owned subsidiary, Axovant Sciences, Inc., or ASI, have entered into a services agreement with Roivant Sciences, Inc., or RSI, a wholly-owned subsidiary of RSL, or the Services Agreement, pursuant to which RSI provides us with services in relation to the identification of potential product candidates, project management of clinical trials and other development activities, and certain administrative and financial functions. Under the terms of our Services Agreement with RSI, we are obligated to pay or reimburse RSI for the costs it, or third parties acting on its behalf, incurs in providing services to us, including administrative and support services as well as research and development services. In addition, we are obligated to pay to RSI at a pre-determined mark-up on the costs incurred in connection with any general and administrative and research and development services provided directly by RSI. We expect that our reliance on RSI will decrease over time as we, ASI and any other future subsidiary of ours continue to hire the necessary personnel to manage the development and potential commercialization of our product candidates.

Sales and Marketing

We do not have our own marketing, sales or distribution capabilities. In order to commercialize our product candidate if approved for commercial sale, we must either develop a sales and marketing infrastructure or collaborate with third parties that have sales and marketing experience. We plan to directly commercialize our product candidates in the United States and the European Union. In other markets for which commercialization may be less capital efficient for us, we may selectively pursue strategic collaborations with third parties in order to maximize the commercial potential of our product candidates.

Manufacturing

We have no experience in drug formulation or manufacturing and do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. While intepirdine was being developed by GSK, it was also being manufactured by GSK. We expect that the drug substance transferred from GSK under the GSK Agreement will be sufficient for us to complete our planned Phase 3 pivotal program, and we have contracted with a third party to fill, finish, supply, store and distribute the drug product for this program. We also will rely on third-party manufacturers to supply us with sufficient quantities of intepirdine to be used, if approved, for the commercialization of intepirdine. If we are unable to initiate or continue our relationship with one or more of these third-party contractors, we could experience delays in our development efforts as we locate and qualify new manufacturers.

Under the Arena Development Agreement, subject to specified exceptions, Arena remains the sole and exclusive manufacturer of nelotanserin, and we will depend on Arena to manufacture sufficient quantities of nelotanserin for our planned clinical trials.

Manufacturing of any product candidate is subject to extensive regulations that impose various procedural and documentation requirements, which govern recordkeeping, manufacturing processes and controls, personnel, quality control and quality assurance, among others. We expect that all of our contract manufacturing organizations will manufacture intepirdine and nelotanserin under current Good Manufacturing Practice, or cGMP, conditions. cGMP is a regulatory standard for the production of pharmaceuticals to be used in humans.

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Competition

We consider intepirdine's most direct competitor to be idalopirdine (Lu AE58054), a 5-HT_6 receptor antagonist being developed by Lundbeck that is currently being studied in three Phase 3 studies. We believe the Phase 2 data for idalopirdine adds further validation to the therapeutic relevance of 5-HT_6 as a potential target for the treatment of neurodegenerative disorders. Based on publicly available information, other companies developing 5-HT_6 receptor antagonists include Acorda Therapeutics (after its acquisition of Biotie Therapies), Avineuro and Suven Life Sciences. These other 5-HT_6 receptor antagonists are all in Phase 2 or earlier stages of development for cognitive disorders.

We consider nelotanserin's most direct competitor to be pimavanserin, a 5-HT_{2A} receptor inverse agonist being developed by Acadia that received FDA approval of its NDA in April 2016 for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis. We believe the FDA approval of pimavanserin adds further validation to the therapeutic relevance of 5-HT_{2A} as a potential target for the treatment of visual hallucinations.

In addition to other 5-HT_6 receptor antagonists and 5-HT_{2A} receptor inverse agonists in active development, we are aware of many biotechnology and pharmaceutical companies as well as academic institutions, government agencies and private and public research institutions that are developing, and may in the future develop and commercialize, products for Alzheimer's disease, Lewy body dementia and other cognitive disorders.

Drug development is highly competitive and subject to rapid and significant technological advancements. Our ability to compete will significantly depend upon our ability to complete necessary clinical trials and regulatory approval processes, and effectively market any drug that we may successfully develop. Our current and potential future competitors include pharmaceutical and biotechnology companies, academic institutions and government agencies. The primary competitive factors that will affect the commercial success of any product candidate for which we may receive marketing approval include efficacy, safety and tolerability profile, dosing convenience, price, coverage and reimbursement. Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and in foreign countries. Our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of our competitors.

Accordingly, our competitors may be more successful than us in obtaining regulatory approval for therapies and in achieving widespread market acceptance of their drugs. It is also possible that the development of a cure or more effective treatment method for Alzheimer's disease or dementia with Lewy bodies or treatments for other related disorders by a competitor could render our product candidates non-competitive or obsolete or reduce the demand for our product candidates before we can recover our development and commercialization expenses.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for intepirdine, nelotanserin, any of our future product candidates, novel discoveries, product development technologies and other know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patents and patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trademarks, trade secrets, know-how, continuing technological innovation and potential in-licensing and acquisition opportunities to develop and maintain our proprietary position.

While we seek broad coverage under our existing patent applications, there is always a risk that an alteration to the process of obtaining patents or changes to the patent law may provide sufficient basis for a competitor to avoid infringement claims. In addition, patents, if granted, expire and we cannot provide any assurance that any patents will be issued from our pending or any future applications or that any potentially issued patents will adequately protect our intellectual property.

As of March 31, 2016, by virtue of assignment of the patent rights under the GSK Agreement, we are the exclusive owner of six granted U.S. patents, and approximately one hundred patents or pending patent applications in numerous

foreign jurisdictions. Our patents and patent applications cover the intepirdine molecule and analogs thereof as a composition of matter, as well as its use alone or in combination with other pharmaceutical agents. These patents and applications start to expire in 2023. The U.S. composition of matter patent for intepirdine naturally expires in 2024 inclusive of patent term adjustment and we expect the term of this patent to be extended up to five years to 2029. We also own pending U.S. and corresponding PCT applications. These applications, if granted, would extend the patent life for certain uses of intepirdine and combinations of intepirdine with other pharmaceutical agents to between 2028 and 2036.

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In October 2015, we assumed RSL's rights and obligations under the development, marketing and supply agreement with Arena, or the Arena Development Agreement for nelotanserin. Pursuant to the Arena Development Agreement, we have exclusive rights under issued patents that cover compositions of matter for nelotanserin and related compounds and methods of treatment utilizing nelotanserin and related compounds in major markets, including the United States, Japan, China, Germany, France, Italy, the United Kingdom, Spain, Canada, Russia, India, Australia and South Korea, and have applications pending in five other jurisdictions. The earliest priority date for the patents on nelotanserin is 2003. The terms of these patents are capable of continuing into 2024 in most jurisdictions without taking into account any patent term extension regimes of any country. We also own a number of provisional applications directed to uses of the nelotanserin molecule alone or in combination with other pharmaceutical agents, which, if granted, would extend the patent life of certain uses of nelotanserin through 2036.

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued for regularly filed applications in the United States are granted a term of 20 years from the earliest effective filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the U.S. Patent and Trademark Office, or the USPTO, delay in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. The actual protection afforded by a patent varies on a product by product basis, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Furthermore, we rely upon trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part by using confidentiality agreements with our commercial partners, collaborators, employees and consultants and invention assignment agreements with our employees. We also have confidentiality agreements and invention assignment agreements with our commercial partners and selected consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Our commercial success will also depend in part on not infringing the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our drugs or processes, obtain licenses or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future drugs may have an adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO, to determine priority of invention.

Government Regulation

FDA Drug Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning or untitled letters, product recalls, product seizures, total or

partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

We cannot market a drug product candidate in the United States until the drug has received FDA approval. The steps required before a drug may be marketed in the United States generally include the following:

- completion of extensive pre-clinical laboratory tests, animal studies, and formulation studies in accordance with the FDA's Good Laboratory Practice (GLP) regulations;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;

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- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice (GCP)requirements to establish the safety and efficacy of the drug for each proposed indication;
- submission to the FDA of an NDA after completion of all pivotal clinical trials;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the active pharmaceutical ingredient, or API, and finished drug product are produced and tested to assess compliance with cGMPs; and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLP regulations. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. If the FDA raises concerns or questions about the conduct of the trial, such as whether human research subjects will be exposed to an unreasonable health risk, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations, including GCP requirements, as well as under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval at each site at which the clinical trial will be conducted. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess pharmacological actions, side effects associated with increasing doses and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine metabolism, pharmacokinetics, the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 clinical trials, also called pivotal trials, are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 clinical trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry,

manufacture and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment user fees. These fees are typically increased annually.

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The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Most such applications for standard review drug products are reviewed within 10 to 12 months; most applications for priority review drugs are reviewed in six to eight months. Priority review can be applied to drugs to treat serious conditions that the FDA determines offer significant improvement in safety or effectiveness. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMPs is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits of the drug outweigh the potential risks. A REMS can include a medication guide, a communication plan for healthcare professionals and elements to assure safe use, such as special training and certification requirements for individuals who prescribe or dispense the drug, requirements that patients enroll in a registry and other measures that the FDA deems necessary to assure the safe use of the drug. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs. Such supplements are typically reviewed within 10 months of receipt.

Post-Approval Requirements

Once an NDA is approved, a product is subject to post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet and social media. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS or surveillance to monitor the effects of an approved product, or restrictions on the distribution or use of the product. In addition, quality-control, drug manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and

certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;

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- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Other Healthcare Laws

Although we currently do not have any products on the market, our current and future business operations may be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, price reporting and physician sunshine laws. Some of our pre-commercial activities are subject to some of these laws.

The federal Anti-Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer or a party acting on its behalf, to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and beneficiaries on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Anti-Kickback Statute has been violated. Violations of this law are punishable by up to five years in prison, and can also result in criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the Affordable Care Act, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

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The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent or not provided as claimed. Persons and entities can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, certain of our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. Penalties for federal civil False Claims Act violations may include up to three times the actual damages sustained by the government, plus mandatory civil penalties of between $5,500 and $11,000 for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the federal False Claims Act is a civil statute, False Claims Act violations may also implicate various federal criminal statutes.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal Anti-Kickback Statute, the Affordable Care Act amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, including the final omnibus rule published on January 25, 2013, mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity. At present, it is unclear if we would be considered a business associate subject to HIPAA based on our business activities and service offerings upon the commercialization of a product. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties.

The Affordable Care Act, through the enactment of the Physician Payments Sunshine Act, imposes, among other things, new annual reporting requirements for covered manufacturers for certain payments and other transfers of value provided to physicians and teaching hospitals, as well as certain ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an aggregate of $1 million per year for "knowing failures."

Many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and/or state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Additionally, to the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws.

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Because we intend to commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs, we intend to develop a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which we will or may become subject. Although the development and implementation of compliance programs designed to establish internal control and facilitate compliance can mitigate the risk of violating these laws, and the subsequent investigation, prosecution, and penalties assessed for violations of these laws, the risks cannot be entirely eliminated.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and individual imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Health Reform

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. There have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs.

In particular, the Affordable Care Act has had, and is expected to continue to have, a significant impact on the healthcare industry. The Affordable Care Act was designed to expand coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, the Affordable Care Act revises the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and imposes a significant annual fee on companies that manufacture or import certain branded prescription drug products. In January 2016, the Centers for Medicare and Medicaid Services issued a final rule regarding the Medicaid Drug Rebate Program, effective April 1, 2016, that, among other things, revises the manner in which the AMP is to be calculated by manufacturers participating in the program and implements certain amendments to the Medicaid rebate statute created under the Affordable Care Act. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare providers and entities, and a significant number of provisions are not yet, or have only recently become, effective.

We cannot predict the full impact of the Affordable Care Act on pharmaceutical companies, as many of the reforms require the promulgation of detailed regulations implementing the statutory provisions, some of which has not yet fully occurred. Further, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our product candidates.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. In August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. These included reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2025 unless additional Congressional action is taken. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

Moreover, the recently enacted Drug Supply Chain Security Act, imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing, which is being phased in over several years beginning in 2015. Among the requirements of this new legislation, manufacturers will be required to provide

certain information regarding the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers will also be required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

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Coverage and Reimbursement

Sales of our products, if and when approved, will depend, in part, on the extent to which the costs of our products will be covered by third-party payors, such as government healthcare programs, private health insurers and managed care organizations. Third-party payors generally decide which drugs they will cover and establish certain reimbursement levels for such drugs. In particular, in the U.S., private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Sales of our product candidates, and those of any future product candidate, will therefore depend substantially on the extent to which the costs of our product candidates, and those of any future product candidate, will be paid by third-party payors. Additionally, the market for our product candidates, and those of any future product candidate, will depend significantly on access to third-party payors' formularies without prior authorization, step therapy, or other limitations such as approved lists of treatments for which third-party payors provide coverage and reimbursement. Additionally, coverage and reimbursement for therapeutic products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will likely be a time-consuming process.

Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs and challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs (including drug prices) has become a priority of federal and state governments. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution by generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could limit our net revenue and results. If these third-party payors do not consider our products to be cost-effective compared to other therapies, they may not cover our products once approved as a benefit under their plans or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis. Decreases in third-party reimbursement for our products once approved or a decision by a third-party payor to not cover our products could reduce or eliminate utilization of our products and have an adverse effect on our sales, results of operations and financial condition. In addition, state and federal healthcare reform measures have been and will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products once approved or additional pricing pressures.

Research and Development

Our research and development expenses totaled $76.6 million for the year ended March 31, 2016 and $14.3 million for the period from October 31, 2014 (date of inception) to March 31, 2015.

Employees

As of March 31, 2016, we had three employees and ASI had 33 employees. As described above under "Services Agreement with Roivant Sciences, Inc., or RSI", we rely on the administrative support and research and development services provided by RSI. Our and ASI's employees are not represented by any collective bargaining unit, and we believe our relations with our employees are good.

Corporate Information

We are an exempted limited company incorporated under the laws of Bermuda on October 31, 2014 under the name Roivant Neurosciences Ltd. We changed our name to Axovant Sciences Ltd. in March 2015. Our registered office is

located in Bermuda at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda, and we also have business operations at Park Place, 55 Par-La-Ville Road, Hamilton HM11, Bermuda. The telephone number of our registered office is +1 (441) 824 8100.

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Available Information

Our Internet address is http://www.axovant.com. The contents of our website are not part of this Annual Report on Form 10-K, and our Internet address is included in this document as an inactive textual reference only. We make our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports available free of charge on our website as soon as reasonably practicable after we file such reports with, or furnish such reports to, the Securities and Exchange Commission, or SEC, pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended. The public may read and copy the materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Additionally, the SEC maintains an internet site that contains reports, proxy and information statements and other information. The address of the SEC's website is www.sec.gov.

Item 1A. Risk Factors

You should carefully consider the following risk factors, in addition to the other information contained in this annual report on Form 10-K, including the section of this report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes. If any of the events described in the following risk factors and the risks described elsewhere in this report occurs, our business, operating results and financial condition could be seriously harmed and the trading price of our common shares could decline. This annual report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this report.

Risks Related to Our Business, Financial Position and Capital Requirements

We have a limited operating history and have never generated any product revenues.

We are a clinical-stage biopharmaceutical company with a limited operating history. We were formed in October 2014, and our operations to date have been focused on organizing and staffing our company, raising capital, acquiring drug development programs and preparing for and advancing our product candidates, intepirdine and nelotanserin, into clinical development. We have not yet demonstrated an ability to successfully complete a large-scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial-scale product, or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, we have no meaningful operations upon which to evaluate our business and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

Our ability to generate revenue and become profitable depends upon our ability to successfully complete the development of our product candidates and other assets for the treatment of various forms of dementia and to obtain the necessary regulatory approvals for their commercialization. We have never been profitable, have no products approved for commercial sale and to date have not generated any revenue from product sales.

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Even if we receive regulatory approval for our product candidates, we do not know when those candidates will generate revenue, if at all. Our ability to generate product revenue depends on a number of factors, including our ability to:

- successfully complete clinical trials and obtain regulatory approval for the marketing of our product candidates;
- set an acceptable price for our product candidates and obtain coverage and adequate reimbursement from third-party payors;
- establish sales, marketing and distribution systems for our product candidates;
- add operational, financial and management information systems and personnel, including personnel to support our clinical, manufacturing and planned future commercialization efforts and operations as a public company;
- initiate and continue relationships with third-party manufacturers and have commercial quantities of our product candidates manufactured at acceptable cost levels;
- attract and retain an experienced management and advisory team;
- achieve broad market acceptance of our products in the medical community and with third-party payors and consumers;
- launch commercial sales of our products, whether alone or in collaboration with others; and
- maintain, expand and protect our intellectual property portfolio.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability. Our expenses could increase beyond expectations if we are required by the FDA, European Medicines Agency, or EMA, Japan's Pharmaceutical and Medical Devices Agency, or PMDA, or comparable regulatory authorities in other countries, to perform studies or clinical trials in addition to those that we currently anticipate. Even if our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with their commercial launch. If we cannot successfully execute any one of the foregoing, our business may not succeed and your investment will be adversely affected.

