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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-K**

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(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended April 30, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD  
FROM TO

Commission File Number 001-36830

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**KalVista Pharmaceuticals, Inc.**

(Exact name of Registrant as specified in its Charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**55 Cambridge Parkway  
Suite 901 East**

**Cambridge, Massachusetts**  
(Address of principal executive offices)

**20-0915291**  
(I.R.S. Employer  
Identification No.)

**02142**  
(Zip Code)

Registrant's telephone number, including area code: (857) 999-0075

Title of Each Class  
**Common Stock, \$0.001 par value per share**

Name of Exchange on Which Registered  
**The NASDAQ Stock Market LLC**

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

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES  NO

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES  NO

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) 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.

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definition of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Non-accelerated filer

Emerging growth company

(Do not check if smaller reporting company)

Accelerated filer

Smaller reporting company

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

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

The aggregate market value of common stock held by non-affiliates of the registrant calculated based on the closing price of \$12.73 of the registrant's common stock as reported on The NASDAQ Global Market on October 31, 2017, the last business day of the registrant's most recently completed second quarter, was \$60,287,969.

The number of shares of Registrant's Common Stock outstanding as of July 16, 2018 was 10,799,895.

**DOCUMENTS INCORPORATED BY REFERENCE**

None.

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## PART I

### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. All statements other than statements of historical fact are “forward-looking statements” for purposes of this Annual Report on Form 10-K. These forward-looking statements may include, but are not limited to, statements regarding our future results of operations and financial position, business strategy, market size, potential growth opportunities, timing and results of preclinical and clinical development activities, and potential regulatory approval and commercialization of product candidates. In some cases, forward looking-statements may be identified by terminology such as “believe,” “may,” “will,” “should,” “predict,” “goal,” “strategy,” “potentially,” “estimate,” “continue,” “anticipate,” “intend,” “could,” “would,” “project,” “plan,” “expect,” “seek” and similar expressions and variations thereof. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the “Risk Factors” section and elsewhere in this Annual Report on Form 10-K. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations, except as required by law.

As used in this Annual Report on Form 10-K, the terms “KalVista,” “the Company,” “we,” “us,” and “our” refer to KalVista Pharmaceuticals, Inc. and, where appropriate, its consolidated subsidiary, unless the context indicates otherwise.

#### **Item 1. Business.**

##### **Overview**

We are a clinical stage pharmaceutical company focused on the discovery, development and commercialization of small molecule protease inhibitors for diseases with significant unmet need. Our first product candidates are inhibitors of plasma kallikrein being developed for two indications: hereditary angioedema (“HAE”) and diabetic macular edema (“DME”). We apply our insights into the chemistry of proteases and, with our current programs, the biology of the plasma kallikrein system, to develop small molecule inhibitors with high selectivity, potency and bioavailability that we believe will make them successful treatments for disease.

We have created a structurally diverse portfolio of oral plasma kallikrein inhibitors and advanced multiple drug candidates into Phase 1 clinical trials for HAE in order to create what we believe will be best-in-class oral therapies. In the case of DME, we are initially developing a plasma kallikrein inhibitor which is administered directly into the eye and anticipate ultimately developing orally delivered drugs. In December 2017 we commenced a Phase 2 clinical trial of KVD001, our most advanced DME drug candidate, which we anticipate will be completed in the second half of 2019.

HAE is a rare and potentially life-threatening condition with symptoms that include episodes of debilitating and often painful swelling in the skin, gastrointestinal tract or airways. Despite having multiple therapies approved, we believe HAE patients are in need of alternatives that better meet their objectives for quality of life and ease of

disease control. Currently marketed therapies are all administered by injection and we anticipate that there will be strong interest in safe and effective, orally delivered, small molecule treatments. Our strategy in HAE is to develop a portfolio of molecules, both to provide best-in-class oral therapeutics as well as to have the opportunity to evaluate molecules for different market segments, such as acute or prophylactic therapy. Our medicinal chemistry program has discovered and patented a large portfolio of structurally diverse plasma kallikrein inhibitors, which enables our selection of only compounds that meet stringent selection criteria for progression.

Based upon results observed in the Phase 1 trial that we initiated in December 2017, we have selected the compound KVD900 to move forward as a potential therapy for on-demand treatment of acute attacks in patients with HAE. We believe that a conveniently administered oral, on-demand product could provide an opportunity to capture a significant portion of the current acute treatment market as well as patients who may currently use prophylactic therapies because of the lack of convenient and effective alternatives. We are currently planning to initiate a Phase 2 clinical trial for KVD900 in late 2018 that should be completed in mid-2019. We anticipate that this trial will be designed as a proof of concept study in HAE patients, intended to determine the safety and efficacy of KVD900 in reducing the severity and duration of attacks when taken at the onset of symptoms.

Our Phase 1 first-in-human study of KVD900 displays what we believe is a very attractive profile for on-demand therapy. In this placebo controlled study in healthy volunteers doses up to 600 mg have been generally well tolerated with no dose-limiting safety signals emerging and no gastrointestinal adverse events noted at any dose level. The pharmacokinetic exposure profile revealed rapid absorption of KVD900 following oral administration to maximal concentrations more than 100x the concentration we believe is required to effectively treat HAE attacks. The rapidity of absorption was such that effective concentrations were reached at most dose levels within 30 minutes of dosing. Exposure to KVD900, determined as both maximal concentration and overall exposure (area under the curve) increased dose-dependently. We believe this combination of rapid uptake and very high drug levels compares favorably to the existing injected therapies, which show no faster absorption and generally much lower peak levels of drug concentration. Our pharmacodynamic analysis of samples collected from the volunteers following administration of KVD900 shows high levels of plasma kallikrein inhibition for as long as 10 hours after a single dose. This data, combined with the level of inhibition of plasma kallikrein activity observed in HAE patient plasma tested in a separate assay, leads us to believe that a single dose of KVD900 may inhibit plasma kallikrein in patients experiencing an acute HAE attack sufficiently to provide a therapeutic alternative that is superior to current treatments.

DME is the leading cause of moderate vision loss in most developed countries and diabetes, the underlying cause of DME, is the leading cause of blindness among adults aged 20 to 74 years old, according to 2014 statistics published by the Center for Disease and Prevention. Our DME program is initially focused on the development of an intravitreally administered small molecule plasma kallikrein inhibitor, KVD001. We believe intravitreal plasma kallikrein inhibitors may be an effective alternative therapy to vascular endothelial growth factor (“VEGF”) inhibitors and further improve visual acuity and decrease macular thickening. Preclinical pharmacokinetic studies using KVD001 have shown that direct injection into the eye delivers a high drug concentration at the desired site of action. The drug concentration is maintained for a prolonged period with a low systemic exposure, potentially supporting an extended dosing schedule. We have successfully completed a first-in-human trial of KVD001 in patients with DME and began a Phase 2 clinical trial in 2017. In addition to KVD001, we also plan to develop an oral plasma kallikrein inhibitor to treat DME. An oral treatment may provide the opportunity to reduce treatment burden, treat patients earlier in disease progression, and provide a convenient and readily accessible treatment option for DME.

In October 2017, our wholly-owned, U.K. based subsidiary KalVista Pharmaceuticals Limited (“KalVista Limited”) and Merck Sharp & Dohme Corp. (“Merck”) entered into an option agreement (the “Option Agreement”) under which we granted to Merck an option to acquire KVD001 through a period following completion of a Phase 2 clinical trial. We also granted to Merck a similar option to acquire investigational orally delivered molecules for DME (the “Oral DME Compounds”) that we will continue to develop as part of our ongoing research and development activities, through a period following the completion of a Phase 2 clinical trial. Under the terms of the Option Agreement, Merck paid to us a non-refundable upfront fee of \$37.0 million in November 2017 and may pay up to an additional \$715 million in milestones as well as royalties on net sales of any products commercialized under the Agreement. Merck also acquired a 9.9% ownership stake in KalVista in a separate transaction that closed concurrently with the Option Agreement.

## Strategy

Key elements of our strategy include:

- *Apply our deep scientific expertise in the area of serine proteases to develop novel oral therapies for indications with high unmet need.* Our core scientific team has decades of experience working on protease inhibitors and developing compounds with high potency, selectivity and bioavailability. We have assembled a team of chemists and biologists who have demonstrated the ability to design and formulate multiple drug candidate programs from a broad variety of chemical classes, as indicated by our extensive intellectual property portfolio. Our initial focus is specifically on development of plasma kallikrein inhibitors for HAE and DME; however, we believe our scientific capabilities also can be applied to other proteases to develop therapies for diseases with high unmet need and orphan indications.
- *Advance multiple HAE product candidates into clinical development.* We intend to develop best-in-class oral therapies for HAE and, to accomplish that goal, we plan to bring multiple drug candidates into clinical trials and compare their performance before determining which program, or programs, to advance. KVD900 has been chosen to advance to later stage development as an on-demand therapy for acute HAE attacks, and we anticipate that we will initiate a Phase 2 clinical trial in HAE patients in late 2018. We are still conducting preclinical development of multiple additional drug candidates and anticipate bringing one additional candidate into clinical development in 2018 and potentially further candidates in 2019. We expect that these additional candidates will be developed for other portions of the HAE market, such as prophylactic treatment, that are still in need of better therapeutic options.
- *Continue to advance our intravitreal DME program and develop an oral therapy.* KVD001, our first product candidate to treat DME, began a Phase 2 clinical trial in 2017. We also intend to develop an oral therapy for this indication, which we believe could dramatically improve the standard of care for patients, since all current therapies are delivered by injection into the eye.
- *Grow our capabilities internally as well as through strategic partnerships.* We intend to retain ownership and control of our pipeline programs to key milestones. For certain indications that can be addressed by a focused organization, such as HAE, we may determine to keep all program rights and develop sales and marketing capabilities. For programs that address larger markets or require greater infrastructure or resources, we may seek a partner that can provide those capabilities such as we did with Merck in DME. Decisions on whether, and when, to engage in partnerships or collaborations will be based upon our evaluations of the relative risks and rewards of those collaborations at each point in the development cycle.

## Plasma Kallikrein in HAE and DME

Plasma kallikrein is a serine protease enzyme that is a key early mediator of inflammation and edema or swelling. The body modulates the inflammatory effects of plasma kallikrein through a circulating inhibitor protein called C1-esterase inhibitor (“C1-INH”). Most patients with HAE have genetic mutations that lead to C1-INH deficiency, which results in an inability to control activated plasma kallikrein in affected tissues. This excessive activation leads to inflammation, edema, and pain.

Published laboratory work has shown that the vitreous fluid of the eye is also a site of increased plasma kallikrein in DME. In diabetic patients, the retina is one of a few tissues in which edema develops. Under normal circumstances the eye is protected from the diffusion of plasma proteins by an effective blood vessel barrier. In diabetes this barrier becomes less effective and allows plasma proteins such as plasma kallikrein to enter the retina and vitreous. While C1-INH can also enter by the same route, animal models of DME have shown that the concentration of C1-INH in the vitreous fluid is insufficient to fully suppress the effects of plasma kallikrein on retinal edema. Over time, this edema leads to retinal damage that causes blindness.

## Hereditary Angioedema

### *Disease Overview*

HAE is a rare and potentially life-threatening genetic condition that occurs in about 1 in 10,000 to 1 in 50,000 people, according to published information from an HAE patient advocacy group. Excessive plasma kallikrein activation not sufficiently controlled by C1-INH leads to HAE attacks, which can vary in regards to the affected tissue or organ and severity. HAE attacks include episodes of intense swelling or edema usually in the skin, gastrointestinal tract or airways. They often lead to temporary disfiguration of various body parts including the hands, feet, face, body trunk, and genitals. In addition, patients often have bouts of excruciating abdominal pain, nausea and vomiting that is caused by swelling in the intestinal wall. Airway swelling is particularly dangerous and can lead to death by asphyxiation.

Attacks can occur spontaneously although they often are associated with anxiety, stress, minor trauma, surgery, or illnesses. Commonly patients are alerted to an impending attack by prodromal symptoms which include rash, fatigue, and muscle aches. Trauma to the oral cavity caused by dental procedures makes HAE patients particularly vulnerable to airway attacks. The frequency of HAE attacks is highly variable, with some patients having attacks several times per week and others very infrequently. Although life-threatening airway swelling is rare, at least half of HAE patients have experienced at least one such attack and airway attacks remain a major cause of mortality in HAE patients. The severity of attacks is unpredictable and not related to their underlying frequency. A patient with only one attack per year can nevertheless be at risk of suffering a laryngeal attack.

The most common cause of HAE is a defect or mutation in the gene responsible for the production of C1-INH. HAE is an autosomal dominant disease, meaning that a defect in only one copy of the gene leads to symptoms and that it occurs at similar rates in both males and females. While HAE can result through inheritance of a defective gene from a parent, a number of cases also arise from novel mutations.

C1-INH is a natural plasma-borne protein that is an inhibitor of multiple serine proteases in both the complement and kallikrein kinin systems. C1-INH is the predominant physiological inhibitor of plasma kallikrein, and thereby suppresses the generation of bradykinin, a potent hormone produced by plasma kallikrein, that activates its receptors on blood vessels to increase vascular leakage. Uncontrolled plasma kallikrein activity leads to the edema that is the hallmark of HAE. A selective plasma kallikrein inhibitor and a bradykinin receptor antagonist are approved therapies for HAE. As such, plasma kallikrein is a clinically validated target for HAE and previous studies have demonstrated that plasma kallikrein inhibition can both treat and prevent HAE attacks.

### *Current Treatments and Market opportunities*

There are a number of marketed and development stage therapeutics for HAE which provide evidence that inhibition of plasma kallikrein activity will give therapeutic benefit in HAE. Ecallantide (Kalbitor®) is a small protein inhibitor of plasma kallikrein that is approved for treatment of acute attacks of HAE. While effective, ecallantide has been associated with cases of anaphylaxis and its approval by the U.S. Food and Drug Administration (“FDA”) includes a black box warning limiting its administration to healthcare professionals. Other therapies employ C1-INH replacement to control plasma kallikrein levels. Marketed C1-INH therapies include Cinryze® and Berinert®, which are purified from human plasma, and Ruconest® which is a recombinant product. Icatibant (Firazyr®) is a synthetic peptide-based antagonist that blocks the activity of bradykinin. All of these products are administered by injection, which is typically less convenient for patients and has the potential to reduce to compliance. We believe that a safe and effective oral agent has the potential to transform treatment for this disease. We also believe that opportunities exist for both acute and prophylactic treatments, and we intend to consider all of our programs as potential therapies in both segments of the market. For this reason, we plan to evaluate multiple formulations and profiles of our programs as part of our clinical development strategy.

### *Our Portfolio of HAE Programs*

Our strategy is to develop and evaluate multiple oral molecules in pursuit of best-in-class therapies for HAE patients. This portfolio approach may lead to development of multiple molecules to address unmet need in both prophylactic and acute market segments. We have promoted multiple molecules into clinical testing and are pursuing additional candidates in order to expand the universe of properties and increase the likelihood of delivery

of one or more best-in-class treatments for HAE. The first of these product candidates to be evaluated in later stage clinical trials will be KVD900. We anticipate KVD900 will enter a proof-of-concept Phase 2 clinical trial in late 2018 that should be completed in mid-2019.

### KVD900

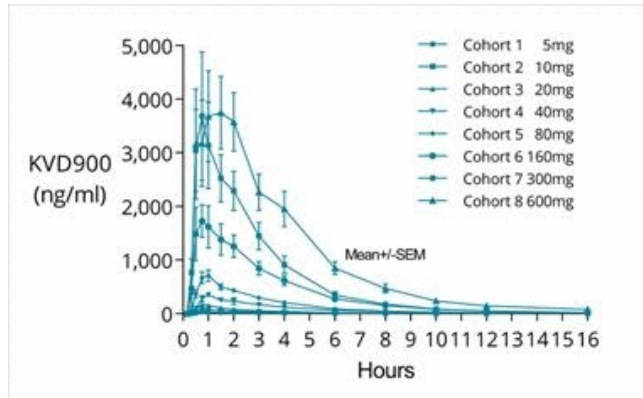
KVD900 is a potent inhibitor of plasma kallikrein displaying 50% inhibition with a concentration of 6nM, and shows very high selectivity against related proteases as shown in Table 1 below. Of particular note is that it is >6000 fold selective against tissue kallikrein (also called tissue kallikrein 1 or KLK1). This enzyme shares the same substrate as plasma kallikrein and has been linked to effects on cardiac safety, making selectivity against it an important element of our design process.

Enzyme (Human)	Fold selectivity
Tissue Kallikrein	>6000
Factor XIa	>6000
Factor XIIa	>6000
Plasmin	>6000
Thrombin	>6000
Trypsin	>6000

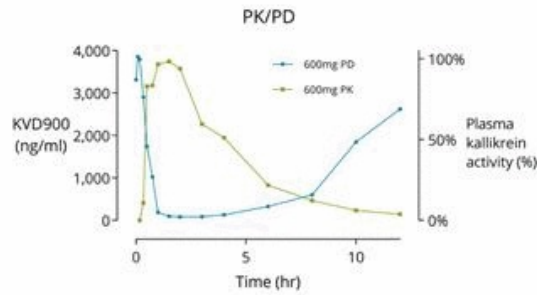
**Table 1: Selectivity of KVD900 against human proteases related to plasma kallikrein.**

Manufacture of KVD900 has been completed at the multi-kilogram scale to support preclinical and clinical testing and multiple formulations have been developed, manufactured and dosed to primates establishing the feasibility of manufacture of clinically acceptable dose forms. These dose forms are designed to enable variable dosing regimens.

The Phase 1, first-in-human study of KVD900 is a multi-part study consisting of a single ascending dose phase, a formulation cross-over and a food effect being conducted in the UK and recruiting up to 84 healthy, male volunteers. In the single ascending dose phase, eight cohorts of volunteers received oral administration of KVD900 up to 600 mg or placebo in a 6:2 ratio to evaluate safety and tolerability. Exposure to KVD900 was assessed using a specific bioanalytical method and a plasma-based assay was used to assess inhibition of plasma kallikrein as the pharmacodynamic effect of KVD900. During the formulation cross-over 8 subjects were administered 100mg KVD900 as a capsule and 7 days later 100 mg KVD900 in a tablet formulation. The food effect phase is ongoing. There were no severe adverse events or gastrointestinal adverse events reported in any cohort. The safety data remains blinded, but over the entire eight cohorts of the single ascending dose phase twelve adverse events (“AE”) were reported, eleven of which were considered unrelated or unlikely related to treatment and resolved without further intervention. The one AE considered possibly related was an episode of lightheadedness reported in the first cohort. The most common AEs were back pain, common cold/flu symptoms, and pyrexia. No AEs were reported in the highest two dose cohorts, and no adverse events were reported during the formulation cross-over. There were no clinically significant changes in vital signs, ECG or safety laboratory findings. Based upon these blinded safety outcomes KVD900 appears to be generally well tolerated. As seen in the graph below, following administration of KVD900 at all dose levels exposure increased rapidly (detectable within 20 minutes) reaching mean maximal concentrations (C<sub>max</sub>) at around 1 hour after dosing. Exposure (both C<sub>max</sub> and AUC) increased dose-dependently throughout the dose range.

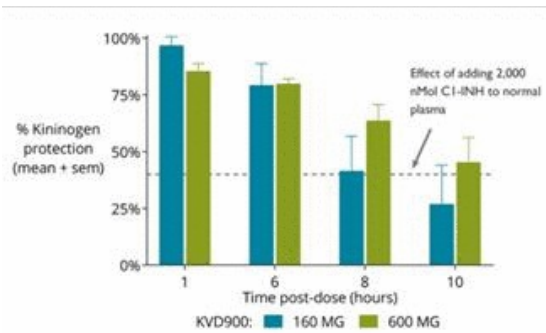


Analysis of the plasma kallikrein activity in the plasma samples revealed strong inhibition by KVD900. Plasma from volunteers was stimulated to produce plasma kallikrein through the addition of dextran sulfate, and the level of plasma kallikrein activity was monitored in an assay. As seen in the graph below, at a dose of 600 mg plasma kallikrein was inhibited by 80% within 30 minutes and complete inhibition was observed within 45 minutes of dosing. The 160 mg and 300 mg dose levels also displayed high levels of inhibition in a similar timeframe.

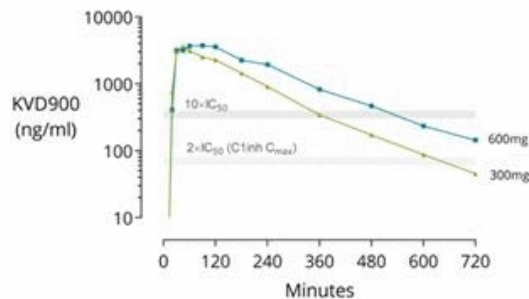


Plasma kallikrein mediates the generation of the hormone bradykinin in the body through a process known as kininogen (“HK”) cleavage. The release of bradykinin leads to the edema in HAE attacks. We therefore tested KVD900 in an assay to determine its ability to prevent HK cleavage in plasma samples in which the plasma kallikrein has been generated by the addition of dextran sulfate. The results are shown below for both 160 mg and 600 mg doses of KVD900. Following a single 160 mg dose of KVD900, we observed that stimulated plasma was protected from HK cleavage for at least six hours, and the 600 mg dose significantly extended this protection period. This data further supports our belief that KVD900 can inhibit plasma kallikrein production for a period sufficient to reduce the duration and severity of HAE attacks.





C1-INH-based therapies for HAE generally yield a Cmax in the range of twice the IC50, which is the threshold level generally accepted as being necessary for efficacy. In contrast, KVD900 dosed at 160 mg achieves a Cmax of 10 times the IC50 and, as shown below, the 300 mg and 600 mg doses both reached well beyond 100 times the IC50. At both doses, the 10 times IC50 level was achieved in less than 30 minutes, which we believe compares favorably to currently approved therapies.



Evidence from studies using other treatments approved for the treatment of acute HAE attacks shows that earlier treatment has a powerful effect on reducing attack duration, yet many patients delay taking treatment. In one outcome study of 207 HAE attacks, treatment was administered more than one hour after attack onset in more than 60% of patients, resulting in a statistically significant, approximately 50% increase in time to resolution of the attack. We believe this delay in administration is due to many factors including the inconvenience and discomfort of injectable therapies, and that patients provided with an oral therapy would be more likely to take it earlier in attack progression. This combination of the rapid uptake of KVD900 to very high blood levels and the likelihood of earlier dosing by patients, could lead to much better management and faster resolution of attacks. We therefore believe that a safe, oral treatment has the potential to become a preferred alternative for patients currently using injectable treatments, including both acute and prophylactic therapies.

Based upon the results of the Phase 1 study, we are currently planning a proof-of-concept Phase 2 clinical trial for KVD900 that we anticipate initiating in late 2018, with data in mid-2019. We intend to submit an Investigational New Drug (“IND”) application to the FDA in 2019 and apply for both Fast Track and Orphan Designation.

#### Additional HAE Development Plans

In parallel with progression of KVD900 for acute therapy, we are committed to expansion of our proprietary compound portfolio to enable development of molecules with a diverse set of properties that maximize our chance of progressing additional best-in-class treatments for HAE. We intend to consider additional formulations of KVD900, or development of one of our other drug candidates, to provide a therapeutic option for the prophylactic segment of the market. Our scientific team has demonstrated the ability to consistently generate new candidate

molecules, enabling a rigorous selection process that only advances programs that meet strict internal criteria. As part of this effort, we have developed assays that provide proprietary insights into inhibition of plasma kallikrein, supporting selection of product candidates at an earlier stage that may have a higher likelihood of demonstrating clinical success. A number of these earlier candidates are being profiled for progression to scale-up manufacture and entry into formal safety studies. We continue to anticipate advancing one additional molecule in our HAE program to the clinic in 2018, and potentially more molecules in 2019.

## **Diabetic Macular Edema**

### *Disease Overview*

DME occurs as a result of diabetes and is caused by the breakdown of the endothelial barrier function in the retina, resulting in the accumulation of fluid in the macula. This leads to edematous thickening of the macula region of the retina and loss of visual acuity, potentially leading to blindness. DME is a major complication associated with diabetes, affecting an estimated 26% of type 1 diabetic patients after 14 years of the disease, and an estimated 29% within their lifetime; 17% of type 1 diabetic patients were estimated to develop clinically significant macular edema within their lifetime. Approximately 900,000 patients in the United States have active DME and are at serious risk of vision loss, according to a study published in 2015.

The current standard of care for DME in the United States is therapy directed against VEGF, a hypoxia-induced protein that stimulates the growth of blood vessels in the retina. FDA approved anti-VEGF therapies for DME are ranibizumab (Lucentis®) and aflibercept (Eylea®). Both of these products are administered via intravitreal injection at roughly monthly intervals. In addition to these two products, a large fraction of patients is treated with bevacizumab (Avastin®), another therapy that works through the same mechanism of binding to VEGF but has not been approved for ophthalmic use. Bevacizumab is priced based on its application in oncology and off-label use by retinal specialists typically results in treatment at a fraction of the cost seen with both ranibizumab and aflibercept. Patients are also treated with laser therapy in some circumstances.

A number of other drug therapies are used to treat DME, including corticosteroid anti-inflammatories such as triamcinolone acetonide, fluocinolone, and dexamethasone. These drugs also are administered via intravitreal injection. Sustained release versions of fluocinolone (Iluvien®) and dexamethasone (Ozurdex®) have recently been approved for use in DME, substantially reducing the number of injections required to obtain and maintain clinical responses. These novel corticosteroid formulations led to 15-letter improvements in visual acuity in approximately 20-30% of patients. Corticosteroid treatment, however, is associated with a dramatic increase in cataract formation and a rise in intraocular pressure, reducing the attractiveness of these agents as potential therapies in many patients.

In a recent large, multi-center clinical trial in DME patients, anti-VEGF therapy led to approximately 20% of patients improving their visual acuity by 15 letters or more after a median of 9 or 10 intravitreal injections, leaving a significant portion of the patients with inadequate control of their disease. Further, in one study conducted for an approved VEGF inhibitor, 40% of patients displayed no visual improvement following anti-VEGF therapy after months of treatment. Unfortunately, even for those patients that do initially respond well to anti-VEGF therapy, their disease recurs within several months of treatment cessation, thus requiring extended rounds of intravitreal injections to achieve and maintain a clinical response.

Research into the biology underlying DME led by our scientific team has identified plasma kallikrein as a potential novel target for this indication. They found that plasma kallikrein levels were higher in vitreous fluid from DME patients compared to patients without diabetic retinopathy. They further found that targeted disruption of the gene for plasma prekallikrein or the administration of a small molecule plasma kallikrein inhibitor led to decreases in retinal thickening in animal retinopathy models. We believe that inhibition of plasma kallikrein provides an opportunity to address DME through a novel mechanism that is independent of the current pathways targeted by anti-VEGF and steroid therapies.

### *Our DME Development Activities*

Our first potential DME therapy is KVD001. KVD001 is a potent inhibitor of human plasma kallikrein with an IC<sub>50</sub> of approximately 10nM and a high degree of selectivity against a broad range of other proteases. We have

developed KVD001 for intravitreal injection because we believe that trials using this delivery modality will provide a relatively early and direct proof-of-concept since the molecule is delivered directly to the site of edema. Since other products such as anti-VEGF therapies are also delivered intravitreally, we believe this will be accepted by both physicians and patients and will not lead to any competitive disadvantages. Another inherent advantage of intravitreal administration is that there is very limited systemic exposure, thus reducing potential systemic safety concerns.

We have completed an open label single ascending dose Phase 1 trial of KVD001 in 14 DME patients, all of whom had previously received anti-VEGF treatment. Following this study, we conducted further preclinical testing to enable multiple monthly injections of KVD001, as well as allow concurrent treatment with KVD001 and anti-VEGF therapies. We believe the ability to provide patients with multiple injections and longer duration of treatment may further enhance the signal of improvement beyond that observed in the single dose Phase 1 trial.

In 2017 we began a Phase 2 trial of KVD001 administered by intravitreal injection in DME patients. This study is anticipated to enroll a total of 123 patients to evaluate the safety and efficacy of KVD001 in patients with DME who have received previous anti-VEGF therapy but continue to demonstrate reduced visual acuity and significant edema. The double-masked study consists of two active arms receiving low or high dose injections, and a sham control arm. Patients will receive a total of four injections over a three-month period, with evaluation at the end of the dosing period and for three months following. The endpoints include safety and tolerability, best corrected visual acuity, central subfield thickness, and the diabetic retinopathy severity scale. Based upon the rates of patient enrollment seen to date, we continue to anticipate that data from this study will be available in the second half of 2019.

KVD001 is subject to the Option Agreement with Merck. Under the terms of that Agreement once we provide certain data including results from the study, Merck will have a defined period to exercise the option on KVD001, as well as to make an additional payment to maintain the option on the Oral DME Compounds.

#### *Potential for Oral DME Therapies*

In parallel with the clinical development of our intravitreal product candidate KVD001, we intend to identify and advance plasma kallikrein inhibitors as oral therapies for DME. We believe that a safe and effective oral therapy has the potential to transform the treatment of DME which to-date has been dominated by drug therapies that must be injected intravitreally. Future trials in DME with oral kallikrein inhibitors may focus on the treatment of earlier stage disease, a stage at which intravitreal injections are not a desirable solution due to their inherently invasive nature and consequent risk of adverse reactions.