We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability. Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. We have never generated any revenues, and we cannot estimate with precision the extent of our future losses. We do not currently have any products that are available for commercial sale and we may never generate revenue from selling products or achieve profitability. We expect to continue to incur substantial and increasing losses through the projected commercialization of our product candidates. Our product candidates have not been approved for marketing in the United States or any other jurisdiction, and we may never receive any such approvals. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to produce revenue and achieve profitability is dependent on our ability to complete the development of our product candidates, obtain necessary regulatory approvals, and have our product candidates manufactured and successfully marketed and commercialized. We cannot assure you that we will be profitable even if we successfully commercialize our product candidates. If we do successfully obtain regulatory approval to market our product candidates, our revenues will be dependent, in part, upon, among other things, the size of the markets in the territories for which we gain regulatory approval, the number of competitors in such markets, the accepted price for our product candidates and whether we own the commercial rights for that territory. If the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of our product candidates, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Failure to become and remain profitable may adversely affect the market price of our common shares and our ability to raise capital and continue operations.

We expect our research and development expenses to be significant in connection with our Phase 3 MINDSET trial of intepirdine in patients with mild-to-moderate Alzheimer's disease, and continue to increase as we conduct clinical trials of intepirdine for DLB and clinical trials of our second product candidate, nelotanserin, for the treatment of multiple aspects of LBD. In addition, if we obtain regulatory approval for intepirdine, we expect to incur increased

sales and marketing expenses. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have an adverse effect on our financial position and working capital.

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We are heavily dependent on the success of intepirdine and nelotanserin, our only product candidates, which are still in clinical development, and if either of these product candidates does not receive regulatory approval or is not successfully commercialized, our business may be harmed.

We currently have no products that are approved for commercial sale and may never be able to develop marketable drug products. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to intepirdine and nelotanserin. Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of these product candidates. We cannot be certain that our product candidates will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are and will remain subject to extensive regulation by the FDA, the EMA, the PMDA and other comparable regulatory authorities that each have differing regulations. We are not permitted to market our product candidates in the United States or in any foreign countries until they receive the requisite approvals from the FDA or comparable regulatory authorities in other countries. We have not submitted marketing applications to the FDA or foreign regulatory authorities and do not expect to be in a position to do so for the foreseeable future. Obtaining marketing approval is an extensive, lengthy, expensive and inherently uncertain process, and regulatory authorities, may delay, limit or deny approval of our product candidates for many reasons, including:

- we may not be able to demonstrate that a product candidate is safe and effective as a treatment for our targeted indications to the satisfaction of the applicable regulatory authorities;
- the regulatory authorities may require additional preclinical studies or registrational studies of the product candidate in mild-to-moderate Alzheimer's disease, which would increase our costs and prolong our development;
- the results of our clinical trials may not meet the level of statistical or clinical significance required for marketing approval;
- the regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the Contract Research Organizations (CROs) that we retain to conduct clinical trials may take actions outside of our control that materially adversely impact our clinical trials;
- the regulatory authorities may not find the data from preclinical studies and clinical trials sufficient to demonstrate that the clinical and other benefits of the product candidate outweigh its safety risks;
- the regulatory authorities may disagree with our interpretation of data from our preclinical studies and clinical trials or may require that we conduct additional studies;
- the regulatory authorities may not accept data generated at our clinical trial sites;
- the regulatory authorities may require, as a condition of approval, limitations on approved labeling or distribution and use restrictions;
- in the United States, the FDA may require development of a risk evaluation and mitigation strategy, or REMS, as a condition of approval;
- the regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers; or
- the regulatory authorities may change their approval policies or adopt new regulations.

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We may require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of our product candidates.

We expect to spend substantial amounts to complete the development of, seek regulatory approvals for and commercialize our product candidates. These expenditures will include costs to GSK under the GSK Agreement, and costs to Arena under the Arena Development Agreement. Under the terms of these agreements, we are obligated to make significant cash payments upon the achievement of specified development, regulatory and sales performance milestones, as well as payments in connection with the sale of resulting products.

Even with the net proceeds from our IPO in June 2015, we will require additional capital to complete the development and potential commercialization of our product candidates. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our development program or any future commercialization efforts. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts.

Based upon our current operating plan, we believe that the net proceeds from our IPO will be sufficient to fund our operating expenses and capital expenditure requirements through the calendar year 2017. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because the length of time and activities associated with successful development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of our planned clinical trials for our product candidates;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA, or the PMDA, and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates or any future product candidates;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale manufacturing activities;
- the cost of establishing sales, marketing and distribution capabilities for our product candidates in regions where we choose to commercialize our products on our own; and
- the initiation, progress, timing and results of our commercialization of our product candidates, if approved for commercial sale.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or potentially discontinue operations.

We may be required to make significant payments to third parties under the agreements pursuant to which we acquired our product candidates.

In December 2014, we acquired the rights to intepirdine under the GSK Agreement, and in October 2015, we acquired the rights to nelotanserin and assumed the obligations under the Arena Development Agreement. Under these agreements, we are subject to significant obligations, including payment obligations upon achievement of specified milestones and payments based on product sales, as well as other material obligations. If these payments become due under the terms of the agreements, we may not have sufficient funds available to meet our obligations and in which case our development efforts would be substantially harmed.

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Raising additional funds by issuing securities may cause dilution to existing shareholders, and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

We expect that significant additional capital will be needed in the future to continue our planned operations. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, strategic alliances and license and development agreements in connection with any collaborations. We do not have any committed external source of funds. To the extent that we raise additional capital by issuing equity securities, our existing shareholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common shareholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. Any debt financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem our shares or make investments. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

We currently have a limited number of employees who are employed by our wholly-owned subsidiary, Axovant Sciences, Inc., and we rely on Roivant Sciences, Inc. to provide various administrative, research and development and other services.

As of March 31, 2016, we had three employees and our wholly-owned subsidiary, ASI, had 33 employees. We rely on the administrative support and research and development services provided by our affiliate, RSI, a wholly-owned subsidiary of RSL. We and ASI have entered into a services agreement with RSI. Personnel and support staff that provide services to us under this services agreement are not required to, and we do not expect that they will, have as their primary responsibility the management and administration of our business or act exclusively for us. Under this services agreement, RSI has the discretion to determine which of its employees will perform services under the agreement. Further, Vivek Ramaswamy, Lawrence T. Friedhoff, M.D., Ph.D., and Michael Adasczik, our Principal Accounting Officer, are employees of RSI, and Marianne L. Romeo is an employee of RSL. As a result, such individuals are unlikely to allocate all of their time and resources to us.

RSI has limited financing and accounting and other resources. If RSI fails to perform its obligations in accordance with the terms of the services agreement, it could be difficult for us to operate our business. In addition, the termination of our relationship with RSI and any delay in appointing or finding a suitable replacement provider (if one exists) could make it difficult for us to operate our business. Any failure by RSI to effectively manage our administrative, research and development or other services could harm our business, financial condition and results of operations.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

We expect to hire, either directly or through ASI, additional employees for our managerial, clinical, scientific and engineering, operational, sales and marketing teams. We may have operational difficulties in connection with identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and

may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

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Many of the other pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates and consultants than what we have to offer. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can discover and develop product candidates and our business may be limited.

Our employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees and contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations, including those of the FDA and other similar regulatory bodies, including those laws and regulations that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; federal and state healthcare fraud and abuse and health regulatory laws and other similar foreign fraudulent misconduct laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter third-party misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including the imposition of significant criminal, civil and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our business and operations would suffer in the event of system failures.

Our computer systems, as well as those of ASI, RSI and our CROs and other contractors and consultants, may sustain damage from computer viruses, unauthorized access, cybercriminals, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of preclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. If we are not successful in defending ourselves against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- significant costs to defend related litigation;

- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize our product candidates or any future product candidate;

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- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased demand for our product candidates or any future product candidate, if approved for commercial sale; and
- loss of revenue.

The product liability insurance we currently carry, and any additional product liability insurance coverage we acquire in the future, may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for our product candidates, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the commercialization of any product candidates we develop.

Risks Related to Clinical Development, Regulatory Approval and Commercialization

Clinical trials are very expensive, time-consuming, difficult to design and implement and involve an uncertain outcome.

Our product candidates are still in development and will require extensive clinical testing before we are prepared to submit an application for marketing approval to regulatory authorities. We cannot predict with any certainty if or when we might submit any such application for regulatory approval for our product candidates or whether any such application will be approved by the applicable regulatory authority in our target markets. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, regulatory authorities may not agree with our proposed endpoints for any clinical trials of our product candidates, which may delay the commencement of our clinical trials. The clinical trial process is also time-consuming. We estimate that clinical trials of our product candidates will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials, and the results of early clinical trials therefore may not be predictive of the results of later-stage clinical programs. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

The commencement and completion of clinical trials may be delayed by several factors, including:

- failure to obtain regulatory approval to commence a trial;
- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- inability to reach agreement on acceptable terms with prospective CROs and clinical trial sites;
- slower than expected rates of patient recruitment or failure to recruit suitable patients to participate in a trial;
- failure to manufacture sufficient quantities of a drug candidate or placebo or failure to obtain sufficient quantities of concomitant medication for use in clinical trials;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

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Further, by way of example, we, the FDA or an institutional review board, or IRB, at a clinical trial site may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including the FDA's current Good Clinical Practice, or GCP, regulations, that we are exposing participants to unacceptable health risks, or if the FDA finds deficiencies in our IND submissions or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be harmed, and our ability to generate revenues may be delayed. In addition, any delays in our clinical trials could increase our costs, slow down the approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and results of operations.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

In addition, we acquired worldwide rights to our product candidates and were not involved in their development prior to such acquisitions. Any difficulties we experience in transitioning and integrating such product candidates into our operations may result in delays in clinical trials as well as problems in our development efforts and regulatory filings, particularly if we do not receive all of the necessary drug products, information, reports and data from third parties in a timely manner. More particularly, we have had no involvement with or control over the preclinical and clinical development of either of our product candidates prior to acquiring the rights to them. We are dependent on GSK and Arena, as applicable, having conducted such research and development in accordance with the applicable protocols, legal, regulatory and scientific standards, having accurately reported the results of all clinical trials and other research conducted prior to our acquisition of the product candidates, having correctly collected and interpreted the data from these trials and other research and having supplied us with complete information, data sets and reports required to adequately demonstrate the results reported through the date of our acquisition of these assets. Problems related to GSK and Arena could result in increased costs and delays in the development of our product candidates, which could adversely affect any future revenues.

The results of our clinical trials may not demonstrate that our product candidates are safe and effective.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support the safety and effectiveness of our product candidates for the particular indications for which they are being developed. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. Failure of a clinical trial to meet its predetermined endpoints would likely cause us to abandon a product candidate and may delay development of any other product candidates. Any delay in, or termination of, our clinical trials will delay the submission of our applications for marketing approval and, ultimately, our ability to commercialize our product candidates and generate product revenues.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites and the eligibility criteria for the study. Furthermore, any negative results we may report in clinical trials of any of our product candidates may make it difficult or impossible to recruit and retain

patients in other clinical trials of our same product candidates. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates, or could render further development impossible. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance.

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We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

Drug development is highly competitive and subject to rapid and significant technological advancements. As a significant unmet medical need exists for the treatment of Alzheimer's disease and other dementias, there are several large and small pharmaceutical companies focused on delivering therapeutics for the treatment of these diseases. Further, it is likely that additional drugs will become available in the future for the treatment of our target indications. We are aware of several companies that are working to develop drugs that would compete against intepirdine and nelotanserin. Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and in foreign countries. Our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of our competitors.

Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drugs that are more effective or less costly than any product candidate that we may develop.

We will face competition from other drugs or from other non-drug products currently approved or that will be approved in the future for the treatment of Alzheimer's disease and other dementias, including Lewy body dementia. Therefore, our ability to compete successfully will depend largely on our ability to:

- develop and commercialize drugs that are superior to other products in the market;
- demonstrate through our clinical trials that our product candidates are differentiated from existing and future therapies;
- attract qualified scientific, product development and commercial personnel;
- obtain patent or other proprietary protection for our medicines;
- obtain required regulatory approvals;
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new medicines.

The availability of our competitors' products could limit the demand, and the price we are able to charge, for any product candidate we develop. The inability to compete with existing or subsequently introduced drugs would have an adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving regulatory and marketing approval for or commercializing drugs before we do, which would have an adverse impact on our business and results of operations.

If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

The activities associated with the development and commercialization of our product candidates, including their design, research, testing, manufacture, safety, efficacy, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA, the PDMA and similar regulatory authorities outside the United States. Failure to obtain marketing approval for our product candidates will prevent us from commercializing them. We have not received approval from regulatory authorities to market any product candidate in any jurisdiction, and we will need to complete pivotal clinical trials successfully for our product candidates before we can submit any

application for regulatory approval. It is possible that our product candidates in the future will never obtain the appropriate regulatory approvals necessary for us to commence product sales.

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We expect to rely on third-party CROs and consultants to assist us in filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information for our product candidates to regulatory authorities for each therapeutic indication to establish safety and efficacy of the product candidate for that indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities.

Our product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events caused by our product candidates could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. If an unacceptable frequency or severity of adverse events are reported in our clinical trials for our product candidates or any future product candidates, our ability to obtain regulatory approval for such product candidates may be negatively impacted.

Furthermore, if any of our products are approved and then cause serious or unexpected side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or require a REMS to impose restrictions on its distribution or other risk management measures;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or to conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients;
- we could elect to discontinue the sale of our product; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.

Even if we obtain FDA approval for our product candidates in the United States, we may never obtain approval for or commercialize them in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Even if we obtain regulatory approval for our product candidates, we will still face extensive regulatory requirements and our products may face future development and regulatory difficulties.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA, the EMA, the PMDA and other comparable foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with current GMP regulations, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records

and documents, requirements regarding the distribution of samples to physicians and recordkeeping and current GCP requirements for any clinical trials that we conduct post-approval. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including any requirement to implement a REMS. If any of our product candidates receives marketing approval, the accompanying labels for such products may limit the approved use of the drug, which could limit sales.

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Regulatory authorities may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. These authorities closely regulate the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. We will be subject to stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act in the United States, and other comparable regulations in foreign jurisdictions, relating to the promotion of prescription drugs may lead to enforcement actions and investigations alleging violations of U.S. federal and state health care fraud and abuse laws, as well as state consumer protection laws and comparable laws in foreign jurisdictions.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on manufacturing such products;
- restrictions on the labeling or marketing of such products;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- withdrawal of the products from the market;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of such products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Government regulations may change and additional government regulations may be enacted, either of which could prevent, limit or delay regulatory approval of our product candidates or any future product candidate. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

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Even if our product candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

Even if our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If they not achieve an adequate level of acceptance, we may not generate significant product revenues and become profitable. The degree of market acceptance for our product candidates, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the efficacy and potential advantages compared to alternative treatments;
- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our product together with other medications.

Because we expect sales of our product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of these products, especially of intepirdine, to find market acceptance would harm our business and could require us to seek additional financing.

If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third-parties, we may not be successful in commercializing our product candidates, even if approved.

We do not have any infrastructure for the sales, marketing or distribution of our products, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any product that may be approved, we must build our sales, distribution, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. To achieve commercial success for any product for which we have obtained marketing approval, we will need a sales and marketing organization.

We plan to commercialize our product candidates in the United States, the European Union, Japan and other major markets. If our product candidates are approved for marketing, we may build a focused sales, distribution and marketing infrastructure to market them. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any product launch, which would adversely impact the commercialization of our product candidates. For example, if the commercial launch of our product candidates for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or attain adequate numbers of physicians to prescribe any drugs; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our product candidates in certain markets overseas. Therefore, our future success will depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator's strategic interest in the product and such collaborator's ability to successfully market and sell the product. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

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If we are unable to build our own sales force or negotiate a collaborative relationship for the commercialization of our product candidates we may be forced to delay the potential commercialization of such products or reduce the scope of our sales or marketing activities for our product candidates. If we elect to increase our expenditures to fund commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market or generate product revenue. We could enter into arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be ideal and we may be required to relinquish rights to one or more of our product candidates or otherwise agree to terms unfavorable to us, any of which may have an adverse effect on our business, operating results and prospects.

If we are unable to establish adequate sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

If we obtain approval to commercialize any products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If our product candidates are approved for commercialization, we may enter into agreements with third parties to market them in certain jurisdictions outside the United States. We expect that we will be subject to additional risks related to international operations or entering into international business relationships, including:

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign reimbursement, pricing and insurance regimes;
- foreign taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

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Our current and future relationships with investigators, health care professionals, consultants, third-party payors, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our products for which we obtain marketing approval. Such laws include:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal false claims laws, including the civil False Claims Act, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners (covered manufacturers are required to submit reports to the government by the 90th day of each calendar year); and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs,

contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

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Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, collectively the Affordable Care Act, was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Although it is too early to determine the full effect of the Affordable Care Act, the law has continued the downward pressure on pharmaceutical pricing, especially under the Medicare program, and increased the industry's regulatory burdens and operating costs. Among the provisions of the Affordable Care Act of importance to our potential drug candidates are the following:

- an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries under their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs in certain states;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

We cannot predict the full impact of the Affordable Care Act on pharmaceutical companies, as many of the reforms require the promulgation of detailed regulations implementing the statutory provisions, some of which has not yet fully occurred. For example, in January 2016, the Centers for Medicare and Medicaid Services issued a final rule regarding the Medicaid Drug Rebate Program, effective April 1, 2016, that, among other things, revises the manner in which the "average manufacturer price" is to be calculated by manufacturers participating in the program and implements certain amendments to the Medicaid rebate statute created under the Affordable Care Act. Further, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This included further reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2025 unless additional Congressional action is taken. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers. Further, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

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Moreover, the Drug Supply Chain Security Act, which was enacted in 2012 as part of the Food and Drug Administration Safety and Innovation Act, imposes new obligations on manufacturers of pharmaceutical products related to product tracking and tracing. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed, or what the impact of such changes on our business, if any, may be.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Coverage and adequate reimbursement may not be available for our product candidates, which could make it difficult for us to sell our products profitably.