#### **Competition**

In HAE, we expect to face competition from several FDA-approved therapeutics, including Cinryze, marketed by Shire in the United States and Europe for the prevention of angioedema attacks in adults and adolescents; Firazyr, marketed by Shire in the United States, Europe and certain other geographic territories for the treatment of acute angioedema attacks in adult patients; Kalbitor, an injectable plasma kallikrein inhibitor marketed by Shire for the resolution of acute attacks in adolescent and adult HAE patients; Berinert and Haegarda, marketed by CSL Behring for the prophylaxis and treatment of acute abdominal, facial or laryngeal attacks of HAE in adults and adolescents; and Ruconest, marketed by Pharming Group for the treatment of acute angioedema attacks in adult patients. We are also aware of companies that are engaged in the clinical development of other product candidates, including a plasma kallikrein monoclonal antibody (SHP643, known as lanadelumab, from Shire) and an oral plasma kallikrein inhibitor (BCX7353, from BioCryst Pharmaceuticals), both for use as prophylaxis in HAE patients. BioCryst is also conducting clinical trials of a liquid, orally delivered formulation of BCX7353 for use as on-demand therapy in acute attacks. We believe several other companies are conducting preclinical and early clinical development of orally delivered HAE therapeutics.

In DME, we expect to face competition from several FDA-approved therapeutics, including anti-VEGF therapies Lucentis, marketed by Roche and Novartis, Eylea, marketed by Regeneron, and off label use of Avastin from Roche. We also face competition from various corticoid steroids including extended release formulations Iluvien, marketed by Alimera, and Ozurdex, marketed by Allergan. We further expect to compete with generic

corticosteroids such as acetonide, fluocinolone, and dexamethasone and we are aware of a number of other companies that have product candidates in early clinical trials, including Novartis, GlaxoSmithKline, Boehringer Ingelheim, Roche, Regeneron, Ohr Pharmaceutical, Aerpio Therapeutics, Thrombogenics and Allegro Ophthalmics. Thrombogenics has begun a clinical trial investigating a non-orally delivered plasma kallikrein inhibitor for the treatment of DME.

### **Intellectual Property**

Our success substantially depends on our ability to obtain and maintain patents and other forms of intellectual property rights for our product candidates, methods used to manufacture our product candidates and methods for treating patients using our product candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon the proprietary rights of others. As of April 30, 2018, we are the owner of nine U.S. patents expiring between 2023 and 2034, absent any extensions, as well as eight pending U.S. patent applications and five pending U.S. provisional applications. Any patents issuing from the foregoing owned or licensed U.S. applications are expected to expire in between 2034 and 2038, absent any adjustments or extensions. As of April 30, 2018, we owned a total of 109 pending foreign applications and 95 patents in multiple jurisdictions. Any issued patents, or those issuing from these foreign patent applications, are expected to expire between 2023 and 2037, absent any adjustments or extensions. As of April 30, 2018, we also controlled four pending international applications that, if issued, are expected to expire in 2037, absent any adjustments or extensions. The chemical structures of KVD001 and KVD900 are included in composition of matter applications.

KVD001 is covered by U.S. patents and patent applications covering composition of matter, methods of treatment, solid form and clinical formulations. The anticipated expiration dates of these patents, or patents arising from applications, range from 2032 to 2038, absent any adjustments or extensions.

Our portfolio of oral plasma kallikrein inhibitors, including KVD900, is covered by U.S. patent applications and pending international applications covering composition of matter, methods of treatment, solid form and clinical formulations and any patents arising from those applications are expected to expire between 2034 to 2038, absent any adjustments or extensions. New U.S. provisional applications directed to solid forms and further compositions of matter were filed in 2017.

In addition, we own a portfolio of patents and patent applications related to the former Carbylan Therapeutics product candidates following the share purchase transaction with KalVista Pharmaceuticals Limited. As of April 30, 2018, this included seven granted U.S. patents expiring between 2028 and 2032, as well as three pending U.S. patent applications which would be expected to expire between 2030 and 2034. Also, as of April 30, 2018, this portfolio included 18 pending foreign applications and 34 foreign granted patents.

Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country.

We also use other forms of protection, such as trademark, copyright and trade secret protection for our intellectual property, particularly where we do not believe patent protection is appropriate or obtainable. We require our employees, consultants, contractors and other advisors to execute nondisclosure and assignment of invention agreements upon commencement of their respective employment or engagement. In addition, we also require confidentiality or service agreements from third parties that receive confidential information or materials.

### **Government Regulation and Product Approval**

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the United Kingdom and European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of

pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

### ***FDA 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 clinical hold, FDA refusal to approve pending new drug applications (“NDA”), warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an Investigational New Drug (“IND”) application, which must become effective before clinical testing may commence in the United States, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA approval requirements prior to marketing a pharmaceutical product 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 manufacturing process, as well as toxicity studies in animals 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 good laboratory practices and good manufacturing practice (“cGMP”). The results of preclinical testing are submitted to the FDA as part of an IND along with the information on product chemistry, manufacturing and controls, and a proposed clinical trial protocol. For the initial IND submission, a 30-day waiting period after the submission of the IND is required prior to the commencement of the clinical trial 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. For subsequent clinical trial protocols submitted to the IND, there is no mandated review time for FDA. Longer duration pre-clinical studies, for example animal tests of reproductive toxicology and carcinogenicity, if required, will be conducted and submitted to the IND throughout the development of the product until sufficient data is available to support submission of an NDA. Clinical trials involve the administration of the investigational drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice (“GCP”), an international standard designed to protect the rights, safety and well-being of trial subjects and to define the roles of clinical trial sponsors, administrators and monitors; as well as (iii) 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 involving testing on U.S. patients 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 trial protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board (“IRB”), for approval prior to the start of the clinical trial. 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 product is tested to assess metabolism, pharmacokinetics, 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 the effectiveness of the drug for a particular indication, dosage tolerance and optimum dose, 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 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 product. 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 trial with other confirmatory evidence may be sufficient in rare instances where the trial is a large multicenter trial demonstrating internal consistency and a statistically persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious or life-threatening outcome and confirmation of the result in a second trial would be practically or ethically impossible.

The manufacturer of an investigational drug in a Phase 2 or 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access.

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 and clinical data, including pharmacology and toxicology results, and the results of other testing and a compilation of data relating to the product's chemistry, manufacture and controls. The cost of preparing and submitting a NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, and once approved, the NDA is also subject to annual product and establishment user fees. These fees are typically increased annually. 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 ten months of the date the FDA files the NDA; most applications for priority review drugs are reviewed within six months of the date the FDA files the NDA. Priority review can be applied to a drug that the FDA determines has the potential to treat a serious or life-threatening condition and, if approved, would be a significant improvement in safety or effectiveness compared to available therapies. 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.

After the FDA evaluates the NDA and the compliance of manufacturing facilities with GMP, 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, the FDA will issue an approval letter. The FDA has committed to reviewing such additional data 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 the indication being supported. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy ("REMS") if it is considered that additional measures are needed to ensure that the benefits of the drug outweigh the potential risks. REMS can include the use of medication guides and communication plans for healthcare professionals, and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the product'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.

### ***Foreign clinical studies to support an NDA***

The FDA will accept as support for marketing approval of a product (NDA) well-designed, well-conducted, clinical studies conducted outside of the United States if the studies have been conducted in accordance with the exact same standards of GCP, as required in the United States, and the protocol was submitted to the IND. FDA may validate the data from the study through an onsite inspection, if necessary. Clinical studies conducted outside the United States are subject to the same rigorous regulatory controls as the United States (see “— Europe / rest of world government regulation” below).

A sponsor or applicant who wishes to rely on a non-IND foreign clinical study to support an IND must submit documentation to the FDA to demonstrate compliance with GCP. The FDA may also request to inspect a foreign clinical study site to confirm compliance.

### ***Orphan drug designation***

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a compound with the potential to treat a rare disease or condition, generally a disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a product available in the United States for such disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested prior to submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the compound and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process of an NDA. The first NDA applicant to receive FDA approval for a drug product containing a compound that has FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that drug product for that orphan indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market a drug product containing the same active moiety for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. A product is clinically superior if it is safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity does not prevent the FDA from approving a drug product containing a different active moiety for the same disease or condition, or the same drug product for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA user fee.

### ***Disclosure of clinical trial information***

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

### ***Pediatric information***

Under the Pediatric Research Equity Act (“PREA”) NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug product for an indication for which orphan designation has been granted.

### ***Post-approval requirements***

Once an NDA is approved, a product will be subject to certain 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. 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, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug product 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. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, or if previously unrecognized problems are subsequently discovered.

### ***Other U.S. healthcare laws and compliance requirements***

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services (“CMS”), other divisions of the U.S. Department of Health and Human Services (such as the Office of Inspector General), the U.S. Department of Justice (“DOJ”), and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs may have to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act (“HIPAA”), and similar state laws, each as amended, as applicable.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act, collectively, the ACA, amended the intent element of the federal statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to commit a violation. This statute has been interpreted broadly 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, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor.



Federal civil and criminal false claims laws, including the federal False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to the federal healthcare programs, including Medicare and Medicaid, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. This includes claims made to programs where the federal government reimburses, such as Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing off-label promotion, may also violate false claims laws. Additionally, PPACA amended the federal Anti-Kickback Statute such that a violation of that statute can serve as a basis for liability under the federal False Claims Act. The majority of states also have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Additionally, to the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offerer or payor knows or should know is likely to influence the beneficiary to order a reimbursable item or service from a particular supplier, and the additional federal criminal statutes created by the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, HIPAA, as amended by HITECH, imposes obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services involving the storage, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information.

Further, pursuant to PPACA, the Centers for Medicare & Medicaid Services, or CMS, has issued a final rule that requires manufacturers of prescription drugs to collect and report information on certain payments or transfers of value to physicians and teaching hospitals, as well as investment interests held by physicians and their immediate family members. The first reports were due in 2014 and must be submitted on an annual basis. The reported data is made available in searchable form on a public website on an annual basis.

Additionally, the federal Physician Payments Sunshine Act within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Moreover, the Drug Supply Chain Security 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.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new

technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private “qui tam” actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

### ***Coverage, pricing and reimbursement***

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage, and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of its products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor’s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor’s determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on its investment in product development.

Different pricing and reimbursement schemes exist in other countries. In the EU, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on healthcare pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

### ***Healthcare reform***

In March 2010, President Obama enacted the ACA, which has the potential to substantially change healthcare financing and delivery by both governmental and private insurers, and significantly impacts the pharmaceutical and biotechnology industry.

Among the ACA provisions of importance to the pharmaceutical industries, in addition to those otherwise described above, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs apportioned among these entities according to their market share in some government healthcare programs that began in 2011;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price;
- 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 during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in 2014 and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- 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;
- requirements to report certain financial arrangements with physicians and teaching hospitals; and
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians.

The current U.S. presidential administration and Congress have sought, and we expect will continue to seek, to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. Since January 2017, the current U.S. presidential administration has issued two executive orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. For example, on October 12, 2017, the current U.S. presidential administration issued an executive order that expands the use of association health plans and allows anyone to purchase short-term health plans that provide temporary, limited insurance. This executive order also calls for the halt of federal payments to health insurers for cost-sharing reductions previously available to lower-income Americans to afford coverage. There is still uncertainty with respect to the impact this executive order could have on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, among other things, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. Additionally, on January 22, 2018, the current U.S. presidential administration signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole”. There is still uncertainty with respect to the impact the current U.S. presidential administration and the Congress may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA 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 on Deficit Reduction did not achieve a targeted deficit reduction of at least \$1.2 trillion for fiscal years 2012 through 2021, triggering the legislation’s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and 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, including hospitals and imaging centers. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our products, if approved, and, accordingly, our financial operations.

#### ***The Foreign Corrupt Practices Act***

The Foreign Corrupt Practices Act (“FCPA”) prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

#### ***Additional regulation***

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern the use, handling and disposal of

various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

#### ***Europe / rest of world government regulation***

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval of a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a clinical trial application must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the clinical trial application is approved in accordance with a country's requirements, clinical trial development may proceed. The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country in the European Union. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of a drug product under European Union regulatory systems, we must submit a marketing authorization application (MAA). The documentation submitted to the FDA in support of an NDA in the United States is almost identical to that required in the European Union, with the exception of, among other things, country-specific document requirements. For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we or our potential collaborators fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

#### ***Other regulations***

We are subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

#### **Employees**

As of April 30, 2018, we had a total of 33 full-time employees, of whom 13 were located in the United States and 20 were located in the United Kingdom. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We have not experienced any work stoppages and consider our relations with employees to be good.

#### **Corporate Information**

We were incorporated in the State of Delaware on March 26, 2004 as Sentrx Surgical, Inc. We changed our name to Carbylan Biosurgery, Inc. on December 14, 2005 and to Carbylan Therapeutics, Inc. ("Carbylan") on March 7, 2014. In June 2016, we entered into a definitive share purchase agreement, with KalVista Pharmaceuticals Ltd. ("KalVista Limited"), a private company limited by shares incorporated and registered in England and Wales and the shareholders of KalVista Limited, pursuant to which the shareholders of KalVista Limited became the majority owners of the company. We changed our name to KalVista Pharmaceuticals, Inc. on November 21, 2016 in

connection with the completion of the share purchase transaction. Our principal executive offices are located at 55 Cambridge Parkway, Ste 901E, Cambridge, MA 02142, and our telephone number is (857) 999-0075. Our website address is [www.kalvista.com](http://www.kalvista.com). The information contained on, or that can be accessed through, our website is not a part of this report. We have included our website address in this report solely as an inactive textual reference.

## Financial Information

We manage our operations and allocate resources as a single reporting segment. Financial information regarding our operations, assets and liabilities, including our net loss for the years ended April 30, 2018, 2017 and 2016 and our total assets as of April 30, 2018 and 2017, is included in our Consolidated Financial Statements in Item 8 of this Annual Report.

## Available Information

We file annual, quarterly, and current reports, proxy statements, and other documents with the Securities and Exchange Commission (“SEC”) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), which are available on our corporate website at [www.kalvista.com](http://www.kalvista.com). The public may read and copy any materials that 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. Also, the SEC maintains an Internet website that contains reports, proxy and information statements, and other information regarding issuers, including us, that file electronically with the SEC. The public can obtain any documents that we file with the SEC at [www.sec.gov](http://www.sec.gov). The information posted on or accessible through these websites are not incorporated into this filing.

## Item 1A. Risk Factors

*Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K, including the consolidated financial statements, the notes thereto and the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this Annual Report on Form 10-K before deciding whether to invest in shares of our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of or that we deem immaterial may also become important factors that adversely affect our business. If any of the following risks actually occur, our business, financial condition, results of operations and future prospects could be materially and adversely affected. In that event, the market price of our stock could decline, and you could lose part or all of your investment.*

### Risks Related to Our Business

***We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.***

Since inception, we have incurred significant operating losses as we focused on our discovery efforts and developing our product candidates. We expect that it will be many years, if ever, before we have a product candidate ready for commercialization. To date, we have financed our operations primarily through private placements of our preferred stock, the Merck Agreement and associated private placement, and through the share purchase transaction with Carbylan. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- continue clinical development of our current product candidates;
- seek to identify additional product candidates;
- acquire or in-license other products and technologies or enter into collaboration arrangements with regards to product discovery;
- initiate clinical trials for additional product candidates;

- seek marketing approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- continue to incur increased costs as a result of operating as a public company.

To become and remain profitable, we must develop and eventually commercialize a product or products with significant market potential. This will require us to be successful in a range of challenging activities, including completing clinical trials of our product candidates, obtaining marketing approval for these product candidates and manufacturing, marketing and selling those products for which we may obtain marketing approval. We may never succeed in these activities and, even if we do, we may never generate revenues that are significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our business and could impair our ability to raise capital, maintain our discovery and preclinical development efforts, expand our business or continue our operations and may require us to raise additional capital that may dilute the ownership interest of common stockholders. A decline in the value of our business could also cause stockholders to lose all or part of their investment.

***Our short operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.***

We are an early stage clinical development company and our operations to date have been limited to organizing and staffing, business planning, raising capital, acquiring and developing the technology, identifying potential product candidates, undertaking preclinical studies and early stage clinical studies of our most advanced product candidates, KVD001, which is currently in a Phase 2 clinical trial, and multiple candidates from our HAE portfolio which we have advanced into Phase 1 clinical trials. We have not yet demonstrated our ability to successfully complete large-scale, pivotal clinical trials, obtain marketing approvals, 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. Substantial time is required to develop a new medicine from the time it is discovered to when it is available for treating patients. Consequently, any predictions made about our future success or viability based on our short operating history to date may not be as accurate as they could be if we had a longer operating history.

In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition from a company with a research focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

***We will need substantial additional funding. If we are unable to raise capital when needed, we may need to delay, reduce or eliminate our product development programs or commercialization efforts.***

We expect our expenses to increase in parallel with our ongoing activities, particularly as we continue our discovery and preclinical development collaborations to identify new clinical candidates and initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding for our continuing operations. If we are unable to raise capital when needed or on attractive terms, we may be forced to delay, reduce or eliminate our discovery and preclinical development programs or any future commercialization efforts.

***Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.***

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 and debt financings. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. 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.

#### **Risks Related to the Discovery and Development of Our Product Candidates**

***We are very early in our development efforts. If we or our collaborators are unable to successfully develop and commercialize one or more of our compounds, or if we experience significant delays in doing so, the business will be materially harmed.***

We currently do not have any products that have gained regulatory approval. We have invested substantially all of our efforts and financial resources in identifying potential drug candidates and funding our preclinical and clinical studies. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our early stage product candidates.

We have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. For example, to execute our business plan, we will need to successfully:

- execute ongoing clinical development activities;
- move other product candidates into development;
- obtain required regulatory approvals for the development and commercialization of one or more of our product candidates;
- maintain, leverage and expand our intellectual property portfolio;
- build and maintain robust sales, distribution and marketing capabilities, either on our own or in collaboration with strategic partners;
- gain market acceptance for one or more of our product candidates;
- develop and maintain any strategic relationships we elect to enter into, including the agreement with Merck; and
- manage our spending as costs and expenses increase due to drug discovery, preclinical development, clinical trials, regulatory approvals and commercialization.

If we are unsuccessful in accomplishing these objectives, we may not be able to successfully develop and commercialize KVD001, KVD900 or other product candidates, and our business will suffer.

***Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.***

We have only recently commenced clinical development of our product candidates and the risk of failure for all of our product candidates is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of its product candidates in humans. Clinical testing is expensive, difficult to design and implement and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Further, the results of preclinical studies and early clinical trials of



its product candidates may not be predictive of the results of later-stage clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval.

We may experience delays in our clinical trials and we do not know whether planned clinical trials will begin or enroll subjects on time, need to be redesigned or be completed on schedule, if at all. There can be no assurance that the Medicines & Healthcare products Regulatory Agency (the “MHRA”), the U.K. regulatory authority, the European Medicines Agency (the “EMA”) or U.S. Food and Drug Administration (the “FDA”) will not put any of our product candidates on clinical hold in the future. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates. Clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, such as:

- delay or failure in reaching agreement with the MHRA, EMA, FDA or a comparable foreign regulatory authority on a trial design that we want to execute;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical study;
- delays in reaching, or failure to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- inability, delay, or failure in identifying and maintaining a sufficient number of trial sites, many of which may already be engaged in other clinical programs;
- delay or failure in recruiting and enrolling suitable subjects to participate in a trial;
- delay or failure in having subjects complete a trial or return for post-treatment follow-up;
- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- the withdrawal of the United Kingdom from the European Union could materially impact the regulatory regime with respect to clinical trials in the United Kingdom or the European Union;
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical studies and increased expenses associated with the services of its clinical research organizations (“CROs”) and other third parties;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- we may experience delays or difficulties in the enrollment of patients that our product candidates are designed to target;
- our third party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have difficulty partnering with experienced CROs that can identify patients that our product candidates are designed to target and run our clinical trials effectively;
- regulators or institutional review boards (“IRBs”) may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;

- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; or
- there may be changes in governmental regulations or administrative actions.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings that would reduce the potential market for our products or inhibit our ability to successfully commercialize our products;
- be subject to additional post-marketing restrictions and/or testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

***If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented and expenses for development of our product candidates could increase.***

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to demonstrate safety and efficacy. We have recently initiated clinical trials of KVD001 and KVD900, and we do not know whether planned or ongoing clinical trials will enroll subjects in a timely fashion, require redesign of essential trial elements or be completed on our projected schedule. In particular, because we are focused on patients with HAE, which is a rare disease, our ability to enroll eligible patients in trials may be limited or may result in slower enrollment than we anticipate. In addition, competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether.

Patient enrollment is affected by other factors including:

- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same disease indication;
- the patient referral practices of physicians;

- the proximity and availability of clinical trial sites for prospective patients;
- ambiguous or negative interim results of our clinical trials, or results that are inconsistent with earlier results;
- feedback from the MHRA, EMA, FDA, IRBs, data safety monitoring boards, or a comparable foreign regulatory authority, or results from earlier stage or concurrent preclinical and clinical studies, that might require modifications to the protocol;
- decisions by the MHRA, EMA, FDA, IRBs, a comparable foreign regulatory authority or us, or recommendations by data safety monitoring boards, to suspend or terminate clinical trials at any time for safety issues or for any other reason; and
- unacceptable risk-benefit profile or unforeseen safety issues or adverse effects.

Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of the company to decline and limit our ability to obtain additional financing.

***If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline.***

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, the commercialization of our products may be delayed or never achieved and, as a result, our stock price may decline.

***If serious adverse events or unacceptable side effects are identified during the development of our product candidates, we may need to abandon or limit the development of some of our product candidates.***

If our product candidates are associated with undesirable effects in preclinical or clinical trials or have characteristics that are unexpected, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. There are risks inherent in the intravitreal administration of drugs like KVD001 which can cause injury to the eye and other complications. Our HAE programs, including KVD900, are in the early stage of clinical testing and we have not yet determined what, if any, significant side effects may occur from dosing. Additional or more severe side effects may be identified for all our programs through further clinical studies. These or other drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

#### **Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters**

***If we are not able to obtain, or if there are delays in obtaining required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.***

Our product candidates must be approved by the FDA pursuant to a new drug application (“NDA”) in the United States and by the EMA and similar regulatory authorities outside the United States prior to commercialization. The process of obtaining marketing approvals, both in the United States and abroad, is expensive and takes many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have no experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third party CROs to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical

data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. 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 not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining marketing approval or prevent or limit commercial use. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may also cause delays in or prevent the approval of an application.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. On March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the withdrawal of the United Kingdom from the European Union could materially impact the regulatory regime with respect to the approval of KVD001, KVD900 or any of our other product candidates in the United Kingdom or the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing KVD001, KVD900 or any of our other product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for KVD001, KVD900 or any of our other product candidates, which could significantly and materially harm our business.

Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

***We may seek orphan drug exclusivity for some of our product candidates, and we may be unsuccessful.***

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a disease with a patient population of fewer than 200,000 individuals in the United States.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug for the same indication during the period of exclusivity. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective, if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve a different drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

***A fast track designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.***

We do not currently have fast track designation for any of our product candidates but may seek such designation. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot assure that the FDA would decide to grant it. Even if it does receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Many drugs that have received fast track designation have failed to obtain drug approval.

***A breakthrough therapy designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval.***

We do not currently have breakthrough therapy designation for any of our product candidates but may seek such designation. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for development.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe, after completing early clinical trials, that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification.

***Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.***

In order to market and sell our products in the European Union and many other jurisdictions, we or our third party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain MHRA or FDA approval. The regulatory approval process outside the United Kingdom and United States generally includes all of the risks associated with obtaining, respectively, MHRA or FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We, or these third parties, may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the MHRA or FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

*Any product candidate for which we obtain marketing approval will be subject to extensive post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.*

Our product candidates and the activities associated with their development and commercialization, including their testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the MHRA, FDA and other regulatory authorities. In the United States, these requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, current good manufacturing practices (“cGMP”) requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, including periodic inspections by the FDA and other regulatory authority, requirements regarding the distribution of samples to physicians and recordkeeping.

The FDA, or other 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. The FDA closely regulates 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. The FDA imposes stringent restrictions on manufacturers’ communications regarding use of their products and if we promote our products beyond their approved indications, we may be subject to enforcement action for off-label promotion. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

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 such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- 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 our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the European Union’s requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

***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 prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

As an example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, (collectively, the “ACA”), was signed into law in 2010 but has continued to be the subject of legislative efforts at revision and repeal. The ACA included a substantial number of major changes to the healthcare system that impact our business, and several other legislations since then, as well as ongoing efforts, have continued to create a complicated planning and operating environment for companies in our industry.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA’s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

***Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.***

In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from its use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed its resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers’ compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with the storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our discovery, preclinical development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

***Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

As with all companies, we are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we may establish, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use 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 employee 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 material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm.

**Risks Related to the Commercialization of Our Product Candidates**

***Even if any of our product candidates receives marketing approval, we may fail to achieve the degree of market acceptance by physicians, patients, third party payors and others in the medical community necessary for commercial success.***

If any of our product candidates receives marketing approval, we may nonetheless fail to gain sufficient market acceptance by physicians, patients, third party payors and others in the medical community. In addition, physicians, patients and third party payors may prefer other novel products to ours. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety and potential advantages and disadvantages compared to alternative treatments;
- the 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 our marketing and distribution support;
- the availability of third party coverage and adequate reimbursement, including patient cost-sharing programs such as copays and deductibles;
- the ability to develop or partner with third-party collaborators to develop companion diagnostics;



- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

In addition, in order to commercialize any product candidates, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If we are unable to enter into such arrangements when needed on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

***We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.***

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our product candidates. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. In addition, our ability to compete may be affected in many cases by insurers or other third party payors seeking to encourage the use of generic products. Generic products are expected to become available over the coming years, potentially creating pricing pressure. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic products.

Many of the companies against which we are competing or we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

***The insurance coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.***

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully

commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services (“CMS”), an agency within the U.S. Department of Health and Human Services, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. Reimbursement agencies in Europe may be more conservative than CMS. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market.

In addition, many private payors contract with commercial vendors who sell software that provide guidelines that attempt to limit utilization of, and therefore reimbursement for, certain products deemed to provide limited benefit to existing alternatives. Such organizations may set guidelines that limit reimbursement or utilization of our products

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

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

We currently hold \$8,000,000 in product liability insurance coverage in the aggregate, with a per incident limit of \$8,000,000, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

### **Risks Related to Our Dependence on Third Parties**

*We have entered, and may in the future seek to enter, into collaborations with third parties for the development and commercialization of our product candidates. If we fail to enter into such collaborations, or such collaborations are not successful, we may not be able to capitalize on the market potential of our product candidates.*

In October 2017, KalVista Limited and Merck entered into the Option Agreement, under which we granted to Merck an option to acquire KVD001 through a period following completion of a Phase 2 clinical trial. We also granted to Merck a similar option to acquire investigational orally delivered molecules for DME that we will continue to develop as part of our ongoing research and development activities, through a period following the completion of a Phase 2 clinical trial. Biopharmaceutical companies are our prior and likely future collaborators for any marketing, distribution, development, licensing or broader collaboration arrangements. With respect to our existing collaboration agreements, and what we expect will be the case with any future collaboration agreements, we have and would expect to have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Moreover, our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay our development program or one or more of our other development programs, delay our potential development schedule or reduce the scope of research activities, or increase our expenditures and undertake discovery or preclinical development activities at our own expense. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development activities, we may not be able to further develop our product candidates or continue to develop our product candidates and our business may be materially and adversely affected.

Future collaborations we may enter into may involve the following risks:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, may divert resources or create competing priorities;
- collaborators may delay discovery and preclinical development, provide insufficient funding for product development of targets selected by us, stop or abandon discovery and preclinical development for a product candidate, repeat or conduct new discovery and preclinical development for a product candidate;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed than our products;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the development of its product candidates;

- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the discovery, preclinical development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend their intellectual property rights or intellectual property rights licensed to us or may use their proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Additionally, subject to its contractual obligations to us, if a collaborator is involved in a business combination, the collaborator might deemphasize or terminate the development of any of our product candidates. If one of our collaborators terminates its agreement with us, they may find it more difficult to attract new collaborators and the perception of us in the business and financial communities could be adversely affected.

If our collaborations do not result in the successful development of products or product candidates, product candidates could be delayed and we may need additional resources to develop product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this proxy statement also apply to the activities of our collaborators.

***Our existing collaboration with Merck is important to our business. If our collaborators cease development efforts under our existing or future collaboration agreements, or if any of those agreements are terminated, these collaborations may fail to lead to commercial products and we may never receive milestone payments or future royalties under these agreements.***

We have entered into a collaboration with Merck to develop KVD001 and other Oral DME Compounds, and these activities currently represent a significant portion of our product development efforts. A significant portion of our future revenue and cash resources is expected to be derived from this agreement or other similar agreements into which we may enter in the future. Revenue from research and development collaborations depends upon continuation of the collaborations, payments for research and development services and product supply, and the achievement of milestones, contingent payments and royalties, if any, derived from future products developed from our research. If we are unable to successfully advance the development of our product candidates or achieve milestones, revenue and cash resources from milestone payments under our collaboration agreements will be substantially less than expected.

We are unable to predict the success of our collaborations and we may not realize the anticipated benefits of our strategic collaborations. Our collaborators have discretion in determining and directing the efforts and resources, including the ability to discontinue all efforts and resources, they apply to the development and, if approval is obtained, commercialization and marketing of the product candidates covered by such collaborations. As a result, our collaborators may elect to de-prioritize our programs, change their strategic focus or pursue alternative technologies in a manner that results in reduced, delayed or no revenue to us. Our collaborators may have other marketed products and product candidates under collaboration with other companies, including some of our competitors, and their corporate objectives may not be consistent with our best interests. Our collaborators may also be unsuccessful in developing or commercializing our products. If our collaborations are unsuccessful, our business, financial condition, results of operations and prospects could be adversely affected. In addition, any dispute or litigation proceedings we may have with our collaborators in the future could delay development programs, create uncertainty as to ownership of intellectual property rights, distract management from other business activities and generate substantial expense.