Market acceptance and sales of any product candidates that we develop, will depend in part on the extent to which reimbursement for these products and related treatments will be available from third-party payors, including government health administration authorities and private health insurers. Third-party payors decide which drugs they will pay for and at which reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a plan-by-plan basis. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Additionally, a third-party payor's decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Each plan determines whether or not it will provide coverage for a drug, what amount it will pay the manufacturer for the drug, and on what tier of its formulary the drug will be placed. The position of a drug on a formulary generally determines the co-payment that a patient will need to make to obtain the drug and can strongly influence the adoption of a drug by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize any product candidates that we develop.

Additionally, there have been a number of legislative and regulatory proposals to change the healthcare system in the United States and in some foreign jurisdictions that could affect our ability to sell any future drugs profitably. These legislative and regulatory changes may negatively impact the reimbursement for any future drugs, following approval.

Risks Related to Our Dependence on Third Parties

We do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of our product candidates.

We have no experience in drug formulation or manufacturing and do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. While intepirdine was being developed by GSK, it was also being manufactured by GSK. We expect that the drug substance transferred from GSK under the GSK Agreement will be sufficient for us to complete our planned Phase 3 pivotal program, and we have contracted with third parties to fill, finish, supply, store and distribute intepirdine for this program. We also will rely on third-party manufacturers to supply us with sufficient quantities of intepirdine to be used, if approved, for the commercialization of intepirdine.

Under the Arena Development Agreement, subject to specified exceptions, Arena remains the sole and exclusive manufacturer of nelotanserin, and we will depend on Arena to manufacture sufficient quantities of nelotanserin for our planned clinical trials. Arena is reliant on its own third-party supplier for the active pharmaceutical ingredient in nelotanserin, and Arena has notified us that it currently does not have an agreement in place for the supply of active pharmaceutical ingredient and is in the process of identifying a new supplier. If we are unable to initiate or continue our relationship with Arena or these other third-party contractors, or if Arena is unable to manufacture and supply nelotanserin to us, whether as a result of its own inability to obtain active pharmaceutical ingredient or otherwise, we could experience delays in our development efforts as new manufacturers for our product candidates are located and qualified.

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Further, our reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including:

- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- failure to comply with cGMP and similar foreign standards;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell our product candidates or any future product candidate in a timely fashion, in sufficient quantities or under acceptable terms;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or regulatory sanctions related to the manufacture of our or other company's products;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our products under specified storage conditions and in a timely manner.

Any of these events could lead to clinical trial delays, failure to obtain regulatory approval or impact our ability to successfully commercialize our products. Some of these events could be the basis for FDA action, including injunction, recall, seizure, or total or partial suspension of production.

We intend to rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we expect to have limited influence over their actual performance.

We intend to rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future nonclinical studies. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs will be required to comply with GLPs and GCPs, which are regulations and guidelines enforced by the FDA and are also required by the competent authorities of the member states of the European Economic Area and comparable foreign regulatory authorities in the form of International Conference on Harmonization guidelines for any of our product candidates that are in preclinical and clinical development. The regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Accordingly, if we or our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the relevant regulatory approval process.

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Our CROs will not be our employees, and we will not control whether or not they devote sufficient time and resources to our clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret and intellectual property protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop could be harmed, our costs could increase, and our ability to generate revenues could be delayed.

If our relationships with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our drug development programs and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries for our product candidates and any future product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our development programs and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our current product candidates or any future product candidate in the United States or in other foreign countries.

There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates or companion diagnostic that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate and companion diagnostic under patent protection could be reduced.

If the patent applications we hold or have in-licensed with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize, future drugs. Any such outcome could have a materially adverse effect on our business.

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The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or whether we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business and financial condition.

Moreover, we may be subject to a third party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly against us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on an international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have an adverse effect on our business.

Third party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights, may delay or prevent the development and commercialization of our product candidates.

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter partes review, and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization. We have conducted searches for information in support of patent protection and otherwise evaluated the patent landscape for our product candidates, and, based on these searches and evaluations to date, we do not believe that there are valid patents which contain granted claims that could be asserted with respect to our product. However, we may be incorrect.

There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly.

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We cannot provide any assurances that third-party patents do not exist which might be enforced against our drugs or product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common shares.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

The United States has recently enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Filing, prosecuting and defending patents covering our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent

protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

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Our reliance on third parties requires us to share our trade secrets and other proprietary information, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. Because we expect to rely on third parties to manufacture our product candidates, and we expect to collaborate with third parties on the development of our product candidates, we must, at times, share trade secrets and other proprietary information with them. We also conduct joint research and development programs that may require us to share trade secrets and other proprietary information under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such proprietary information becomes known by our competitors, is inadvertently incorporated into the technology of others, or is disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our confidential information, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees', consultants' or independent contractors' former employers, clients, or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

Risks Related to Our Common Shares

An active trading market for our common shares may not be sustained.

Prior to our IPO, there was no public market for our common shares. Although our common shares are listed on the NYSE, we cannot assure you that an active trading market for our common shares will continue to develop or be sustained. As a result of RSL owning approximately 75.6% of our common shares, trading in our common shares may be less liquid than the shares of companies with broader public ownership. If an active market for our common shares is not sustained, you may not be able to sell your shares quickly or at the market price. An inactive market may also impair our ability to raise capital to continue to fund operations by selling common shares and may impair our ability to acquire other companies or technologies by using our common shares as consideration.

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The market price of our common shares is likely to be highly volatile, and you may lose some or all of your investment.

The market price of our common shares is likely to be highly volatile and may be subject to wide fluctuations in response to a variety of factors, including the following:

- any delay in the commencement, enrollment and ultimate completion of clinical trials;
- results of clinical trials of our product candidates or those of our competitors;
- any delay in filing applications for marketing approval and any adverse development or perceived adverse development with respect to applicable regulatory authorities' review of those applications;
- failure to successfully develop and commercialize our current product candidates or any future product candidate;
- inability to obtain additional funding;
- regulatory or legal developments in the United States and other countries applicable to our product candidates;
- adverse regulatory decisions;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for our current product candidates or any future product candidate, or the inability to do so at acceptable prices;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- changes in the market valuations of similar companies;
- market conditions in the pharmaceutical and biotechnology sectors, and the issuance of new or changed securities analysts' reports or recommendations;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- significant lawsuits, including patent or shareholder litigation, and disputes or other developments relating to our proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- sales of our common shares by us or our shareholders in the future;
- trading volume of our common shares;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, as well as general economic, political, regulatory and market conditions, may negatively affect the market price of our common shares, regardless of our actual operating performance.

Volatility in our share price could subject us to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant share price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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We are a "controlled company" within the meaning of the applicable rules of the New York Stock Exchange and, as a result, qualify for exemptions from certain corporate governance requirements. If we rely on these exemptions, you will not have the same protections afforded to shareholders of companies that are subject to such requirements.

RSL controls a majority of the voting power of our outstanding common shares. As a result, we are a "controlled company" within the meaning of the New York Stock Exchange, or NYSE, corporate governance requirements. Under these rules, a company of which more than 50% of the voting power for the election of directors is held by an individual, group or another company is a "controlled company" and may elect not to comply with certain corporate governance requirements, including the requirements:

- that a majority of the Board of Directors consists of independent directors;
- for an annual performance evaluation of the nominating and corporate governance and compensation committees;
- that we have a nominating and corporate governance committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities; and
- that we have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibility.

We have elected to use certain of these exemptions and we may continue to use all or some of these exemptions in the future. As a result, you may not have the same protections afforded to shareholders of companies that are subject to all of the NYSE corporate governance requirements.

RSL owns a significant percentage of our common shares and is able to exert significant control over matters subject to shareholder approval.

Based on common shares outstanding as of March 31, 2016, RSL beneficially owns approximately 75.6% of the voting power of our outstanding common shares, and has the ability to substantially influence us through this ownership position. For example, RSL may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. RSL's interests may not always coincide with our corporate interests or the interests of other shareholders, and it may act in a manner with which you may not agree or that may not be in the best interests of our other shareholders. So long as RSL continues to own a significant amount of our equity, it will continue to be able to strongly influence or effectively control our decisions.

If securities or industry analysts do not publish research or reports about our business, or publish negative reports about our business, our share price and trading volume could decline.

The trading market for our common shares will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If our financial performance fails to meet analyst estimates or one or more of the analysts who cover us downgrade our common shares or change their opinion of our common shares, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

Because we do not anticipate paying any cash dividends on our common shares in the foreseeable future, capital appreciation, if any, would be your sole source of gain.

We have never declared or paid any cash dividends on our common shares. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common shares would be your sole source of gain on an investment in our common shares for the foreseeable future. Additionally, we are subject to Bermuda legal constraints that may affect our ability to pay dividends on our common shares and make other payments.

Future sales of our common shares, or the perception that such sales may occur, could depress our share price, even if our business is doing well.

Sales of a substantial number of our common shares in the public market, or the perception by investors that our stockholders intend to sell substantial amounts of our common stock in the public market, could depress the market price of our common shares, even if our business is doing well. Such a decrease in our share price could in turn impair our ability to raise capital through the sale of additional equity securities.

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All of the shares sold in our IPO are freely transferable without restrictions or further registration under the Securities Act. The remaining 75,000,000 shares outstanding, representing a majority of our common stock, are held by RSL. If RSL were to sell a substantial portion of these shares, or if the market perceived that RSL intends to sell these shares, it could negatively affect our share price. Prior to RSL's corporate reorganization and recapitalization in December 2015, any decision by RSL to sell or otherwise dispose of our shares required the unanimous agreement of all of the directors of RSL, including Vivek Ramaswamy, our principal executive officer. Subsequent to RSL's corporate reorganization and recapitalization in December 2015, any such decision only requires a majority of RSL's directors, meaning that all or a portion of the shares of our common stock held by RSL may be sold without Vivek Ramaswamy's consent. However, any such sales must be made in compliance with the Securities Act and the rules and regulations thereunder, which could limit the number of our shares that RSL could sell in any 90-day period.

We have also filed a registration statement on Form S-8 under the Securities Act to register the 9,500,000 common shares that may be issued under our equity incentive plans from time to time. Shares registered under this registration statement are available for sale in the public market subject to vesting arrangements and exercise of options, as well as Rule 144 in the case of our affiliates.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance with our public company responsibilities and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the NYSE and other applicable securities rules and regulations impose various requirements on public companies. Our management and other personnel expect to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance, which could make it more difficult for us to attract and retain qualified members of our Board of Directors.

We previously identified a material weakness in our internal control over financial reporting. Although we believe this material weakness has since been remediated, we may identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal control over financial reporting, which may result in material misstatements of our financial statements or cause us to fail to meet our reporting obligations.

In connection with the preparation of our financial statements as of and for the period from October 31, 2014 (date of inception) to March 31, 2015, we and our independent registered public accounting firm identified a material weakness in our internal control over financial reporting, as defined in the standards established by the Public Company Accounting Oversight Board of the United States. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

We did not design or maintain an effective control environment because we did not maintain a sufficient complement of personnel with an appropriate level of knowledge of accounting, experience and training commensurate with our financial reporting requirements. This material weakness resulted in material audit adjustments related to the affiliate charge for share-based compensation. Our limited personnel also resulted in our inability to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives, as demonstrated by, among other things, our insufficient segregation of duties in our finance and accounting functions. During this time, we relied on RSI for information systems and financial and accounting support. RSI had limited staff and performed nearly all aspects of our financial reporting process, including, but not limited to, accessing the underlying accounting records and systems, posting and recording journal entries and taking responsibility for the preparation of the financial statements.

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During the year ended March 31, 2016, we implemented processes and procedures intended to mitigate the identified material weakness. This included the expansion of our staff by hiring a full-time principal financial officer and principal accounting officer. We have also hired additional finance and accounting personnel with appropriate training to build our financial management and reporting infrastructure. We formalized and implemented our accounting policies and internal controls and the related documentation, including for share-based compensation. We believe that, as a result, we have fully remediated the material weakness discussed above as of March 31, 2016. However, we cannot assure you that the measures we have taken to date, or any measures we may take in the future, will be sufficient to identify or prevent future material weaknesses. If other material weaknesses or other deficiencies occur, our ability to accurately and timely report our financial position could be impaired, which could result in late filings of our annual and quarterly reports under the Exchange Act, restatements of our consolidated financial statements, a decline in our stock price, suspension or delisting of our common stock from the NYSE, and could adversely affect our reputation, results of operations and financial condition.

As a public company, we will be obligated to develop and maintain proper and effective internal controls over financial reporting, and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common shares.

The Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley, requires, among other things, that we assess the effectiveness of our internal control over financial reporting annually and disclosure controls and procedures quarterly. In particular, beginning with the fiscal year ending on March 31, 2017, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of Sarbanes- Oxley, or Section 404. Section 404 of Sarbanes-Oxley also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. However, for as long as we remain an "emerging growth company" as defined in the JOBS Act, we intend to utilize the provision exempting us from the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

We are beginning the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404, and we may not be able to complete our evaluation, testing and any required remediation in a timely fashion. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we may hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge to assist with compiling the system and process documentation necessary for our management to perform the evaluation needed to comply with Section 404.

During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or other deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or other deficiency in our internal control over financial reporting once that firm begins its Section 404 audits of internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common shares could decline, and we could be subject to sanctions or investigations by the NYSE, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common shares less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including exemption from compliance with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earlier of (1) March 31, 2021, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.0 billion, (3) the date on which we are deemed to be a large accelerated filer, which means the market value of our common shares that are held by non-affiliates exceeds $700.0 million as of the prior September 30, the end of our second fiscal quarter, and (4) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company” which would allow us to take advantage of many of the same exemptions from disclosure requirements including exemption from compliance with the auditor attestation requirements of Section 404 and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We cannot predict if investors will find our common shares less attractive because we may rely on these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and our share price may be more volatile.

We are a Bermuda company and it may be difficult for you to enforce judgments against us or our directors and executive officers.

We are a Bermuda exempted company. As a result, the rights of our shareholders are governed by Bermuda law and our memorandum of association and bye-laws. The rights of shareholders under Bermuda law may differ from the rights of shareholders of companies incorporated in another jurisdiction. It may be difficult for investors to enforce in the United States judgments obtained in U.S. courts against us based on the civil liability provisions of the U.S. securities laws. It is doubtful whether courts in Bermuda will enforce judgments obtained in other jurisdictions, including the United States, against us or our directors or officers under the securities laws of those jurisdictions or entertain actions in Bermuda against us or our directors or officers under the securities laws of other jurisdictions.

Bermuda law differs from the laws in effect in the United States and may afford less protection to our shareholders.

We are organized under the laws of Bermuda. As a result, our corporate affairs are governed by the Bermuda Companies Act 1981, as amended, or the Companies Act, which differs in some material respects from laws typically applicable to U.S. corporations and shareholders, including the provisions relating to interested directors, amalgamations, mergers and acquisitions, takeovers, shareholder lawsuits and indemnification of directors. Generally, the duties of directors and officers of a Bermuda company are owed to the company only. Shareholders of Bermuda companies typically do not have rights to take action against directors or officers of the company and may only do so in limited circumstances. Shareholder class actions are not available under Bermuda law. The circumstances in which shareholder derivative actions may be available under Bermuda law are substantially more proscribed and less clear than they would be to shareholders of U.S. corporations. The Bermuda courts, however, would ordinarily be expected to permit a shareholder to commence an action in the name of a company to remedy a wrong to the company where the act complained of is alleged to be beyond the corporate power of the company or illegal, or would result in the violation of the company’s memorandum of association or bye-laws. Furthermore, consideration would be given by a Bermuda court to acts that are alleged to constitute a fraud against the minority shareholders or, for instance, where an act requires the approval of a greater percentage of the company’s shareholders than those who actually approved it.

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When the affairs of a company are being conducted in a manner that is oppressive or prejudicial to the interests of some shareholders, one or more shareholders may apply to the Supreme Court of Bermuda, which may make such order as it sees fit, including an order regulating the conduct of the company's affairs in the future or ordering the purchase of the shares of any shareholders by other shareholders or by the company. Additionally, under our bye-laws and as permitted by Bermuda law, each shareholder has waived any claim or right of action against our directors or officers for any action taken by directors or officers in the performance of their duties, except for actions involving fraud or dishonesty. In addition, the rights of our shareholders and the fiduciary responsibilities of our directors under Bermuda law are not as clearly established as under statutes or judicial precedent in existence in jurisdictions in the United States, particularly the State of Delaware. Therefore, our shareholders may have more difficulty protecting their interests than would shareholders of a corporation incorporated in a jurisdiction within the United States.

There are regulatory limitations on the ownership and transfer of our common shares.

Common shares may be offered or sold in Bermuda only in compliance with the provisions of the Companies Act and the Bermuda Investment Business Act 2003, which regulates the sale of securities in Bermuda. In addition, the Bermuda Monetary Authority must approve all issues and transfers of shares of a Bermuda exempted company. However, the Bermuda Monetary Authority has, pursuant to its statement of June 1, 2005, given its general permission under the Exchange Control Act 1972 and related regulations for the issue and free transfer of our common shares to and among persons who are non-residents of Bermuda for exchange control purposes as long as the shares are listed on an appointed stock exchange, which includes the NYSE. This general permission would cease to apply if we were to cease to be listed on the NYSE.

We have anti-takeover provisions in our bye-laws that may discourage a change of control.

Our bye-laws contain provisions that could make it more difficult for a third party to acquire us without the consent of our Board of Directors. These provisions provide for:

- a classified Board of Directors with staggered three-year terms;
- directors only to be removed for cause;
- an affirmative vote of 66 2/3% of our voting shares for certain "business combination" transactions that have not been approved by our Board of Directors;
- restrictions on the time period in which directors may be nominated; and
- our Board of Directors to determine the powers, preferences and rights of our preference shares and to issue the preference shares without shareholder approval.

These anti-takeover defenses could discourage, delay or prevent a transaction involving a change in control of our company and may prevent our shareholders from receiving the benefit from any premium to the market price of our common shares offered by a bidder in a takeover context. Even in the absence of a takeover attempt, the existence of these provisions may adversely affect the prevailing market price of our common shares if the provisions are viewed as discouraging takeover attempts in the future. These provisions could also discourage proxy contests, make it more difficult for you and other shareholders to elect directors of your choosing and cause us to take corporate actions other than those you desire.

We may reduce the voting power of your common shares without your consent.

Under our amended and restated bye-laws, in the event that any U.S. person holds, directly, indirectly or constructively, 9.5% or more of the total voting power of our issued share capital, excluding any U.S. person that held, directly, indirectly or constructively, 9.5% or more of the total voting power of issued share capital immediately prior to the closing of our IPO, the aggregate votes conferred by the common shares held by such person (or by any person through which such U.S. person indirectly or constructively holds shares) will be reduced by our Board of Directors to the extent necessary such that the common shares held, directly, indirectly or constructively, by such U.S. person will constitute less than 9.5% of the voting power of all issued and outstanding shares. RSL, certain of its affiliates, and Vivek Ramaswamy, our principal executive officer, will not be subject to these provisions. Further, our Board of Directors may determine that shares shall carry different or no voting rights as it reasonably determines, based on the advice of counsel, to be appropriate to (1) avoid the existence of any U.S. person who holds 9.5% or more of the total voting power of our issued share capital or (2) avoid adverse tax, legal or regulatory consequences to us, any subsidiary of ours or any holder of our common shares or its affiliates.

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These provisions may discourage potential investors from acquiring a stake or making a significant investment in our company as well as discourage a takeover attempt, which may prevent our shareholders from receiving the benefit of any such transactions as well as adversely affect the prevailing market price of our common shares if viewed as discouraging takeover attempts in the future.

We may become subject to unanticipated tax liabilities.

We are incorporated under the laws of, and managed and controlled from, Bermuda. We may, however, become subject to income, withholding or other taxes in certain jurisdictions by reason of our activities and operations, and it is also possible that taxing authorities in any such jurisdictions could assert that we are subject to greater taxation than we currently anticipate. Any such non-Bermudan tax liability could materially adversely affect our results of operations.

Taxing authorities could reallocate our taxable income among our subsidiaries, which could increase our overall tax liability.

We and RSL, our principal shareholder, are based in Bermuda, and we currently have a subsidiary in the United States. If we succeed in growing our business, we expect to conduct increased operations through our subsidiaries in various tax jurisdictions pursuant to transfer pricing arrangements between us, our parent company and our subsidiaries. If two or more affiliated companies are located in different countries, the tax laws or regulations of each country generally will require that transfer prices be the same as those between unrelated companies dealing at arms' length and that appropriate documentation is maintained to support the transfer prices. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable tax authorities.

If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arms' length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

Changes in our effective tax rate may reduce our net income in future periods.

Our tax position could be adversely impacted by changes in tax rates, tax laws, tax practice, tax treaties or tax regulations or changes in the interpretation thereof by the tax authorities in Europe, the United States, Bermuda and other jurisdictions as well as being affected by certain changes currently proposed by the OECD and their action plan on Base Erosion and Profit Shifting. Such changes may become more likely as a result of recent economic trends in the jurisdictions in which we operate, particularly if such trends continue. If such a situation were to arise, it could adversely impact our tax position and our effective tax rate. Failure to manage the risks associated with such changes, or misinterpretation of the laws providing such changes, could result in costly audits, interest, penalties and reputational damage, which could adversely affect our business, results of our operations and our financial condition.

Our actual effective tax rate may vary from our expectation and that variance may be material. A number of factors may increase our future effective tax rates, including: (1) the jurisdictions in which profits are determined to be earned and taxed; (2) the resolution of issues arising from any future tax audits with various tax authorities; (3) changes in the valuation of our deferred tax assets and liabilities; (4) increases in expenses not deductible for tax purposes, including transaction costs and impairments of goodwill in connection with acquisitions; (5) changes in the taxation of share-based compensation; (6) changes in tax laws or the interpretation of such tax laws, and changes in generally accepted accounting principles; and (7) challenges to the transfer pricing policies related to our structure.

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U.S. holders of our common shares may suffer adverse tax consequences if we are characterized as a passive foreign investment company.

Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest, and gains from the sale or exchange of investment property and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. If we are characterized as a PFIC, U.S. holders of our common shares may suffer adverse tax consequences, including having gains realized on the sale of our common shares treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on our common shares by individuals who are U.S. holders, and having interest charges apply to distributions by us and the proceeds of sales of our common shares.

Our status as a PFIC will depend on the composition of our income and the composition and value of our assets (which, assuming we are not a "controlled foreign corporation," or a CFC, under Section 957(a) of the Code for the year being tested, may be determined in large part by reference to the market value of our common shares, which may be volatile) from time to time. Our status may also depend, in part, on how quickly we utilize the cash proceeds from our IPO in our business. We believe that we were not a CFC prior to our IPO and were not a CFC at any point after our IPO in the taxable year that ended on March 31, 2016. Based on this belief, with respect to the taxable year that ended on March 31, 2016 and foreseeable future taxable years, we believe that we were not a PFIC and presently do not anticipate that we will be a PFIC based upon the expected value of our assets, including any goodwill, and the expected composition of our income and assets. However, our status as a PFIC is a fact-intensive determination made on an annual basis and we cannot provide any assurances regarding our PFIC status for the current or future taxable years.

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Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We lease our principal offices in Bermuda at Clarendon House, 2 Church Street, Hamilton HM 11, Bermuda, and we also have business operations at Park Place, 55 Par-La-Ville Road, Hamilton HM 11, Bermuda. We also lease office space in New York, New York.

We believe that all of our facilities are in good condition and are well maintained and that our current arrangements will be sufficient to meet our needs for the foreseeable future and that any required additional space will be available on commercially reasonable terms to meet space requirements if they arise.

Item 3. Legal Proceedings

From time to time, we may become involved in legal proceedings relating to claims arising from the ordinary course of business. We are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal proceeding against us that we believe could have an adverse effect on our business, operating results or financial condition.

Item 4. Mine Safety Disclosures.

Not applicable.

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PART II.

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information for Common Stock

In June 2015, we completed our IPO of common shares and our stock began trading on the NYSE under the symbol "AXON". Prior to that time, there was no public market for our common stock. Shares sold in our initial public offering on June 11, 2015 were priced at $15.00 per share.

The following table reflects the range of the high and low sale price per share of our common stock, as reported on the NYSE for the periods indicated. These prices reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

	Common Stock Price	
	High	Low
Year Ended March 31, 2016		
First Quarter[1]	$31.17	$18.18
Second Quarter	$22.88	$9.99
Third Quarter	$21.30	$11.01
Fourth Quarter	$18.33	$8.86

[1] Our common stock commenced trading on the NYSE on June 11, 2015.

Stockholders

American Stock Transfer & Trust Company is the transfer agent and registrar for our common stock. As of the close of business on June 3, 2016, we had 99,150,000 shares of common stock outstanding held by two holders of record. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have never declared or paid cash dividends on our common stock. We anticipate that we will retain all of our future earnings, if any, for use in the expansion and operation of our business and do not anticipate paying cash dividends in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our Board of Directors.

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Performance Graph

The following graph illustrates a comparison of the total cumulative stockholder return for our common shares since the market close on June 11, 2015, the date of the pricing of our initial public offering of common shares at a price of $15.00 per share, with the cumulative total returns of the S&P 500 Index and the Dow Jones US Pharmaceuticals & Biotechnology Index.

The graph assumes an initial investment of $100 at the market close on June 11, 2015, in our common shares, and in each of the indexes with relative performance tracked through March 31, 2016, assuming reinvestment of the full amount of all dividends, if any.

Historical stockholder return is not necessarily indicative of the performance to be expected for any future periods. This performance graph shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, or incorporated by reference into any of our filings under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

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Recent Sales of Unregistered Equity Securities

None.

Use of Proceeds from Initial Public Offering

On June 16, 2015, we closed our IPO, in which we issued and sold 24,150,000 common shares at a public offering price of $15.00 per share, including 3,150,000 common shares sold pursuant to the exercise in full of the underwriters' option to purchase additional shares, for gross proceeds of $362.3 million. All of the common shares issued and sold in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (Registration No. 333-204073), which was declared effective by the SEC on June 10, 2015. Jefferies LLC, Evercore Group L.L.C., RBC Capital Markets LLC, JMP Securities LLC and Robert W. Baird & Co. acted as underwriters. The net proceeds to us were approximately $334.5 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

As of March 31, 2016, we have used $58.3 million of the net proceeds from the IPO primarily to fund the preclinical and clinical development of intepirdine and nelotanserin, to expand our internal research and development capabilities, and for general corporate purposes.

Such uses are consistent with the planned use of proceeds described in our prospectus dated June 10, 2015 filed with the SEC on June 11, 2015 pursuant to Rule 424(b) under the Securities Act.

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Item 6. Selected Financial Data

In the table below, we provide you with our selected consolidated financial data for the periods presented. We have prepared this information using our audited consolidated financial statements. You should read the following selected consolidated financial data in conjunction with our consolidated financial statements and related notes included in this Annual Report on Form 10-K and "Item 7 — Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report on Form 10-K. The selected financial data in this section are not intended to replace our consolidated financial statements and the related notes. Our historical results are not necessarily indicative of our future results.

Statements of Operations Data	Year Ended March 31, 2016	Period From October 31, 2014 (Date of Inception) to March 31, 2015
	(In thousands, except share and per share data)	
Operating expenses:		
Research and development expenses (includes $30,622 and $3,178 of share-based compensation expense for the year ended March 31, 2016, and for period from October 31, 2014 (Date of inception) to March 31, 2015, respectively)	$76,644	$14,324
General and administrative expenses (includes $41,764 and $5,118 of share-based compensation expense for the year ended March 31, 2016, and for period from October 31, 2014 (Date of inception) to March 31, 2015, respectively)	56,518	6,722
Total operating expenses	133,162	21,046
Loss before provision for income tax	(133,162)	(21,046)
Income tax (benefit) expense	(17)	1
Net loss and comprehensive loss	$(133,145)	$(21,047)
Net loss per common share — basic and diluted	$(1.41)	$(1.32)
Weighted average common shares outstanding — basic and diluted	94,465,164	15,986,842

	As of March 31,	
	2016	2015
Balance Sheet Data	(In thousands)	
Cash	$276,251	$ —
Working capital	266,331	(2,760)
Total assets	282,498	1,117
Long-term liabilities	—	5,000
Accumulated deficit	(154,192)	(21,047)
Total shareholders' equity (deficit)	266,743	(7,751)

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Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the audited consolidated financial statements and the related notes thereto included elsewhere in this Annual Report on Form 10-K.

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements can be identified by the use of words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "int "may," "plan," "project," "will," "would," or the negative or plural of these words or similar expressions or variations. Such forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, and those discussed in the section titled "Risk Factors," set forth in Part I, Item 1A of this Annual Report on Form 10-K and in our other filings with the SEC. You should not rely upon forward-looking statements as predictions of future events. Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Overview

We are a clinical-stage biopharmaceutical company focused on acquiring, developing and commercializing novel therapeutics for the treatment of dementia. We intend to develop a pipeline of product candidates to comprehensively address the cognitive, functional and behavioral aspects of dementia and related neurological disorders. Our vision is to become the leading company focused on the treatment of dementia by addressing all forms and aspects of the disease.

Our near-term focus is to develop our lead product candidate, intepirdine, previously referred to as RVT-101, a selective 5-HT_6 receptor antagonist, for the treatment of Alzheimer's disease and dementia with Lewy bodies, or DLB, and to develop nelotanserin, our second product candidate, a potent and highly selective 5-HT_{2A} inverse agonist, for the treatment of REM behavior disorder, or RBD, in DLB patients, and visual hallucinations in patients with Lewy body dementia. In the long-term, we intend to develop a broader pipeline of product candidates to comprehensively address the cognitive, behavioral and functional aspects of dementia. We have determined that we have one operating and reporting segment.

We were founded in October 2014 and our operations to date have been limited to organizing and staffing our company, raising capital, acquiring our product candidates and preparing for and advancing our product candidates, intepirdine and nelotanserin, into clinical development. In June 2015, we completed our IPO, from which we raised proceeds of $334.5 million, net of underwriting discounts and issuance costs. We intend to use these proceeds to fund our planned clinical development programs. To date, we have not generated any revenue and we recorded net losses of $133.1 million and $21.0 million for the year ended March 31, 2016 and for the period from October 31, 2014 (date of inception) through March 31, 2015, respectively.

Our products in development, their stage of development, their mechanism of action and the indications for which they are intended to address are described in more detail in Part I, Item 1. Business of this Annual Report on Form 10-K.

Asset Purchase Agreement with GlaxoSmithKline for Intepirdine

Under the GSK Agreement, we made an upfront payment of $5.0 million and also expect to make an additional $5.0 million payment in June 2016, which we had recorded as a contingent payment liability in the accompanying consolidated balance sheet. We are also obligated to pay GSK $35.0 million, $25.0 million and $10.0 million upon the receipt of marketing approval of intepirdine in the United States, the European Union and Japan, respectively, as well as an additional one-time payment of $85.0 million for the first calendar year in which we achieve global net sales of $1.2 billion for intepirdine.

Under the GSK Agreement we are also obligated to pay a fixed 12.5% royalty based on net sales of intepirdine, subject to reduction on account of expiration of patent and regulatory exclusivity or upon generic entry.

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Arena Development Agreement for Nelotanserin

In October 2015, we exercised an option to acquire global rights, title, interest and obligations in and to nelotanserin from our parent company RSL. In May 2015, RSL entered into a development, marketing and supply agreement for nelotanserin with Arena, and we entered into a Waiver and Option Agreement with RSL. Upon the exercise of our option, we assumed RSL's rights and obligations under the development, marketing and supply agreement with Arena, or the Arena Development Agreement. Under the Waiver and Option Agreement, we recorded $5.3 million as research and development expense, which was 110% of any payments made to Arena by RSL and any costs incurred by RSL in connection with the development of nelotanserin. We will be responsible for future contingent payments under the Arena Development Agreement, including up to $4.0 million in potential development milestone payments, up to $37.5 million in potential regulatory milestone payments and up to $60.0 million in potential commercial milestone payments. Under the Arena Development Agreement, we are also obligated to purchase finished drug product under a fixed price equal to 15% of net sales of nelotanserin.

Services Agreement with Roivant Sciences, Inc., or RSI

We and our wholly-owned subsidiary, Axovant Sciences, Inc., or ASI, have entered into a services agreement with Roivant Sciences Inc., or RSI, a wholly-owned subsidiary of RSL, or the Services Agreement, pursuant to which RSI provides us with services in relation to the identification of potential product candidates, project management of clinical trials and other development activities and certain administrative and financial functions. We and ASI amended and restated our Services Agreement with RSI on October 13, 2015 for the fiscal year commencing April 1, 2015. Under the terms of our Services Agreement with RSI, we are obligated to pay or reimburse RSI for the costs it, or third parties acting on its behalf, incurs in providing services to us, including administrative and support services as well as research and development services. In addition, we are obligated to pay to RSI at a pre-determined mark-up on the costs incurred directly by RSI in connection with any general and administrative and research and development services.

We expect that our reliance on RSI will decrease over time as we, ASI and any other future subsidiary of ours continue to hire the necessary personnel to manage the development and potential commercialization of our product candidates. For the year ended March 31, 2016, we incurred expenses of $7.6 million, inclusive of the mark-up, under the Services Agreement. For the period from October 31, 2014 (date of inception) to March 31, 2015 we incurred expenses of $2.0 million, inclusive of the mark-up, under the Services Agreement. We have recorded these charges as research and development expense and general and administrative expense in our consolidated statements of operations.

Financial Operations Overview

Revenue

We have not generated any revenue from the sale of any products, and we do not expect to generate any revenue unless and until we obtain regulatory approval of and begin to commercialize one of our product candidates in development.