Moreover, to the extent that any of our existing or future collaborators were to terminate a collaboration agreement, we may be forced to independently develop these product candidates, including funding preclinical studies or clinical trials, assuming marketing and distribution costs and defending intellectual property rights, or, in certain instances, abandon product candidates altogether, any of which could result in a change to our business plan and have a material adverse effect on our business, financial condition, results of operations and prospects.

***We contract with third parties for the manufacture of our product candidates for preclinical and clinical testing and we expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products at an acceptable cost and quality, which could delay, prevent or impair our development or commercialization efforts.***

We do not own or operate facilities for the manufacture of our product candidates, and we do not have any manufacturing personnel. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing and we do not have backup sources of supply established for our candidates. We review the manufacturing process for each of our candidates and assess the risk to supply and, as appropriate, establish multiple manufacturers and/or establish stock levels to support future activities and do not believe we are currently substantially dependent on any one third party. Despite the drug substance and product risk management, this reliance on third parties presents a risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

Any performance failure on the part of our existing or future manufacturers of drug substance or drug products could delay clinical development or marketing approval. If current suppliers cannot supply us with our Phase 2 requirements as agreed, we may be required to identify alternative manufacturers, which would lead us to incur added costs and delays in identifying and qualifying any such replacement.

The formulation used in early studies frequently is not a final formulation for commercialization. Additional changes may be required by the FDA or other regulatory authorities on specifications and storage conditions. These may require additional studies and may delay our clinical trials.

We expect to rely on third party manufacturers or third-party collaborators for the manufacture of commercial supply of any other product candidates for which our collaborators or we obtain marketing approval.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

We may be unable to establish any agreements with third party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third party manufacturers, reliance on third party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third party manufacturers may not be able to comply with cGMP, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

***We may not successfully engage in strategic transactions, including any additional collaborations we seek, which could adversely affect our ability to develop and commercialize product candidates, impact our cash position, increase our expenses and present significant distractions to our management.***

From time to time, we may consider strategic transactions, such as additional collaborations, acquisitions of companies, asset purchases and out- or in-licensing of product candidates or technologies that we believe will complement or augment our existing business. In particular, we will evaluate and, if strategically attractive, seek to enter into additional collaborations, including with major biotechnology or biopharmaceutical companies. The competition for collaborators is intense, and the negotiation process is time-consuming and complex. Any new collaboration may be on terms that are not optimal for us, and we may not be able to maintain any new collaboration if, for example, development or approval of a product candidate is delayed, sales of an approved product candidate do not meet expectations or the collaborator terminates the collaboration. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future strategic partners. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the strategic partner's resources and expertise, the terms and conditions of the proposed collaboration and the proposed strategic partner's evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. Moreover, even if we acquire assets with promising markets or technologies, we may not be able to realize the benefit of acquiring such assets due to an inability to successfully integrate them with our existing technologies and we may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic acquisition that delay or prevent us from realizing their expected benefits or enhancing our business.

We cannot assure you that following any such collaboration, or other strategic transaction, we will achieve the expected synergies to justify the transaction. For example, such transactions may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. Also, such strategic alliance, joint venture or acquisition may be prohibited.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks that would have a material and adverse effect on our business, financial condition, results of operations and prospects. Conversely, any failure to enter any additional collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and have a negative impact on the competitiveness of any product candidate that reaches market.

#### **Risks Related to Our Intellectual Property**

***If we are unable to obtain and maintain intellectual property protection for our technology and products or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.***

Our success depends in large part on our ability to obtain and maintain patent protection in the European Union, the United States and other countries with respect to our proprietary technology and products. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates. This patent portfolio includes issued patents and pending patent applications covering compositions of matter and methods of use.

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. We may choose not to seek patent protection for certain innovations and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope. It is also possible that we will fail to identify patentable aspects of our discovery and preclinical development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

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, India and China do not allow patents for methods of treating the human body. Publications of discoveries in the 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 that we were the first to file for patent protection of such inventions. If a third party has also filed a United States patent application prior to the effective date of the relevant provisions of the America Invents Act (i.e. before March 16, 2013) covering our product candidates or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the USPTO to determine priority of invention in the United States. 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 European Union, the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Moreover, we may be subject to a third party preissuance 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 with 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.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

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. 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.

The risks described elsewhere pertaining to our patents and other intellectual property rights also apply to the intellectual property rights that we license, and any failure to obtain, maintain and enforce these rights could have a material adverse effect on our business. In some cases we may not have control over the prosecution, maintenance or enforcement of the patents that we license, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain and enforce the licensed patents. Any inability on our part to protect adequately our intellectual property may have a material adverse effect on our business, operating results and financial position.

***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, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance 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. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

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

Because competition in our industry is intense, competitors may infringe or otherwise violate our issued patents, patents of our licensors or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringed their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or 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 proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could be significant. 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.



***Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.***

Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference or derivation proceedings before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We seek to protect our confidential proprietary information, in part, by entering into confidentiality and invention or patent assignment agreements with our employees and consultants, however, we cannot be certain that such agreements have been entered into with all relevant parties. Moreover, to the extent we enter into such agreements, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate them, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

#### **Risks Related to Employee Matters, Facilities, Managing Growth and Macroeconomic Conditions**

***Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.***

We are highly dependent on the research and development, clinical and business development expertise of the principal members of our management, scientific and clinical team. Although we have entered into employment letter agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with

the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery and preclinical development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to provide services to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

***We may face operational disruptions due to lack of adequate facilities.***

We are highly dependent upon our U.K. operations to conduct our scientific research, and we are currently in the process of moving those operations to new facilities. We have experienced delays in the preparation of these facilities for occupancy and we may continue to experience further delays. If we are unable to finalize and occupy these facilities in a timely fashion our scientific and business activities could be disrupted, which could materially harm our business and future prospects.

***We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and, if any of our product candidates receive marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

***The U.K. vote to leave the European Union, known as Brexit, could negatively impact our business and operations.***

The majority of our scientific operations are based in the United Kingdom and we have received significant funding through United Kingdom government sources and tax credits. In addition, we have used the United Kingdom as our European location for interactions with European Union regulatory authorities related to clinical development and other activities executed or planned in the European Union. The ongoing Brexit process is complicated and many of the details of future interactions between the United Kingdom and European Union remain unresolved. There are many risks and uncertainties associated with this process, including whether Brexit has a negative economic impact on either the United Kingdom or the European Union member states, or interactions with the European Union regulatory regime are changed as a result of Brexit, any of which could have an adverse impact on our business or future operations. For additional risks related to Brexit, see “*If we are not able to obtain, or if there are delays in obtaining required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.*”

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

Our internal computer systems and those of our CROs, collaborators and third-parties on whom we rely are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Furthermore, we have little or no control over the security measures and computer systems of our third-party collaborators. While we and, to our knowledge, our third party collaborators have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or our third party collaborators, it could result in a material disruption of our drug development programs. For example, the loss of research data could delay development of our product candidates and the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and we may incur substantial costs to attempt to recover or reproduce the data. If any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and/or the further development of our product candidates could be delayed.

**Risks Related to Ownership of Our Common Stock**

***Our stock price is volatile and our stockholders may not be able to resell shares of our common stock at or above the price they paid.***

The trading price of our common stock is highly volatile and could be subject to wide fluctuations in response to various factors, many of which are beyond our control. These factors include those discussed in this “Risk Factors” section of this Annual Report on Form 10-K and others such as:

- announcement of a strategic transaction, including the acquisition of our company or its assets;
- our decision to initiate a clinical trial or not to initiate a clinical trial;
- announcements of significant changes in our business or operations, including the decision not to pursue drug development programs;
- additions or departures of key personnel;
- adverse results or delays in clinical trials;
- changes in reimbursement or third-party coverage of treatments for HAE or DME, or changes to treatment recommendations or guidelines applicable to the treatment of HAE or DME;
- announcements relating to collaboration partnerships or other strategic transactions undertaken by us;
- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to any of our product candidates;
- any adverse changes to our relationship with any manufacturers or suppliers;
- the success of our testing and clinical trials;
- the success of our efforts to acquire or license or discover additional product candidates;
- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the pharmaceutical industry in general;
- achievement of expected product sales and profitability;
- manufacture, supply or distribution shortages;
- actual or anticipated fluctuations in our operating results;
- FDA or other regulatory actions affecting us or our industry or other healthcare reform measures in the United States, the United Kingdom or the European Union;

- changes in financial estimates or recommendations by securities analysts;
- trading volume of our common stock;
- sales of our common stock by us, our executive officers and directors or our stockholders in the future; and
- general economic and market conditions and overall fluctuations in the United States equity markets.

In addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business, which could seriously harm our financial position. Any adverse determination in litigation could also subject us to significant liabilities.

***If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse opinion regarding our stock, our stock price and trading volume could decline.***

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If any analysts who cover us issue an adverse regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If any of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

***We incur significant costs as a result of operating as a public company, and our management devotes substantial time to compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would harm our business.***

We incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and regulations regarding corporate governance practices. The listing requirements of The NASDAQ Global Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel have devoted, and will continue to need to devote, a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations increase our legal and financial compliance costs and make some activities more time consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

We are subject to Section 404 of The Sarbanes-Oxley Act of 2002, or Section 404, and the related rules of the SEC which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Beginning with this annual report filed with the SEC for the year ending April 30, 2018, Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404.

During the course of the review and testing of our internal control for the purpose of providing the reports required by these rules, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The NASDAQ Global Market or other adverse consequences that would materially harm our business.

***If we fail to establish or maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.***

Pursuant to Section 404 of the Sarbanes-Oxley Act, beginning in the year ended April 30, 2018, our management is required annually to deliver a report that assesses the effectiveness of our internal control over financial reporting and, subject to exemptions allowed as an “emerging growth company,” our independent registered public accounting firm will be required annually to deliver an attestation report on the effectiveness of our internal control over financial reporting. If we are unable to maintain effective internal control over financial reporting, we may not be able to produce accurate financial statements, and investors may therefore lose confidence in our operating results, our stock price could decline and we may be subject to litigation or regulatory enforcement actions.

***Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.***

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquirer or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least 66 2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of at least 66 2/3% of the shares entitled to vote at an election of directors to adopt, amend or repeal certain provisions of our bylaws and our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;

- the requirement that a special meeting of stockholders may be called only by or at the direction of our board of directors pursuant to a resolution adopted by a majority of the total number of directors that our board of directors would have if there were no vacancies, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us. In addition, these provisions would apply even if we were to receive an offer that some stockholders may consider beneficial.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

***Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.***

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

***Our ability to use our net operating losses to offset future taxable income, if any, may be subject to certain limitations.***

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" (generally defined as a greater than 50-percentage-point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period) is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, to offset future taxable income. We experienced an ownership change in November 2016 that substantially limited our use of the NOLs available to us for U.S. federal income tax purposes. If we undergo additional ownership changes (some of which changes may be outside our

control), our ability to utilize our NOLs could be further limited by Section 382 of the Code. Our NOLs may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs. Furthermore, our ability to utilize our NOLs is conditioned upon our attaining profitability and generating U.S. federal taxable income. We have incurred net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; thus, we do not know whether or when we will generate the U.S. federal taxable income necessary to utilize our NOLs. See the risk factors described above under “-Risks Related to Our Limited Operating History, Financial Condition and Capital Requirements.”

***We do not currently intend to pay dividends on our common stock, and, consequently, our stockholders’ ability to achieve a return on their investment will depend on appreciation in the price of our common stock.***

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, our stockholders are not likely to receive any dividends on their common stock for the foreseeable future. Since we do not intend to pay dividends, our stockholders’ ability to receive a return on their investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

**Item 1B. Unresolved Staff Comments.**

None.

**Item 2. Properties.**

Our corporate headquarters are located in Cambridge, Massachusetts where we occupy approximately 2,700 square feet of office space under a five-year lease. We maintain approximately 4,500 square feet of office and research laboratory space in Porton Down, United Kingdom, under a lease which is currently running on a month by month basis through July 2018. We also maintain approximately 1,000 square feet of leased research laboratory space in Boston, Massachusetts.

In April 2018, we entered into a lease for approximately 8,873 square feet of new office and research laboratory space in Porton Down, United Kingdom, that we anticipate occupying in August 2018.

We believe that our current and planned facilities are adequate to meet our needs for the immediate future, and that, should it be needed, suitable additional space will be available to accommodate any such expansion of our operations.

**Item 3. Legal Proceedings.**

From time to time, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. We are currently not aware of any such legal proceedings or claims that we believe will have a material adverse effect on our business, financial condition or operating results.

**Item 4. Mine Safety Disclosures.**

Not Applicable.

## PART II

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

#### Price Range of Common Stock

Our common stock is traded on the NASDAQ stock market under the symbol "KALV" as of November 21, 2016, the date of the share purchase transaction with KalVista Pharmaceuticals Ltd. Prior to November 21, 2016, our common stock was traded on the NASDAQ stock market under the symbol "CBYL" since April 9, 2015. The following table sets forth the quarterly high and low sales prices per share of our common stock. The per share prices below reflect a 14 for 1 reverse stock split effected on November 21, 2016:

	High	Low
Year ended April 30, 2018		
First Fiscal Quarter	\$ 8.19	\$ 6.82
Second Fiscal Quarter	\$ 15.80	\$ 5.48
Third Fiscal Quarter	\$ 13.84	\$ 8.50
Fourth Fiscal Quarter	\$ 11.37	\$ 8.80
Year ended April 30, 2017		
First Fiscal Quarter	\$ 20.02	\$ 7.56
Second Fiscal Quarter	\$ 9.10	\$ 6.16
Third Fiscal Quarter	\$ 10.65	\$ 6.09
Fourth Fiscal Quarter	\$ 8.74	\$ 6.20

As of June 30, 2018 there were 46 holders of record of our common stock. The last reported sale price of the common stock on June 30, 2018 was \$8.12 per share.

#### Dividends

We have never declared or paid cash dividends on our capital stock. We do not expect to pay dividends on our common stock for the foreseeable future. Instead, we anticipate that all of our earnings, if any, will be used for the operation and growth of our business. Any future determination to declare cash dividends would be subject to the discretion of our board of directors and would depend upon various factors, including our results of operations, financial condition and capital requirements, restrictions that may be imposed by applicable law and our contracts and other factors deemed relevant by our board of directors.



## Securities Authorized for Issuance under Equity Compensation Plans

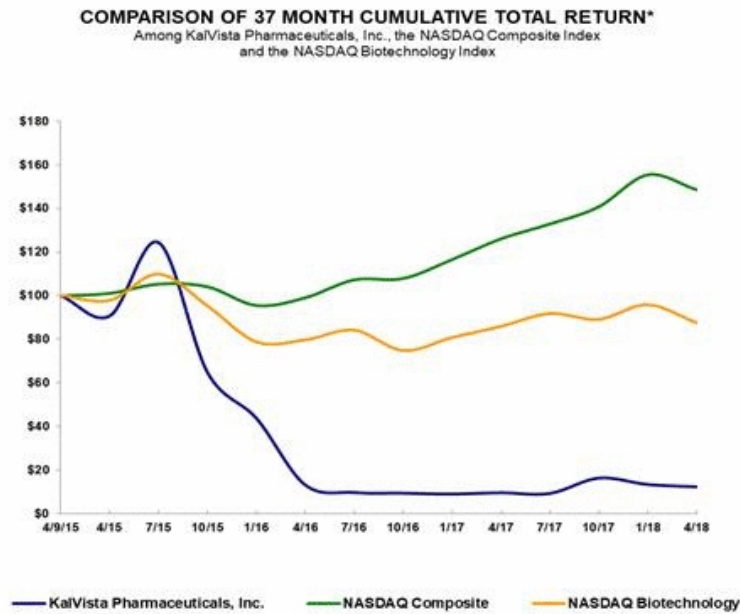
The following table provides information as of April 30, 2018, with respect to the shares of our common stock that may be issued under our existing equity compensation plans.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by stockholders (1)(2)	833,639	\$ 5.60	1,176,367
Equity compensation plans not approved by stockholders (3)	85,055	\$ 8.45	—
<b>Total</b>	<b>918,694</b>		<b>1,176,367</b>

- (1) Includes 165,148 shares subject to options issued pursuant to the Carbylan 2015 Incentive Plan, 197,719 shares subject to options issued pursuant to the Enterprise Management Incentives Plan and 470,772 shares subject to options issued pursuant to the 2017 Equity Incentive Plan. The 2017 Equity Incentive Plan contains provisions that provide for automatic increases to the authorized number of shares as of January 1st each year, of up to 4% of the outstanding shares of stock on the last day of the immediately preceding calendar year, or a lesser number of shares as approved by our board of directors. There are currently 1,076,367 shares available for future issuance under the 2017 Equity Incentive Plan. There are 100,000 shares of common stock available for future issuance under the 2017 Employee Stock Purchase Plan. As of April 30, 2018, no purchase periods under the 2017 Employee Stock Purchase Plan have been authorized by the board of directors.
- (2) Shares reserved for issuance under the 2017 Equity Incentive Plan may be granted as restricted stock, restricted share units and other equity awards, as well as for grants of stock options and stock appreciation rights.
- (3) Consists of options issued pursuant to inducement grants.

**Stock Price Performance Graph**

The graph below matches KalVista Pharmaceuticals, Inc.'s cumulative 37-month total shareholder return on common stock with the cumulative total returns of the NASDAQ Composite index and the NASDAQ Biotechnology index. The graph tracks the performance of a \$100 investment in our common stock and in each index (with the reinvestment of all dividends) from April 9, 2015, the date our common stock became publicly traded, to April 30, 2018.



	4/9/15	4/15	7/15	10/15	1/16	4/16	7/16	10/16	1/17	4/17	7/17	10/17	1/18	4/18
KalVista Pharmaceuticals, Inc.	100.00	90.65	124.28	64.75	43.71	13.17	9.73	9.43	9.03	9.62	9.30	16.35	13.41	12.36
NASDAQ Composite	100.00	101.15	105.40	104.16	95.59	99.15	107.35	107.95	116.62	126.11	132.87	140.73	155.36	148.53
NASDAQ Biotechnology	100.00	97.66	109.77	95.15	78.61	79.60	84.03	74.67	80.62	85.76	91.64	89.00	95.71	87.45

**Recent Sales of Unregistered Securities**

None.

**Item 6. Selected Financial Data.**

The following selected financial data should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” the financial statements and related notes and other financial information included in this Annual Report on Form 10-K.

We derived the financial data for the years ended April 30, 2018, 2017, 2016 and 2015 and the balance sheet data as of April 30, 2018, 2017, 2016 and 2015 from our audited consolidated financial statements, which are included elsewhere in this Annual Report on Form 10-K. Historical results are not necessarily indicative of the results to be expected in future periods.

	For the Years Ended April 30,			
	2018	2017	2016	2015
	<i>(in thousands, except share and per share data)</i>			
<b>Consolidated Statement of Operations Data:</b>				
Revenue	\$ 8,394	\$ 1,504	\$ 2,133	\$ 1,804
Operating expenses				
Research and development	18,237	12,666	14,661	8,285
General and administrative	8,862	11,177	2,653	1,608
Total operating expenses	27,099	23,843	17,314	9,893
Operating loss	(18,705)	(22,339)	(15,181)	(8,089)
Other income, net	2,900	3,736	3,745	863
Net loss	\$ (15,805)	\$ (18,603)	\$ (11,436)	\$ (7,226)
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.53)	\$ (4.47)	\$ (26.17)	\$ (34.94)
Weighted average common shares outstanding, basic and diluted	10,321,780	4,646,764	591,298	263,358

	April 30,			
	2018	2017	2016	2015
	<i>(in thousands)</i>			
<b>Consolidated Balance Sheet Data:</b>				
Cash and cash equivalents	\$ 51,055	\$ 30,950	\$ 21,764	\$ 2,526
Property and equipment, net	1,836	97	74	100
Working capital	36,164	31,180	21,422	1,950
Total assets	61,389	34,345	24,745	3,890
Total liabilities	23,216	3,018	3,249	1,840
Stockholders' equity (deficit)	27,253	31,327	(37,112)	(23,554)

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

*The following discussion and analysis should be read in conjunction with our audited consolidated financial statements and the related notes that appear elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results may differ materially from those discussed in these forward-looking statements due to a number of factors, including those set forth in the section entitled "Risk Factors" and elsewhere in this Annual Report on Form 10-K. For further information regarding forward-looking statements, please refer to the "Special Note Regarding Forward-Looking Statements" at the beginning of Part I of this Annual Report on Form 10-K.*

### **Management Overview**

We are a clinical stage pharmaceutical company focused on the discovery, development and commercialization of small molecule protease inhibitors for diseases with significant unmet need. Our first product candidates are inhibitors of plasma kallikrein being developed for two indications: hereditary angioedema ("HAE") and diabetic macular edema ("DME"). We apply our insights into the chemistry of proteases and, with our current programs, the biology of the plasma kallikrein system, to develop small molecule inhibitors with high selectivity, potency and bioavailability that we believe will make them successful treatments for disease.

We have created a structurally diverse portfolio of oral plasma kallikrein inhibitors and advanced multiple drug candidates into Phase 1 clinical trials for HAE in order to create best-in-class oral therapies. In December 2017, we initiated a first-in-human study of KVD900, the next candidate from our HAE portfolio to commence clinical testing. Based upon the results observed to date in that study, we have determined to advance KVD900 into later stage clinical testing as a potential on-demand therapy for treatment of acute HAE attacks. We currently are planning a Phase 2 proof of concept trial that we expect to initiate before the end of 2018 and complete in mid-2019. In the case of DME, we are initially developing a plasma kallikrein inhibitor which is administered directly into the eye and anticipate ultimate development of orally delivered drugs. Also in December 2017 we commenced a Phase 2 clinical trial of KVD001, our most advanced DME drug candidate, that we anticipate will complete in the second half of 2019.

We have devoted substantially all our efforts to research and development, including clinical trials of our product candidates. We have not completed the development of any product candidates. Pharmaceutical drug product candidates, like those being developed by us, require approvals from the FDA or foreign regulatory agencies prior to commercial sales. There can be no assurance that any product candidates will receive the necessary approvals and any failure to receive approval or delay in approval may have a material adverse impact on our business and financial results. We are subject to a number of risks and uncertainties similar to those of other life science companies developing new products, including, among others, the risks related to the necessity to obtain adequate additional financing, to successfully develop product candidates, to obtain regulatory approval of product candidates, to comply with government regulations, to successfully commercialize our potential products, to the protection of proprietary technology and to our dependence on key individuals.

We have funded operations primarily through the issuance of preferred stock and common stock, the share purchase transaction with Carbylan, the Option Agreement and grant income. As of April 30, 2018, we had an accumulated deficit of \$71.7 million and \$51.1 million of cash and cash equivalents. Our working capital is anticipated to fund our operations for at least the next twelve months from the date the audited consolidated financial statements are issued. Accordingly, the audited consolidated financial statements have been prepared on a going concern basis.

### **Financial Overview**

#### **Revenue**

Our revenue consists primarily of a portion of the upfront fees from the Option Agreement, which is recognized as revenue on a proportional performance basis as the related research and development activities are conducted.

We have received grant income to support our research and development activities primarily through an agreement with the Technology Strategy Board (“TSB”), a United Kingdom government organization. Under the terms of the grant the TSB had authorized a total amount of up to \$7.3 million over the lifetime of the agreements between us and TSB, to accelerate the development of the oral drug program. As of April 30, 2018, the development activities related to the TSB grant have been completed and we do not anticipate any further reimbursements.

#### **Research and Development Expenses**

Research and development expenses primarily consist of costs associated with our research activities, including the preclinical and clinical development of product candidates. We contract with clinical research organizations to manage our clinical trials under agreed upon budgets for each study, with oversight by our clinical program managers. We account for all goods and services, including non-refundable advance payments, as expenses, and all research and development costs are expensed as incurred.

We expect to continue to incur substantial expenses related to development activities for the foreseeable future as we conduct clinical development, manufacturing and toxicology studies. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials, additional drug manufacturing requirements, and later stage toxicology studies such as carcinogenicity studies. The process of conducting preclinical studies and clinical trials necessary to obtain regulatory approval is costly and time consuming. The probability of success for each product candidate is affected by numerous factors, including preclinical data, clinical data, competition, manufacturing capability and commercial viability. Accordingly, we may never succeed in achieving marketing approval for any of our product candidates.

Completion dates and costs for clinical development programs as well as our research program can vary significantly for each current and future product candidate and are difficult to predict. As a result, we cannot estimate with any degree of certainty the costs associated with development of our product candidates at this point in time. We anticipate making determinations as to which programs and product candidates to pursue and how much funding to direct to each program and product candidate on an ongoing basis in response to the scientific success of early research programs, results of ongoing and future clinical trials, our ability to enter into collaborative agreements with respect to programs or potential product candidates, as well as ongoing assessments as to the commercial potential of each current or future product candidate.

#### **General and Administrative Expenses**

General and administrative expenses consist primarily of the costs associated with general management, obtaining and maintaining our patent portfolio, professional fees for accounting, auditing, consulting and legal services, and general overhead expenses.

We expect ongoing general and administrative expenses to increase in the future as we expand our operating activities, maintain and expand the patent portfolio and incur additional costs associated with the management of a public company and maintaining compliance with exchange listing and SEC requirements. These potential increases will likely include management costs, legal fees, accounting fees, directors’ and officers’ liability insurance premiums and expenses associated with investor relations.

#### **Other Income, Net**

Other income consists of bank interest, research and development tax credits from the United Kingdom government’s tax incentive programs set up to encourage research and development in the United Kingdom and realized and unrealized exchange rate gains/losses on cash held in foreign currencies.

#### **Income Taxes**

We historically have incurred net losses and have no corporation tax liabilities. We file U.S. Federal tax returns, as well as certain state returns. We also file returns in the United Kingdom. Under the U.K. government’s

research and development tax incentive scheme, we have incurred qualifying research and development expenses and filed claims for research and development tax credits in accordance with the relevant tax legislation. The research and development tax credits are paid out to us in cash and reported as other income. Because of the operating losses and the full valuation allowance provided on all deferred tax assets, including the net operating losses, no tax provision has been recognized in the periods presented.

### **Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of our financial statements and the reported revenue and expenses during the reported periods. We evaluate these estimates and judgments, including those described below, on an ongoing basis. We base our estimates on historical experience, known trends and events, contractual milestones and 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. See also Note 2, "Summary of Significant Accounting Policies" to our Consolidated Financial Statements included in Item 8 of this report, which discusses the significant assumptions used in applying our accounting policies. Those accounting policies and estimates that we deem to be critical are as follows:

#### ***Revenue Recognition***

We recognize revenue from research and development arrangements and grant income. Revenue is realized or realizable and earned when all of the following criteria are met: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the seller's price to the buyer is fixed or determinable; and (iv) collectability is reasonably assured.

For arrangements that involve the delivery of more than one element, such as the Option Agreement, each product, service and/or right to use assets is evaluated to determine whether it qualifies as a separate unit of accounting. This determination is based on whether the deliverable has "stand-alone value" to the customer. The consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The estimated selling price of each deliverable is determined using the following hierarchy of values: (i) vendor-specific objective evidence of fair value, (ii) third party evidence of selling price and (iii) best estimate of selling price ("BESP"). The BESP reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a standalone basis. The consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation.

Commencing in October 2017, we began recognizing revenue under the Merck arrangement. We determined that the research license granted did not have standalone value from the respective research and development services, as the license could not be used on its own by Merck for its intended purpose of developing and commercializing KVD001 and the Oral DME Compounds. As a result, the research license has been combined with the respective research and development services for KVD001 and the Oral DME Compounds as two units of accounting (the "KVD001 Unit of Accounting" and the "Oral DME Unit of Accounting"). We allocated the allocable consideration of \$37.0 million to these two units of accounting using the relative selling price method.

Neither vendor-specific objective evidence or third party evidence is available for any of the units of accounting identified at arrangement inception. Accordingly, the selling price of each unit of accounting was developed using management's best estimate of selling price ("BESP"). BESP for the KVD001 Unit of Accounting and the Oral DME Unit of Accounting were determined by applying a risk-adjusted analysis of discounted cash flows and the allocable arrangement consideration was allocated among the separate units of accounting using the relative selling price method.

The amount allocated to the KVD001 Unit of Accounting and the Oral DME Unit of Accounting will be recognized as revenue on a proportional performance basis as the research and development activities are conducted through completion of the respective Phase 2 clinical trials. If the period over which revenue is attributed changes or the estimates of proportional performance change, the reported revenue could be materially impacted.

#### ***Preclinical and Clinical Trial Accruals***

We base our accrued expenses related to clinical trials on estimates of patient enrollment and related expenses at clinical investigator sites as well as estimates for services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that conduct and manage clinical trials on our behalf. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us and based on contracted amounts applied to the level of patient enrollment and activity according to the clinical trial protocol. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

If we do not identify costs that we have begun to incur, or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

#### ***Income Taxes***

We account for income taxes under the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized. Given our history of losses, we currently provide a full valuation allowance on our net deferred tax assets.