Research and Development Expense

Since our inception, our operations have primarily been focused on organizing and staffing our company, raising capital and acquiring our product candidates and preparing for and advancing our product candidates, intepirdine and nelotanserin, into clinical development. Our research and development expenses include:

- employee-related expenses, such as salaries, share-based compensation, benefits and travel expense for research and development personnel;
- costs allocated to us under the Services Agreement;
- expenses incurred under agreements with CROs, as well as consultants who assist in the development of our product candidates;
- manufacturing costs in connection with producing materials for use in conducting preclinical and clinical studies;
- costs for planning and developing clinical studies for Alzheimer's disease and other forms of dementia including evaluating intepirdine for patients with DLB;

- costs for planning and developing clinical studies for nelotanserin for patients with Lewy body dementia;
- milestone payments and other costs that we incur under the GSK Agreement and the Arena Development Agreement;
- costs for sponsored research; and
- depreciation expenses for assets used in research and development activities.

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Research and development activities will continue to be central to our business model. For the year ended March 31, 2016 the majority of our research and development expenses have been associated with advancing our lead product candidate intepirdine. For the period from October 31, 2014 (date of inception) to March 31, 2015 our research and development expenses were substantially all related to intepirdine. We expect our research and development expense to increase significantly primarily as a result of our ongoing Phase 3 MINDSET study for intepirdine, our initiation of the intepirdine HEADWAY-DLB study in patients with DLB, and in other forms of dementia, and commencement of our development program for nelotanserin in Lewy body dementia. These increases will be partially offset by decreases in our share-based compensation expense primarily as a result of the RSL private financing and recapitalization. We also expect our share-based compensation expense attributable to RSL common share awards to become less variable because of the December 2015 merger of BVC Ltd., or BVC, with and into RSL, a transaction we refer to in this report as the BVC Merger. Refer to Note E "Related Party Transactions," in the accompanying notes to consolidated financial statements included in this Annual Report on Form 10-K.

Product candidates in later stages of clinical development, such as intepirdine and nelotanserin, generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials.

The duration, costs and timing of clinical trials of our products in development and any other product candidates will depend on a variety of factors that include, but are not limited to, the following:

- the number of trials required for approval;
- the per patient trial costs;
- the number of patients who participate in the trials;
- the number of sites included in the trials;
- the countries in which the trial is conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- the potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up;
- the timing and receipt of regulatory approvals; and
- the efficacy and safety profile of the product candidates.

In addition, the probability of success of our products in development and any other product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval of our product candidates for any indication in any country. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of any clinical trial we conduct, or when and to what extent we will generate revenue from the commercialization and sale of our products in development or other product candidates, if at all.

General and Administrative Expense

General and administrative expenses consist primarily of share-based compensation, legal and accounting fees, consulting services, services received under the Services Agreement and employee salaries and related benefits for general and administrative personnel.

We anticipate that our general and administrative expenses will increase in the future to support our growth and our operations as a public company. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, lawyers and accountants, among other expenses. We also expect to incur additional expenses associated with maintaining compliance with NYSE rules and SEC requirements, insurance, and investor relations costs. In addition, we expect to incur expenses associated with building a sales, commercial and marketing team before our products in development obtain regulatory approval for marketing. These increases will be partially offset by decreases in our share-based compensation expense primarily as a result of the RSL private financing and recapitalization. We also expect our share-based compensation expense attributable to RSL common share awards to become less variable because of the BVC Merger.

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Results of Operations for the Year Ended March 31, 2016 and Period from October 31, 2014 (Date of Inception) to March 31, 2015

The following table summarizes our results of operations for the year ended March 31, 2016 and period from October 31, 2014 (date of inception) to March 31, 2015 (in thousands):

	Year Ended March 31, 2016	Period From October 31, 2014 (Date Of Inception) To March 31, 2015
Operating expenses:		
Research and development expenses (includes $30,622 and $3,178 of share-based compensation expense for the year ended March 31, 2016, and for period from October 31, 2014 (Date of inception) to March 31, 2015, respectively)	$76,644	$ 14,324
General and administrative expenses (includes $41,764 and $5,118 of share-based compensation expense for the year ended March 31, 2016, and for period from October 31, 2014 (Date of inception) to March 31, 2015, respectively)	56,518	6,722
Total operating expenses	133,162	21,046

Research and Development Expenses

Research and development expenses were $76.6 million for the year ended March 31, 2016, and consisted primarily of share-based compensation expense of $30.6 million, contract research organization (CRO) fees of $17.4 million, $5.3 million for the acquisition of nelotanserin, contract manufacturing organization (CMO) fees, employee salaries and benefits and payments made to consultants and other third party vendors engaged in the pursuit of developing our product candidates. The share-based compensation expense for the year ended March 31, 2016 was impacted by share-based compensation expense of $19.3 million related to the RSL common share awards and RSL options issued by RSL to RSI employees.

On December 4, 2015, BVC, a non-public entity, which held a non-controlling ownership interest in RSL, our parent company, was merged with and into RSL, with RSL as the surviving entity. The compensation amounts of $19.3 million include share-based compensation expense for BVC awards issued to RSI employees prior to the BVC Merger. Prior to the BVC Merger, we recorded share-based compensation expense, in relation to the share-based awards issued by BVC to RSI employees based on the changes in fair value of BVC share-based awards. As these BVC share based awards were not based on our or RSL's shares, they were remeasured at each reporting period date until performance was completed.

As a result of the BVC Merger, all outstanding BVC share-based awards were converted into RSL common share awards, with the same vesting and forfeiture terms as the original grant. The RSL common share awards are fair valued on the date of grant and that fair value is recognized over the requisite service period. At the time of the BVC Merger on December 4, 2015, the unvested BVC awards that were converted into common shares of RSL were remeasured at the estimated fair value of RSL and that fair value is recognized over the remaining requisite service period. On December 8, 2015 following the BVC Merger, RSL had a recapitalization in conjunction with a private financing.

Research and development expenses were $14.3 million for the period from October 31, 2014 (date of inception) to March 31, 2015 and consisted primarily of an up-front payment of $5.0 million and a contingent payment of $5.0 million to be made, to GSK in connection with our asset purchases for intepirdine and $4.3 million of professional

costs related thereto, as well as costs allocated under the Services Agreement, and employee salaries and related benefits including share-based compensation expense of $3.2 million.

General and Administrative Expenses

General and administrative expenses were $56.5 million for the year ended March 31, 2016, and consisted primarily of share-based compensation expense of $41.8 million and employee salaries and related benefits, legal and professional fees, and direct and indirect costs allocated to us under the Services Agreement. The share-based compensation expense for the year ended March 31, 2016 includes share-based compensation expense of $34.1 million for RSL common share awards issued to RSI employees. These compensation amounts include share-based compensation expense for BVC awards issued to RSI employees prior to the BVC Merger. Prior to the BVC Merger we recorded share-based compensation expense in relation to the share-based awards issued by BVC to RSI employees based on the changes in fair value of share-based awards which were remeasured at each reporting period date until performance was completed as discussed above.

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General and administrative expenses were $6.7 million for the period from October 31, 2014 (date of inception) to March 31, 2015 and were primarily attributable to employee salaries and related benefits, share-based compensation, legal and professional fees and consulting services associated with the formation of our company and corporate matters and certain direct and indirect costs associated with services performed by RSI. We recorded share-based compensation of $5.1 million for the period from October 31, 2014 (date of inception) to March 31, 2015.

Liquidity and Capital Resources

Overview

We completed our IPO in June 2015, in which we sold 24,150,000 common shares at a price of $15.00 per share, including 3,150,000 common shares sold pursuant to the exercise in full of the underwriters' option to purchase additional shares, for gross proceeds of $362.3 million. We received net proceeds of $334.5 million, after deducting underwriting discounts and commissions and offering expenses of $27.7 million. As of March 31, 2016, our principal source of liquidity was our cash balance totaling $276.3 million.

For the year ended March 31, 2016, we used $53.3 million and $5.3 million of cash in our operating and investing activities, respectively. We have incurred and expect to continue to incur significant and increasing operating losses at least for the next several years. We do not expect to generate revenue unless and until we successfully complete development and obtain regulatory approval for one of our products in development. Our cash utilization may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our planned clinical trials and our expenditures on other research and development activities. We anticipate that our expenses will increase substantially as we:

- continue our planned Phase 3 MINDSET trial of intepirdine for the treatment of mild-to-moderate Alzheimer's disease designed to support regulatory approval in the United States and Europe, and initiate additional registrational studies to support regulatory approval in Japan;
- continue our twelve month open-label extension study of intepirdine for patients completing the MINDSET study;
- continue the intepirdine HEADWAY-DLB study for the development of intepirdine for dementia with Lewy bodies;
- commence extension studies for patients completing the HEADWAY-DLB study and our nelotanserin phase 2 studies;
- potentially commence future studies of intepirdine for the treatment of severe Alzheimer's disease and other forms of dementia, such as Parkinson's disease dementia and vascular dementia;
- continue the development of nelotanserin in Lewy body dementia and other indications;
- seek to identify, acquire, develop and commercialize additional product candidates;
- integrate acquired technologies into a comprehensive regulatory and product development strategy;
- achieve milestones under our agreements with third parties that will require us to make substantial payments to those parties;
- maintain, expand and protect our intellectual property portfolio;
- hire scientific, clinical, regulatory, manufacturing, quality control, commercial and administrative personnel;
- add operational, financial and management information systems and personnel, including personnel to support our drug development efforts;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- scale up external manufacturing capabilities to commercialize our product candidates;
- ultimately establish a sales, marketing and distribution infrastructure for drug candidates for which we may obtain regulatory approval; and
- operate as a public company.

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Under the terms of the GSK Agreement, we also expect to make an additional payment of $5.0 million in June 2016. Our primary use of cash is to fund the research and development of our product candidates. We expect that our existing cash, including net proceeds from our IPO, will be sufficient to fund our operating expenses and capital expenditure requirements through the calendar year 2017. However, we have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect. Our existing funds will not be sufficient to enable us to complete all necessary development and to commercially launch all of our products. Accordingly, we may be required to obtain further funding through other public or private offerings of our capital stock, debt financing, collaboration and licensing arrangements or other sources. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or potentially discontinue operations.

Until such time, if ever, as we can generate substantial revenue from sales of our products in development, we expect to finance our cash needs through a combination of equity offerings, debt financings and potential collaboration, license or development agreements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our shareholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our shareholders' rights. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Taking any of these actions could harm our business, results of operations, financial condition and future prospects.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following table sets forth a summary of our cash flows (in thousands):

	Year Ended March 31, 2016	Period From October 31, 2014 (Date Of Inception) To March 31, 2015
Net cash used in operating activities	$(53,347)	$ (683)
Net cash used in investing activities	(5,346)	(5,009)
Net cash provided by financing activities	334,944	5,692

Operating Activities

Cash flows from operating activities consist of net loss adjusted for non-cash items, including depreciation and share-based compensation expense, as well as the effect of changes in working capital and other activities.

For the year ended March 31, 2016, net cash used in operating activities was $53.3 million and was primarily attributable to a net loss of $133.1 million which includes costs incurred for research and development activities, including CRO fees, manufacturing, regulatory and other clinical trial costs and our general and administrative expenses, partially offset by $72.4 million of non-cash share-based compensation expense.

For the period from October 31, 2014 (date of inception) to March 31, 2015, net cash used in operating activities was $0.7 million. Net cash used in operating activities was primarily attributable to the payments made by RSI on our

behalf.

Investing Activities

For the year ended March 31, 2016, net cash used in investing activities was $5.3 million primarily for the payment made to RSL for nelotanserin. For the period from October 31, 2014 (date of inception) to March 31, 2015, net cash used in investing activities was $5.0 million for the payment made to GSK in connection with our asset purchases for intepirdine.

Financing Activities

For the year ended March 31, 2016, net cash provided by financing activities was $334.9 million, which was primarily attributable to the net proceeds from the IPO of our common shares of $334.5 million. For the period from October 31 2014 (date of inception) to March 31, 2015, net cash provided by financing activities was $5.7 million which reflects the capital contribution from RSL.

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Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under the SEC's rules. Accordingly, our operating results, financial condition and cash flows are not subject to off-balance sheet risks.

Contractual Obligations

Our long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business. We have entered into commitments under the GSK Agreement, the Arena Development Agreement and the Services Agreement with RSI. In addition, we have entered into various services agreements with third parties for pharmaceutical manufacturing and research activities. The manufacturing agreements can be terminated by us with 30 days written notice. We expect to enter into other commitments as the business further develops.

During 2015, we entered into two subleases with RSI for office space. Under the terms of the subleases, RSI has annual rent obligations of $0.9 million through 2020. RSI pays the rent directly and then invoices us for the rent for our proportionate share of the space based upon the relative numbers of full-time equivalent employees located on the premises. As a result, our rent obligations are not fixed. The subleases expire on June 30, 2016 and March 31, 2017, respectively. For the year ended March 31, 2016, we incurred $0.6 million in rent expense under this arrangement with RSI.

As of March 31, 2016, we did not have any ongoing material financial commitments, other than pursuant to the GSK Agreement and the Arena Development Agreement. As described in this report, we previously accrued $5.0 million as research and development expense for a contingent payment liability under our agreement with GSK. We expect to pay this amount to GSK in June 2016.

Recent Accounting Pronouncements

For detailed information regarding recently issued accounting pronouncements and the expected impact on our financial statements, see Note B "Summary of Significant Accounting Policies," in the accompanying notes to consolidated financial statements included in this Annual Report on Form 10-K.

Application of Critical Accounting Policies and Significant Judgments and Estimates

The discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the dates of the balance sheets and the reported amounts of expenses during the reporting periods. In accordance with U.S. GAAP, we evaluate our estimates and judgments on an ongoing basis. Significant estimates include assumptions used in the determination of some of our costs incurred under our services agreement with RSI and ASI, which costs are charged to research and development and general and administrative expense, as well as assumptions used to estimate the fair value of our common shares. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We define our critical accounting policies as those under U.S. GAAP that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles.

Our significant accounting policies are more fully described in Note B to our consolidated financial statements included in this Annual Report on Form 10-K. Not all of these significant accounting policies, however, require that we make estimates and assumptions that we believe are "critical accounting estimates." We have discussed our accounting policies with the audit committee of our board of directors, and we believe that our estimates relating to contingent payment liabilities, research and development accruals, share-based compensation and income taxes

described below have the greatest potential impact on our consolidated financial statements, and are “critical accounting estimates.”

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Contingent Payment Liability

One significant estimate relates to the probability and timing of the contingent payment liability recorded in the balance sheet. Such liability relates to our asset purchase agreement with GSK (see Note C to our consolidated financial statements). We expect to pay $5.0 million to GSK in June 2016 (see Note I to our consolidated financial statements). Should the specified criteria for payment not be met, or be met in a period different from our expectation, there could be significant fluctuation in our financial results in future periods.

Share-Based Compensation

We recognize share-based compensation expense related to stock options granted to employees based on the estimated fair value of the awards on the date of grant, net of forfeitures. We estimate the grant date fair value, and the resulting share-based compensation expense, using the Black-Scholes option-pricing model. The grant date fair value of the share-based awards is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards.

We recognize share-based compensation expense related to stock options granted to non-employees issued in exchange for services based on the estimated fair value of the awards on the date of grant, net of forfeitures. We estimate the grant date fair value, and the resulting share-based compensation expense, using the Black-Scholes option-pricing model; however, the fair value of the stock options granted to non-employees is remeasured each reporting period until the service is complete, and the resulting increase or decrease in value, if any, is recognized as expense or income, respectively, during the period the related services are rendered.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions, which determine the fair value of share-based awards. These assumptions include:

Expected Term. Our expected term represents the period that our share-based awards are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term).

Expected Volatility. Because we did not have an extended trading history for our common shares, the expected volatility was estimated using weighted average measures of implied volatility and the historical volatility of our peer group of companies for a period equal to the expected life of the stock options. Our peer group of publicly traded biopharmaceutical companies was chosen based on their similar size, stage in the life cycle or area of specialty.

Risk-Free Interest Rate. The risk-free interest rate is based on the rates paid on securities issued by the U.S. Treasury with a term approximating the expected life of the stock options.

Expected Dividend. We have never paid, and do not anticipate paying, cash dividends on our common shares. Therefore, the expected dividend yield was assumed to be zero.

In addition to the Black-Scholes assumptions, we estimate our forfeiture rate based on an analysis of our actual forfeitures and will continue to evaluate the adequacy of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover behavior and other factors. The impact from any forfeiture rate adjustment would be recognized in full in the period of adjustment and if the actual number of future forfeitures differs from our estimates, we might be required to record adjustments to share-based compensation in future periods.

A significant component of total share-based compensation expense relates to the RSL common share awards and RSL options issued by RSL to RSI employees. For the year ended March 31, 2016 we recorded share-based compensation expense of $53.4 million in relation to the RSL common share awards and RSL stock options issued by RSL to RSI employees. These share-based compensation amounts include compensation expense for BVC awards prior to the BVC Merger on December 4, 2015. For the period from October 31, 2014 (date of inception) to March 31, 2015, we incurred share-based compensation expense of $0.4 million, inclusive of the mark-up, under the Services Agreement. Share-based compensation expense is allocated to us by RSL based upon the relative percentage of time utilized by RSI employees on our matters. Prior to the BVC Merger, we recorded share-based compensation expense, in relation to the share-based awards issued by BVC to RSI employees based on the changes in fair value of BVC share-based awards. As these BVC share-based awards were not based on our or RSL's shares, they were remeasured at each reporting period date until performance was completed. As a result of the BVC Merger, all outstanding BVC share-based awards were converted into RSL common share awards, with the same vesting and forfeiture terms as the original grant. The RSL common share awards are fair valued on the date of grant and that fair value is recognized

over the requisite service period. At the time of the BVC Merger on December 4, 2015, the unvested BVC awards that were converted into common shares of RSL were remeasured at the estimated fair value of RSL and that fair value is recognized over the remaining requisite service period. On December 8, 2015 following the BVC Merger, RSL had a recapitalization in conjunction with a private financing.

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The RSL common share awards are valued at fair value on the date of grant and that fair value is recognized over the requisite service period. As a result of the BVC Merger, the converted BVC awards will not be remeasured prospectively. The estimated fair value of these RSL common share awards was determined by the valuation of the December 8, 2015 RSL private financing. Prior to the BVC Merger, the fair value of BVC awards were based on RSL's valuation after considering the fair value of RSL's ownership interest in us and RSL's other investments, discounted cash flow analysis, transactions entered into and contemplated by RSL and relevant industry and comparable public company data. As RSL is a non-public entity, therefore the BVC awards prior to the BVC Merger and the RSL common share awards following the BVC Merger are classified as Level 3 due to their unobservable nature. Significant judgment and estimates were used to estimate the fair value of these awards, as they are not publicly traded. RSL common share awards are subject to specified vesting schedules and requirements (a mix of time-based, performance-based and corporate event-based, including targets for RSL's post-IPO market capitalization and future financing events). We estimated the fair value of each RSL option on the date of grant using the Black-Scholes closed-form option-pricing model.

Research and Development Expense Accruals

Research and development costs are expensed as incurred. Clinical study costs are accrued over the service periods specified in the contracts and adjusted as necessary based upon an ongoing review of the level of effort and costs actually incurred. Payments for a product license prior to regulatory approval of the product and payments for milestones achieved prior to regulatory approval of the product are expensed in the period incurred as research and development. Milestone payments made in connection with regulatory approvals are capitalized and amortized to cost of revenue over the remaining useful life of the asset. Research and development costs are charged to expense when incurred and primarily consist of the intellectual property and research and development materials acquired from GSK and Arena, certain costs charged by RSI under its services agreement with us and ASI (See Note E) and expenses from third parties who conduct research and development activities on our behalf. We expense in-process research and development projects acquired as asset acquisitions which have not reached technological feasibility and which have no alternative future use.

Income Taxes

We account for income taxes in accordance with ASC 740, Income Taxes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recorded when, after consideration of all positive and negative evidence, it is not more likely than not that our deferred tax assets will be realizable. When uncertain tax positions exist, we recognize 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. When and if we were to recognize interest and penalties related to unrecognized tax benefits, they would be reported in tax expense.

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Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Market risk is the potential loss arising from adverse changes in market rates and market prices such as interest rates, foreign currency exchange rates, and changes in the market value of equity instruments. We do not believe we are currently exposed to any material market risk. As of March 31, 2016, we had cash of $276.3 million, consisting of non-interest bearing deposits dominated in the U.S. dollar.

Item 8. Financial Statements and Supplementary Data

All financial statements and schedules required to be filed hereunder are listed in the Index to Financial Statements and are incorporated herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision of our principal executive officer and principal financial officer, we evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2016, the end of the period covered by this report. The term "disclosure controls and procedures" (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act), means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. Based on this evaluation our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of March 31, 2016 at the reasonable assurance level.

Material Weakness Previously Identified

Our management previously identified deficiencies in our internal control over financial reporting that constituted a material weakness as of March 31, 2015. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the company's annual or interim consolidated financial statements will not be prevented or detected on a timely basis. We did not design or maintain an effective control environment because we did not maintain a sufficient complement of personnel with an appropriate level of knowledge of accounting, experience and training commensurate with our financial reporting requirements. This material weakness resulted in material audit adjustments related to the affiliate charge for share-based compensation. Our limited personnel also resulted in our inability to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives, as demonstrated by, among other things, our insufficient segregation of duties in our finance and accounting functions.

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Remediation of Previously Identified Material Weakness

Subsequent to the identification of the material weakness, we hired an experienced principal financial officer and principal accounting officer and additional skilled accounting and finance staff members, and we formalized and implemented our accounting policies and internal controls and the related documentation, including share-based compensation, which support the accurate and timely preparation of consolidated financial statements that are fairly presented in accordance with U.S. GAAP. These improvements to our internal controls were implemented during the fiscal year ended March 31, 2016, and were in place in connection with the preparation of our consolidated financial statements for the year ended March 31, 2016. As such, we believe that these initiatives have remediated the material weakness in internal control over financial reporting as of March 31, 2016.

Management's Annual Report on Internal Control Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by rules of the SEC for newly public companies.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

Changes in Internal Control over Financial Reporting

During the quarter ended March 31, 2016, we finalized the implementation and operation of our controls over share-based compensation. These changes in our internal control over financial reporting during the quarter ended March 31, 2016 represent changes that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

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PART III.

We will file a definitive proxy statement for our 2016 annual meeting of stockholders (the "2016 Proxy Statement") with the SEC, pursuant to Regulation 14A, not later than 120 days after the end of our fiscal year. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the 2016 Proxy Statement that specifically address the items set forth herein are incorporated by reference.

Item 10. Director, Executive Officers and Corporate Governance

The information required by this item will be contained in our 2016 Proxy Statement under the captions "Discussion of Proposals," "Information About Corporate Governance," "Information About Our Executive Officers" and "Section 16(a) Beneficial Ownership Reporting Compliance" and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this item will be contained in our 2016 Proxy Statement under the captions "Information About Corporate Governance" and "Executive Compensation" and is incorporated herein by reference.

Item 12. Securities Ownership of Certain Beneficial Owners and Management and Related Stockholders Matters

The information required by this item will be contained in our 2016 Proxy Statement under the captions "Principal Stockholders, "Information About Our Executive Officers" and "Equity Compensation Plan Information" and is incorporated herein by reference.

Item 13. Certain Relationship and Related Transactions, and Director Independence

The information required by this item will be contained in our 2016 Proxy Statement under the captions "Certain Relationship and Related Party Transactions" and is incorporated herein by reference.

Item 14. Principal Accounting Fee and Services

The information required by this item will be contained in our 2016 Proxy Statement under the captions "Independent Registered Public Accounting Firm Fees and Other Matters" and "Discussion of Proposals" and is incorporated herein by reference.

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PART IV. FINANCIAL INFORMATION

Item 15. Exhibits and Financial Statements Schedules

(a) Documents filed as part of this Annual Report on Form 10-K:
(1) Financial Statements. The Consolidated Financial Statements are included as Appendix A hereto and are filed as part of this Annual Report on Form 10-K. The Consolidated Financial Statements include:

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Consolidated Statements of Operations and Comprehensive Loss for the Year Ended March 31, 2016 and for the period from October 31, 2014 (Date of Inception) to March 31, 2015	72
Consolidated Statements of Shareholders' Equity (Deficit) for the Year Ended March 31, 2016 and for the period from October 31, 2014 (Date of Inception) to March 31, 2015	73
Consolidated Statements of Cash Flows for the Year Ended March 31, 2016 and for the period from October 31, 2014 (Date of Inception) to March 31, 2015	74
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(2) Exhibits. The exhibits set forth on the Exhibit Index following the signature page to this annual report are filed as part of this Annual Report on Form 10-K. This list of exhibits identifies each management contract or compensatory plan or arrangement required to be filed as an exhibit to this Annual Report on Form 10-K.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AXOVANT SCIENCES LTD.

By: /s/ Vivek Ramaswamy
Vivek Ramaswamy
Principal Executive Officer

June 6, 2016

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KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Vivek Ramaswamy and Gregory Weinhoff, jointly and severally, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign this Annual Report on Form 10-K of Axovant Sciences Ltd., and any or all amendments (including post-effective amendments) thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agents, or his, her or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.
Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated

Signature	Title	Date
/s/ Vivek Ramaswamy Vivek Ramaswamy	Chief Executive Officer and Director (Principal Executive Officer)	June 6, 2016
/s/ Gregory Weinhoff Gregory Weinhoff	Principal Financial Officer	June 6, 2016
/s/ Michael Adasczik Michael Adasczik	Principal Accounting Officer	June 6, 2016
/s/ Berndt Modig Berndt Modig	Director	June 6, 2016
/s/ Lawrence Olanoff Lawrence Olanoff	Director	June 6, 2016
/s/ Atul Pande Atul Pande	Director	June 6, 2016
/s/ Gary Pisano Gary Pisano	Director	June 6, 2016
/s/ Ilan Oren Ilan Oren	Director	June 6, 2016
/s/ Marianne L. Romeo Marianne L. Romeo	Director	June 6, 2016

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Axovant Sciences Ltd.:

We have audited the accompanying consolidated balance sheets of Axovant Sciences Ltd. and its subsidiaries as of March 31, 2016 and March 31, 2015, and the related consolidated statements of operations and comprehensive loss, shareholders' equity (deficit) and cash flows for the year ended March 31, 2016 and for the period from October 31, 2014 (date of inception) to March 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Axovant Sciences Ltd. and its subsidiaries at March 31, 2016 and March 31, 2015, and the results of their operations and their cash flows for the year ended March 31, 2016 and for the period from October 31, 2014 (date of inception) to March 31, 2015 in conformity with accounting principles generally accepted in the United States of America.

/s/ PricewaterhouseCoopers LLP

Florham Park, New Jersey
June 6, 2016

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AXOVANT SCIENCES LTD.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	March 31, 2016	March 31, 2015
Assets		
Current assets:		
Cash	$276,251	$ —
Prepaid expenses and other current assets	4,865	4
Income tax receivable	970	—
Deferred financing costs	—	1,104
Total current assets	282,086	1,108
Property, plant and equipment, net	89	9
Deferred tax assets	323	—
Total assets	$282,498	$ 1,117
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$622	$ 403
Due to Roivant Sciences Ltd. and Roivant Sciences, Inc.	1,814	2,307
Accrued expenses	8,319	1,158
Contingent payment liability	5,000	—
Total current liabilities	15,755	3,868
Contingent payment liability	—	5,000
Total liabilities	15,755	8,868
Commitments and contingencies (Note I)		
Shareholders' equity (deficit):		
Common shares, par value $0.00001 per share, 1,000,000,000 shares authorized, 99,150,000 and 75,000,000 issued and outstanding at March 31, 2016 and March 31, 2015, respectively	1	1
Common shares subscribed	—	(1)
Additional paid-in capital	420,934	13,296
Accumulated deficit	(154,192)	(21,047)
Total shareholders' equity (deficit)	266,743	(7,751)
Total liabilities and shareholders' equity (deficit)	$282,498	$ 1,117

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

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AXOVANT SCIENCES LTD.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Year Ended March 31, 2016	Period From October 31, 2014 (Date Of Inception) To March 31, 2015
Operating expenses:		
Research and development expenses (includes $30,622 and $3,178 of share-based compensation expense for the year ended March 31, 2016, and for period from October 31, 2014 (Date of inception) to March 31, 2015, respectively)	$76,644	$14,324
General and administrative expenses (includes $41,764 and $5,118 of share-based compensation expense for the year ended March 31, 2016, and for period from October 31, 2014 (Date of inception) to March 31, 2015, respectively)	56,518	6,722
Total operating expenses	133,162	21,046
Loss before provision for income tax	(133,162)	(21,046)
Income tax (benefit) expense	(17)	1
Net loss and comprehensive loss	$(133,145)	$(21,047)
Net loss per common share — basic and diluted	$(1.41)	$(1.32)
Weighted average common shares outstanding — basic and diluted	94,465,164	15,986,842

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

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AXOVANT SCIENCES LTD.
Consolidated Statements of Shareholders' Equity (Deficit)
(in thousands, except share and per share data)

	Common Shares		Common Shares Subscribed	Additional Paid in Capital	Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Shares	Amount				
Balance at October 31, 2014	10,000,000	$ —	$ —	$ —	$ —	$ —
Capital contribution	—	—	—	5,000	—	5,000
Common stock issued to RSL	65,000,000	1	(1)	—	—	—
Share-based compensation expense	—	—	—	518	—	518
Capital contribution — share-based compensation	—	—	—	7,778	—	7,778
Net loss	—	—	—	—	(21,047)	(21,047)
Balance at March 31, 2015	75,000,000	$ 1	$ (1)	$ 13,296	$ (21,047)	$ (7,751)
Sale of common shares in initial public offering ($15.00 per share), net of underwriting discounts and commissions and offering expenses of $27,748	24,150,000	—	—	334,502	—	334,502
Common shares subscription paid	—	—	1	—	—	1
Capital contribution	—	—	—	750	—	750
Share-based compensation expense	—	—	—	17,994	—	17,994
Capital contribution — share-based compensation (Note E)	—	—	—	54,392	—	54,392
Net loss	—	—	—	—	(133,145)	(133,145)
Balance at March 31, 2016	99,150,000	$ 1	$ —	$ 420,934	$ (154,192)	$ 266,743

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

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AXOVANT SCIENCES LTD.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended March 31, 2016	Period From October 31, 2014 (Date Of Inception) To March 31, 2015
Cash flows from operating activities:		
Net loss	$(133,145)	$(21,047)
Adjustments to reconcile net loss to net cash used in operating activities:		
In-process research and development expenses	5,252	10,000
Share-based compensation	72,386	8,296
Depreciation and amortization	14	—
Deferred tax assets	(323)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(4,860)	(4)
Accounts payable	219	117
Due to Roivant Sciences Ltd. and Roivant Sciences, Inc.	(311)	1,487
Accrued liabilities	8,391	468
Income tax receivable	(1,155)	—
Income tax payable	185	—
Net cash used in operating activities	(53,347)	(683)
Cash flows from investing activities:		
Purchase of in-process research and development	(5,252)	(5,000)
Purchase of property, plant and equipment	(94)	(9)
Net cash used in investing activities	(5,346)	(5,009)
Cash flows from financing activities:		
Cash proceeds from issuance of common shares in initial public offering, net of underwriting discount	336,893	—
Initial public offering costs paid	(2,351)	(25)
Cash capital contribution from Roivant Sciences Ltd.	751	5,000
Repayment of amounts due to Roivant Sciences Ltd. and Roivant Sciences, Inc. for amounts paid on behalf of the Company	(627)	—
Due to Roivant Sciences Ltd. and Roivant Sciences, Inc. for amounts paid on behalf of the Company	278	717
Net cash provided by financing activities	334,944	5,692
Net change in cash	276,251	—
Cash—beginning of period	—	—
Cash—end of period	$276,251	$—
Non-cash financing activities:		

Unpaid initial public offering costs	$—	$1,079
Supplemental disclosure of cash paid:		
Income taxes	$1,279	$—

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

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AXOVANT SCIENCES LTD.
Notes to Consolidated Financial Statements
Note A—Description of Business

Axovant Sciences Ltd. (the ‘‘Company’’) is a clinical-stage biopharmaceutical company focused on acquiring, developing and commercializing novel therapeutics for the treatment of dementia. The Company intends to develop a pipeline of product candidates to comprehensively address the cognitive, functional and behavioral aspects of dementia and related neurological disorders. The Company was founded on October 31, 2014 as a Bermuda Exempted Limited Company and a wholly-owned subsidiary of Roivant Sciences Ltd. (‘‘RSL’’), under the name Roivant Neurosciences Ltd. The Company changed its name to Axovant Sciences Ltd. in March 2015. On February 24, 2015, Axovant Sciences, Inc. (“ASI”) was formed, and on March 7, 2015 it became a wholly-owned subsidiary of the Company based in the United States of America.

From its inception, the Company has devoted substantially all of its efforts to organizing and staffing the Company, raising capital, acquiring product candidates and preparing for and advancing its product candidates, intepirdine, previously referred to as RVT-101, and nelotanserin, into clinical development. The Company has determined that it has one operating and reporting segment.

Note B—Summary of Significant Accounting Policies

[1] Basis of Presentation:

The Company’s fiscal year ends on March 31, and its fiscal quarters end on June 30, September 30, and December 31. The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification (‘‘ASC’’) and Accounting Standards Update (‘‘ASU’’) of the Financial Accounting Standards Board (‘‘FASB’’). The consolidated financial statements include the accounts of the Company and ASI, its wholly-owned subsidiary. The Company has no unconsolidated subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

[2] Use of Estimates:

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company regularly evaluates estimates and assumptions related to assets, liabilities, costs, expenses and compensation expense allocated to the Company under its services agreement with Roivant Sciences, Inc. (“RSI”) and ASI, contingent liabilities, share-based compensation and research and development costs. The Company bases its estimates and assumptions on historical experience and on various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

[3] Risks and Uncertainties:

The Company is subject to risks common to companies in the pharmaceutical industry including, but not limited to, uncertainties related to commercialization of products, regulatory approvals, dependence on key products, dependence on key customers and suppliers, and protection of intellectual property rights.

[4] Concentrations of Credit Risk:

Financial instruments that potentially subject the Company to concentration of credit risk include cash. At March 31, 2016 substantially all of the cash balances are deposited in three banking institutions and are all in excess of insured levels.

[5] Property, Plant and Equipment:

Property, plant and equipment, consisting of computer equipment, is recorded at cost. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred. Upon disposal, retirement or sale, the related cost and accumulated depreciation is removed from the accounts and any resulting gain or loss is included in the results of operations. Depreciation will be recorded for property, plant and equipment using the straight-line method over the estimated useful lives of three to five years, once the asset is installed and placed in service.

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The Company reviews the recoverability of all long-lived assets, including the related useful lives, whenever events or changes in circumstances indicate that the carrying amount of a long-lived asset might not be recoverable. Recoverability is measured by comparison of the book values of the assets to future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value, which is measured based on the projected discounted future net cash flows arising from the assets.