### **Results of Operations**

#### **Year Ended April 30, 2018 Compared to Year Ended April 30, 2017**

The following table sets forth the key components of our results of operations for the years ended April 30, 2018 and 2017:

	Years Ended April 30,		Increase (Decrease)
	2018	2017	
	<i>(in thousands)</i>		
<u>Income</u>			
Revenue	\$ 8,394	\$ 1,504	\$ 6,890
<u>Operating Expenses</u>			
Research and development expenses	18,237	12,666	5,571
General and administrative expenses	8,862	11,177	(2,315)
<u>Other income</u>			
Interest, exchange rate gain and other income	2,900	3,736	(836)

*Revenue.* Revenue was \$8.4 million in the year ended April 30, 2018 compared to \$1.5 million in the prior year. The increase of \$6.9 million was due to \$8.0 million of revenue from the Option Agreement in the year ended April 30, 2018, which was offset by a decrease in grant revenue of \$1.1 million. We expect that our reported revenues will increase in future periods as the proceeds from the Option Agreement are recognized as services are performed.

*Research and Development Expenses.* Research and development expenses were \$18.2 million in the year ended April 30, 2018 compared to \$12.7 million in the prior year, primarily due to an increase in spending on the intravitreal, clinical stage oral programs, and early stage research activities which was somewhat offset by a decrease in spending on our additional oral programs. The increase in expense also reflects an increase in the

exchange rate of the British Pound Sterling (“GBP”), which is the currency in which most of our research and development expense is currently incurred. Approximately \$0.7 million of the overall increase in research and development expense was due to the increase in exchange rates.

Research and development expenses by major programs or categories were as follows:

	Years Ended April 30,		Increase (Decrease)	
	2018	2017		
	<i>(in thousands)</i>			
Intravitreal	\$ 3,020	\$ 571	\$ 2,449	429%
Clinical stage oral programs	4,212	2,785	1,427	51%
Additional oral programs	1,142	2,552	(1,410)	-55%
Early stage research activities	9,863	6,758	3,105	46%
<b>Total</b>	<b>\$ 18,237</b>	<b>\$ 12,666</b>	<b>\$ 5,571</b>	<b>44%</b>

Expenses for the intravitreal program were \$3.0 million in the year ended April 30, 2018 compared to \$0.6 million in the prior year due to the initiation of a Phase 2 clinical trial for KVD001. We anticipate that expenses will continue to increase as the Phase 2 clinical trial for KVD001 progresses in fiscal year 2019.

Expenses for the clinical stage oral programs were \$4.2 million in the year ended April 30, 2018 compared to \$2.8 million in the prior year due to the commencement of the first-in-human study for KVD900. We anticipate that expenses will continue to increase as we initiate additional clinical development activities for KVD900 in fiscal year 2019.

Expenses for the additional oral programs were \$1.1 million in the year ended April 30, 2018 compared to \$2.6 million in the prior year due to KVD900 entering the clinical stage of development in the year ended April 30, 2018. We anticipate that expenses will continue to increase as we continue to pursue additional preclinical oral drug candidates for our HAE portfolio as well as DME in fiscal year 2019.

Expenses for early stage research activities were \$9.9 million in the year ended April 30, 2018 compared to \$6.8 million in the prior year due to increased headcount and additional projects compared to the same period in the prior year. We anticipate that expenses will continue to increase as multiple projects are assessed in discovery and drug candidates are advanced into early stage development.

*General and Administrative Expenses.* General and administrative expenses were \$8.9 million in the year ended April 30, 2018 compared to \$11.2 million in the prior year. The decrease of \$2.3 million was substantially due to a \$3.8 million decrease in professional fees attributable to the Carbylan transaction, partially offset by increases in payroll and related expenses of \$0.4 million, \$0.5 million of stock-based compensation and \$0.6 million of other administrative expenses. We expect to continue to incur increasing expenses related to our operations as a public company.

*Other Income.* Other income was \$2.9 million for the year ended April 30, 2018 compared to \$3.7 million for the prior year. The decrease of \$0.8 million was primarily due to a \$2.8 million decrease in foreign currency exchange rate gains from cash and accounts payable denominated in foreign currency which was offset by a \$2.0 million increase in income from research and development tax credits due to an increase in tax credit eligible spending during the year ended April 30, 2018.



## Year Ended April 30, 2017 Compared to Year Ended April 30, 2016

The following table sets forth the key components of our results of operations for the years ended April 30, 2017 and 2016:

	Years Ended April 30,		Increase (Decrease)
	2017	2016	
	<i>(in thousands)</i>		
<b>Income</b>			
Revenue	\$ 1,504	\$ 2,133	\$ (629)
<b>Operating Expenses</b>			
Research and development expenses	12,666	14,661	(1,995)
General and administrative expenses	11,177	2,653	8,524
<b>Other income</b>			
Interest, exchange rate gain and other income	3,736	3,745	(9)

*Revenue.* Revenue was \$1.5 million in the year ended April 30, 2017 compared to \$2.1 million in the prior year. In the year ended April 30, 2017, \$1.2 million was received from the principal TSB grant and the balance from other grant sources. The decrease was due to the completion of some grant programs during the year as well as a slight decrease in amounts earned on the TSB grant during the year.

*Research and Development Expenses.* Research and development expenses were \$12.7 million in the year ended April 30, 2017 compared to \$14.7 million in the prior year, primarily due to a decrease in spending on the Intravitreal and Oral programs, which was somewhat offset by an increase in spending on our additional earlier stage oral programs and expenses related to early stage research activities. The reduction in expense also reflects a decline in the exchange rate of the GBP, which is the currency in which most of our research and development expense is currently incurred. Approximately \$2.0 million of the overall decline in research and development expense was due to the decline in exchange rates.

Research and development expenses by major programs or categories were as follows:

	Years Ended April 30,		Increase (Decrease)	
	2017	2016		
	<i>(in thousands)</i>			
Intravitreal	\$ 571	\$ 3,583	\$ (3,012)	-84%
Oral	2,785	4,264	(1,479)	-35%
Additional oral programs	2,552	2,262	290	13%
Early stage research activities	6,758	4,552	2,206	48%
Total	\$ 12,666	\$ 14,661	\$ (1,995)	-14%

Expenses for the intravitreal program declined in the year ended April 30, 2017 compared to the prior year due to completion of toxicology studies that were required to support further clinical development. Expenses for the oral program decreased in the year ended April 30, 2017 compared to the prior year as a result of the completion of toxicology studies in the prior year.

The additional oral programs expenses in the year ended April 30, 2017 increased to \$2.6 million from \$2.3 million in the prior year due to expenses incurred in connection with the progression of multiple candidates through discovery characterization, initial scale-up manufacture and entry into early toxicology assessment.

Early stage research expenses for the year ended April 30, 2017 increased to \$6.8 million compared to \$4.6 million in the prior year due to an increase in headcount and expansion of early stage discovery activities.

*General and Administrative Expenses.* General and administrative expenses were \$11.2 million for the year ended April 30, 2017 which was an increase of \$8.5 million compared to \$2.7 million in the prior year. The increase in general and administrative expenses for the year ended April 30, 2017 was substantially due to \$5.6 million of professional fees and regulatory costs the majority of which were associated with the share purchase transaction completed in November 2016 as well as \$0.8 million of severance costs and \$2.1 million of payroll related, facilities and other administrative expenses as we expanded the management team and other key positions, and incurred costs associated with operations as a public company.

*Other Income.* Other income was \$3.7 million for the year ended April 30, 2017 compared to \$3.7 million for the prior year. A \$0.3 million decrease in foreign currency exchange rate gains from accounts denominated in foreign currency was offset by a \$0.3 million increase in income from research and development tax credits.

## Liquidity and Capital Resources

We have incurred losses since inception and cash outflows from operating activities for the years ended April 30, 2018 and 2017. As of April 30, 2018, we have received cumulative equity funding totaling \$67.7 million, \$37.0 million from the Option Agreement and grant income of \$8.9 million. We have an accumulated deficit of \$71.7 million. We anticipate that we will continue to incur net losses for the foreseeable future as we continue the research and development efforts on our product candidates, hire additional staff, including clinical, scientific, operational, financial and management personnel, and incur additional costs associated with being a public company.

We plan to continue to fund our operations with cash and cash equivalents on hand at April 30, 2018 along with future issuances of debt and/or equity securities and potential collaborations or strategic partnerships with other entities. Capital raises from issuances of convertible debt and equity securities could result in additional dilution to stockholders. Incurrence of debt could result in debt service obligations and operating and financing covenants that may restrict operations. We can provide no assurance that financing will be available in the amounts anticipated to be required or on acceptable terms, if at all. If we are not able to secure adequate additional working capital when it becomes needed, we may be required to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible and/or suspend or curtail planned research programs. Any of these actions could materially harm our business and prospects.

### Cash Flows

The following table shows a summary of the net cash flow activity for the years ended April 30, 2018 and 2017:

	Years Ended	
	April 30,	
	2018	2017
	<i>(in thousands)</i>	
Cash flows provided by (used in) operating activities	\$ 10,558	\$ (23,722)
Cash flows provided by (used in) investing activities	(1,427)	34,065
Cash flows provided by financing activities	8,986	2
Effect of exchange rate changes on cash	1,988	(1,159)
Net increase in cash and cash equivalents	\$ 20,105	\$ 9,186

### Net cash provided by (used in) operating activities

Net cash provided by operating activities of \$10.6 million for the year ended April 30, 2018 consisted primarily of a net loss of \$15.8 million, \$0.6 million of favorable non-cash adjustments, and increases of \$29.2 million in deferred revenue and \$1.1 million of accrued expenses offset by an increase in the research and development tax credit receivable of \$4.3 million and a \$0.7 million increase of prepaid expenses. Compared to the prior year, the increase in cash flows provided by operating activities was primarily due to the upfront payment associated with the Option Agreement. Net cash used in operating activities of \$23.7 million for the year ended April 30, 2017 consisted primarily of a net loss of \$18.6 million, adverse working capital movements of \$4.2 million and the impact of foreign currency re-measurement gains of \$1.4 million. Included in the net cash used for operating activities was \$5.6 million of expenses related to the share purchase transaction.

### ***Net cash provided by (used in) investing activities***

Net cash used in investing activities for the year ended April 30, 2018 primarily consisted of the acquisition of laboratory equipment and capital expenditures related to the offices in Cambridge, Massachusetts and Porton Down, United Kingdom. We expect to incur additional capital expenditures in fiscal year 2019 related primarily to the build out and occupancy of our new administrative and research facility in Porton Down, United Kingdom. Net cash provided by investing activities for the year ended April 30, 2017 consisted of the net cash acquired in the Carbylan transaction of \$34.1 million.

### ***Net cash provided by financing activities***

Net cash provided by financing activities for the year ended April 30, 2018 primarily consisted of proceeds from the sale of common stock to Merck in October 2017.

### ***Operating Capital Requirements***

To date, we have not generated any revenues from the sale of products and we do not have any products that have been approved for commercialization. We do not expect to generate significant product revenue unless and until we obtain regulatory approval for, and commercialize, one of our current or future product candidates. We anticipate that we will continue to incur losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, product candidates, and begin to commercialize any approved products. We are subject to all of the risks inherent in the development of new therapeutic products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We expect to incur additional costs associated with operating as a public company. We currently anticipate that, based upon our operating plans and existing capital resources, we have sufficient funding to operate for at least the next 12 months.

Until such time, if ever, as we can generate substantial revenues, we expect to finance our cash needs through a combination of equity or debt financings, collaborations, strategic partnerships or licensing arrangements. To the extent that additional capital is raised through the sale of stock or convertible debt securities, the ownership interest of existing stockholders will be diluted, and the terms of these newly issued securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing, if available, may involve agreements that include increased fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, selling or licensing intellectual property rights and other operating restrictions that could adversely impact our ability to conduct business. Additional fundraising through collaborations, strategic partnerships or licensing arrangements with third parties may require us to relinquish valuable rights to product candidates, including our other technologies, future revenue streams or research programs, or grant licenses on terms that may not be favorable. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate product development or future commercialization efforts or grant rights to develop and commercialize its other product candidates even if we would otherwise prefer to develop and commercialize such product candidates internally.

### ***Contractual Obligations and Commitments***

We enter into contracts in the normal course of business with contract research organizations and clinical trial sites for the conduct of clinical trials, preclinical and clinical studies, professional consultants and other vendors for clinical supply manufacturing or other services. These contracts generally provide for termination on notice, and therefore are cancelable contracts and not included in the table of contractual obligations and commitments in Note 8 to the consolidated financial statements. Contractual obligations related to the expected future costs to be incurred to complete the ongoing toxicology studies and clinical trials, which have cancellation provisions, total \$8.9 million at April 30, 2018. There are no long-term debt payment obligations as of April 30, 2018.

The table below summarizes our non-cancelable lease commitments:

Contractual Obligations	Payments Due by Period (In thousands)				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Lease obligations	\$ 2,360	\$ 560	\$ 719	\$ 535	\$ 546

As a result of the terms of grant income received in prior years, upon successful regulatory approval and following the first commercial sale of certain products, we will be required to pay royalty fees of up to \$1 million within 90 days of the first commercial sale of the product subject to certain caps and follow on payments depending upon commercial success and type of product. Given the stage of development of the current pipeline of products it is not possible to predict with certainty the amount or timing of any such liability.

#### Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

#### Recent Accounting Pronouncements

For information regarding recent accounting pronouncements, please refer to Note 2, Summary of Significant Accounting Policies within our consolidated financial statements.

#### Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

##### Interest Rate Risk

We have exposure to market risk in interest income sensitivity, which is affected by changes in the general level of interest rates. However, because of the short-term nature of the bank deposit arrangements and the very low interest rates prevailing in the United Kingdom and the United States, a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operations. We do not believe that our cash or cash equivalents have significant risk of default or illiquidity.

##### Foreign Exchange Rate Risk

We maintain cash balances primarily in both USD and GBP to fund ongoing operations and manage foreign exchange risk. Cash and cash equivalents as of April 30, 2018 was \$51.1 million and consisted of readily available checking and bank deposit accounts held primarily in both USD and GBP. As of April 30, 2018, 60% of cash and cash equivalents were held in USD and 40% in GBP. We currently incur significant expense primarily in GBP and convert USD as needed to fund those expenses. We do not currently engage in exchange rate hedging or other similar activities to address our exchange rate risk. A 10% change in the exchange rate would result in a net gain or loss of approximately \$1.7 million.

##### Effects of Inflation

We do not believe that inflation and changing prices had a significant impact on the results of operations for any periods presented herein.

#### Item 8. Financial Statements and Supplementary Data.

The financial statements and related financial statement schedules required to be filed are listed in Item 15 and 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*

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of April 30, 2018. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits 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 ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of April 30, 2018 our Chief Executive Officer and Chief Financial Officer have concluded that, as of April 30, 2018, our disclosure controls and procedures were effective at the reasonable assurance level.

#### *Management’s Annual Report on Internal Control Over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, with the participation of our principal executive officer and principal financial officer, assessed the effectiveness of our internal control over financial reporting as of April 30, 2018. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 2013 Internal Control – Integrated Framework. Based on our assessment, our management has concluded that, as of April 30, 2018, our internal control over financial reporting is effective based on those criteria.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. For as long as we remain an “emerging growth company” as defined in Section 2(a) of the Securities Act of 1933, or the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, we intend to take advantage of the exemption permitting us not to comply with the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

*Changes in Internal Controls over Financial Reporting*

There were no changes in our internal control over financial reporting that occurred during the quarter ended April 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information.**

None.

### PART III

#### Item 10. Directors, Executive Officers and Corporate Governance.

The following table sets forth certain information concerning our directors and executive officers as of April 30, 2018.

Name	Age	Position/Office Held with the Company	Director Since
T. Andrew Crockett	43	Chief Executive Officer, Director	2016
Richard Aldrich (3)	64	Director	2016
Albert Cha, M.D., Ph.D. (1)(2)	46	Director	2007
Arnold L. Oronsky, Ph.D. (1)(3)	78	Director	2016
Joshua Resnick, M.D. (2)	43	Director	2016
Edward W. Unkart (1)	68	Director	2014
Benjamin L. Palleiko	52	Chief Financial Officer	
Edward P. Feener, Ph.D.	57	Chief Scientific Officer	
Andreas Maetzel, M.D., M.Sc., Ph.D.	54	Senior VP of Medical	
Christopher M. Yea, Ph.D.	55	Chief Development Officer	

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and governance committee.

The following includes certain information regarding our directors individual experience, qualifications, attributes and skills that led the Board to conclude that they should serve as directors.

**T. Andrew Crockett, M.B.A.**, has served as a member of our Board and as our Chief Executive Officer since November 2016 and as a director and CEO of our wholly owned subsidiary, KalVista Pharmaceuticals Limited, since inception in 2011. From 2010 until November 2015, Mr. Crockett was the Chief Executive Officer and member of the board of directors of Vantia Ltd., where he served as Vice President of Business Development prior to his promotion. He continues to sit on the board of directors. Mr. Crockett has also held various senior management positions including Vice President of Business Development and Director of Clinical and Regulatory Affairs in biotech and specialty pharmaceutical companies in the United States and United Kingdom. Mr. Crockett received a B.A. from the University of Utah and M.B.A. from The Wharton School, University of Pennsylvania, with a major in finance. We believe Mr. Crockett is qualified to serve on our Board because of his founding role with the Company and his broad experience in the biotech industry.

**Richard Aldrich** has served as Chairman of our Board since November 2016. Mr. Aldrich is a co-founder and Partner of Longwood Fund. Mr. Aldrich serves as Chairman of the Board of Concert Pharmaceuticals and lead director of Ovascience. Mr. Aldrich also serves as a Director of Longwood portfolio companies Renovia Inc., Axial Biotherapeutics, Sitryx Pharmaceuticals and Colorescience Inc., and is a Board observer at Bicycle Therapeutics and Pulmocide Ltd. Prior to co-founding Longwood, he was General Partner of RA Capital, a biotechnology investment fund he co-founded in 2001. Mr. Aldrich was also a founding employee of Vertex Pharmaceuticals where he held the position of Senior Vice President and Chief Business Officer and managed all commercial and operating functions from 1989 to 2001. Prior to joining Vertex, Mr. Aldrich held several management positions at Biogen, Inc. Mr. Aldrich also served on the board of directors of the Massachusetts Eye & Ear Infirmary from 2001 to 2015. He received his B.S. in Business from Boston College, and an M.B.A. from the Amos Tuck School at Dartmouth College. We believe Mr. Aldrich is qualified to serve on our Board because of his lengthy experience in the biotech industry, both as a senior executive and as an investor.

**Albert Cha, M.D., Ph.D.**, has served as a member of KalVista's board of directors since the consummation of the Carbylan Therapeutics, Inc. transaction in 2016. Dr. Cha served as a member of the Carbylan board of directors starting in November 2007. In September 2000, Dr. Cha joined Vivo Capital, a healthcare investment firm, where he has served in various positions, most recently as a Managing Partner. Dr. Cha currently serves as a member of the boards of directors of Biohaven Pharmaceutical Holding Company Ltd. (NYSE: BHVN), Ascendis Pharma A/S (NASDAQ: ASND) and several privately-held biotechnology and medical device companies. During the past five years, he also served as a member of the boards of directors of Aclaris Therapeutics, Inc. (NASDAQ: ACRS), Sierra Oncology, Inc. (formerly ProNAi Therapeutics, Inc.) (NASDAQ: SRRRA) and AirXpanders, Inc. (ASX: AXP). Dr. Cha received a B.S. and an M.S. from Stanford University and an M.D. and a Ph.D. from the University of California at Los Angeles. We believe Dr. Cha is qualified to serve on our Board because of his medical background, venture capital experience and significant experience serving as a director of other life sciences companies.

**Arnold L. Oronsky, Ph.D.**, has served as a member of our Board since November 2016. Dr. Oronsky has been a full-time member of InterWest's healthcare team since 1994, where he currently serves as a Senior Partner. In addition to being a Senior Partner at InterWest, Dr. Oronsky also serves as a Senior Lecturer in the Department of Medicine at Johns Hopkins Medical School. He is a member of the board of directors of Dynavax Technologies, TESARO and a number of private pharmaceutical companies. Dr. Oronsky was formerly Vice President for Discovery Research for the Lederle Laboratories division of American Cyanamid Company where he directed all of the research for new drugs and supervised approximately three hundred employees. Dr. Oronsky holds a Ph.D. in Immunology from Columbia University and has published over 125 scientific articles. We believe Dr. Oronsky is qualified to serve on our Board because of his lengthy experience in the biotech industry as an investor and public company Board member.

**Joshua Resnick, M.D., M.B.A.**, has served as a member of our Board since November 2016. Dr. Resnick has been a Partner at SV Health Investors ("SV") since January 2016. Before joining SV in January 2016, Dr. Resnick was President and Managing Partner at MRL Ventures Fund ("MRL Ventures"), the early-stage therapeutics-focused corporate venture fund that he built and managed within Merck & Co from December 2014 to January 2016. Prior to MRL Ventures, Dr. Resnick was a Venture Partner with Atlas Venture ("Atlas"), focusing on company formation, Seed and Series A investing. During his tenure at Atlas, Dr. Resnick was also the Founder and Chief Executive Officer of two start-ups in the immuno-oncology and neuro spaces. Prior to Atlas, Dr. Resnick was a Partner at Prism Venture Partners, where he focused on early-stage biopharmaceutical, medical device, tools and diagnostics investments. Dr. Resnick is also an Attending Physician at Massachusetts General Hospital, as well as Brigham and Women's Hospital since 2006, and an Instructor in Medicine at Harvard Medical School. Dr. Resnick graduated Magna Cum Laude with a B.A. from Williams College and received his M.D. and M.B.A. from the University of Pennsylvania School of Medicine and The Wharton School of Business. We believe Dr. Resnick is qualified to serve on our Board because of his industry experience as a biotech public and private company investor.

**Edward W. Unkart** has served as a member of our Board since December 2014. From August 2006 to August 2009, Mr. Unkart served as a member of the board of directors of XTENT, a publicly traded manufacturer of drug-eluting stent systems, where he was the chair of the company's audit committee and a member of the nominating and governance committee. From October 2004 to June 2009, Mr. Unkart served as a member of the board of directors of VNUS Medical Technologies, a publicly traded medical device company, where he was the Chair of the company's audit committee and a member of the compensation committee. From January 2005 to December 2008, Mr. Unkart served as Vice President of Finance and Administration and Chief Financial Officer of SurgRx, a manufacturer of medical devices. Mr. Unkart also currently serves on the board of directors of a privately held medical device company. Mr. Unkart is a Certified Public Accountant and holds a B.S. and an M.B.A. from Stanford University. We believe Mr. Unkart is qualified to serve on our Board because of his finance and accounting expertise and education and his experience gained through his board and officer positions at other life sciences companies.



**Benjamin L. Palleiko** joined in August 2016 as Chief Financial Officer of KalVista Limited and, following the reverse merger transaction, was appointed Chief Financial Officer of KalVista. Prior to joining us, Mr. Palleiko was a Managing Director of H.C. Wainwright & Co. LLC since January 2015. Mr. Palleiko also co-founded a private oncology drug development company, Cielo Therapeutics, Inc., in July 2012. Mr. Palleiko served as Chief Financial Officer of Nostrum Pharmaceuticals LLC from January 2012 to December 2013, and previously as Senior Vice President and Chief Financial Officer of Ore Pharmaceutical Holdings Inc. and Penwest Pharmaceuticals Co. Earlier in his career Mr. Palleiko was an investment banker with the firms Robertson Stephens and SunTrust Robinson Humphrey. Mr. Palleiko holds a B.A. in Quantitative Economics from Tufts University and an M.B.A. in Finance and M.A. in International Relations from the University of Chicago. He served as a Naval Aviator in the U.S. Navy.

**Edward P. Feener, Ph.D.**, is a scientific co-founder of KalVista and joined as our Chief Scientific Officer in November 2016. Previously, Dr. Feener was an Associate Professor of Medicine at Harvard Medical School and Senior Investigator in the Section on Vascular Cell Biology at Joslin Diabetes Center from July 1989 to October 2016. He has more than 27 years of research experience in vascular biology and diabetic complications. His laboratory identified novel mechanisms of action for the plasma kallikrein system, which are implicated in diabetic macular edema, vascular injury, and angioedema.

**Andreas Maetzel, M.D., M.Sc., Ph.D.**, joined as our Senior Vice President of Medical in March 2017. Dr. Maetzel was most recently Vice President, Global Medical Affairs at BioCryst Pharmaceuticals from August 2014 to February 2017. Prior to that he was Vice President, Clinical Development & Regulatory Affairs at Cornerstone Therapeutics Inc from May 2013 to February 2014. From September 2011 to April 2013, Dr. Maetzel held a clinical development role at BioCryst. He previously held positions in health technology assessment strategy at Amgen and in strategy consulting. He is Visiting Scientist at the University Hospital Zurich and Charité Hospital Berlin, and maintains an appointment as Adjunct Professor, Institute for Health Policy, Management & Evaluation, University of Toronto. Dr. Maetzel obtained both a Ph.D. and M.Sc. in Clinical Epidemiology from the University of Toronto and a Dr. Med. at the University of Hannover, Germany.

**Christopher M. Yea, Ph.D.**, has served as the Chief Development Officer of KalVista Limited since November 2015 and became our Chief Development Officer as of November 2016 in connection with the reverse acquisition transaction. Prior to joining us, he was the Chief Operating Officer at Vantia, Ltd. from its spin-out from Ferring Pharmaceuticals in 2008, until November 2015. Prior to the spin-out of Vantia, Dr. Yea led the Biology group and was responsible for transition of candidates into development at Ferring Pharmaceuticals. Following post-doctoral work he spent several years at Roussel-UCLAF and Hoechst Marion Roussel. Dr. Yea holds a B. Sc. and Ph.D. in Biochemistry from the University of Bristol, UK.

#### **Code of Business Conduct and Ethics**

Our board of directors has adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including our Chief Executive Officer and other executive and senior officers. The full text of our code of conduct is posted on the investor relations section of our website (<http://ir.kalvista.com/>). The reference to our website address in this report does not include or incorporate by reference the information on our website into this report. We intend to disclose future amendments to certain provisions of our code of conduct, or waivers of these provisions, on our website or in public filings.

### **Audit Committee**

Our audit committee oversees our corporate accounting and financial reporting process. Among other matters, the audit committee:

- Selects a firm to serve as the independent registered public accounting firm to audit our financial statements;
- Ensures the independence of the independent registered public accounting firm;
- Discusses the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and that firm, our interim and year-end operating results;
- Establishes procedures for employees to anonymously submit concerns about questionable accounting or audit matters;
- Considers the adequacy of our internal controls;
- Reviews material related party transactions or those that require disclosure; and
- Approves or, as permitted, pre-approves all audit and non-audit services to be performed by the independent registered public accounting firm.

The current members of our audit committee are Arnold L. Oronsky, Ph.D., Albert Cha, M.D., Ph.D. and Edward W. Unkart. Mr. Unkart serves as the Chairman of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq. Our Board has determined that Mr. Unkart is an audit committee financial expert as defined under the applicable rules of the SEC and has the requisite financial sophistication as defined under the applicable rules and regulations of Nasdaq. Under the rules of the SEC, members of the audit committee must also meet heightened independence standards. Our Board has determined that each of Drs. Oronsky and Cha and Mr. Unkart are independent under the applicable rules of Nasdaq and the SEC. Our audit committee has been established in accordance with the rules and regulations of the Exchange Act. The audit committee operates under a written charter that satisfies the applicable standards of the SEC and Nasdaq. A copy of the audit committee charter is available to security holders on the Company's website at <http://ir.kalvista.com/>.

### **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Exchange Act requires our directors, executive officers and any persons who own more than 10% of our common stock, to file initial reports of ownership and reports of changes in ownership with the SEC. Such persons are required by SEC regulation to furnish us with copies of all Section 16(a) forms that they file. Based solely upon our review of the copies of such forms provided to us and written representations from our named executive officers and directors with respect to fiscal year 2018, we believe that all Section 16(a) filing requirements during fiscal year 2018 were complied with except for one late Form 4 filing by Richard Aldrich with respect to shares held by Longwood Capital, which was filed on October 19, 2017.

### **Item 11. Executive Compensation.**

The following is a discussion and analysis of compensation arrangements of our named executive officers, or "NEOs," and directors for the year ended April 30, 2018. As an "emerging growth company" as defined in the JOBS Act, we are not required to include a Compensation Discussion and Analysis section and have elected to comply with the scaled disclosure requirements applicable to emerging growth companies.

We seek to ensure that the total compensation paid to our executive officers is reasonable and competitive. Compensation of our executives is structured around the achievement of individual performance and near-term corporate targets as well as long-term business objectives.

Pursuant to SEC regulations, our NEOs are our Chief Executive Officer, and the two other highest paid executives. Our NEOs for the fiscal year ended April 30, 2018 were as follows

- T. Andrew Crockett, Chief Executive Officer;
- Benjamin L. Palleiko, Chief Financial Officer;
- Christopher M. Yea, Chief Development Officer

Each year, the compensation committee of our board of directors review and determine the compensation of our NEOs.

### Director Compensation Policy

Our Board approves the form and amount of non-employee director compensation. Our Compensation Committee makes recommendations on the form and amount of non-employee director compensation. We pay our independent directors an annual retainer of \$35,000. In addition, each independent director who serves as the Chairman of our audit committee, compensation committee or nominating and corporate governance committee will receive, for his or her service in such capacity, an additional annual retainer of \$15,000, \$10,000 or \$7,500, respectively, and each other independent director who is a member of the audit committee, compensation committee or nominating and corporate governance committee will receive an annual retainer of \$7,500, \$5,000 or \$3,750, respectively. We reimburse each non-employee member of our board of directors for reasonable out-of-pocket expenses incurred in connection with attending our board and committee meetings.

### 2018 Director Compensation Table

The following table sets forth information for the year ended April 30, 2018 regarding the compensation awarded to, earned by or paid to our non-employee directors.

Name	Fees Earned or Paid in Cash (\$)	Option Awards (1) (\$)	All Other Compensation (\$)	Total (\$)
Richard Aldrich	\$ 63,750	\$ 27,857	—	\$ 91,607
Albert Cha, M.D., Ph.D.	\$ 45,000	\$ 27,857	—	\$ 72,857
Arnold L. Oronsky, Ph.D.	\$ 46,250	\$ 27,857	—	\$ 74,107
Joshua Resnick, M.D.	\$ 40,000	\$ 27,857	—	\$ 67,857
Rajeev Shah*	\$ 45,632	\$ 27,857	—	\$ 73,489
Edward W. Unkart	\$ 50,000	\$ 27,857	—	\$ 77,857

\* Mr. Shah resigned as a member of the board of directors on April 16, 2018

(1) Amounts shown were computed in accordance with FASB ASC Topic 718 and exclude the value of estimated forfeitures. The assumptions used in the valuation of these awards are set forth in Note 7 to our consolidated financial statements. As of April 30, 2018, each of our non-employee directors held the following outstanding options awards:

Name	Shares Subject to Outstanding Option Awards
Richard Aldrich	18,000
Albert Cha, M.D., Ph.D.	18,000
Arnold L. Oronsky, Ph.D.	18,000
Joshua Resnick, M.D.	18,000
Rajeev Shah	8,333
Edward W. Unkart	18,000

## Summary Compensation Table

The following table presents summary information regarding the total compensation for services rendered in all capacities that was awarded to and earned by our NEOs during the years ended April 30, 2018 and 2017.

	Fiscal Year	Salary	Bonus\$(1)	Option Awards\$(2)	All Other Compensation(3)	Total (\$)
T. Andrew Crockett	2018	\$ 450,000	\$ 675,000	\$ 901,976	\$ 15,300	\$ 2,042,276
<i>Chief Executive Officer</i>	2017	\$ 390,076	\$ 213,750	\$ —	\$ 1,500	\$ 605,326
Benjamin L. Palleiko	2018	\$ 340,000	\$ 307,000	\$ 163,031	\$ 10,800	\$ 820,831
<i>Chief Financial Officer</i>	2017	\$ 239,492	\$ 95,000	\$ 589,390	\$ —	\$ 923,882
Christopher M. Yea	2018	\$ 334,567	\$ 306,266	\$ 163,031	\$ 20,074	\$ 823,938
<i>Chief Development Officer</i>	2017	\$ 250,378	\$ 107,605	\$ —	\$ 15,232	\$ 373,215

- (1) The amount reported in the Bonus Column represents the annual cash discretionary bonuses earned by our NEOs pursuant to the achievement of certain Company and individual performance objectives. For fiscal year 2018, a portion of these amounts were paid to the NEOs in October 2017 and a portion was paid in June 2018.
- (2) The amounts reported in the Option Awards column represent the grant date fair value of the stock options granted to our NEOs during fiscal years 2018 and 2017 as computed in accordance with ASC 718. The assumptions used in the valuation of these awards are set forth in Note 7 to our consolidated financial statements. The amounts reported in this column exclude the impact of estimated forfeitures related to service-based vesting conditions. Note that the amounts reported in this column reflect the accounting cost for these stock options, and do not correspond to the actual economic value that may be received by the NEOs from the options.
- (3) "Other Compensation" consists of Company contributions to the 401(k) Plan or other retirement plan.

### Agreements with our Named Executive Officers

We have entered into employment agreements with our NEOs that provide for at-will employment (except outside of the U.S. if such concept is not generally applicable) and include each NEO's base salary, a discretionary annual incentive bonus opportunity and standard employee benefit plan participation. These agreements also provide for severance benefits upon certain terminations of employment or a change in control of our company. See "—Potential Payments Upon Termination or Change of Control" below for additional details about these agreements.

### Retirement Benefits

We do not maintain any qualified or non-qualified defined benefit plans or supplemental executive retirement plans that cover our NEOs. Our 401(k) plan permits eligible employees to defer their annual eligible compensation subject to certain limitations imposed by the Internal Revenue Service. We match up to 4% of employee contributions to our 401(k) plan.

### Potential Payments Upon Termination or Change in Control

Each of our NEOs is party to an individual agreement that provides for certain severance benefits as described below.

*Mr. Crockett and Mr. Palleiko—Termination of Employment Apart from a Change in Control and in Connection with a Change in Control.* Pursuant to the terms of Mr. Crockett's and Mr. Palleiko's employment agreements, if the executive's employment is terminated either by us without "cause" or by the executive for "good reason" (as such terms are defined in the executive's employment agreement), the executive will be entitled to (1) a lump sum payment equal to 15 months of his respective base salary for Mr. Crockett and nine months of his respective base salary for Mr. Palleiko and (2) reimbursement for continuation coverage under COBRA for 15 months for Mr. Crockett and nine months for Mr. Palleiko. If within two years immediately following the consummation of a "change in control" (as such term is defined in the executive's employment agreement), Mr. Crockett's or Mr. Palleiko's employment is terminated either by us without cause or by the executive for good reason, the executive will be entitled to (1) a lump sum cash payment equal to 21 months of his respective base salary for Mr. Crockett and 15 months of his respective base salary for Mr. Palleiko, (2) lump sum payment equal to their full target bonus for the fiscal year in which such termination of employment occurs for Mr. Crockett and Mr. Palleiko, (3) reimbursement for continuation coverage under COBRA for 21 months for Mr. Crockett (with months

19-21 consisting of a taxable lump sum cash bonus) and 15 months for Mr. Palleiko and (4) full vesting and exercisability (to the extent applicable) of all outstanding unvested equity-based awards for Mr. Crockett and Mr. Palleiko.

*Dr. Yea—Termination of Employment Apart from a Change in Control and in Connection with a Change in Control.* Pursuant to the terms of Dr. Yea’s service contract and certain modifications thereto that have been approved by our Compensation Committee, if his employment is terminated by us other than for certain “cause-type” reasons, including, but not limited to, any act that would warrant summary termination under local common law, Dr. Yea will be entitled to (1) 12 months of his base salary and (2) 12 months of continued health and life insurance benefits. Pursuant to the terms of Dr. Yea’s service contract, if within three months immediately following the consummation of a “change in control” (as such term is defined in his service contract) or the transfer of Dr. Yea’s employment under the Transfer of Undertakings (Protection of Employment) Regulations of 2006 (TUPE), Dr. Yea gives one month of notice of this intention to terminate his employment, he will be entitled to the same severance payments and benefits described above. In addition, pursuant to the terms of Dr. Yea’s service contract and certain modifications thereto that have been approved by our Compensation Committee, if Dr. Yea’s employment is terminated within two years immediately following the consummation of a “change in control” (as such term is defined in his service contract), in a manner that would otherwise trigger the severance payments and benefits described above, he will be entitled to (1) 12 months of his base salary; (2) a lump sum payment equal to his full target bonus for the fiscal year in which such termination of employment occurs and (3) 12 months of continued health and life insurance benefits. In addition, our Compensation Committee has approved that in the event that Dr. Yea’s employment is terminated within two years immediately following the consummation of a “change in control” (as such term is defined in his service contract), in a manner that would otherwise trigger the severance payments and benefits described above, he will also be entitled to full vesting and exercisability (to the extent applicable) of all of his outstanding unvested equity-based awards

*Mr. Crockett, Mr. Palleiko and Dr. Yea—Severance Subject to Release of Claims and Restrictive Covenants.* Our obligation to provide our Chief Executive Officer and Chief Financial Officer with any severance payments or other benefits under his employment agreement is conditioned on the executive signing and not revoking a separation agreement and effective release of claims in our favor. Mr. Crockett and Mr. Palleiko also entered into an Employee Confidentiality, Invention Assignment and Non-Compete Agreement, and the equivalent terms were included in Dr. Yea’s employment agreement, that prohibits each of them from competing with us and soliciting our employees or other third parties that have a relationship with us for one year, or six months in the case of Dr. Yea, following their termination of employment for any reason.

#### Outstanding Equity Awards at 2018 Fiscal Year-End

The following table sets forth specified information concerning unexercised stock options for each of the name executive officers outstanding as of April 30, 2018.

Name	Grant Date (1)	Number of Securities Underlying Unexercised Options (#) Exercisable (2)	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)(3)	Option Expiration Date
T. Andrew Crockett	5/25/17	42,854	144,146	7.07	5/24/27
Benjamin L. Palleiko	11/22/16	20,563 (4)	28,791	8.39	11/21/26
	12/29/16	25,285 (5)	35,399	6.74	12/28/26
	5/25/17	7,745	26,055	7.07	5/24/27
Christopher M. Yea	3/31/16	82,740 (6)	34,070	0.0043	3/30/26
	5/25/17	7,745	26,055	7.0700	5/24/27

(1) The awards granted on March 31, 2016 were granted pursuant to our EMI Plan; the awards granted on November 22, 2016 and December 29, 2016 were granted pursuant to our 2015 Incentive Plan and the awards granted on May 25, 2017 were granted pursuant to our 2017 Equity Incentive Plan.

(2) Unless otherwise noted in these footnotes, all stock options vest monthly over a four year period following the grant date, subject to continued service to us through each vesting date.

- (3) Represents the fair market value of a share of our common stock, as determined by our board of directors, on the stock option's grant date. Please see Note 2 to our consolidated financial statements for a discussion of how we have valued our common stock.
- (4) This option vests 25% on November 22, 2017 and 1/48 of the total shares monthly thereafter, subject to continued service to us through each vesting date.
- (5) This option vests 25% on August 26, 2017 and 1/48 of the total shares monthly thereafter, subject to continued service to us through each vesting date.
- (6) This option vests 25% on June 29, 2016 and 1/48 of the total shares monthly thereafter, subject to continued service to us through each vesting date.

#### **Compensation Committee Interlocks and Insider Participation**

During the fiscal year ended April 30, 2018, our compensation committee consisted of Dr. Cha, Dr. Resnick and, until his resignation on April 16, 2018, Rajeev Shah. None of the members of our compensation committee has at any time been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers on our Board or compensation committee.

#### **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

The following table presents information as to the beneficial ownership of our common stock as of July 31, 2018 for:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each NEO as set forth in the summary compensation table above;
- each of our directors; and
- all executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Unless otherwise indicated below, to our knowledge, the persons and entities named in the table have sole voting and sole investment power with respect to all shares beneficially owned, subject to community property laws where applicable. Shares of our common stock subject to options that are currently exercisable or exercisable within 60 days of July 31, 2018 are deemed to be outstanding and to be beneficially owned by the person holding the options for the purpose of computing the percentage ownership of that person, but are not treated as outstanding for the purpose of computing the percentage ownership of any other person.

Percentage ownership of our common stock in the table is based on 10,799,895 shares of our common stock issued and outstanding on June 30, 2018. Unless otherwise indicated, the address of each of the individuals and entities named below is c/o KalVista Pharmaceuticals, Inc., 55 Cambridge Parkway, Suite 901E, Cambridge, Massachusetts 02142.

Name of Beneficial Owner	Shares of Common Stock Beneficially Owned (1)			
	Common Stock	Securities Exercisable Within 60 Days	Number of Shares Beneficially Owned	Percent
<b>5% Stockholders:</b>				
Entities affiliated with SV Life Sciences (1)	2,579,490	—	2,579,490	23.9%
Entities affiliated with RA Capital (2)	1,441,070	—	1,441,070	13.3%
Merck & Co., Inc. (3)	1,070,589	—	1,070,589	9.9%
Longwood Fund II, L.P. (4)	934,484	—	934,484	8.7%
Eventide Asset Management, LLC (5)	709,000	—	709,000	6.6%
<b>Named Executive Officers and Directors:</b>				
T. Andrew Crockett (6)	281,420	58,437	339,857	3.1%
Benjamin L. Palleiko (7)	—	65,580	65,580	*
Christopher M. Yea, Ph.D. (8)	82,969	103,036	186,005	1.7%
Richard Aldrich (9)	934,484	12,500	946,984	8.8%
Albert Cha, M.D., Ph.D. (10)	300,325	12,500	312,825	2.9%
Arnold Oronsky, Ph.D. (11)	329,942	12,500	342,442	3.2%
Joshua Resnick, M.D. (12)	2,579,490	12,500	2,591,990	24.0%
Edward Unkart (13)	—	12,500	12,500	*
All 10 directors and executive officers as a group (14)	4,606,664	331,909	4,938,573	44.4%

\*Represents beneficial ownership of less than 1% of our outstanding shares of common stock.

- (1) **SV Life Sciences.** Share ownership information is based upon a Schedule 13D/A1 filed by (i) SV Life Sciences Fund IV, L.P. a Delaware limited partnership ("SVLS IV LP") and SV Life Sciences Fund IV Strategic Partners, L.P. a Delaware limited partnership ("Strategic Partners"), on March 2, 2017. Consists of (i) 2,508,279 shares of our common stock owned directly by SVLS IV LP; and (ii) 71,211 shares of our common stock owned directly by Strategic Partners. SVLS IV LP and Strategic Partners (each a "*SVLS Fund*", or collectively the "*SVLS Funds*") may be deemed to beneficially own the shares held by each other SVLS Fund because of certain contractual relationships among the SVLS Funds and their affiliates. The SVLS Funds disclaim beneficial ownership of shares held by any other SVLS Fund except to the extent of any pecuniary interest therein. SVLS IV GP, the general partner of SVLS IV LP and Strategic Partners, may be deemed to share voting and dispositive power over the shares held by SVLS IV LP and Strategic Partners. SVLS IV GP disclaims beneficial ownership of shares held by SVLS IV LP and Strategic Partners except to the extent of any pecuniary interest therein. SVLSF IV, LLC, the general partner of SVLS IV GP, may be deemed to share voting and dispositive power over the shares held by SVLS IV LP and Strategic Partners. SVLSF IV, LLC disclaims beneficial ownership of shares held by SVLS IV LP and Strategic Partners except to the extent of any pecuniary interest therein. Dr. Resnick, one of our directors, is a partner of SV Life Sciences. The address for SV Life Sciences Fund is One Boston Place, Suite 3900, Boston, MA 02108.
- (2) **RA Capital.** Share ownership information is based upon a Form 4 filed by RA Capital Management, LLC (the "*Adviser*") on October 16, 2017. Consists of (i) 1,171,353 shares held by RA Capital Healthcare Fund, L.P. (the "*Fund*"); and (ii) 269,717 shares held in an account owned by Blackwell Partners LLC-Series A (the "*Blackwell Account*"). The Adviser is the general partner of the Fund and the investment adviser of the Blackwell Account. Peter Kolchinsky is the sole manager of the Adviser, and Mr. Shah is a managing director of the Adviser. Mr. Shah has no pecuniary interest in the reported securities held in the Blackwell Account and therefore disclaims beneficial ownership of those securities. Mr. Shah served as one of our directors until April 16, 2018 and is the Managing Director and Portfolio Manager of the Adviser. Mr. Shah disclaims beneficial ownership of the reported securities held by the Fund except to the extent of his pecuniary interest therein. The address for RA Capital Healthcare Fund, L.P. is 20 Park Plaza, Ste. 1200, Boston, MA 02116.

- (3) **Merck & Co., Inc.** Share ownership information is based upon a Schedule 13G filed by Merck & Co., Inc. (“**Merck**”) on October 16, 2017. The reported securities are owned directly by Merck Sharp & Dohme Corp. (“**MSD**”), which is a wholly owned subsidiary of Merck. Merck is an indirect beneficial owner of the reported securities. The address for Merck is 2000 Galloping Hill Road, Kenilworth, NJ 07033. The address for MSD is One Merck Drive, Whitehouse Station, NJ 08889
- (4) **Longwood Fund II, L.P.** Share ownership information is based upon a Schedule 13D filed on behalf of each of the following persons: Longwood Fund II, L.P., Longwood Fund II GP, LLC, Christoph Westphal, M.D., Ph.D., and Richard Aldrich (collectively, the “**Reporting Persons**”) on October 20, 2017. The securities are owned directly by Longwood Fund II, LP, a Delaware limited partnership (“**Longwood II**”). Longwood Fund II GP, LLC, a Delaware limited liability company (“**Longwood II GP**”), is the general partner of Longwood II and exercises voting and investment power with respect to the securities owned directly by Longwood II. Longwood II’s investment adviser is Longwood Fund Management, LLC (“Longwood Management”). Each of the Reporting Person, who is a member of the Issuer’s board of directors, and Christoph Westphal, M.D., Ph.D. (“**Westphal**”) are the Managers (and are members) of Longwood II GP and may be deemed to share voting and investment power with respect to the securities owned by Longwood II. Mr. Aldrich, one of our directors, is a managing member of Longwood Fund Management LLC. Michelle Dipp, M.D., Ph.D., Christoph Westphal, M.D. and Mr. Aldrich are the managers of the Fund II General Partner and share voting and dispositive power with respect to the securities held by Longwood Fund II, L.P., each of whom disclaims beneficial ownership of the shares held by Longwood Fund II, L.P. except to the extent of her or his pecuniary interest therein. The address for Longwood Fund II L.P. is Prudential Tower, 800 Boylston Street, Suite 1555, Boston, MA 02199.
- (5) **Eventide Assets Management, LLC.** Share ownership information is based upon a Schedule 13G filed by Eventide Asset Management, LLC on February 12, 2018. Eventide Asset Management, LLC, a Delaware limited liability company located at One International Place, Suite 3510, Boston, MA 02110 is the beneficial owner of 709,000 common shares, as of December 31, 2017, by virtue of being the investment adviser to registered investment companies (mutual funds). All 709,000 common shares were held by the Eventide Healthcare & Life Sciences Fund.
- (6) **T. Andrew Crockett.** Consists of (i) 281,420 shares of our common stock held by Mr. Crockett; and (ii) 58,437 shares of our common stock issuable to Mr. Crockett upon exercise of stock options within 60 days of June 30, 2018.
- (7) **Benjamin L. Palleiko.** Consists of 65,580 shares of our common stock issuable to Mr. Palleiko upon exercise of stock options within 60 days of June 30, 2018.
- (8) **Christopher Yea.** Consists of (i) 82,969 shares of our common stock held by Dr. Yea; and (ii) 103,036 shares of our common stock issuable to Dr. Yea upon exercise of stock options within 60 days of June 30, 2018.
- (9) **Rich Aldrich.** Consists of (i) common stock referenced in footnote (4) above; and (ii) 12,500 shares of our common stock issuable to Mr. Aldrich upon exercise of stock options exercisable within 60 days of June 30, 2018. Mr. Aldrich, one of the Company’s directors, is managers of Longwood Fund II, LP, a Delaware limited partnership. Longwood Fund II GP, LLC (the “**Fund II General Partner**”) and share voting and dispositive power with respect to the securities held by Longwood Fund II, L.P.
- (10) **Albert Cha.** Consists of (i) 298,141 shares of our common stock held by Vivo Ventures Fund VI, L.P.; (ii) 2,184 shares of our common stock held by Vivo Ventures VI Affiliates Fund, L.P.; and (iii) 12,500 shares of our common stock issuable to Dr. Cha upon exercise of stock options exercisable within 60 days of June 30, 2018. Vivo Ventures Fund VI, L.P., and Vivo Ventures VI Affiliates Fund, L.P. are Delaware limited partnerships, whose general partner is Vivo Ventures VI, LLC, a Delaware limited liability company. Dr. Cha, one of the Company’s directors, is a managing member of Vivo Ventures Fund VI, LLC and exercises shared voting and investment power with the other managing members of Vivo Ventures VI, LLC with respect to the securities held by Vivo Ventures VI, L.P. and Vivo Ventures VI Affiliates Fund, L.P. Each managing member of Vivo Ventures VI, LLC hereby disclaims any beneficial ownership of any shares directly held by Vivo Ventures Fund VI, L.P. and Vivo Ventures VI Affiliates Fund, L.P., except to the extent of the pecuniary interest therein. The address of Vivo Ventures Fund VI, L.P. and Vivo Ventures VI Affiliates Fund, L.P. is 505 Hamilton Avenue, Suite 207, Palo Alto, California 94301.



- (11) **Arnold Oronsky.** Consists of (i) 329,942 shares of our common stock held by InterWest Partners IX, L.P., a California limited partnership (“*InterWest*”), whose general partner is InterWest Management Partners IX, LLC, a California limited liability company; and (ii) 12,500 shares of our common stock issuable to Dr. Oronsky upon exercise of stock options exercisable within 60 days of June 30, 2018. Dr. Oronsky, one of the Company’s directors, currently serves as a Managing Director of InterWest. Each managing director and venture member of InterWest Management Partners IX, LLC shares voting and investment power with respect to the securities held by InterWest and disclaims beneficial ownership of such shares except to the extent of his or her pecuniary interest therein. The address for InterWest Partners IX, L.P. is 2710 Sand Hill Road, Second Floor, Menlo Park, California 94025.
- (12) **Joshua Resnick.** Consists of the common stock referenced in footnote (1) above; and (ii) 12,500 shares of our common stock issuable to Dr. Resnick upon exercise of stock options exercisable within 60 days of June 30, 2018. Dr. Resnick, one of the Company’s directors, is a partner of SV Life Sciences.
- (13) **Edward Unkart.** Consists of 12,500 shares of our common stock issuable to Mr. Unkart upon exercise of stock options within 60 days of June 30, 2018.
- (14) **All Executive Officers and Directors as a Group.** Consists of (i) 4,606,664 shares of common stock held by all our directors and executive officers as a group; and (ii) 331,909 shares of our common stock issuable to all our directors and executive officers as a group upon exercise of stock options exercisable within 60 days of June 30, 2018.

### **Item 13. Certain Relationships and Related Transactions, and Director Independence.**

Under the rules and regulations of The Nasdaq Stock Market (“*Nasdaq*”), a majority of the members of a listed company’s board of directors must qualify as “independent,” as affirmatively determined by such board. The Board consults with the Company’s counsel to ensure that the Board’s determinations are consistent with all relevant securities and other laws and regulations regarding the definition of “independent,” including those set forth in pertinent Nasdaq listing standards, as in effect from time to time.

Consistent with these considerations, our Board has determined that all of our directors, other than Mr. Crockett, qualify as “independent” directors in accordance with Nasdaq listing requirements. Mr. Crockett is not considered independent because he is an employee of KalVista. The Nasdaq independence definition includes a series of objective tests, such as that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his family members has engaged in various types of business dealings with us. In addition, as required by Nasdaq rules, our Board has made a subjective determination as to each independent director that no relationships exist, which, in the opinion of our Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, our Board reviewed and discussed information provided by the directors and us with regard to each director’s business and personal activities and relationships as they may relate to us and our management. There are no family relationships among any of our directors or executive officers.

As required under Nasdaq rules and regulations, our independent directors meet in regularly scheduled executive sessions at which only independent directors are present. As described more fully below, all of the committees of our Board are comprised entirely of directors determined by the Board to meet the independence standards applicable to those committees prescribed by Nasdaq, the SEC and the Internal Revenue Service.

### **Indemnification Agreements and Directors’ and Officers’ Liability Insurance**

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us to indemnify these individuals and, in certain cases, affiliates of such individuals, to the fullest extent permitted by Delaware law against liabilities that may arise by reason of their service to us or at our direction, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified. We also maintain an insurance policy that insures our directors and officers against certain liabilities, including liabilities arising under applicable securities laws.

## Policies and Procedures for Transactions with Related Persons

We have adopted a written related person transaction approval policy that has governed the review of related person transactions since the closing of our initial public offering. Pursuant to this policy, if we want to enter into a transaction with a related person or an affiliate of a related person, our Chief Financial Officer will review the proposed transaction to determine, based on applicable Nasdaq and SEC rules, if such transaction qualifies as a related person transaction. If our Chief Financial Officer determines that the proposed transaction is a related person transaction, then the proposed transaction shall be submitted to the audit committee for pre-approval at the next regular or special audit committee meeting; if our Chief Financial Officer, in consultation with our Chief Executive Officer, determines that it is not practicable to wait until the next meeting of the audit committee, then our Chief Financial Officer may submit the proposed transaction to the Chairman of the audit committee. In the event that our Chief Executive Officer or Chief Financial Officer becomes aware of a related person transaction that has not been previously approved or previously ratified under our related person transaction approval policy, the transaction, if ongoing, will be promptly submitted to the audit committee or the Chairman of the audit committee for consideration. If the transaction is already completed, the audit committee or the Chairman of the audit committee shall evaluate the transaction to determine if rescission of the transaction and/or any disciplinary action is appropriate.

### Item 14. Principal Accounting Fees and Services.

The following table summarizes the fees for services provided by Deloitte & Touche LLP for fiscal years ended April 30, 2018 and 2017.

<u>Fees Billed to KalVista</u>	<u>Fiscal Year 2018</u>	<u>Fiscal Year 2017</u>
Audit fees (1)	\$ 398,467	\$ 474,555
Audit-related fees	—	—
Tax fees	—	—
All other fees (2)	—	286,937
<b>Total fees</b>	<b>\$ 398,467</b>	<b>\$ 761,492</b>

- (1) "Audit fees" include fees for professional services rendered for the audits of our financials statements, review of our quarterly financial statements, and services normally provided by the independent registered accounting firm in connection with statutory and regulatory filings.
- (2) "All other fees" consist of the aggregate fees billed for products and services provided by Deloitte & Touche LLP and PriceWaterhouseCoopers LLP, other than those included in "Audit Fees" and "Tax Fees."

### Pre-Approval Policies and Procedures

Our audit committee generally pre-approves all audit and permissible non-audit services provided by the independent registered public accounting firm. These services may include audit services, audit-related services, tax services and other services. Pre-approval is detailed as to the particular service or category of services and is generally subject to a specific budget. The independent registered public accounting firm and management are required to periodically report to the audit committee regarding the extent of services provided by the independent registered public accounting firm in accordance with this pre-approval, and the fees for the services performed to date. Our audit committee may also pre-approve particular services on a case-by-case basis. All of the services relating to the fees described in the table above were approved by our audit committee.

**PART IV**

**Item 15. Exhibits, Financial Statement Schedules.**

- (a) The following documents are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K:
- (1) *Consolidated Financial Statements.* See Index to Financial Statements beginning on page F-1 of this Annual Report, which are incorporated by reference.
  - (2) *Financial Statement Schedules.* All schedules have been omitted because the information required to be presented in them is not applicable or is shown in the financial statements or related notes.
  - (3) *Exhibits.* We have filed, or incorporated into this Annual Report on Form 10-K by reference, the exhibits listed on the accompanying Exhibit Index.
- (b) *Exhibits.*

Exhibit Number	Description of Document	Incorporated by reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	<a href="#">Amended and Restated Certificate of Incorporation.</a>	S-1/A	333-201278	3.2	January 23, 2015	
3.2	<a href="#">Certificate of Amendment of Amended and Restated Certificate.</a>	8-K	001-36830	3.1	November 23, 2016	
3.3	<a href="#">Certificate of Amendment of Amended and Restated Certificate.</a>	8-K	001-36830	3.2	November 23, 2016	
3.4	<a href="#">Amended and Restated Bylaws.</a>	8-K	001-36830	3.2	April 16, 2015	
4.1	<a href="#">Form of Common Stock Certificate.</a>	S-1/A	333-201278	4.2	January 23, 2015	
4.2	<a href="#">Registration Rights Agreement, dated June 15, 2016, by and among the Registrant and the Sellers.</a>	8-K	001-36930	10.1	November 23, 2016	
10.1#	<a href="#">Form of Indemnification Agreement.</a>	S-1	333-201278	10.14	December 29, 2014	
10.2#	<a href="#">Carbylan 2015 Incentive Plan and forms of award agreements.</a>	S-1/A	333-201278	10.3	January 23, 2015	
10.3#	<a href="#">2017 Equity Incentive Plan.</a>	DEF 14A	001-36830	Appendix A	March 2, 2017	
10.4#	<a href="#">2017 Employee Stock Purchase Plan.</a>	DEF 14A	001-36830	Appendix B	March 2, 2017	
10.5#	<a href="#">Employment Agreement between the Registrant and T. Andrew Crockett, dated March 14, 2017.</a>	10-Q	001-36830	10.1	March 16, 2017	
10.6#	<a href="#">Employment Agreement between the Registrant and Benjamin L. Palleiko, dated March 14, 2017.</a>	10-Q	001-36830	10.2	March 16, 2017	
10.7	<a href="#">Forms of Equity Agreements.</a>	8-K	001-36830	99.1	June 29, 2018	
10.8	<a href="#">Office Lease Agreement by and between the Registrant and 55 Cambridge Parkway, LLC, dated May 30, 2017.</a>	10-K	001-36830	10.12	July 27, 2017	
10.9	<a href="#">Underlease by and between the Registrant and Wiltshire Council, dated April 30, 2018.</a>	8-K	001-36830	10.1	May 2, 2018	
10.10	<a href="#">Option Agreement, dated October 6, 2017, by and between KalVista Pharmaceuticals Limited and Merck Sharp &amp; Dohme Corp.</a>	10-Q	001-36830	10.1	December 14, 2017	

Exhibit Number	Description of Document	Incorporated by reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.11	<a href="#">Stock Purchase Agreement, dated October 6, 2017, by and between the Registrant and Merck Sharp &amp; Dohme Corp.</a>	10-Q	001-36830	10.2	December 14, 2017	
10.12	<a href="#">Voting Agreement, dated October 6, 2017, by and between the Registrant and Merck Sharp &amp; Dohme Corp.</a>	10-Q	001-36830	10.3	December 14, 2017	
10.13#	<a href="#">Executive Employment Agreement dated August 21, 2017, by and between the Registrant and Andreas Maetzel.</a>	10-Q	001-36830	10.4	December 14, 2017	
10.14#	<a href="#">Forms of Equity Agreements under the 2017 Equity Incentive Plan.</a>	8-K	001-36830	99.1	June 29, 2018	
10.15#	<a href="#">Service Agreement dated November 1, 2015, by and between KalVista Pharmaceuticals Ltd and Dr. Christopher M. Yea.</a>					X
21.1	<a href="#">Subsidiary of the Registrant.</a>	10-K	001-36830	21.1	July 27, 2017	
23.1	<a href="#">Consent of Deloitte &amp; Touche LLP.</a>					X
23.2	<a href="#">Consent of Deloitte LLP.</a>					X
24.1	<a href="#">Power of Attorney. (See signature page hereto.)</a>					X
31.1	<a href="#">Certification of Principal Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>					X
31.2	<a href="#">Certification of Principal Financial Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>					X
32.1*	<a href="#">Certification of Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>					X
32.2*	<a href="#">Certification of Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>					X
101.INS	XBRL Instance Document.					X
101.SCH	XBRL Taxonomy Extension Schema Document.					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.					X

# Management contract or compensatory plan or arrangement.

\* This certification is deemed not filed for purpose of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

\*\* All schedules and exhibits to the Share Purchase Agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon request.