[6] Research and Development Expense:

Research and development costs are expensed as incurred. Clinical study costs are accrued over the service periods specified in the contracts and adjusted as necessary based upon an ongoing review of the level of effort and costs actually incurred. Payments for a product license prior to regulatory approval of the product and payments for milestones achieved prior to regulatory approval of the product are expensed in the period incurred as research and development. Milestone payments made in connection with regulatory approvals are capitalized and amortized to cost of revenue over the remaining useful life of the asset. Research and development costs are charged to expense when incurred and primarily consist of the intellectual property and research and development materials acquired from GSK and Arena (See Note C), certain costs charged by RSI under its services agreement with the Company and Axovant Sciences, Inc. (See Note E) and expenses from third parties who conduct research and development activities on behalf of the Company. The Company expenses in-process research and development projects acquired as asset acquisitions which have not reached technological feasibility and which have no alternative future use. Clinical study costs are accrued over the service periods specified in the contracts and adjusted as necessary based upon an ongoing review of the level of effort and costs actually incurred. For the year ended March 31, 2016, the Company recorded $76.6 million of research and development expense, of which $30.6 million was attributable to share-based compensation expense. For the period from October 31, 2014 (date of inception) through March 31, 2015, the Company recorded $14.3 million of research and development expense, of which $3.2 million was attributable to share-based compensation expense.

[7] Income Taxes:

The Company accounts for income taxes in accordance with ASC 740, Income Taxes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recorded when, after consideration of all positive and negative evidence, it is not more likely than not that the Company's deferred tax assets will be realizable. 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. When and if the Company were to recognize interest and penalties related to unrecognized tax benefits, they would be reported in tax expense in the consolidated statement of operations.

[8] Share-Based Compensation:

The Company accounts for share-based awards to employees and directors in accordance with the provisions of ASC 718, Compensation—Stock Compensation. Under ASC 718, share-based awards are valued at fair value on the date of grant and that fair value is recognized over the requisite service period. The Company values its stock options using the Black-Scholes option pricing model. Certain assumptions need to be made with respect to utilizing the Black-Scholes option pricing model, including the expected life of the award, volatility of the underlying shares, the risk-free interest rate and anticipated forfeiture of the share-based awards. The expected life of the stock options is calculated using the method allowed by the provisions of ASC 718. The risk-free interest rate is based on the rates paid on securities issued by the U.S. Treasury with a term approximating the expected life of the equity award. The expected share price volatility for the Company's common shares was estimated by taking the average historical price volatility for industry peers. Estimates of pre-vesting award forfeitures are based on the Company's expectations of future employee turnover. The Company will adjust its estimate of forfeitures over the requisite service period based

on the extent to which actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures will be recognized through a cumulative catch-up adjustment in the period of change and will also impact the amount of compensation expense to be recognized in future periods.

The Company accounts for share-based payments to non-employees issued in exchange for services based upon the fair value of the equity instruments issued, in conformity with authoritative guidance issued by the FASB. Compensation expense for stock options issued to non-employees is calculated using the Black-Scholes option pricing model and is recorded over the service performance period. Options subject to vesting are required to be periodically remeasured over their service performance period, which is generally the same as the vesting period.

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[9] Net Loss per Common Share:

Basic net loss per common share is computed by dividing net loss applicable to common shareholders by the weighted-average number of common shares of outstanding during the period. Diluted net loss per common share is computed by dividing the net loss applicable to common shareholders by the diluted weighted-average number of common shares outstanding during the period calculated in accordance with the treasury stock method. Stock options to purchase 5.9 million common shares were not included in the calculation of diluted weighted-average common shares outstanding for the year ended March 31, 2016 because they were anti-dilutive. Stock options to purchase 4.0 million common shares were not included in the calculation of diluted weighted-average common shares outstanding for the period from October 31, 2014 (date of inception) through March 31, 2015 because they were anti-dilutive.

[10] Financial Instruments:

ASC Topic 820, Fair Value Measurement ("ASC 820"), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). 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.

ASC 820 identifies fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tier fair value hierarchy that distinguishes among the following:

- Level 1-Valuations are based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.
- Level 2-Valuations are based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly.
- Level 3-Valuations are based on inputs that are unobservable (supported by little or no market activity) and significant to the overall fair value measurement.

To the extent the 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.

The Company's financial instruments consist of cash and accounts payable. These financial instruments are stated at their respective historical carrying amounts, which approximates fair value due to their short-term nature.

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[11] Recent Accounting Pronouncements:

In November 2015, the FASB issued ASU No. 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes. This amendment will simplify the presentation of deferred tax assets and liabilities on the balance sheet and require all deferred tax assets and liabilities to be treated as non-current ASU 2015-17 is effective for fiscal years, and interim periods within those fiscal years beginning after December 15, 2016, with early adoption permitted. The Company has adopted ASU 2015-17. The adoption of ASU 2015-17 did not have a significant impact on the Company's consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU 2016-02, Leases, which is a comprehensive new lease standard that amends various aspects of existing accounting guidance for leases. The core principle of ASU 2016-02 will require lessees to present the assets and liabilities that arise from leases on their balance sheets. ASU 2016-02 is effective for annual periods beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted. The Company is currently evaluating the new standard and its impact on the Company's consolidated financial position and results of operations.

In March 2016, the FASB issued ASU No. 2016-09, “Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting” (ASU No. 2016-09). This ASU makes several modifications to Topic 718 related to the accounting for forfeitures, employer tax withholding on share-based compensation, and the financial statement presentation of excess tax benefits or deficiencies. ASU No. 2016-09 also clarifies the statement of cash flows presentation for certain components of share-based awards. The standard is effective for interim and annual reporting periods beginning after December 15, 2016, with early adoption permitted. The Company expects to adopt this guidance when effective and is currently evaluating the effect that the updated standard will have on its consolidated financial statements and related disclosures.

Note C—Asset Acquisitions

[1] Intepirdine (RVT-101):

On December 17, 2014 the Company entered into an asset purchase agreement (the "Asset Purchase Agreement") to acquire certain intellectual property and research and development materials from GlaxoSmithKline (“GSK”), which the Company initially named RVT-101, now known as intepirdine, in exchange for the following consideration:

- $5.0 million in cash paid at closing, December 17, 2014;
- $5.0 million in a deferred payment payable upon the earlier of (a) the Company having determined in good faith that it has received definitive guidance from the U.S. Food and Drug Administration (the ‘‘FDA’’) that a single Phase 3 trial with intepirdine for Alzheimer’s disease will be sufficient for New Drug Application (‘‘NDA’’) approval, (b) filing of an NDA for intepirdine for Alzheimer’s disease incorporating data from one Phase 3 trial for Alzheimer’s disease, and (c) the Company not having dosed the first patient in a second Phase 3 trial for intepirdine within six (6) months following the dosing of the first patient in the Company’s first Phase 3 trial for intepirdine. Should the FDA require the Company to complete additional clinical work prior to commencement of the first Phase 3 trial, the Company will have no obligation to make this deferred payment to GSK;
- $35.0 million, $25.0 million and $10.0 million upon approval of intepirdine in the United States, the European Union and Japan, respectively;
- A one-time payment of $85.0 million for the first calendar year in which the Company achieves global net sales of $1.2 billion of intepirdine; and
- a fixed royalty of 12.5% on annual net product sales in certain territories, subject to reduction on a product-by-product and country-by-country basis, on account of expiration of patent and regulatory exclusivity or upon generic entry.

For the consideration above, the Company also received a small quantity of inventory of intepirdine, and certain research and development historical records. The Company did not hire, or receive, any GSK employees working on the development of intepirdine, or any research, clinical or manufacturing equipment. Additionally, the Company did not assume from GSK any contracts, licenses or agreements between GSK and any third party with respect to intepirdine. The Company has independently developed all clinical processes and procedures for the Phase 3 MINDSET study through the use of internal and external resources.

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As the intellectual property and inventory of intepirdine acquired had no alternative future use on the date of acquisition, the Company recorded the $5.0 million upfront payment as research and development expense at the closing date, December 17, 2014. In addition, the Company assessed the likelihood of making the deferred payment as probable (Refer to Note I) and recorded an additional $5.0 million amount as research and development expense at the date of the transaction.

[2] Nelotanserin:

On October 28, 2015 the Company acquired the global rights to nelotanserin, an inverse agonist of the 5-HT_{2A} receptor, from RSL. Pursuant to the terms of the Option and Waiver Agreement between RSL and the Company entered into in May 2015 (the "Option and Waiver Agreement"), RSL granted the Company an option to acquire all of RSL's rights, title and interest in and to the development, marketing and supply agreement for nelotanserin with Arena Pharmaceuticals, GmbH (''Arena'') (the ''Arena Development Agreement''), together with any amendments and related side letters or other agreements. The option became exercisable beginning on September 16, 2015 and, if not exercised, would have expired on December 16, 2016. The Company exercised the option on October 28, 2015 and acquired all of RSL's rights, title, interests and obligations under the Arena Development Agreement for nelotanserin and accounted for the acquisition of nelotanserin as an asset acquisition. The Company recorded $5.3 million as research and development expense which reflects 110% of payments made by RSL to Arena, including a $4.0 million up-front payment, and costs incurred in connection with the development of nelotanserin, in each case pursuant to the Waiver and Option Agreement prior to the exercise of the option.

Pursuant to the Arena Development Agreement the Company is obligated to pay Arena up to an aggregate of $4.0 million in development, $37.5 million in regulatory and $60.0 million in commercialization milestones based on the net sales of nelotanserin. The Company is also obligated to purchase finished drug product under a fixed price equal to 15% of net sales of nelotanserin.

For the consideration above, the Company also received a small quantity of inventory of nelotanserin, and certain research and development historical records. The Company did not hire, or receive, any employees working on the development of nelotanserin, or any research, clinical or manufacturing equipment. Additionally, the Company did not assume from Arena any contracts, licenses or agreements between Arena and any third party with respect to nelotanserin. The Company will need to independently develop all clinical processes and procedures for future clinical studies of nelotanserin through the use of internal and external resources.

As the intellectual property and inventory of nelotanserin acquired had no alternative future use on the date of acquisition, it was accounted for as an asset acquisition and the Company recorded the $5.3 million upfront payment as research and development expense related to its option exercised with RSL on October 28, 2015.

Note D—Accrued Expenses

As of March 31, 2016 and 2015 accrued expenses consisted of the following (in thousands):

	March 31, 2016	March 31, 2015
Research and development expenses	$5,659	$—
Salaries, bonuses, and other compensation expenses	1,893	56
Legal expenses	183	832
Other expenses	584	270
Total accrued expenses	$8,319	$1,158

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Note E—Related Party Transactions

[1] Services Agreement:

During 2015, the Company and ASI entered into a services agreement with RSI (the ‘‘Services Agreement’’) under which RSI agreed to provide certain administrative and research and development services to the Company. The Company and ASI amended and restated its Services Agreement with RSI on October 13, 2015 for the fiscal year commencing April 1, 2015. Under the Services Agreement, as amended and restated, the Company will pay or reimburse RSI for any expenses it, or third parties acting on its behalf, incurs for the Company. For any general and administrative and research and development activities performed by RSI employees, RSI will charge back the employee compensation expense plus a pre-determined mark-up. Employee compensation expense, inclusive of base salary and fringe benefits, is determined based upon the relative percentage of time utilized on Company matters. All other costs will be billed back at cost. The accompanying audited consolidated financial statements include third-party expenses that have been paid by RSI and RSL.

Under the Services Agreement, for the year ended March 31, 2016 the Company incurred expenses of $7.6 million, inclusive of the mark-up. For the period from October 31, 2014 (date of inception) to March 31, 2015 the Company incurred expenses of $2.0 million, inclusive of the mark-up.

On December 4 2015, BVC Ltd. ("BVC"), a non-public entity, which held a non-controlling ownership interest in RSL, the parent of the Company, was merged with and into RSL (the " BVC Merger"), with RSL as the surviving entity. Prior to the BVC Merger the Company recorded share-based compensation expense, in relation to the share-based awards issued by BVC to RSI employees based on the changes in fair value of share-based awards which were remeasured at each reporting period date until performance was completed. As such, because the share-based awards were not based on the Company’s or RSL’s shares, they were remeasured at fair value at each reporting period until the awards vest. As a result of the BVC Merger, all outstanding BVC share-based awards were converted into RSL common share awards with the same vesting and forfeiture terms as the original grant. On December 8, 2015 following the BVC Merger, RSL recapitalized in conjunction with a private financing.

Share-based compensation expense is allocated to the Company by RSL based upon the relative percentage of time utilized by RSI employees on Company matters. For the year ended March 31, 2016, the Company recorded share-based compensation expense of $53.4 million in relation to the RSL common share awards and RSL stock options issued by RSL to RSI employees. These share-based compensation amounts include compensation expense for BVC awards prior to the BVC Merger on December 4, 2015. For the period from October 31, 2014 (date of inception) to March 31, 2015, the Company incurred share-based compensation expense of $0.4 million, inclusive of the mark-up, under the Services Agreement.

The RSL common share awards are valued at fair value on the date of grant and that fair value is recognized over the requisite service period. At the time of the BVC Merger on December 4, 2015, the unvested BVC awards that were converted into common shares of RSL were remeasured at the estimated fair value of RSL and that fair value is recognized over the remaining requisite service period. As a result of the BVC Merger, the converted BVC awards will not be remeasured prospectively. The estimated fair value of these RSL common share awards was determined by the valuation of the December 8, 2015 RSL private financing. Prior to the BVC Merger, the fair value of BVC awards were based on RSL’s valuation after considering the fair value of RSL's ownership interest in the Company and RSL's other investments, discounted cash flow analysis, transactions entered into and contemplated by RSL and relevant industry and comparable public company data. RSL is a non-public entity and therefore BVC awards prior to the BVC Merger and the RSL common share awards following the BVC Merger are classified as Level 3 due to their unobservable nature. Significant judgment and estimates were used to estimate the fair value of these awards, as they are not publicly traded. RSL common share awards are subject to specified vesting schedules and requirements (a mix of time-based, performance-based and corporate event-based, including targets for RSL’s post-IPO market capitalization and future financing events). The Company estimated the fair value of each RSL option on the date of grant using the Black-Scholes closed-form option-pricing model.

Compensation expense will be allocated to the Company over the required service period over which these RSL common share awards and RSL stock options would vest and will be based upon the relative percentage of time utilized by RSI employees on Company matters. For the year ended March 31, 2016, and for the period from October

31, 2014 (date of inception) to March 31, 2015, the Company recorded compensation arrangement expense of $1.0 million and $0.3 million provided to Vivek Ramaswamy as RSI's Chief Executive Officer by one of RSL's investors, respectively.

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[2] Stock Options:
During the year ended March 31, 2016 and for the period from October 31, 2014 (date of inception) to March 31, 2015 the Company granted stock options to purchase 215,000 and 527,500 shares, respectively, of the Company's common stock to employees of RSI as compensation for support services provided to the Company. The fair value of the stock options granted to RSI employees is accounted for by the Company in accordance with the authoritative guidance for non-employee equity awards and is remeasured on each valuation date until performance is complete using the Black-Scholes pricing model. (Refer to Note G).
Each award is subject to a specified vesting schedule. Compensation expense will be recognized by the Company over the required service period to earn each award. The Company recorded $1.1 million of share-based compensation expense for the year ended March 31, 2016. The share-based compensation was recorded as research and development and general and administrative expense in the consolidated statement of operations. The total remaining unrecognized compensation cost related to the non-vested stock options amounted to $4.5 million as of March 31, 2016, which will be recognized over the weighted-average remaining requisite service period of 2.87 years. For the period from October 31, 2014 (date of inception) to March 31, 2015, the Company incurred compensation expense of $0.1 million which the Company recorded as research and development and general and administrative expense in the consolidated statements of operations. Refer to Note G for additional disclosures.

[3] Information Sharing and Cooperation Agreement:
In March 2015, the Company entered into an information sharing and cooperation agreement (the “Cooperation Agreement”) with RSL. The Cooperation Agreement, among other things, grants the Company a right of first review on any potential dementia-related product or investment opportunity that RSL may consider pursuing and obligates the Company to deliver periodic financial statements and other financial information to RSL and comply with other specified financial reporting requirements.
On May 1, 2015, the Company received an offer notice, as defined in the Cooperation Agreement, from RSL relating to the opportunity to acquire, from Arena, certain rights to develop and market nelotanserin. On May 8, 2015, the Company entered into a Waiver and Option Agreement with RSL with respect to such opportunity and RSL entered into the Arena Development Agreement.
Pursuant to the terms of the Waiver and Option Agreement, RSL granted the Company an option to acquire all of RSL’s right, title, interest and obligations in and to the Arena Development Agreement, together with any amendments and related side letters or other agreements. The option became exercisable beginning on September 16, 2015 and, if not exercised, would have expired on December 16, 2016. The Company exercised the option on October 28, 2015. (Refer to Note C). Following exercise of the option, the Services Agreement between the Company and RSI was applied with regard to any reimbursements made by the Company to RSL.