**Item 16. Form 10-K Summary.**

None.

**SIGNATURES**

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

KalVista Pharmaceuticals, Inc.

Date: July 30, 2018

By:                                 /s/ T. Andrew Crockett  
                                T. Andrew Crockett  
                                Chief Executive Officer

**POWER OF ATTORNEY**

Each person whose individual signature appears below hereby authorizes and appoints Thomas Andrew Crockett and Benjamin L. Palleiko, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this annual report on Form 10-K 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, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>                                /s/ T. Andrew Crockett</u> T. Andrew Crockett	Chief Executive Officer and Director (Principal Executive Officer)	July 30, 2018
<u>                                /s/ Benjamin L Palleiko</u> Benjamin L. Palleiko	Chief Financial Officer (Principal Financial and Accounting Officer)	July 30, 2018
<u>                                /s/ Richard Aldrich</u> Richard Aldrich	Director and Chairman	July 30, 2018
<u>                                /s/ Albert Cha</u> Albert Cha, M.D., Ph.D.	Director	July 30, 2018
<u>                                /s/ Arnold Oronsky</u> Arnold L. Oronsky, Ph.D.	Director	July 30, 2018
<u>                                /s/ Joshua Resnick</u> Joshua Resnick, M.D.	Director	July 30, 2018
<u>                                /s/ Edward W Unkart</u> Edward W. Unkart	Director	July 30, 2018

**KALVISTA PHARMACEUTICALS, INC.**  
**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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<a href="#"><u>Consolidated Balance Sheets</u></a>	F-4
<a href="#"><u>Consolidated Statements of Operations and Comprehensive Loss</u></a>	F-5
<a href="#"><u>Consolidated Statements of Changes in Convertible Preferred Shares and Stockholders' Equity (Deficit)</u></a>	F-6
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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of KalVista Pharmaceuticals, Inc.

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of KalVista Pharmaceuticals, Inc. and subsidiaries (the "Company") as of April 30, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, changes in convertible preferred shares and stockholders' equity (deficit), and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of April 30, 2018 and 2017, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

### Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

Boston, Massachusetts  
July 30, 2018

We have served as the Company's auditor since 2016.



## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of KalVista Pharmaceuticals Limited

We have audited the accompanying statements of operations and comprehensive loss, changes in convertible preferred shares and shareholders' deficit, and cash flows of KalVista Pharmaceuticals Limited (the "Company") for the year ended April 30, 2016. 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, such financial statements present fairly, in all material respects, the results of operations and cash flows of the Company for the year ended April 30, 2016, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2 to the financial statements, the statement of operations and comprehensive loss for the year ended April 30, 2016 has been restated to correct a misstatement.

/s/ Deloitte LLP

Reading, United Kingdom

August 22, 2016

(July 27, 2017 as to the effects of the adjustment of net loss per share arising from the Carbylan transaction discussed in Note 2 and the misstatement of other comprehensive loss discussed in Note 2)

**KALVISTA PHARMACEUTICALS, INC.**  
**Consolidated Balance Sheets**  
**April 30, 2018 and 2017**  
(in thousands except share and per share amounts)

	<u>2018</u>	<u>2017</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 51,055	\$ 30,950
Research and development tax credit receivable	6,834	2,250
Grants and other receivables	—	297
Prepaid expenses and other current assets	1,491	701
<b>Total current assets</b>	<u>59,380</u>	<u>34,198</u>
Other assets	173	50
Property and equipment, net	1,836	97
<b>Total assets</b>	<u>\$ 61,389</u>	<u>\$ 34,345</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,433	\$ 1,153
Accrued expenses	3,087	1,865
Deferred revenue - current portion	18,475	—
Capital lease liability - current portion	221	—
<b>Total current liabilities</b>	<u>23,216</u>	<u>3,018</u>
Long-term liabilities:		
Deferred revenue - net of current portion	10,862	—
Capital lease liability - net of current portion	58	—
<b>Total long-term liabilities</b>	<u>10,920</u>	<u>—</u>
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock, \$0.001 par value, 100,000,000 authorized		
Shares issued and outstanding: 10,799,895 at April 30, 2018 and 9,713,042 at April 30, 2017	11	10
Additional paid-in capital	100,011	89,815
Accumulated deficit	(71,660)	(55,855)
Accumulated other comprehensive loss	(1,109)	(2,643)
<b>Total stockholders' equity</b>	<u>27,253</u>	<u>31,327</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 61,389</u>	<u>\$ 34,345</u>

See notes to consolidated financial statements.

**KALVISTA PHARMACEUTICALS, INC.**  
**Consolidated Statements of Operations and Comprehensive Loss**  
**Years Ended April 30, 2018, 2017 and 2016**  
(in thousands, except share and per share amounts)

	2018	2017	2016
Revenue	\$ 8,394	\$ 1,504	\$ 2,133
Operating expenses:			
Research and development expenses	18,237	12,666	14,661
General and administrative expenses	8,862	11,177	2,653
<b>Total operating expenses</b>	<b>27,099</b>	<b>23,843</b>	<b>17,314</b>
<b>Operating loss</b>	<b>(18,705)</b>	<b>(22,339)</b>	<b>(15,181)</b>
Other income:			
Interest income	82	36	50
Foreign currency exchange rate (loss) gain	(1,574)	1,371	1,661
Other income	4,392	2,329	2,034
<b>Total other income</b>	<b>2,900</b>	<b>3,736</b>	<b>3,745</b>
<b>Net loss</b>	<b>(15,805)</b>	<b>(18,603)</b>	<b>(11,436)</b>
Other comprehensive income (loss):			
Foreign currency translation adjustments	1,534	(2,568)	(2,240)
<b>Comprehensive loss</b>	<b>\$ (14,271)</b>	<b>\$ (21,171)</b>	<b>\$ (13,676)</b>
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.53)	\$ (4.47)	\$ (26.17)
Weighted average common shares outstanding, basic and diluted	10,321,780	4,646,764	591,298

See notes to consolidated financial statements.

**KALVISTA PHARMACEUTICALS, INC.**  
**Consolidated Statements of Changes in Convertible Preferred Shares and Stockholders' Equity (Deficit)**  
**Years Ended April 30, 2018, 2017, and 2016**  
(in thousands, except share and per share amounts)

	Series B Preferred Stock		Series A Preferred Stock		Total Preferred Stock	
	Number of Shares	Amount	Number of Shares	Amount	Shares	Amount
Balance, May 1, 2015	—	\$ -	15,900,000	\$ 25,606	15,900,000	\$ 25,606
Issuance of Series B convertible preferred stock net of issuance costs of approximately \$186	8,422,898	33,002	—	—	8,422,898	33,002
Issuance of ordinary shares	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—
Net loss	—	—	—	—	—	—
Foreign currency translation	—	—	—	—	—	—
<b>Balance, April 30, 2016</b>	<b>8,422,898</b>	<b>33,002</b>	<b>15,900,000</b>	<b>25,606</b>	<b>24,322,898</b>	<b>58,608</b>
Issuance of ordinary shares	—	—	—	—	—	—
Carbylan transaction	(8,422,898)	(33,002)	(15,900,000)	(25,606)	(24,322,898)	(58,608)
Stock-based compensation expense	—	—	—	—	—	—
Net loss	—	—	—	—	—	—
Foreign currency translation	—	—	—	—	—	—
<b>Balance, April 30, 2017</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>
Issuance of common stock	—	—	—	—	—	—
Issuance of common stock from stock options exercised	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—
Net loss	—	—	—	—	—	—
Foreign currency translation	—	—	—	—	—	—
<b>Balance, April 30, 2018</b>	<b>—</b>	<b>\$ —</b>	<b>—</b>	<b>\$ —</b>	<b>—</b>	<b>\$ —</b>

	Ordinary Shares		Common Stock		Additional	Accumulated	Accumulated	Other	Total
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Comprehensive Income (Loss)	Stockholders' Equity (Deficit)	
Balance, May 1, 2015	1,302,367	\$ 2	—	\$ -	\$ 94	\$ (25,816)	\$ 2,165	\$ (23,555)	
Issuance of Series B convertible preferred stock net of issuance costs of approximately \$186	—	—	—	—	—	—	—	—	
Issuance of ordinary shares	865,000	1	—	—	—	—	—	1	
Stock-based compensation expense	—	—	—	—	118	—	—	118	
Net loss	—	—	—	—	—	(11,436)	—	(11,436)	
Foreign currency translation	—	—	—	—	—	—	(2,240)	(2,240)	
Balance, April 30, 2016	2,167,367	3	—	—	212	(37,252)	(75)	(37,112)	
Issuance of ordinary shares	396,719	2	—	—	—	—	—	2	
Carbylan transaction	(2,564,086)	(5)	9,713,042	10	89,209	—	—	89,214	
Stock-based compensation expense	—	—	—	—	394	—	—	394	
Net loss	—	—	—	—	—	(18,603)	—	(18,603)	
Foreign currency translation	—	—	—	—	—	—	(2,568)	(2,568)	
Balance, April 30, 2017	—	—	9,713,042	10	89,815	(55,855)	(2,643)	31,327	
Issuance of common stock	—	—	1,070,589	1	9,100	—	—	9,101	
Issuance of common stock from stock options exercised	—	—	16,264	—	36	—	—	36	
Stock-based compensation expense	—	—	—	—	1,060	—	—	1,060	
Net loss	—	—	—	—	—	(15,805)	—	(15,805)	
Foreign currency translation	—	—	—	—	—	—	1,534	1,534	
<b>Balance, April 30, 2018</b>	<b>—</b>	<b>\$ —</b>	<b>10,799,895</b>	<b>\$ 11</b>	<b>\$ 100,011</b>	<b>\$ (71,660)</b>	<b>\$ (1,109)</b>	<b>\$ 27,253</b>	

See notes to consolidated financial statements.

**KALVISTA PHARMACEUTICALS, INC.**  
**Consolidated Statements of Cash Flows**  
**Years Ended April 30, 2018, 2017, and 2016**  
(in thousands)

	2018	2017	2016
<b>Cash flows from operating activities:</b>			
Net loss	\$ (15,805)	\$ (18,603)	\$ (11,436)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	180	40	33
Stock-based compensation expense	1,060	394	118
Foreign currency remeasurement loss	(651)	(1,371)	(1,661)
Changes in operating assets and liabilities, net of changes from business acquired:			
Research and development tax credit receivable	(4,256)	(600)	(1,148)
Grants and other receivables	319	29	(137)
Prepaid expenses and other current assets	(746)	(81)	(475)
Other assets	(123)	—	—
Accounts payable	217	(1,599)	374
Accrued expenses	1,132	(1,931)	1,176
Deferred revenue	29,231	—	—
<b>Net cash provided by (used in) operating activities</b>	<b>10,558</b>	<b>(23,722)</b>	<b>(13,156)</b>
<b>Cash flows from investing activities:</b>			
Cash acquired in transaction	—	34,139	—
Acquisition of property and equipment	(1,427)	(74)	(11)
<b>Net cash provided by (used in) investing activities</b>	<b>(1,427)</b>	<b>34,065</b>	<b>(11)</b>
<b>Cash flows from financing activities:</b>			
Capital lease principal payments	(151)	—	—
Proceeds from issuance of common stock	9,137	2	1
Proceeds from issuance of Series B Preferred Stock, net of issuance costs	—	—	33,002
<b>Net cash provided by financing activities</b>	<b>8,986</b>	<b>2</b>	<b>33,003</b>
Effect of exchange rate changes on cash and cash equivalents	1,988	(1,159)	(598)
<b>Net increase in cash and cash equivalents</b>	<b>20,105</b>	<b>9,186</b>	<b>19,238</b>
Cash and cash equivalents, beginning year	30,950	21,764	2,526
Cash and cash equivalents, end of year	<u>\$ 51,055</u>	<u>\$ 30,950</u>	<u>\$ 21,764</u>
<b>Supplemental disclosures of cash flow information:</b>			
Conversion of preferred stock and ordinary shares to common stock	\$ -	\$ 58,613	\$ -
Capital leases	\$ 513	\$ -	\$ -
Acquisition of property and equipment in accounts payable	\$ 291	\$ -	\$ -

See notes to consolidated financial statements.

**KALVISTA PHARMACEUTICALS, INC.**  
**Notes to Consolidated Financial Statements**

**Note 1. Description of Business, Basis of Presentation and Going Concern**

KalVista Pharmaceuticals, Inc. (“KalVista” or the “Company”) is a clinical stage pharmaceutical company focused on the discovery, development and commercialization of small molecule protease inhibitors for diseases with significant unmet need. The Company’s first product candidates are inhibitors of plasma kallikrein being developed for two indications: hereditary angioedema (“HAE”) and diabetic macular edema (“DME”). The Company applies its insights into the chemistry of proteases and, with current programs, the biology of the plasma kallikrein system, to develop small molecule inhibitors with high selectivity, potency and bioavailability that it believes will make them successful treatments for disease.

KalVista has created a structurally diverse portfolio of oral plasma kallikrein inhibitors and advanced multiple drug candidates into Phase 1 clinical trials for HAE in order to create best-in-class oral therapies. In December 2017, the Company initiated a first-in-human study of KVD900, the next candidate from its HAE portfolio to commence clinical testing. Based upon the results observed to date in that study, the Company has determined to advance KVD900 into later stage clinical trials as a potential on-demand therapy for acute HAE attacks. In the case of DME, the Company is initially developing a plasma kallikrein inhibitor which is administered directly into the eye and anticipates ultimate development of orally delivered drugs. Also in December 2017 KalVista commenced a Phase 2 clinical trial of KVD001, the Company’s most advanced DME drug candidate, that it anticipates will complete in the second half of 2019.

In October 2017, the Company’s wholly-owned, U.K. based subsidiary KalVista Pharmaceuticals Limited (“KalVista Limited”) and Merck Sharp & Dohme Corp. (“Merck”) entered into an option agreement (the “Option Agreement”) under which the Company granted to Merck an option to acquire KVD001 through a period following completion of a Phase 2 clinical trial. The Company also granted to Merck a similar option to acquire investigational orally delivered molecules for DME (the “Oral DME Compounds”) that the Company will continue to develop as part of its ongoing research and development activities, through a period following the completion of a Phase 2 clinical trial. Under the terms of the Option Agreement, Merck paid to the Company a non-refundable upfront fee of \$37 million in November 2017. See Note 5 for further discussion of the arrangement with Merck.

The Company’s headquarters is located in Cambridge, Massachusetts, with research activities located in Porton Down, United Kingdom and Boston, Massachusetts.

The Company has devoted substantially all of its efforts to research and development, including clinical trials of its product candidates. The Company has not completed the development of any product candidates. Pharmaceutical drug product candidates, like those being developed by the Company, require approvals from the U.S. Food and Drug Administration (“FDA”) or foreign regulatory agencies prior to commercial sales. There can be no assurance that any product candidates will receive the necessary approvals and any failure to receive approval or delay in approval may have a material adverse impact on the Company’s business and financial results. The Company has not yet commenced commercial operations. The Company is subject to a number of risks and uncertainties similar to those of other life science companies developing new products, including, among others, the risks related to the necessity to obtain adequate additional financing, to successfully develop product candidates, to obtain regulatory approval of product candidates, to comply with government regulations, to successfully commercialize its potential products, to the protection of proprietary technology and to the dependence on key individuals.

The Company has funded its operations primarily through the issuance of preferred stock and common stock, the share purchase transaction with Carbylan Therapeutics, Inc. (“Carbylan”), the Option Agreement and grant income. As of April 30, 2018, the Company had an accumulated deficit of \$71.7 million and cash and cash equivalents totaling \$51.1 million. The Company’s working capital, primarily cash, is anticipated to fund the Company’s operations for at least 12 months beyond the date of issuance of the consolidated financial statements. Accordingly, the consolidated financial statements have been prepared on a going concern basis.

The Company will need to expend substantial resources for research and development, including costs associated with the clinical testing of its product candidates and will need to obtain additional financing to fund its operations and to conduct trials for its product candidates. The Company will seek to finance future cash needs through equity offerings, future grants, corporate partnerships and product sales.

The Company has never been profitable and has incurred significant operating losses in each year since inception. Cash requirements may vary materially from those now planned because of changes in the Company's focus and direction of its research and development programs, competitive and technical advances, patent developments, regulatory changes or other developments. Additional financing will be required to continue operations after the Company exhausts its current cash resources and to continue its long-term plans for clinical trials and new product development. There can be no assurance that any such financing can be obtained by the Company, or if obtained, what the terms thereof may be, or that any amount that the Company is able to raise will be adequate to support the Company's working capital requirements until it achieves profitable operations. If adequate additional working capital is not secured when needed, the Company may be required to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible and/or suspend or curtail planned research programs. Any of these actions could materially harm the Company's business and prospects.

## **Note 2. Summary of Significant Accounting Policies**

**Principles of consolidation:** The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

**Use of estimates:** The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosure of contingent assets and liabilities, at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates.

**Foreign currency:** The functional currency of the Company's foreign subsidiary is the Great Britain Pound Sterling. Assets and liabilities of the foreign subsidiary are translated using the exchange rate existing on each respective balance sheet date. Revenues and expenses are translated using average exchange rates prevailing throughout the year. The translation adjustments resulting from this process are included as the only component of the accumulated other comprehensive loss. In addition, the Company's foreign subsidiary engages in transactions and holds balances denominated and settled in currencies other than the functional currency, and transaction gains or losses are recorded in the consolidated statement of operations.

**Segment Reporting:** The Chief Operating Decision Maker, the CEO, manages the Company's operations as a single operating segment for the purposes of assessing performance and making operating decisions.

**Cash and cash equivalents:** Cash and cash equivalents consist of bank deposits and money market accounts. Cash equivalents are carried at cost which approximates fair value due to their short-term nature. The Company considers all highly liquid investments with an original maturity of 90 days or less to be cash equivalents.

The Company maintains its cash and cash equivalent balances with financial institutions that management believes are of high credit quality. The Company's cash and cash equivalent accounts at times may exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk of cash and cash equivalents.

**Research and development tax credit receivable:** The research and development tax credit receivable consists of research and development expenses that have been claimed as research and development tax credits in accordance with the relevant U.K. tax legislation. These refundable tax credits are payable to the Company in cash and are carried on the consolidated balance sheet at the amount claimed and expected to be received from the U.K. government.



**Property and equipment:** Property and equipment are stated at cost less accumulated depreciation. Expenditures for repairs and maintenance are charged to expense as incurred. Upon retirement or sale, the costs of the assets disposed of and the related accumulated depreciation are eliminated from the accounts and any resulting gain or loss is reflected in the statement of operations. Depreciation is provided using the straight-line method over the estimated useful lives of the assets, which are as follows:

<u>Asset Classification</u>	<u>Estimated Useful Life</u>
Machinery and equipment	1-5 Years
Computer equipment	3-4 Years
Motor vehicles	4 Years
Leasehold improvements	5 Years or term of lease, if shorter

The Company assesses the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying value of such assets, or asset groups, may not be recoverable. Whenever events or changes in circumstances suggest that the carrying amount of long-lived assets may not be recoverable, the future undiscounted cash flows expected to be generated by the asset, or asset groups, from its use or eventual disposition is estimated. If the sum of the expected future undiscounted cash flows is less than the carrying amount of those assets, or asset groups, an impairment loss is recognized based on the excess of the carrying amount over the fair value of the assets, or asset groups.

**Revenue recognition:** The Company recognizes revenue from research and development arrangements and grant income. Revenue is realized or realizable and earned when all of the following criteria are met: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the seller's price to the buyer is fixed or determinable; and (iv) collectability is reasonably assured.

Grant income is received for the development and commercialization of product candidates through sponsored research arrangements with non-profit organizations and from federal research and development grant programs. Revenue is recognized as qualifying research and development costs are incurred. The existing grant program is sponsored by the U.K. government and is substantially complete, with no significant further reimbursements anticipated.

For arrangements that involve the delivery of more than one element, such as the Option Agreement, each product, service and/or right to use assets is evaluated to determine whether it qualifies as a separate unit of accounting. This determination is based on whether the deliverable has "stand-alone value" to the customer. The consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The estimated selling price of each deliverable is determined using the following hierarchy of values: (i) vendor-specific objective evidence of fair value, (ii) third-party evidence of selling price and (iii) best estimate of selling price ("BESP"). The BESP reflects the Company's best estimate of what the selling price would be if the deliverable was regularly sold by the Company on a stand-alone basis. The consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation.

**Research and development:** Research and development costs are expensed as incurred and include, but are not limited to:

- Employee-related expenses including salaries, benefits, travel, and share-based compensation expense for research and development personnel;
- Costs associated with preclinical and development activities;
- Costs associated with regulatory operations.

**Income taxes:** The Company uses the asset and liability method for accounting for income taxes. Under this method, 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 their respective income 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 Company evaluates the realizability of its deferred tax assets and establishes a valuation allowance when it is more likely than not that all or a portion of deferred tax assets will not be realized. The Company has provided a full valuation allowance on its deferred tax assets.

Relative to accounting for uncertainties in tax positions, 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. For those tax positions where it is more likely than not that a tax benefit will be sustained, the Company records the largest amount of tax benefit with a greater than 50% likelihood of being realized upon ultimate settlement with a taxing authority having full knowledge of all relevant information. For those income tax positions where it is not more likely than not that a tax benefit will be sustained, the Company does not recognize a tax benefit in the financial statements.

The Company recognizes interest and penalties related to uncertain tax positions, if any, as a component of income tax expense. As the Company has no uncertain tax positions, there were no interest or penalties charges recognized in the statement of operations for any years.

**Stock based compensation:** The Company accounts for stock based compensation arrangements at fair value. The fair value is recognized over the period during which the recipient is required to provide services (usually the vesting period), on a straight-line basis.

**Net Loss per Share Attributable to Common Shareholders:** Basic and diluted net loss per share is presented in conformity with the two-class method required for participating securities. Under the two-class method, basic net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding during the period. Net loss attributable to common stockholders is determined by allocating undistributed earnings between holders of common and convertible preferred shares, based on the contractual dividend rights contained in the preferred share agreement. Where there is an undistributed loss, no amount is allocated to the convertible preferred shares. Diluted net loss per share is computed by dividing net loss by the sum of the weighted average number of common stock and the number of dilutive potential common stock equivalents outstanding during the period. Potential dilutive common share equivalents consist of the incremental common shares issuable upon the exercise of vested share options or the conversion of preferred stock.

Potential dilutive common share equivalents consist of:

	<u>2018</u>	<u>April 30, 2017</u>	<u>2016</u>
Preferred stock	—	—	24,322,898
Stock options	388,366	148,469	76,643

In computing diluted earnings per share, common stock equivalents are not considered in periods in which a net loss is reported, as the inclusion of the common stock equivalents would be anti-dilutive. As a result, there is no difference between the Company's basic and diluted loss per share in the periods presented (in thousands, except share and per share amounts):

Basic and diluted net loss per share	April 30,		
	2018	2017	2016
Net loss	\$ (15,805)	\$ (18,603)	\$ (11,436)
Less: dividend on Series A	—	(935)	(1,918)
Less: dividend on Series B	—	(1,237)	(2,121)
Loss available to common stockholders	(15,805)	(20,775)	(15,475)
Weighted average common shares, basic and diluted	10,321,780	4,646,764	591,298
Net loss per share, basic and diluted	\$ (1.53)	\$ (4.47)	\$ (26.17)

The weighted average shares outstanding, reported loss per share and potential dilutive common share equivalents for the periods prior to November 21, 2016, the date of the Carbylan transaction, have been retrospectively adjusted to reflect historical weighted-average number of common shares outstanding multiplied by the exchange ratio established in the share purchase agreement.

**Fair value measurement:** The Company classifies fair value measurements using a three-level hierarchy that prioritizes the inputs used to measure fair value. This hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows: Level 1, quoted market prices in active markets for identical assets or liabilities; Level 2, observable inputs other than quoted market prices included in Level 1, such as quoted market prices for markets that are not active or other inputs that are observable or can be corroborated by observable market data; and Level 3, unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities, including certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs.

The Company's financial instruments as of April 30, 2018 and 2017 consisted primarily of cash and cash equivalents, grants receivable, capital lease obligations and accounts payable. The carrying amount of these assets and liabilities approximate fair value given the short term maturity of these instruments.

**Correction:** The statements of operations and comprehensive loss for the year ended April 30, 2016 was restated in the prior year to correct errors in the foreign currency translation adjustments which were reported as a gain rather than a loss and to correct the resulting summation of comprehensive loss. As a result of the correction of these errors, the total comprehensive loss for the year ended April 30, 2016 increased from a loss of \$9,196,000 to a loss of \$13,676,000. There is no impact on the Company's previously reported net loss, the balance sheet, the statement of changes in convertible preferred shares and stockholders' equity (deficit) or the statement of cash flows for any period.

**Recently issued accounting pronouncements not yet adopted:** In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards update ("ASU") 2014-09, "Revenue from Contracts with Customers," requiring an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The updated standard will replace most existing revenue recognition guidance in US GAAP when it becomes effective. The Company will adopt the updated standard in the first quarter of fiscal 2019 using the modified retrospective method of adoption. The adoption of this standard is not expected to have a material impact on the consolidated financial statements.

In February 2016, the FASB issued new lease accounting guidance in ASU No. 2016-02, "Leases" (Topic 842). Under the new guidance, lessees will be required to recognize for all leases (with the exception of short-term leases) at the commencement date: (1) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and (2) a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. The new lease guidance is effective for

the Company beginning May 1, 2019. The Company is assessing the impact that adoption of this new guidance will have on the consolidated financial statements, but expects to recognize a material lease obligation and right of use asset. See additional discussion of the Company's lease obligation included in Note 8.

#### **Recently adopted accounting pronouncements**

In March 2016, the FASB issued ASU No. 2016-09, Compensation –Stock Compensation (Topic 718) (“ASU 2016-09”) to require changes to several areas of employee share-based payment accounting in an effort to simplify share-based reporting. The update revises requirements in the following areas: minimum statutory withholding, accounting for income taxes and forfeitures. The Company adopted this standard effective May 1, 2017, and is now accounting for forfeitures as incurred. The adoption of this standard did not have a material impact on the consolidated financial statements.

#### **Note 3. Property and Equipment**

At April 30, 2018 and 2017, property and equipment consisted of (in thousands):

	2018	2017
Laboratory equipment	\$ 1,277	\$ 373
Office equipment	33	31
Furniture & fixtures	76	6
Leasehold improvements	1,005	—
	2,391	410
Less accumulated depreciation	(555)	(313)
	<u>\$ 1,836</u>	<u>\$ 97</u>

For the years ended April 30, 2018, 2017, and 2016, depreciation expense was \$180,000, \$40,000 and \$33,000, respectively.

#### **Note 4. Accrued Expenses**

At April 30, 2018 and 2017, accrued expenses consisted of (in thousands):

	2018	2017
Accrued research expense	\$ 1,192	\$ 348
Accrued compensation	1,393	1,300
Accrued professional fees	164	146
Other accrued expenses	338	71
	<u>\$ 3,087</u>	<u>\$ 1,865</u>

#### **Note 5. Merck Arrangement**

On October 6, 2017, the Company's wholly-owned U.K. based subsidiary KalVista Pharmaceuticals Limited (“KalVista Limited”) and Merck Sharp & Dohme Corp. (“Merck”) entered into an option agreement (the “Option Agreement”). The Company is the guarantor of KalVista Limited's obligations under the Option Agreement. Under the terms of the Option Agreement, the Company, through KalVista Limited, has granted to Merck an option to acquire KVD001 through a period following completion of a Phase 2 clinical trial. The Company, through KalVista Limited, has also granted to Merck a similar option to acquire investigational orally delivered molecules for DME that the Company will continue to develop as part of its ongoing research and development activities, through a period following the completion of a Phase 2 clinical trial. The Company, through KalVista Limited, also granted to Merck a non-exclusive license to use the compounds solely for research purposes, and is required to use its diligent efforts to develop the two compounds through the completion of Phase 2 clinical trials. The Company will fund and retain control over the planned Phase 2 clinical trial of KVD001 as well as development of the investigational oral

DME compounds through Phase 2 clinical trials unless Merck determines to exercise its options earlier, at which point Merck will take responsibility for all development and commercialization activities for the compounds. The Company's development efforts under the Option Agreement are governed by a joint steering committee consisting of equal representatives from the Company and Merck.

Under the terms of the Option Agreement, Merck paid a non-refundable upfront fee of \$37 million to KalVista Limited in November 2017. If Merck exercises both options under the Option Agreement, KalVista Limited could receive up to an additional \$715 million composed of option exercise payments and clinical, regulatory, and sales-based milestone payments. In addition, the Company is eligible for tiered royalties on global net sales ranging from mid-single digits to double digit percentages. Merck may terminate the Option Agreement at any time upon written notice to the Company. KalVista Limited may terminate the Option Agreement in the event of Merck's material breach of the Option Agreement, subject to cure.

Concurrent with the Option Agreement, the Company and Merck also entered into a stock purchase agreement (the "Stock Purchase Agreement") pursuant to which Merck paid approximately \$9.1 million to purchase 1,070,589 new shares of the Company's common stock at a price of \$8.50 per share.

The Company determined that the Option Agreement and the Stock Purchase Agreement were negotiated and executed contemporaneously, and therefore should be combined as one arrangement for accounting purposes. The Company evaluated the arrangement in accordance with the provisions of ASC 605-25. The Company determined that the arrangement contains the following deliverables: (i) a non-exclusive license to use the two compounds solely for research purposes, (ii) research and development services related to the development of KVD001 through completion of a Phase 2 clinical trial, (iii) research and development services related to the development of the Oral DME Compounds, and (iv) unregistered shares of the Company's common stock.

The Company has determined that Merck's options to acquire KVD001 and the Oral DME Compounds are substantive options. Merck is not contractually obligated to exercise the options. The Company has determined that Merck's options to acquire KVD001 and the Oral DME Compounds are not priced at a significant and incremental discount. Consequently, the Company determined that Merck's options are not deliverables in the arrangement.

The Company further determined that the research license granted did not have standalone value from the respective research and development services, as the license could not be used on its own by Merck for its intended purpose of developing and commercializing KVD001 and the Oral DME Compounds on a standalone basis. As a result, the research license has been combined with the respective research and development services for KVD001 and the Oral DME Compounds as two units of accounting (the "KVD001 Unit of Accounting" and the "Oral DME Unit of Accounting"). The Company has concluded that the common stock deliverable identified at the inception of the arrangement has standalone value from the other deliverables and therefore represents a separate unit of accounting (the "Common Stock Unit of Accounting").

Therefore, the Company has identified three units of accounting under the arrangement as follows: (i) the KVD001 Unit of Accounting, (ii) the Oral DME Unit of Accounting, and (iii) the Common Stock Unit of Accounting. Allocable arrangement consideration at inception of the arrangement is comprised of the non-refundable up-front payment of \$37.0 million and the payment for the common stock of \$9.1 million. The Company allocated the \$9.1 million payment to the common stock, as this represented the fair value of the shares issued based on arms-length negotiations between the Company and Merck. The amount allocated to the common stock is recorded to stockholders' equity at the date of issuance. The Company allocated the remaining allocable consideration of \$37.0 million to the remaining units of accounting using the relative-selling price method.

The Company determined that neither vendor-specific objective evidence or third-party evidence is available for any of the units of accounting identified at arrangement inception. Accordingly, the selling price of each unit of accounting was developed using management's best estimate of selling price.

The Company developed the Best Estimate of Selling Price (“BESP”) for the KVD001 Unit of Accounting and Oral DME Unit of Accounting by applying an analysis of discounted cash flows and the allocable arrangement consideration was allocated among the separate units of accounting using the relative selling price method. The amount allocated to each Unit of Accounting will be recognized as revenue on a proportional performance basis. For the fiscal year ended April 30, 2018, the Company recognized approximately \$8.0 million of revenue with respect to the arrangement with Merck. As of April 30, 2018, deferred revenue on the consolidated balance sheet is \$29.3 million.

#### **Note 6. Grant Income**

Grant income is primarily recognized through an agreement with the Technology Strategy Board (“TSB”), a United Kingdom government organization. The Company recognizes revenue for reimbursements of research and development costs as the services are performed up to an agreed upon threshold. The Company records these reimbursements as revenue and not as a reduction of research and development expenses, as the Company has the risks and rewards as the principal in the research and development activities. Any services performed and not yet collected upon are shown as a receivable. During years ended April 30, 2018, 2017 and 2016, revenue recognized through the TSB grant amounted to \$0.4 million, \$1.2 million and \$1.8 million, respectively. As of April 30, 2018, the development activities related to the TSB grant have been completed and the Company does not anticipate any further reimbursements from this grant.

The Company evaluates the terms of sponsored research agreement grants and federal grants to assess the Company’s obligations and if the Company’s obligations are satisfied by the passage of time, revenue is recognized as described above. For grants with refund provisions, the Company reviews the grant to determine the likelihood of repayment. If the likelihood of repayment of the grant is determined to be remote, the grant is recognized as revenue. If the probability of repayment is determined to be more than remote, the Company records the grant as a deferred revenue liability, until such time that the grant requirements have been satisfied.

#### **Note 7. Stock-Based Compensation**

The Company has three plans that provide for equity-based compensation. There are two legacy plan that were maintained by Carbylan and KalVista Limited and for which no further grants are to be made. Under the 2017 Equity Incentive Plan (“2017 Plan”), 1,712,287 shares of the Company’s common stock are reserved for issuance upon exercise of stock options. As of April 30, 2018, 1,076,367 stock options remain available for grant under the 2017 Plan.

Initial awards generally vest 25% after one year and then ratably on a monthly basis over the next three years. Recurring grants typically vest on a monthly basis over four years. Stock option grants expire after ten years.

The Company recognizes stock-based compensation expense over the requisite service period based on the grant date fair value of the award. The Company has elected to use the Black-Scholes option pricing model to determine the fair value of awards granted. The determination of the fair value of stock-based awards utilizing the Black-Scholes model is affected by the share price and a number of assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. Due to insufficient history of the Company’s stock price, the stock-price volatility assumption is based on the historical volatility of a peer group of publicly traded companies. The expected life of the awards is estimated based on the simplified method. The risk-free interest rate assumption is based on observed interest rates appropriate for the terms of the awards. The dividend yield assumption is based on history and expectation of paying no dividends. Forfeitures have not been material in the periods presented.

The fair value of the share-based awards was measured with the following weighted-average assumptions for the fiscal years ended April 30:

	2018	2017	2016
Risk-free interest rate	1.94%	2.08%	1.38%
Expected life of the options	6.25 years	6.25 years	6.25 years
Expected volatility of the underlying stock	76.9%	82.3%	80.9%
Expected dividend rate	0%	0%	0%

Stock-based compensation was reflected in the Company's consolidated statement of operations and comprehensive loss as follows (in thousands):

	Year ended April 30,		
	2018	2017	2016
Research and development	\$ 320	\$ 143	\$ 118
General and administrative	740	251	—
Total stock-based compensation expense	\$ 1,060	\$ 394	\$ 118

A summary of option activity for the year ended April 30, 2018 and changes during the years then ended is presented below:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at May 1, 2017	537,768	\$ 4.82	9.05	\$ 1,631
Exercised	(16,264)	2.13		
Granted	409,320	7.10		
Cancelled	(12,130)			
Outstanding at April 30, 2018	918,694	\$ 5.87	8.51	\$ 3,465
Exercisable at April 30, 2018	388,366	\$ 4.57	8.02	\$ 1,967
Vested and expected to vest at April 30, 2018	918,694	\$ 5.87	8.51	\$ 3,465

The weighted-average grant date fair value of stock options granted during the years ended, April 30, 2018, 2017, and 2016 was \$4.87, \$5.68 and \$1.41, respectively.

As of April 30, 2018, there was \$2.5 million of unrecognized compensation expense related to unvested awards, which is expected to be recognized over a weighted-average period of 2.55 years

#### Note 8. Commitments and Contingencies

**Clinical Studies:** The Company enters into contractual agreements with contract research organizations in connection with preclinical and toxicology studies and clinical trials. Amounts due under these agreements are invoiced to the Company on predetermined schedules during the course of the toxicology studies and clinical trials and are not refundable regardless of the outcome. The Company has a contractual obligation related to the expected future costs to be incurred to complete the ongoing toxicology studies and clinical trials. The remaining commitment, which has cancellation provisions, totals \$8.9 million at April 30, 2018.

**Lease commitments:** The Company is party to several operating leases for office and laboratory space as well as certain lab equipment. Rent expense was \$0.6 million, \$0.5 million and \$0.1 million for the years ended April 30, 2018, 2017, 2016, respectively, and is reflected in general and administrative expenses and research and development expenses as determined by the underlying activities.

Future minimum payments under these leases as of April 30, 2018 are as follows (in thousands):

Year ended April 30:	Capital Leases	Operating Leases
2019	\$ 229	\$ 331
2020	58	329
2021	—	332
2022	—	335
2023 and thereafter		746
Total minimum lease payments	287	<u>\$ 2,073</u>
Less amounts representing interest	(8)	
Present value of minimum payments	279	
Current portion	(221)	
Long-term portion	<u>\$ 58</u>	

**Indemnification:** In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves future claims that may be made against the Company but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations. No amounts associated with such indemnifications have been recorded to date.

**Contingencies:** From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. There were no contingent liabilities requiring accrual at April 30, 2018 and 2017.

As a result of the terms of grant income received in prior years, upon successful regulatory approval and following the first commercial sale of certain products, the Company will be required to pay royalty fees of up to \$1 million within 90 days of the first commercial sale of the product subject to certain caps and follow on payments depending upon commercial success and type of product. Given the stage of development of the current pipeline of products it is not possible to predict with certainty the amount or timing of any such liability.

#### Note 9. Income Taxes

The Company has incurred net losses since inception and, consequently, has not recorded any U.S. Federal and state income tax expense or benefit for the years presented. The Company files tax returns in the United Kingdom as well as U.S. Federal and various state tax returns. Tax years 2018 and 2017 in the U.K. subsidiary remain open to examination by the Her Majesty's Revenue and Customs ("HMRC"). Further, HMRC will be able to open an inquiry under the 'discovery assessment' for the 2014 tax year until April 30, 2018 if HMRC discovers facts which were not disclosed or readily inferable from the tax returns or accounts. The U.S. returns are open for all tax years since inception. The Company is not currently under examination in any jurisdiction for any tax years.

The components of the Company's loss before income taxes for the years ended April 30 consisted of the following:

	2018	2017	2016
Domestic	\$ (4,020)	\$ (2,110)	\$ —
Foreign	<u>(11,785)</u>	<u>(16,493)</u>	<u>(11,436)</u>
	<u>\$ (15,805)</u>	<u>\$ (18,603)</u>	<u>\$ (11,436)</u>



A reconciliation between the effective tax rates and statutory rates for the years ended April 30, is as follows:

	2018	2017	2016
Income tax benefit at U.S. federal statutory rate	30.40%	34.00%	34.00%
Foreign rate differential	(4.26)%	(11.72)%	(14.00)%
Nondeductible expenses	(16.34)%	(9.16)%	(6.85)%
Other	(4.52)%	(1.29)%	—
Effect of change in tax rates	(3.61)%	—	—
Valuation allowance	(1.67)%	(11.83)%	(13.15)%
	<u>0.00%</u>	<u>0.00%</u>	<u>0.00%</u>

The Company has net operating loss carry forwards available to offset future taxable income for federal and state income tax purposes. The ability to utilize the Company's domestic net operating losses is limited due to changes in ownership as defined by Section 382 of the Internal Revenue Code (the "Code"). Under the provisions of Sections 382 and 383 of the Code, a change of control, as defined in the Code, imposes an annual limitation on the amount of the Company's net operating loss and tax credit carryforwards, and other tax attributes that can be used to reduce future tax liabilities. The Company determined that an ownership change occurred as a result of the Company's transaction in November 2016. As a result of this ownership change, the Company's U.S. federal and California NOL carryforwards may be limited to the extent of recognizing any previously unrecognized built-in gains of Carbylan as of November 2016.

The tax effect of significant temporary differences representing deferred tax assets and liabilities as of April 30, 2018 and 2017 is as follows (in thousands):

	2018	2017
Net operating loss ("NOL") carryforwards	\$ 6,596	\$ 5,602
Other	240	282
Valuation allowance	(6,836)	(5,884)
Net deferred tax asset	<u>\$ —</u>	<u>\$ —</u>

Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of NOL carryforwards. As a result of the fact that the Company has incurred tax losses from inception, management has determined that it is more likely than not that the Company will not recognize the benefits of net deferred tax assets and, as a result, a full valuation allowance has been established against its net deferred tax assets as of April 30, 2018 and 2017. During the years ended April 30, 2018, 2017, and 2016 the valuation allowance changed by \$1.0 million, \$3.0 million and \$0.4 million, respectively. Realization of deferred tax assets is dependent upon the generation of future taxable income. As of April 30, 2018, the Company had NOL carryforwards for federal income tax purposes of approximately \$4.6 million that begin to expire in 2036, NOL carryforwards for state income taxes of \$3.4 million that begin to expire in 2036 and NOL carryforwards for U.K. income taxes of \$29.2 million that do not expire.

In December 2017, the Tax Cuts and Jobs Act ("TCJA") was signed into law. Among other things, the TCJA permanently lowers the corporate federal income tax rate to 21% from the existing maximum rate of 35%, effective for tax years including or commencing January 1, 2018. As a result of the reduction of the corporate federal income tax rate to 21%, U.S. GAAP requires companies to revalue their deferred tax assets and deferred tax liabilities as of the date of enactment, with the resulting tax effects accounted for in the reporting period of enactment. This revaluation resulted in a reduction of the Company's deferred tax assets of \$578,000 and a corresponding reduction in the valuation allowance. As a result, there was no impact on our consolidated statements of operations from the reduction in tax rate. The other provisions of the TCJA did not have a material impact on the consolidated financial statements.

The Company recognizes the financial statement effects of a tax position when it becomes more likely than not, based upon the technical merits, that the position will be sustained upon examination. The Company has no unrecognized tax benefits as of April 30, 2018 and 2017, respectively. The Company does not expect any material changes in the next 12 months in unrecognized tax benefits. The Company has not recognized interest and penalties related to uncertain tax positions.

**Note 10. Defined Contribution Plans**

Participation in a personal pension plan is available to all U.K. based employees of the Company upon commencement of their employment. Employer contributions are made in accordance with the terms and conditions of the employment contract. Employees may contribute in accordance with the prevailing statutory limitations. Employees of the U.S. parent company are eligible to participate in the Company's 401(k) Plan. The Company will match up to 4% of employee contributions to the Plan. Total employer contributions to both plans for the years ended April 30, 2018, 2017, and 2016 were \$219,000, \$90,000 and \$70,000 respectively.

**Note 11. Other Income**

As of April 30, 2018 and 2017, the Company had research and development tax credits totaling \$6.8 million and \$2.2 million, respectively. This tax credit is related to a tax scheme for small and medium enterprises in the United Kingdom as well as the R&D expenditure credit system. The Company is able to file a claim for cash credit in proportion to the Company's R&D expenditure for the year. This amount was included in other income, as it is a refundable credit that does not depend on the Company's ongoing tax status or position. The Company recognized \$4.4 million, \$2.3 million and \$2.0 million related to these programs in the years ended April 30, 2018, 2017, and 2016, respectively.

**Note 12. Unaudited Quarterly Financial Information (in thousands):**

	Quarter ended July 31, 2017	Quarter ended October 31, 2017	Quarter ended January 31, 2018	Quarter ended April 30, 2018
<b>Fiscal year 2018</b>				
Revenue	\$ 96	\$ 1,127	\$ 2,331	\$ 4,840
Operating expenses	5,549	7,064	6,677	7,809
Net loss	(4,928)	(4,986)	(5,234)	(657)
Net loss per share	\$ (0.51)	\$ (0.50)	\$ (0.49)	\$ (0.06)
	Quarter ended July 31, 2016	Quarter ended October 31, 2016	Quarter ended January 31, 2017	Quarter ended April 30, 2017
<b>Fiscal year 2017</b>				
Revenue	\$ 975	\$ 197	\$ 248	\$ 114
Operating expenses	6,095	4,223	8,365	5,200
Net loss	(3,436)	(3,297)	(7,644)	(4,202)
Net loss per share	\$ (6.66)	\$ (5.98)	\$ (1.03)	\$ (0.43)

**SERVICE AGREEMENT**

- (1) KALVISTA PHARMACEUTICAS LIMITED
  - (2) DR CHIRSTOPHER MARTYN YEA
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DATED: 1<sup>st</sup> November 2015

BETWEEN:

1. **KALVISTA PHARMACEUTICALS LIMITED** (company no. 07543947) whose registered office is at Building 227 Tetricus Science Park, Porton Down, Salisbury, Wiltshire, SP4 0JQ (the “**Company**”); and
2. **DR CHRISTOPHER MARTYN YEA** of \*\*\*\*\* (the “**Executive**”).

**RECITALS:**

- (A) The Company has requested the Executive to serve the Company as Chief Development Officer on the terms and conditions contained in this Agreement and the Executive has agreed so to do.
- (B) All references in this Agreement to legislation shall be deemed to include a reference to statutory amendments, statutory re-enactments or superseding legislation and all statutory regulations thereunder.
- (C) The clause headings in this Agreement are for the convenience of the parties only and shall not affect its interpretation in any way.

**OPERATIVE PROVISIONS**

**1. DEFINITIONS**

Unless the contrary intention appears, the following definitions apply:

“ <b>Board</b> ”	the board of directors of the Company from time to time or any committee of the board of directors to Which powers have been properly delegated. including a remuneration committee;
“ <b>Business</b> ”	the business carried on by the Company (or any part of the business carried on by the Company) as at the Termination Date or at any time during the Relevant Period and the business of any Group Company at the Termination Date, in either case in respect of which the Executive has been concerned or involved to any material extent and/or has possessed Confidential Information at any time during the Relevant Period;
“ <b>Change of Control</b> ”	occurs if a person who controls any body corporate ceases to do so or if another person acquires Control of it, but does not occur in the circumstances described in clause 17.6;

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<b>“Control”</b>	in relation to a body corporate , the power of a person to secure that the affairs of the body corporate are conducted in accordance with the wishes of that person (i) by means of the holding of shares, or the possession of voting power, in or in relation to that or any other body corporate or (ii) as a result of any powers conferred by the articles of association or any other document regulating that or any other body corporate;
<b>“Client”</b>	any person, firm, company or other entity (i) who or which at any time during the Relevant Period was to the knowledge of the Executive provided with goods or services by the Company or any Group Company or was negotiating with the Company or any Group Company for the supply of goods or services by the Company or any Group Company or (ii) about whom or which the Executive has confidential information, and in each case with whom or which the Executive or any person who reported directly to him had dealings at any time during the Relevant Period;
<b>“Commencement Date”</b>	the date of this Agreement;
<b>“Competing Business”</b>	any business in the fields of ophthalmology or hereditary angioedema (HAE) which competes or is preparing to compete with the business, carried on by the Company or any Group Company in which the Executive has been involved to a material extent during the Relevant Period;
<b>“Confidential Information”</b>	the information specified in clause 14.2;
<b>“Contractual Benefits”</b>	means the contractual benefits to which the Executive is entitled pursuant to clause 11.1 and 11.2;
<b>“Group Company”</b>	means any parent undertaking of the Company and any subsidiary undertaking of the Company or of any such parent undertaking (where “parent undertaking” and “subsidiary undertaking” have the meanings attributed to them under section 1162 Companies Act 2006);

<b>“Intellectual Property Rights”</b>	means all existing and future copyright, design rights, registered designs, trade marks, patents, domain names, database rights, applications for any of these, the right to apply for any of these and all other intellectual property rights, in any part of the world, for the full term and any renewals and extensions of such rights;
<b>“Key Employee”</b>	any officer or employee of or consultant to the Company or any Group Company earning £50,000 (including bonuses and commission, if any, but excluding any appropriate VAT) or more on an annualised basis of the Company or any Group Company with whom the Executive in the course of his employment has had dealings at any time during the Relevant Period;
<b>“Material”</b>	all ideas, information, methods, techniques, inventions, processes, reports, drawings, plans, research, know-how, systems, software, Confidential Information, creative works, concepts and other material produced, invented, created, developed, reduced to practice or discovered by the Executive (either alone or with others) relating to the business of the Company or pertaining to, resulting from or suggested by the work the Executive does for the Company (either alone or with others), during the term of this Agreement;
<b>“Material Interest”</b>	any direct or indirect interest, whether as an agent, beneficiary, consultant, director, employee, partner, proprietor, shareholder (other than a minority shareholder holding not more than 3% of any class of securities quoted or dealt in on Recognised Investment Exchange), or otherwise;
<b>“Recognised Investment Exchange”</b>	a recognised investment exchange or an overseas investment exchange, each as defined in section 285 of the Financial Services and Markets Act 2000;
<b>“Relevant Period”</b>	the period of 12 months immediately preceding the Termination Date;
<b>“Restricted Goods or Services”</b>	goods or services of a type provided by the Company or any Group Company at the Termination Date;



<b>“Share Plan”</b>	any share option, share award, share purchase or other share-based arrangement, however structured, operated by the Company, any Group Company or any third party;
<b>“Supplier”</b>	means any person, firm, company or other entity who or which at any time during the Relevant Period: (i) supplied goods or services (other than utilities and goods or services supplied for administrative purposes) to the Company or any Group Company or (ii) was negotiating with the Company or any Group Company to supply goods or services (other than utilities and goods or services supplied for administrative purposes) to the Company or any Group Company, and in each case with whom or which the Executive or any person who reported directly to him had material dealings at any time during the Relevant Period;
<b>“Termination Date”</b>	the date on which this Agreement terminates irrespective of the cause or manner; and
<b>“WTR”</b>	the Working Time Regulations 1998.

## **2. APPOINTMENT**

- 2.1 The Company shall employ the Executive and the Executive shall serve the Company as Chief Development Officer and shall serve any other Group Company as may from time to time be required by the Board upon the following terms and conditions.
- 2.2 The Company shall be entitled at any time to appoint any other person or persons to act jointly with the Executive.

## **3. TERM AND NOTICE**

- 3.1 The appointment under this Agreement shall commence on the Commencement Date and shall (subject to the terms of this Agreement) continue until the expiration of not less than three months’ prior written notice to be given by either party to the other.
- 3.2 The Executive’s period of continuous employment is deemed to have commenced on the Commencement Date.
- 3.3 Without prejudice to clause 3.4, on notice being served by either party for any reason to terminate this Agreement or at any time subsequently during the unexpired period of this Agreement, the Company may elect (but shall not be obliged) to terminate this Agreement summarily on payment to the Executive of his Salary only (at the rate then payable under clause 10) calculated over the unexpired period of this Agreement (subject to deduction of applicable tax and National Insurance Contributions) that would have been payable during the shorter of:
- 3.3.1 the minimum period of notice to which the Executive would have been entitled under clause 3.1; and

3.3.2 any unexpired period of notice.

3.4 Should this Agreement be terminated by the Company in accordance with clause 3.1 or clauses 17.1.1 to 17.1.6, the Company will pay the Executive severance pay (“Severance Pay”) within 10 working days of the Termination Date consisting of:

3.4.1 9 months’ basic Salary as per clause 10.1: and

3.4.2 9 months’ Contractual Benefits.

This clause 3.4 will not apply where the Executive resigns or the Company terminates this Agreement pursuant to clauses 17.1.7 to 17.1.13.

3.5 Where the Executive is entitled to Severance Pay, and should he receive a payment in lieu in accordance with clause 3.3, the Severance Pay will be reduced by the amount paid to the executive during the period of notice.

3.6 If there is a Change of Control of the Company, or the Executive’s employment is transferred to an entity other than the Company or any Group Company pursuant to the Transfer of Undertakings (Protection of Employment Regulations 2006 (a “Transfer”), the Executive may serve one month’s notice to terminate this Agreement within three months following the Change of Control or Transfer, and receive the Severance Pay.

#### **4. HOURS OF WORK**

The Executive’s normal working hours are 9.0.0 am - 5.30 pm but he will work such additional hours (including at weekends), without additional pay, as are reasonably necessary in order for him properly to carry out his duties under this Agreement. By signing this Agreement the Executive agrees to exclude Regulation 4(1) WTR.

#### **5. DUTIES AND POWERS**

The Executive will perform such duties and exercise such powers on behalf of the Company as may from time to time be assigned or delegated to or vested In him by the Board and such duties and powers may relate or concern the business of any Group Company consistent with his status as Chief Development Officer.

#### **6. OBLIGATIONS**

6.1 During the continuance of this Agreement the Executive will, unless prevented by ill health or accident:

6.1.1 devote the whole of his working time, skill, ability and attention to the business of the Company;

6.1.2 in all respects conform to and comply with lawful directions given and regulations made by the Board;

- 6.1.3 ensure that the Board is aware as soon as practicable of any matter that might affect the interests of the Company and/or any Group Company;
- 6.1.4 at all times comply with the codes, policies, procedures and rules of the Company and any Group Company and of any association of professional body to which the Company and any Group Company and/or the Executive may from time to time belong;
- 6.1.5 well and faithfully serve the Company and use his utmost endeavours to promote its interests; and
- 6.1.6 generally co-operate to the fullest extent with the Board and any delegated authority from the Board.

## **7. RESTRICTIONS DURING EMPLOYMENT**

- 7.1 Other than in the proper and normal course of his duties, the Executive will not at any time during the continuance of his employment , without the prior written consent of the Board:
  - 7.1.1 have any Material interest in any trade, business or occupation whatsoever other than the business of the Company or any Group Company;
  - 7.1.2 incur on behalf of the Company or any Group Company any capital expenditure in excess of such sum as may be authorised from time to time by resolution of the Board;
  - 7.1.3 enter into on behalf of the Company or any Group Company any commitment, contract or arrangement which is otherwise than in the normal course of the Company's or the relevant Group Company's business or is outside the scope of his normal duties or authorisations or is of an unusual or onerous or longterm nature;
  - 7.1.4 engage any person on terms which vary from those established from time to time by resolution of the Board;
  - 7.1.5 employ or engage or attempt to employ or engage, induce, solicit or entice away or attempt to induce, solicit or entice away any agent, consultant, employee, officer or worker of the Company or any Group Company;
  - 7.1.6 directly or indirectly make preparations to compete with any business carried on by the Company or any Group Company;
  - 7.1.7 induce or attempt to induce any Client or customer of the Company or any Group Company to cease conducting any business or to reduce the amount of business or adversely to vary the terms upon which any business is conducted with the Company or any Group Company or to exclude the Company or any Group Company from new business opportunities in relation to goods or services of a kind normally dealt in by the Company or any Group Company;
  - 7.1.8 inform any agent, client, consultant, customer, employee , officer, supplier or worker of the Company or any Group Company or any third party agent who may be in the habit of dealing with the Company or any Group Company that he may resign or has resigned from the Company or any Group Company or that he has accepted employment with or is to join or be associated with any competitor of the Company or any Group Company.

7.2 Notwithstanding Clause 7.1, the Executive may hold office as a non-executive director of a business which is not a Competing Business with the prior written consent of the CEO of the Company.

7.3 Notwithstanding Clause 7.1, the Executive may be engaged as a consultant of Vantia Limited.

## **8. INFORMATION**

The executive will at all times and as soon as reasonably practicable give to the Board (in writing if so requested) or such person as the Board may from time to time determine all information, advice and explanations as it may reasonably require in connection with matters relating to his employment under this Agreement or with the business of the Company generally.

## **9. LOCATION**

9.1 The Executive's normal place of work will be Tetricus Science Park, Salisbury, but the Company reserves the right to change this, whether on a permanent or temporary basis, to any place within the United Kingdom. If the Company requires the Executive to work permanently at a place which necessitates a move from his address at the time, any such change will only be effected after reasonable consultation.

9.2 The Executive must travel to such places and at such times and for such periods (whether within or outside the UK) as may be reasonably necessary for the proper performance of his duties. The Company does not envisage at the present time that the Executive will be required to work outside the United Kingdom for a continuous period of more than one month during his employment. The Executive will be given written notification if there is a change in this position.

## **10. REMUNERATION AND BENEFITS**

10.1 Subject to the provisions of this clause the Executive will be entitled to a salary at the rate of £153,000 per annum (the "Salary"). Such Salary shall accrue from day to day and will be paid monthly in arrears on such day of each calendar month as the Company may nominate.

10.2 The Executive's Salary will be reviewed annually by the Board in each calendar year unless otherwise agreed. Any increase awarded will be entirely a matter for the discretion of the Board.

10.3 The Executive will be eligible to participate in a discretionary performance related bonus each year dependent upon the achievement of pre-determined personal and corporate objectives. In making any bonus award, the Board will assess the Executive's success in achieving the pre-determined objectives and any bonus will only be paid if the Executive remains in the Company's employment and is not under notice (either given or received) on the bonus payment date. The target amount of bonus for which the Executive will be eligible will be 25% of the Executive's Salary (less applicable tax and National Insurance contributions) and which shall be remitted in the proportions and on the basis set out in clause 10.1.

10.4 The Company will be entitled to deduct from any amount payable to the Executive by way of salary or otherwise under or in relation to this Agreement any amount required by law to be deducted including, but without limitation; income tax and National Insurance contributions and any other amount for the time being due and owing by the Executive to the Company including the recoupment of the lease premium, if any.