[4] Family Relationships:
Geetha Ramaswamy, MD, the Vice President, Medical Affairs for ASI, is the mother of Vivek Ramaswamy, the Chief Executive Officer of ASI and the Company’s principal executive officer. Shankar Ramaswamy, MD, the Vice President of Corporate Development of ASI, is the brother of Vivek Ramaswamy. In March 2015, Geetha Ramaswamy was granted a stock option for 262,500 common shares of the Company and Shankar Ramaswamy was granted a stock option for 750,000 common shares of the Company, in each case with an exercise price of $0.90 per share. Shankar Ramaswamy, while previously employed by RSI, was also granted restricted stock in BVC. Following the BVC Merger, this restricted stock in BVC was converted into RSL common share awards, subject to vesting and forfeiture terms consistent with the original grant. (Refer to Note E[1]). For the year ended March 31, 2016 the Company has recorded share-based compensation expense of $0.5 million related to the RSL common share awards held by Shankar Ramaswamy (inclusive of the compensation expense noted above for BVC awards prior to the BVC Merger on December 4, 2015), which the Company has recorded as research and development expense in the consolidated statements of operations.

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Note F—Shareholders' Equity

[1] Overview:

The Company's Memorandum of Association, filed on October 31, 2014 in Bermuda, authorized the issuance of one class of shares. The total number of shares which the Company was authorized to issue was 10,000, each with a par value of $1.00 per share. Upon the Company's formation, RSL subscribed for 100 shares of the Company's share capital. On December 17, 2014, RSL paid the initial $5.0 million payment to GSK upon the closing of the transaction on behalf of the Company (see Note C) which is reflected in the financial statements as an additional capital contribution. There were no additional shares issued in connection with such contributions to additional paid-in-capital as RSL owned 100% of the share ownership. On March 18, 2015, upon approval of the Board of Directors, the Company issued an additional 650 shares, increasing the total number of issued and outstanding shares to 750, which were reflected in the accompanying financial statements as 65,000,000 and 75,000,000, respectively, post stock split. Effective March 18, 2015, upon approval of the Board of Directors and the Company's sole member, RSL, the Company effected a stock split of the authorized, issued and outstanding shares of the Company at a ratio of 100,000-to-1. The stock split increased the total number of authorized shares from 10,000 to 1,000,000,000, increased the total number of shares issued and outstanding from 750 to 75,000,000, and decreased par value per share from $1.00 to $0.00001. All information in the accompanying financial statements and notes thereto regarding share amounts of the common stock and prices per share of the common stock has been adjusted to reflect the application of the stock split on a retroactive basis.

[2] Transactions:

On June 16, 2015, the Company completed its initial public offering ("IPO") of common shares. The Company sold 24,150,000 shares at a price of $15.00 per share, which included 3,150,000 common shares issued upon the full exercise of the underwriters' option to purchase additional shares, for gross proceeds of $362.3 million. The Company received net proceeds of $334.5 million, net of an aggregate of $27.7 million in underwriting discounts and commissions and offering expenses. The cash proceeds from the IPO are currently deposited with three banking institutions and are substantially in excess of federally insured levels.

In April 2015, RSL made a cash capital contribution of $0.8 million. No additional common shares of the Company were issued in connection with this capital contribution.

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Note G—Share-Based Compensation

Stock Options:

In March 2015, the Company adopted its 2015 Equity Incentive Plan (the ‘‘2015 Plan’’), under which 7.5 million of the Company’s common shares were originally reserved for grant. The Company's employees, directors and consultants are eligible to receive non-qualified and incentive stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, and other stock awards under the plan. Options granted to consultants and employees generally vest over four years and have a ten-year contractual term. Options granted to members of the Board of Directors vest over three years and have a ten-year contractual term. In May 2015, the Company’s Board of Directors amended the 2015 Plan to increase the number of common shares authorized for issuance thereunder to 9.5 million common shares, effective upon the IPO. On April 1, 2016 the number of common shares authorized for issuance increased automatically to 12.5 million in accordance with the 2015 Plan. Stock options granted under the 2015 Plan provide option holders, if approved by the Board of Directors, the right to exercise their options prior to vesting. In the event that an option holder exercises the unvested portion of any option, such unvested portion will be subject to a repurchase option held by the Company at the lower of (1) the fair market value of its common shares on the date of repurchase and (2) the exercise price of the options. Any common shares underlying such unvested portion will continue to vest in accordance with the original vesting schedule of the option.

At March 31, 2016, a total of 3.6 million common shares were available for future issuance under the 2015 Plan.

The Company estimated the fair value of each option on the date of grant using the Black-Scholes closed-form option-pricing model applying the weighted average assumptions in the following table.

	Year Ended March 31, 2016	Period From October 31, 2014 (Date of Inception to March 31, 2015)
Expected stock price volatility	77.9%	74.9%
Expected risk free interest rate	1.7%	1.62%
Expected term, in years	6.58	6.72
Expected dividend yield	—%	—%

The following table presents a summary of option activity and data under the Company's stock incentive plans through March 31, 2016:

	Number of Options	Weighted Average Exercise Price	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Options outstanding at October 31, 2014	—	$ —	$ —	—	$ —
Granted	4,012,500	0.90	14.30	9.96	—
Exercised	—	—	—	—	—
Forfeited	—	—	—	—	—
Cancelled	—	—	—	—	—
Options outstanding at March 31, 2015	4,012,500	0.90	14.30	9.96	56,576,250
Granted	1,983,808	12.10	11.89	—	—
Exercised	—	—	—	—	—
Forfeited	(102,725)	4.99	13.41	—	—
Cancelled	—	—	—	—	—
Options outstanding at March 31, 2016	5,893,583	4.60	13.50	9.11	47,172,525
Options vested and expected to vest at March 31, 2016	5,709,233	4.42	13.55	9.10	46,404,866
Options exercisable at March 31, 2016	4,919,096	2.35	13.99	9.01	47,165,850

At March 31, 2016 and 2015 there were 1.0 million and no vested options, respectively, outstanding on such dates.

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For the year ended March 31, 2016 and for the period from October 31, 2014 (date of inception) through March 31, 2015, the Company recorded share-based compensation expense related to stock options issued to employees and directors of $16.3 million and $0.5 million, respectively. For the year ended March 31, 2016 and for the period from October 31, 2014 (date of inception) through March 31, 2015, the Company recorded $1.1 million and $0.1 million, respectively, of share-based compensation expense related to stock options issued to non-employees (Note E[2]). This share-based compensation expense is included in research and development and general and administrative expenses in the accompanying consolidated statements of operations.

Prior to the IPO, the fair value of the Company's common shares underlying stock options was estimated on each grant date by the Board of Directors. In order to determine the fair value of the Company's common shares underlying granted stock options, the Board of Directors considered, among other things, valuations of the common shares prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. In connection with the Company's IPO and after preliminary discussions with the underwriters, the Company reassessed the determination of the fair value of the common shares underlying 4,012,500 stock options granted in March 2015 and 527,500 stock options granted in April 2015. As a result, the Company determined that the fair value of the common shares as of April 13, 2015 was $15.00 per share, which was higher than the fair values of $0.90 per share and $1.04 per share as initially determined by the Board of Directors on the dates of grant in March 2015 and April 2015, respectively. The use of this higher share price increased both recognized and unrecognized share-based compensation expense and also impacted the valuation of the RSL awards share compensation expense discussed in Note F[1].

At March 31, 2016, total unrecognized compensation expense related to non-vested options was $60.1 million and is expected to be recognized over the remaining weighted-average service period of 3.06 years.

Note H—Income Taxes

The loss before income taxes and the related tax benefit are as follows (in thousands):

	Year ended March 31, 2016	Period from October 31, 2014 (Date of Inception) through March 31, 2015
(Loss) income before income taxes:		
Bermuda	$(119,207)	$(21,047)
United States	(13,955)	1
Total loss before income taxes	$(133,162)	$(21,046)
Current taxes:		
United States	306	1
Bermuda	—	—
Total current tax expense	306	1
Deferred taxes:		
United States	(323)	—
Bermuda	—	—

Total deferred tax benefit	(323)	—
Total income tax (benefit) expense	(17)	1

The Company's provision for income taxes is based primarily on income taxes in the United States for federal, state and local income taxes. The Company's effective tax rate for both the year ended March 31, 2016 and for the period October 31, 2014 (date of inception) to March 31, 2015 was 0% primarily due to the organization of the Company as a Bermuda Exempted Limited Company, for which there is no current tax regime, due to U.S. permanent unfavorable differences, and a valuation allowance that effectively eliminates the Company's net deferred tax assets in the United States. As of March 31, 2016, the Company had an aggregate income tax receivable of $1.0 million from various federal, state, and local jurisdictions.

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Deferred taxes reflect the tax effects of the differences between the amounts records as assets and liabilities for financial reporting purposes and the comparable amounts recorded for income tax purposes. Significant components of the deferred tax assets (liabilities) at March 31, 2016 and 2015 are as follows (in thousands):

	March 31, 2016	March 31, 2015
Research tax credits	$283	$ —
Other	11	—
Depreciation	29	
Share-based compensation	6,919	—
Subtotal	7,242	—
Valuation allowance	(6,919)	—
Total deferred tax assets	323	—

The Company assesses the realizability of the deferred tax assets at each balance sheet date based on available positive and negative evidence in order to determine the proper amount, if any, required for a valuation allowance. As a result of this assessment, a valuation allowance of $6.9 million related to share-based compensation has been recorded as of March 31, 2016. There was no valuation allowance as of March 31, 2015. The Company believes that it is more likely than not, given the weight of available evidence, that all other deferred tax assets will be realized. The Company will continue to assess the realizability of deferred tax assets at each balance sheet date in order to determine the proper amount, if any, required for a valuation allowance.

As of March 31, 2016 and 2015, the Company had unrecognized tax benefits of $0.3 million and $0, respectively, which if recognized would be reflected as an income tax benefit.

The Company files income tax returns in the United States federal, state and local jurisdictions. ASI filed its initial U.S. federal, state and local income tax returns for the fiscal year ended March 31, 2015 in December 2015. The Company is subject to tax examinations for fiscal year 2015 and forward in all applicable tax jurisdictions.

Note I—Commitments and Contingencies

The Company has entered into commitments under the Agreements with GSK and Arena (Refer to Note C) and a Services Agreement with RSI (Refer to Note E[1]). In addition, the Company has entered into services agreements with third parties for pharmaceutical manufacturing and research activities. The manufacturing agreements can be terminated by the Company with 30 days written notice. The Company expects to enter into other commitments as the business further develops.

During 2015, the Company entered into two subleases with RSI for office space. Under the terms of the subleases, RSI has annual rent obligations of $0.9 million through 2020. RSI pays the rent directly and then invoices the Company for the rent based on the Company's proportionate share of the space based upon the relative numbers of full-time equivalent employees located on the premises. As a result, the Company's rent obligations are not fixed. The subleases expire on June 30, 2016 and March 31, 2017, respectively. For the year ended March 31, 2016, the Company incurred $0.6 million in rent expense under this arrangement with RSI.

As of March 31, 2016, the Company did not have any ongoing material financial commitments, other than pursuant to the GSK Agreement and Arena Development Agreement. Under the terms of the asset purchase agreement with GSK (Refer to Note C[1]), the Company is obligated to pay GSK an additional $5.0 million upon the earliest to occur of one of three specified events which the Company expects to pay in June 2016. The Company had recorded the obligation as a contingent payment liability in the accompanying balance sheet.

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Note J—Selected Quarterly Financial Data (Unaudited)

The following table presents selected quarterly financial data for the year ended March 31, 2016 and for the period from October 31, 2014 (date of inception) to March 31, 2015.

	First Quarter Ended [1] June 30, 2015	Second Quarter Ended [1] September 30, 2015	Third Quarter Ended December 31, 2015	Fourth Quarter Ended March 31, 2016	Period From October 31, 2014 (Date of Inception) To December 31, 2014	Fourth Quarter Ended March 31, 2015
Total operating expenses	$24,879	$15,142	$62,554	$30,587	$10,762	$10,284
Net loss and comprehensive loss	(24,953)	(15,166)	(63,356)	(29,671)	(10,762)	(10,285)
Net loss per share attributable to common stockholders - basis and diluted	(0.31)	(0.15)	(0.64)	(0.30)	(1.08)	(0.51)

[1]During the quarter ended March 31, 2016, the Company identified an error in its previously reported June 30, 2015 and September 30, 2015 consolidated financial statements related to the calculation of share-based compensation expense allocated from BVC. The Company determined that the error is not material to the previously reported financial statements; however, the amounts previously reported for those periods have been revised in the table above and will be revised in future filings to correct for this error. The effect of this revision decreased research and development expenses by $1.1 million and general and administrative expenses by $2.0 million, and these adjustments resulted in a total decrease of $3.1 million of share-based compensation expense and the related capital contribution, operating expenses and net loss and comprehensive loss for those previously reported three months ended June 30, 2015, and an increase in those same measures by the same amount for the previously reported three months ended September 30, 2015. Net loss per share attributable to common stockholders was also decreased by $0.04 and increased by $0.03 for the three months ended June 30, 2015 and September 30, 2015, respectively.

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Index to Exhibits

Exhibit Number	Description of Document
2.1*	Asset Purchase Agreement, by and among the Registrant and Glaxo Group Limited and GlaxoSmithKline Intellectual Property Development Limited, dated as of December 17, 2014, incorporated herein by reference to Exhibit 2.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-204073), filed on May 11, 2015.
3.1	Certificate of Incorporation as currently in effect, incorporated herein by reference to Exhibit 3.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-204073), filed on May 11, 2015.
3.2	Memorandum of Association, as currently in effect, incorporated herein by reference to Exhibit 3.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-204073), filed on May 11, 2015.
3.3	Amended and Restated Bye-laws, as currently in effect, incorporated herein by reference to Exhibit 3.4 of the Registrant's Amendment No. 2 to Registration Statement on Form S-1/A (File No. 333-204073) filed on June 11, 2015.
10.1	Amended and Restated Services Agreements, dated as of October 13, 2015, by and among Roivant Sciences, Inc., Axovant Sciences, Inc. and the Registrant, incorporated herein by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-37418), filed on February 09, 2016.
10.2	Information Sharing and Cooperation Agreement, dated as of March 18, 2015, by and between Roivant Sciences Ltd. and the Registrant, incorporated herein by reference to Exhibit 10.7 of the Registrant's Registration Statement on Form S-1 (File No. 333-204073), filed on May 11, 2015.
10.3*	Development, Marketing and Supply Agreement, dated May 8, 2015, between Roivant Sciences Ltd. and Arena Pharmaceuticals GmbH, incorporated herein by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-37418), filed on February 09, 2016.
10.4	Waiver and Option Agreement, dated as of May 8, 2015, by and between Roivant Sciences Ltd. and the Registrant, incorporated herein by reference to Exhibit 10.9 of the Registrant's Amendment No.1 to Registration Statement on Form S-1/A (File No. 333-204073), filed on May 22, 2015.
10.5+	2015 Equity Incentive Plan, as amended, incorporated herein by reference to Exhibit 10.1 of the Registrant's Amendment No.1 to Registration Statement on Form S-1/A (File No. 333-204073), filed on May 22, 2015.
10.6+	Forms of Option Grant Notice and Option Agreement under 2015 Equity Incentive Plan, as amended, incorporated herein by reference to Exhibit 10.2 of the Registrant's Amendment No.1 to Registration Statement on Form S-1/A (File No. 333-204073), filed on May 22, 2015.

10.7+	Form of Early Exercise Stock Purchase Agreement under 2015 Equity Incentive Plan as amended, incorporated herein by reference to Exhibit 10.3 of the Registrant's Amendment No.1 to Registration Statement on Form S-1/A (File No. 333-204073), filed on May 22, 2015.
10.8+	Form of Executive Officer Employment Agreement with Axovant Sciences, Inc, incorporated herein by reference to Exhibit 10.7 of the Registrant's Amendment No.1 to Registration Statement on Form S-1/A (File No. 333-204073), filed on May 22, 2015.
10.9+	Employment Offer Letter, dated as of April 25, 2015, by and between Lawrence Friedhoff and Axovant Sciences, Inc., incorporated herein by reference to Exhibit 10.8 of the Registrant's Amendment No.1 to Registration Statement on Form S-1/A (File No. 333-204073), filed on May 22, 2015.
10.10+	Employment Offer Letter, dated as of March 23, 2015, by and between Marianne Romeo Dinsmore and the Registrant, incorporated herein by reference to Exhibit 10.9 of the Registrant's Amendment No.2 to Registration Statement on Form S-1/A (File No. 333-204073), filed on June 01, 2015.
10.11+	Form of Indemnification Agreement with directors and executive officers, incorporated herein by reference to Exhibit 10.4 of the Registrant's Amendment No.1 to Registration Statement on Form S-1/A (File No. 333-204073), filed on May 22, 2015.
10.12†+	Non-Employee Director Compensation Policy.

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21.1	Subsidiaries of the Registrant.
23.1	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.
24.1	Power of Attorney (included on signature page).
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS XBRL	Instance Document
101.SCH XBRL	Taxonomy Extension Schema
101.CAL XBRL	Taxonomy Extension Calculation Linkbase
101.DEF XBRL	Taxonomy Extension Definition Linkbase
101.LAB XBRL	Taxonomy Extension Label Linkbase
101.PRE XBRL	Taxonomy Extension Presentation Linkbase

† Filed herewith.
+Indicates management contract or compensatory plan.
*Confidential treatment has been granted for portions omitted from this exhibit (indicated by asterisks) and those portions have been separately filed with the Securities and Exchange Commission.
** These certifications are being furnished solely to accompany this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.