## **11. INSURED BENEFITS AND PENSION**

11.1 During the period of this Agreement, the Company will procure and maintain:

- 11.1.1 a policy of private medical insurance cover for the Executive and his spouse or civil partner and his children under 25 years;
- 11.1.2 a policy of life assurance of not less than three times the Executive's Salary under Clause 10.1; and
- 11.1.3 a policy of permanent health insurance for the Executive.

Such insured benefits will be pursuant to schemes of the Company's choice and the Executive will be responsible for any taxation or statutory levy assessed upon him in respect of such benefit. Any entitlement to benefit from those schemes is conditional upon the Executive (and spouse/civil partner and children) satisfying all the conditions imposed by the insurer and subject always to the rules of such schemes. The Company reserves the right to vary the cover provided under such schemes and the provider of the benefit, in its discretion, from time to time.

11.2 During each year of the Executive's employment the Company shall contribute an amount equal to 6% of his Salary to the Company's pension scheme (the "Scheme") subject to the rules of the Scheme as may be amended from time to time. Full details of the Scheme are available on request from the Company.

## **12. EXPENSES AND TRAVEL ALLOWANCE**

The Executive will make such journeys on the business of the Company as may be reasonably required of him. All reasonable travelling, hotel and other expenses wholly, exclusively and necessarily incurred by- him in the performance of his business duties under this Agreement will be reimbursed to him monthly by the Company on production of appropriate vouchers or receipts.

## **13. HOLIDAYS**

13.1 The Company's holiday year runs from 1st January to 31st December.

13.2 In each holiday year the Executive will be entitled to 28 days' paid holiday plus public holidays (pro-rata for part-time staff).

13.3 Application for leave of absence must be submitted in writing on the appropriate leave forms. The Executive must complete such holiday request forms as requested by the Company. Proposed holiday dates must be agreed in advance with the Executive's supervisor. Such agreement is to be obtained before the Executive has committed to bookings or any other alternative positive arrangements.

13.4 The Company reserves the right to nominate up to 4 days of holiday entitlement to be taken in the event that the Company decides to close the business over the Christmas/New Year period. The Executive will be notified by the Company either individually or by way of a general notice to staff no later than 31st January in each year of the number of days holiday required to be retained for this purpose.

- 13.5 Up to 5 days holiday can be carried over to a subsequent year. Should the Executive wish to carry over holiday entitlement in addition to this, the express permission of the CEO will be required. The Executive will not be entitled to receive pay in lieu of any unused holiday entitlement except in accordance with clause 13.6 and 13.7 below.
- 13.6 In the year of commencement or termination of employment, holiday entitlement will be calculated on a pro-rata basis for each complete month worked. On termination of employment at the discretion of the Company the Executive may be required to take outstanding holiday during the notice period. Alternatively, the Executive will be paid in lieu of any unused holiday entitlement. The Executive will be required to repay the Company for holiday taken in excess of entitlement and any sums so due may be deducted from any money owing to the Executive.
- 13.7 For the purpose of calculating any pay due or owed in accordance with clause 13.6 above, one day's pay shall be 1/260 of the basic annual Salary.
- 13.8 The Company reserves the right to require the Executive to work on a public holiday in return for which the Executive shall be entitled to extra holiday, equal to the period worked, to be taken as agreed with the Executive's supervisor.

#### **14. CONFIDENTIALITY**

- 14.1 The Executive recognises that confidential information (which may include commercially sensitive information) is important to the business of the Company and will from time to time become known to the Executive. The Executive acknowledges that the following restraints are necessary for the reasonable protection of the Company, of its business, the business of the other Group Companies, its or their clients, customers and their respective affairs,
- 14.2 The Executive will during the continuance of his employment and after the Termination Date observe strict secrecy as to the affairs and dealings of the Company and any Group Company and (1) will not during the continuance of his employment (except in the proper performance of his duties of employment) or after the Termination Date (without limit in time), without the prior written consent of the Board, make use of or divulge to any person and (2) during the continuance of his employment, will use his best endeavours to prevent the publication or disclosure of:
- 14.2.1 financial information relating to the Company and any Group Company including (but not limited to) management accounts, sales forecasts, dividend forecasts, profit and loss accounts and balance sheets, draft accounts, results, order schedules, profit margins, pricing strategies and other information regarding the performance or future performance of the Company or any Group Company;
  - 14.2.2 client or customer lists and contact lists, details of the terms of business with, the fees and commissions charged to or by and the requirements of customers or clients, prospective customers or clients, buyers and suppliers of the Company or any Group Company;
  - 14.2.3 any information relating to expansion plans, business strategy, marketing plans, and presentations, tenders, projects, joint ventures or acquisitions and developments contemplated, offered or undertaken by the Company or any Group Company;
  - 14.2.4 A details of the employees, officers and workers of and consultants to the Company or any Group Company, their job skills and capabilities and of the remuneration and other benefits paid to them;

- 14.2.5 copies or details of and information relating to the Materials, know-how, research activities, inventions, creative briefs, ideas, computer programs (whether in Source code or object code) secret processes, designs and formulae or other intellectual property undertaken, commissioned or produced by or on behalf of the Company or any Group Company;
- 14.2.6 confidential reports or research commissioned by or provided to the Company or any Group Company and any trade secrets and confidential transactions of the Company or any Group Company;
- 14.2.7 details of any marketing, development, pre-selling or other exploitation of any intellectual property or other rights of the Company or any Group Company, any proposed options or agreements to purchase, licence or otherwise exploit any intellectual property of the Company or any Group Company, any intellectual property which is under consideration for development by the Company or any Group Company, any advertising, marketing or promotional campaign which the Company or any Group Company is to conduct; and
- 14.2.8 any information which the Executive ought reasonably to know is confidential and any information which has been given to the Company or any Group Company in confidence by agents, buyers, clients, consultants, customers, suppliers or other persons.
- 14.3 The list in clause 14.2 is indicative only and is not exhaustive.
- 14.4 The obligations contained in clause 14.2 will cease to apply to the Confidential Information upon it coming into the public domain, other than as a result or in connection with the direct or indirect disclosure by the Executive in breach of clause 14.2.
- 14.5 The Executive undertakes that he will not while an employee of the Company nor after the Termination Date disclose, publish or reveal to any unauthorised person any incident, conversation or information concerning any director, employee, agent or consultant of the Company or any Group Company or any of its customers, guests or visitors which comes to his knowledge during the continuance of his employment, or any incident, conversation or information relating to his employment by the Company unless duly authorised in advance in writing by the Board so to do. The Executive acknowledges and understands that this undertaking includes an agreement on his part not to publish or procure or facilitate or encourage the publication of any such matter in any book, newspaper, periodical or pamphlet or by broadcasting on television, cable, satellite, film, internet or any other medium now known or devised after the date of this Agreement or by communication to any third party including a representative of the media.
- 14.6 The Executive will not at any time during the continuance of his employment with the Company make otherwise than for the benefit of the Company (or any Group Company for whom the Executive is directed to provide his services) any notes or memoranda relating to any matter within the scope of the business of the Company or any Group Company or concerning any of the dealings or affairs of the Company or any Group Company.
- 14.7 Nothing in this Agreement shall preclude the Executive from making a protected disclosure as the same is defined in section 43A Employment Rights Act 1996.

**15. COMPANY PROPERTY**

- 15.1 The Executive shall promptly whenever requested by the Company and in any event upon the termination of this Agreement (for whatsoever cause) deliver up to the Company or its authorised representative all statistics, documents, records or papers, software, tapes, disks, cassettes, programs, notes or memoranda which may be in his possession or under his control and which relate in any way to the property, business or affairs of the Company or any Group Company and no copies or extracts will be retained by him and he will at the same time deliver up to the Company or its authorised representative all credit cards, motor cars, motor keys, computers, laptops, personal organisers, mobile phones and all other property of the Company or any Group Company in his possession or under his control.
- 15.2 The Company may withhold any sums owing to the Executive on the termination of his employment until the obligations in clause 15.1 have been complied with.

**16. INTELLECTUAL PROPERTY**

- 16.1 The Executive will promptly disclose and deliver all Material to the Company, or as it may direct. To the extent the executive becomes aware of anything he reasonably considers will be patentable he will inform the Company of it. The Company will be entitled to make such use of the Material as it deems appropriate (including seeking any Intellectual Property Rights protection for the same) and the Executive will not use the Material in any manner, save as is necessary in performing his duties pursuant to this Agreement, and will keep confidential and will not disclose, or permit any third party to use, the Material and/or Intellectual Property Rights, in any manner, at any time either during or after the term of this Agreement.
- 16.2 To the extent that the Intellectual Property Rights have not vested in the Company by operation of law, the Executive hereby irrevocably assigns to the Company, including by way of future assignment, with full title guarantee, absolutely and free from all encumbrances, all his legal and beneficial right, title and interest in any and all Intellectual Property Rights in, or relating to, the Material together with all accrued rights of action in respect of any infringement of any such Intellectual Property Rights, including without limitation the right to apply for patent protection.
- 16.3 The Executive will, without charge to, but at the cost and expense of, the Company, execute and do all such acts, matters, documents and things as may be necessary or reasonably required to obtain patent, decision or other protection for any of the Material or improvements or developments of or to the Material and to vest title to the Intellectual Property Rights in, or relating to, the Material in the Company (or such company as it directs) absolutely.
- 16.4 To the extent permitted by law, the Executive hereby irrevocably and unconditionally waives any and all moral rights conferred by Chapter IV of the Copyright, Designs and Patents Act 1988 or any rights of a similar nature under law now or in the future in force in any other jurisdiction in and to any and all Material, such waiver in favour of the Company, its successors in title and assigns.
- 16.5 The provisions of this clause will not be affected by reason of the termination of this Agreement for whatever reason and will continue after it ends.
- 16.6 The Company is under no obligation to apply for or seek to obtain patent, design or other protection in relation to any of the Material or in any way to use, exploit or seek to benefit from any of the Material.



16.7 The Executive hereby warrants and agrees that all Material created by him will be created solely by him and will be original and/or if created by or with a third party he has obtained a full unconditional assignment of any and all Intellectual Property Rights on or relating to such Material.

**17. TERMINATION**

17.1 The Company will be entitled to terminate this Agreement at any time, without giving the period of notice set out in clause 3.1 or payment in lieu of such notice, by summary notice in writing if the Executive:

17.1.1 is adjudicated bankrupt or makes any arrangement or composition with his creditors;

17.1.2 becomes a patient under any statute dealing with mental health;

17.1.3 resigns as a director of the Company or any Group Company otherwise than at the request of the Board or the directors of any Group Company;

17.1.4 is incapacitated due to sickness, or disability or mental illness for a continuous period of 60 working days or for periods aggregating 60 working days in any consecutive period of 12 months (notwithstanding the fact that such dismissal would terminate the Executive's entitlement under any permanent health or permanent disability insurance scheme in force in respect of the Executive);

17.1.5 is found to be addicted or habitually under the influence of alcohol or any drug, the possession of which is controlled by law (other than any drug prescribed for the Executive by a medical practitioner);

17.1.6 neglects to carry out any action, where the effect of so doing may, in the reasonable opinion of the Board, seriously damage the interests of the Company or any Group Company or negligently breaches any legislation or any regulation to which the Company or any Group Company may be subject which results in any penalties being imposed on him or any penalties being imposed on any directors of the Company or any Group Company or the Company itself;

17.1.7 wilfully carries out, or wilfully neglects to carry out any act ion , where the effect of so doing may, in the reasonable opinion of the Board, seriously damage the interests of the Company or any Group Company or wilfully breaches any legislation or any regulation to which the Company or any Group Company may be subject which results in any penalties being imposed on him or any penalties being imposed on any directors of the Company or any Group Company or the Company itself;

17.1.8 is guilty of any serious breach of any of the provisions of this Agreement or directions of the Board or is guilty of any continued or successive breaches of any of such provisions or directions having received a written warning by the Board;

17.1.9 is convicted of any criminal offence (other than a minor motoring offence that does not render him unable properly to discharge his duties);

17.1.10 commits any other act warranting summary termination at common law;

- 17.1.11 knowingly commits any deliberate act of discrimination, victimisation or harassment on any unlawful ground;
- 17.1.12 commits a material breach of any of the provisions of the articles of association of the Company; or
- 17.1.13 is disqualified from being a director of a company by reason of an order made by a competent court.

The termination by the Company of the appointment will be without prejudice to any claim which the Company may have for damages arising from a breach of this Agreement by the Executive.

- 17.2 Any delay or forbearance by the Company in exercising any right of termination hereunder will not constitute a waiver of such right.
- 17.3 The Company is under no obligation to vest in or assign to the Executive any powers or duties or to provide any work for the Executive and the Company will have the right (in its absolute discretion): (i) during the whole or any part of any period of notice to terminate this Agreement; and/or (ii) otherwise when in the opinion of the Board the interests of the Company so require, suspend the Executive from the performance of his duties and/or require the Executive:
  - 17.3.1 not to perform his duties and/or to carry out alternative duties of a broadly similar nature to the work he normally performs; and/or
  - 17.3.2 to abstain from contacting any client, consultant, customer, supplier, adviser, agent, director, employee or worker of the Company or of any Group Company); and/or
  - 17.3.3 not to enter any premises of the Company or any Group Company; and/or
  - 17.3.4 to resign from any or all offices in the Company and any Group Company; and/or
  - 17.3.5 to return to the Company all documents and other materials (including copies) belonging to the Company and/or any Group Company except that (subject to the provisions of clause 14) the Executive will be entitled to retain until the Termination Date or for as long as he continues as a director of the Company or any Group Company copies of board papers received by him during the course of his employment in his capacity as a director of the Company or any Group Company.
- 17.4 Salary and, subject clause 11, Contractual Benefits (excluding bonus and share options) will not cease to be payable to the Executive by reason of any suspension or exclusion pursuant to clause 19.3 and the Executive will throughout any such period of suspension or exclusion continue to be an employee of the Company and will continue to be bound by the duty of fidelity and by the terms of this Agreement and may not directly or indirectly be employed by nor provide services to any third party, except subject to clause 7.3, nor make any preparations to compete with the Company or any Group Company.
- 17.5 If the employment of the Executive is terminated:
  - 17.5.1 by reason of the liquidation of the Company for the purposes of amalgamation or reconstruction; or

- 17.5.2 as part of any arrangement for the amalgamation of the undertaking of the Company not involving liquidation or for the transfer of the whole or part of the undertaking of the Company to any of its subsidiaries or associates; and
- 17.5.3 the Executive is offered employment of a similar nature with the amalgamated or reconstructed or transferee company on terms not generally less favourable to him than the terms of this Agreement,

the Executive will have no claim against the Company or Group Company or associate of the Company in respect of that termination.

## **18. SICKNESS**

- 18.1 If the Executive is at any time prevented by ill health from performing his duties under this Agreement he will, if required, furnish the Board with evidence satisfactory to them of his incapacity. Subject to that, he will receive his full remuneration for the first 60 working days off due to ill health in any period of 12 consecutive months (payment to be inclusive of any statutory sick pay or social security benefits to which he may be entitled). If he continues to be incapacitated for a period longer than 60 working days in any period of 12 consecutive months, then any further remuneration payable to him will be at the express discretion of the Board without prejudice to the Company's right to dismiss the Executive under clause 17.1.4 above.
- 18.2 If so required by the Board at any time, (and whether or not the Executive is absent by reason of sickness, injury or other incapacity) the Executive will undergo, at the expense of the Company, medical or psychological examinations by such doctor or doctors as the Board nominates. The Executive authorises the Company pursuant to the Access to Medical Reports Act 1988 to have unconditional access to any such report (including copies of and documents referred to in such reports) prepared as a result of any such examination and authorises the doctor(s) concerned to discuss the same with any appropriate representative of the Company.
- 18.3 If the Executive is absent from his employment as a result of sickness or injury he will:
- 18.3.1 notify the Company by telephone as soon as practicable on the first day of his absence;
  - 18.3.2 if the period of absence is less than eight consecutive calendar days, submit to the Company on his return a certificate of sickness completed by himself;
  - 18.3.3 if the period of absence is eight consecutive calendar days or more, submit to the Company without delay a medical certificate signed by a practising medical practitioner in respect of the duration of the absence after the first week and will send further medical certificates in respect of any continued absence every seven days.
- 18.4 The Company may also require a medical certificate from the Executive's doctor and/or any doctor(s) nominated by it, confirming that the Executive is fit to return to work after any period of absence. The Company has the right to postpone the Executive's return to work (and the continuance or reinstatement of his normal pay, if appropriate) until the Company's nominated doctor has confirmed he is fit to return to his current role and duties.

**19. GRIEVANCE, DISMISSAL AND DISCIPLINARY PROCEDURES**

- 19.1 The disciplinary rules applicable to the Executive are set out in the Company's dismissal and disciplinary policy.
- 19.2 The Company's dismissal and disciplinary policy from time to time sets out the procedure applicable to the taking of disciplinary decisions relating to the Executive or to a decision to dismiss the Executive.
- 19.3 The Company may at any time and from time to time in its discretion suspend the Executive from his duties on payment of full Salary and/or exclude the Executive from any premises of the Company and/or any Group Company whilst it carries out any investigation or disciplinary process.
- 19.4 If the Executive is dissatisfied with a disciplinary decision relating to him or any decision to dismiss him he should apply in accordance with the procedure set out in the Company's dismissal and disciplinary policy, in writing to the Chairman. If the Executive wishes to seek redress of any grievance relating to his employment, he should apply in accordance with the procedure set out in the Company's grievance procedure, in writing to the Chairman. Further details are given in the relevant policies.
- 19.5 The Executive hereby agrees that he will not at any time after the termination of this Agreement either personally or by his agent, directly or indirectly, falsely represent himself as being in any way still connected with or interested in the business of the Company.

**20. PROTECTION OF THE COMPANY'S INTERESTS**

- 20.1 The Executive agrees with the Company that he will not directly or indirectly:
- 20.1.1 for a period of six months immediately following the Termination Date:
- 20.1.1.1 carry on or be interested in a Competing Business, save that he may hold up to 3% of any class of securities quoted or dealt in on a recognised investment exchange or 20% of any class of securities not so dealt;
  - 20.1.1.2 act as a consultant, employee or officer or any other capacity in a Competing Business;
  - 20.1.1.3 either on his own account or on behalf of any Competing Business supply Restricted Goods or Services to any Client;
  - 20.1.1.4 on behalf of any Competing Business deal with a Client;
  - 20.1.1.5 either on his own account or for any person, firm or company or other undertaking employ or otherwise engage the services of any Key Employee whether or not any such Key Employee would in entering into the employment or engagement commit a breach of contract;
  - 20.1.1.6 either on his own account or on behalf of any Competing Business deal with a Supplier;

- 20.1.2 for a period of 12 months immediately following the Termination Date:
- 20.1.2.1 either on his own account or for any company, firm, person or other undertaking induce, solicit or entice or endeavour to induce, solicit or entice any Key Employee to cease working for or providing their services to the Company or any relevant Group Company whether or not any such Key Employee would by entering into the employment or engagement commit a breach of contract;
  - 20.1.2.2 either on his own account or on behalf of any Competing Business directly or indirectly induce, solicit or entice or endeavour to induce, solicit or entice any Client to cease conducting any business with the Company or any Group Company or to reduce the amount of business conducted with the Company or any Group Company or adversely to vary the terms upon which any business is conducted with the Company or any Group Company or to exclude the Company or any Group Company from new business opportunities in relation to any Restricted Goods or Services;
  - 20.1.2.3 on behalf or any Competing Business directly or indirectly induce, solicit or entice or endeavour to induce, solicit or entice any Supplier to cease conducting business with the Company or any Group Company or to reduce the amount of business conducted with the Company or any Group Company or adversely to vary the terms upon which any business is conducted with the Company or any Group Company.
- 20.2 The Executive will not at any time after the Termination Date or, if later, the date on which he ceases to be a director of the Company or any Group Company) present himself or allow himself to be held out or presented as being in any way connected with or interested in the business of the Company or any Group Company (other than as a shareholder or consultant, if that is the case).
- 20.3 The Executive agrees that each of the restrictions set out in sub-clauses 20.1.1 to 20.1.2.2 constitute entirely separate, severable and independent restrictions on him. The Executive acknowledges that he has had the opportunity to receive independent legal advice on the terms and effect of the provisions of this Agreement, including the restrictions above.
- 20.4 The duration of each of the restrictions set out in clause 20.1 above will be reduced pro rata by any period during which the Company suspends the Executive from the performance of his duties pursuant to clause 17.3 above.
- 20.5 If the Executive accepts employment or engagement (whether as a consultant or in any other capacity) with any third party during the period of any of the restrictions set out in clause 20.1 he will on or before such acceptance provide the third party with full details of these restrictions.
- 20.6 The Executive will not induce, procure, authorise or encourage any other person, firm, corporation or organisation to do or procure to be done anything that if done by the Executive would be a breach of any of the provisions of sub-clauses 20.1.1 to 20.1.2.2.

20.7 Other than when the Executive exercises his right under clause 3.6 above, if the Executive's employment is transferred to an entity other than the Company or any Group Company ("the new employer") pursuant to the Transfer of Undertakings (Protection of Employment) Regulations 2006, he will, if required, enter into an agreement with the new employer that will contain provisions that provide protection to the new employer similar to that provided to the Company and any Group Company in clauses 20.1.1 to 20.1.2.2 above.

## **21. APPLICATION OF RESTRICTIONS**

21.1 The Executive agrees that the restrictions in clause 20 above are no wider or more restrictive than is reasonably necessary for the protection of the goodwill, trade connections, employee base and Confidential Information of the Business.

21.2 The benefit of the restrictions in clause 20 above extend to any Group Company and the Company contracts as trustee for any other Group Company that (without prejudice to the Company's right to enforce any such restriction both for itself and for any other Group Company) any such other Group Company may enforce the same against the Executive. The Executive will at any time (whether before or after the Termination Date) upon written request execute under seal directly with any other Group Company a deed or deeds in its favour provided that the same does not contain restrictions or other provisions which are more restrictive or onerous than those contained in this Agreement.

21.3 It is hereby agreed and declared that each of the restrictions contained in clause 20 of this Agreement shall be read and construed independently of the others and that all such restrictions are considered reasonable by the parties to this Agreement but, in the event that any such restriction shall be found or held to be void in circumstances where it would be valid if some part of it were deleted, the parties to this Agreement agree that such restriction shall apply with such deletion as may be necessary to make it valid and effective and that any such modification shall not affect the validity of any other restriction contained in this Agreement.

21.4 If the Company requires the Executive not to perform any of his duties and/or excludes the Executive from the Company's premises as set out in clause 20 above for some or all of any period of notice ("Garden Leave Period"), the period of the post-termination restrictions set out in clause 20 will be reduced by the length of the Garden Leave Period served before the Termination Date.

## **22. DIRECTORSHIP**

22.1 The Executive will, if so requested, become a director of the Company or any Group Company and remain in such capacity without any additional remuneration.

22.2 In the event of the Executive holding office as a director of the Company or any Group Company at the date of his ceasing for any reason to be an employee of the Company he will immediately, if so required by the Board, resign such directorship without compensation but without prejudice to his rights under this Agreement.

22.3 In the course of any such directorship the Executive will act at all times in the best interests of the Company and shall adhere to the highest standards of corporate governance applicable to a company of the size and nature of the Company.

**23. DATA PROTECTION**

- 23.1 The Executive consents to the Company and/or any Group Company and its or their duly authorised agents and employees holding and processing both electronically and manually the data (including personal sensitive data and information contained in email, email attachments and other forms of electronic communications) it collects, stores or processes which relates to the Executive, in the course of the Executive's employment, for the purposes of the administration and management of its employees and its business and for compliance with applicable procedures, laws and regulations. It may also be necessary for the Company and/or any Group Company to forward such data to other offices it may have or to another Group Company outside the European Economic Area where such a company has offices for storage and processing for administration purposes and the Executive consents to the Company and/or any Group Company doing so as may be necessary from time to time.
- 23.2 To ensure regulatory compliance and for the protection of its workers, clients/customers and business, the Company reserves the right to monitor, intercept, review and access the Executive's telephone log, internet usage, voicemail, email and other communication facilities provided by the Company which the Executive may use during his employment. The Company will use this right of access reasonably but it is important that the Executive is aware that communications and activities on the equipment or premises of the Company and any Group Company cannot be presumed to be private.
- 23.3 The Executive agrees to abide by the terms of the Company's email/communications policy from time to time in force.

**24. POWER OF ATTORNEY**

The Executive hereby irrevocably and by way of security appoints the Company and each other director of the Company from time to time, jointly and severally to be his attorney in his name and on his behalf to perform, sign, execute and deliver all acts, things and documents which he is obliged to execute and perform, sign and execute under the provisions of this Agreement (including, but not limited to clauses 16.3 and 22.2) and the Executive hereby agrees immediately on the request of the Company to ratify and confirm all such acts, things and documents signed, executed or performed in the pursuance of this power.

**25. NOTICES**

Any notice under this Agreement will be given in writing by either party to the other and will be deemed to be duly served if hand delivered or sent by facsimile or by first-class pre-paid post addressed, in the case of the Company, to its registered office marked for the attention of the Secretary of the Company and in the case of the Executive, to his address last known to the Company. Any such notice will, in the case of delivery, be deemed to have been served at the time of delivery and, in the case of posting, on the expiration of 48 hours after it has been posted by first-class mail.

**26. OTHER AGREEMENTS**

The Executive acknowledges and warrants that this is the entire and only agreement and understanding of the parties and that there are no agreements or arrangements whether written or oral between the Company and the Executive relating to the employment of the Executive. This Agreement supersedes all previous arrangements between any Group Company and the Executive as to the employment of the Executive. The Executive acknowledges that he is not entering into this Agreement in reliance upon any representation not expressly set out in this Agreement. In particular, no collective agreement forms any part of the Executive's terms of employment.

**27. COUNTERPARTS**

This Agreement may be executed in any number of counterparts and by the parties to it on separate counterparts, each of which will be an original but all of which together will constitute one and the same instrument. The Agreement is not effective until each party has executed at least one counterpart and it has been received by the other party (transmission by facsimile being acceptable for this purpose) and the Agreement has been dated by agreement between the representatives of the parties.

**28. GOVERNING LAW AND JURISDICTION**

The validity, construction and performance of this Agreement and any claim, dispute or matter arising under or in connection with it or its enforceability will be governed by and construed in accordance with the laws of England and Wales. Each party irrevocably submits to the exclusive jurisdiction of the Courts of England over any claim, dispute or matter arising under or in connection with this Agreement or its enforceability or the legal relationships established by this Agreement.



THIS DEED has been executed by or on behalf of the parties on the date written at the top of page 1.

EXECUTED as a DEED )

by KALVISTA PHARMACEUTICALS LIMITED )

acting by: )

/s/ T. Andrew Crockett , Director

\_\_\_\_\_, Secretary

SIGNED as a DEED and DELIVERED ) /s/ Christopher Martyn Yea

by DR CHRISTOPHER MARTYN YIZA )

in the presence of: )

*Witness signature:* /s/ Clive Balcombe

*Witness name:* Clive Balcombe

*Witness address:* \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**EXHIBIT 23.1**

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in Registration Statement Nos. 333-2152815 and 333-217009 on Form S-3 and Registration Statement Nos. 333-203721, 333-215184, 333-216032 and 333-217008 each on Form S-8 of our report dated July 30, 2018, relating to the financial statements of KalVista Pharmaceuticals, Inc. appearing in this Annual Report on Form 10-K of KalVista Pharmaceuticals, Inc. for the year ended April 30, 2018.

/s/ Deloitte & Touche LLP  
Boston, Massachusetts

July 30, 2018

## **EXHIBIT 23.2**

### **CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in Registration Statement Nos. 333-215185 and 333-217009 each on Form S-3 and Registration Statement Nos. 333-203721, 333-215184, 333-216032 and 333-217008 each on Form S-8 of our report dated August 22, 2016 (July 27, 2017 as to the effects of the adjustment of net loss per share arising from the Carbylan transaction discussed in Note 2 and the misstatement of other comprehensive loss discussed in Note 2), relating to the financial statements of KalVista Pharmaceuticals Limited (which report expresses an unqualified opinion and includes an emphasis of matter paragraph relating to the restatement of other comprehensive loss discussed in Note 2) appearing in this Annual Report on Form 10-K of KalVista Pharmaceuticals, Inc. for the year ended April 30, 2018.

/s/ Deloitte LLP  
Reading, United Kingdom

July 30, 2018

**CERTIFICATION PURSUANT TO  
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, T. Andrew Crockett, certify that:

1. I have reviewed this Annual Report on Form 10-K of KalVista Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 30, 2018

By: /s/ T. Andrew Crockett  
T. Andrew Crockett  
Chief Executive Officer

**CERTIFICATION PURSUANT TO  
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Benjamin L. Palleiko, certify that:

1. I have reviewed this Annual Report on Form 10-K of KalVista Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 30, 2018

By: /s/ Benjamin L. Palleiko  
Benjamin L. Palleiko  
Chief Financial Officer

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, T. Andrew Crockett, Chief Executive Officer of KalVista Pharmaceuticals, Inc. (Company), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- this Annual Report on Form 10-K of the Company for the year ended April 30, 2018 (Report), as filed with the Securities and Exchange Commission, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- the information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: July 30, 2018

By: /s/ T. Andrew Crockett  
T. Andrew Crockett  
Chief Executive Officer

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Benjamin L. Palleiko, Chief Financial Officer of KalVista Pharmaceuticals, Inc. (Company), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- this Annual Report on Form 10-K of the Company for the year ended April 30, 2018 (Report), as filed with the Securities and Exchange Commission, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- the information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: July 30, 2018

By: /s/ Benjamin L. Palleiko  
Benjamin L. Palleiko  
Chief Financial Officer

