UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(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, 2025
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

KalVista Pharmaceuticals, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**20-0915291**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
55 Cambridge Parkway Suite 901 East Cambridge, Massachusetts	**02142**
(Address of principal executive offices)	**(Zip Code)**

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

Securities registered pursuant to Section 12(g) of the Act

Title of Each Class	**Trading Symbol**	**Name of Exchange on Which Registered**
Common Stock, $0.001 par value per share	**KALV**	**The Nasdaq Stock Market LLC**

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant period pursuant to §240.10D-1(b). ☐

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 $10.27 of the registrant's common stock as reported on The Nasdaq Global Market on October 31, 2024, the last business day of the registrant's most recently completed second quarter, was approximately $440,082,646.

The number of shares of Registrant's Common Stock outstanding as of June 25, 2025 was 49,953,739.

DOCUMENTS INCORPORATED BY REFERENCE

Information required in responses to Part III of Form 10-K is hereby incorporated by reference to portions of the Registrant's Proxy Statement for the Annual Meeting of Stockholders to be held in 2025. The Proxy Statement will be filed by the Registrant with the Securities and Exchange Commission no later than 120 days after the end of the Registrant's fiscal year ended April 30, 2025.

Table of Contents

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 current and future nonclinical, preclinical and clinical development activities, macroeconomic conditions, including rising inflation and fluctuating interest rates, labor shortages, supply chain issues, uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto and global regional conflicts, our future results of operations and financial position, business strategy, market size, potential growth opportunities, the efficacy and safety profile of our product candidates, expected timing and results of our clinical trials, and receipt and timing of potential regulatory designations, 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 subsidiaries, unless the context indicates otherwise.

Item 1. Business.

Overview

Our Company

We are a global biopharmaceutical company dedicated to developing and delivering life-changing oral therapies for individuals affected by rare diseases with significant unmet needs. On July 3, 2025, the U.S. Food and Drug Administration (the "FDA") approved our new drug application ("NDA") for the use of EKTERLY® (sebetralstat), a novel, orally delivered, small molecule plasma kallikrein inhibitor, for the treatment of acute attacks of hereditary angioedema ("HAE") in adult and pediatric patients aged 12 years and older. EKTERLY (sebetralstat) is the first and only oral, on-demand therapy for HAE.

The efficacy and safety of EKTERLY was established by the results from the phase 3 KONFIDENT clinical trial, published in the *New England Journal of Medicine* in May 2024. Based on data from KONFIDENT, together with confirmatory evidence from pharmacokinetic/pharmacodynamic studies, the 600 mg dose of EKTERLY (sebetralstat) was considered by the FDA to be the optimal dose and included in the approved labeling. The KONFIDENT clinical trial met all primary and key secondary endpoints and demonstrated a favorable safety profile. HAE attacks treated with 600 mg of sebetralstat achieved the primary endpoint of beginning of symptom relief significantly faster than placebo ($p=0.0013$) with a median time to beginning of symptom relief of 1.79 hours (CI 1.33, 2.27) as compared to 6.72 hours with placebo (CI 2.33, >12). Consistent with previous studies, sebetralstat was well-tolerated, with a safety profile similar to placebo. There were no patient withdrawals due to any adverse event and no treatment-related serious adverse events (SAEs) were observed. Treatment-related adverse event rates were 2.2% for 600 mg sebetralstat as compared to 4.8% for placebo. Primary and key secondary endpoints were analyzed in a fixed, hierarchical sequence and adjusted for multiplicity. Key secondary endpoints showed:

- Attacks treated with 600mg of sebetralstat achieved a significantly faster time to a reduction in attack severity from baseline, compared to placebo ($p=0.0032$); and
- Attacks treated with 600mg sebetralstat demonstrated a significantly faster time to complete attack resolution as compared to placebo ($p<0.0001$).

Prior to the approval of EKTERLY (sebetralstat), all on-demand treatment options approved in the U.S. for HAE required intravenous or subcutaneous administration, which carries a significant treatment burden. Even with the use of long-term prophylaxis as a preventative therapy, most people living with HAE continue to have unpredictable attacks and require ready access to on-demand medication. We believe EKTERLY (sebetralstat) has the potential to fundamentally shift the manner in which HAE is managed, based upon extensive and continuing research conducted with patients, physicians and payers.

Key Updates

In August 2024, the European Medicines Agency ("EMA") validated the submission of our Marketing Authorization Application ("MAA") for sebetralstat. This application is currently being reviewed by the EMA's Committee for Medicinal Products for Human Use under the centralized licensing procedure for all 27 Member States of the European Union, as well as the European Economic Area ("EEA") countries Norway, Iceland and Liechtenstein. In September 2024, we announced MAA submissions to the regulatory authorities in the United Kingdom, Switzerland, Australia, and Singapore via the Access Consortium framework for which we have obtained a four-way sharing agreement by the Medicines and Healthcare product Regulatory Agency ("MHRA"), Swissmedic, the Therapeutic Goods Administration and Health Sciences Authority. The Access Consortium is designed to maximize regulatory collaboration across countries and support a timely review process. In January 2025, we announced that Japan's Ministry of Health, Labour and Welfare ("MHLW") had granted sebetralstat orphan drug designation, and we also submitted an NDA for sebetralstat to that agency. To enable the broadest possible global availability of sebetralstat, if approved, we intend to engage commercial partners in certain international markets.

Sebetralstat has received fast track and orphan drug designations from the FDA, orphan drug Designation from Japan's MHLW, as well as orphan drug designation and an approved Pediatric Investigational Plan from the EMA. In November 2023, sebetralstat was granted orphan drug status in Switzerland. In February 2024, the U.K. MHRA awarded the Innovation Passport for sebetralstat.

In November 2024, we, as guarantor, and KalVista Pharmaceuticals Limited, our wholly owned subsidiary (the "Subsidiary"), entered into a Purchase and Sale Agreement the ("PSA") with DRI Healthcare Acquisitions LP (the "Purchaser"), an affiliate of DRI Healthcare Trust, pursuant to which the Subsidiary sold to the Purchaser the right to receive payments from the Subsidiary at a tiered percentage of future worldwide net sales of sebetralstat. Under the terms of the PSA, the Subsidiary received an upfront payment of $100.0 million in exchange for tiered payments on worldwide net sales of sebetralstat, as follows: 5.00% on annual net sales up to and including $500.0 million; 1.10% on annual net sales above $500.0 million and up to and including $750.0 million; and 0.25% on annual net sales above $750.0 million. The Subsidiary is entitled to a potential one-time sales-based milestone payment of $50.0 million if annual global net sales of sebetralstat meet or exceed $550.0 million in any calendar year before January 1, 2031. If sebetralstat is approved prior to October 1, 2025, the Subsidiary will have the option to receive a one-time payment of $22.0 million. If the Subsidiary chooses to receive this optional payment, the royalty rate on net sales up to and including $500 million will increase from 5.00% to 6.00%, and the sales-based milestone amount will increase from $50.0 million to $57.0 million.

In April 2025, KalVista Pharmaceuticals Limited licensed commercialization rights in Japan to Kaken Pharmaceutical, Co., Ltd. for sebetralstat. We received an upfront payment of $11.0 million on June 20, 2025, with an additional payment of up to $11.0 million upon achievement of a regulatory milestone anticipated in early 2026. Beyond these payments, we are eligible for commercial milestone payments of up to $2.0 million, plus royalties based on the Japan National Health Insurance (NHI) price, with the royalty rate as a percentage of sales approximately in the mid-twenties.

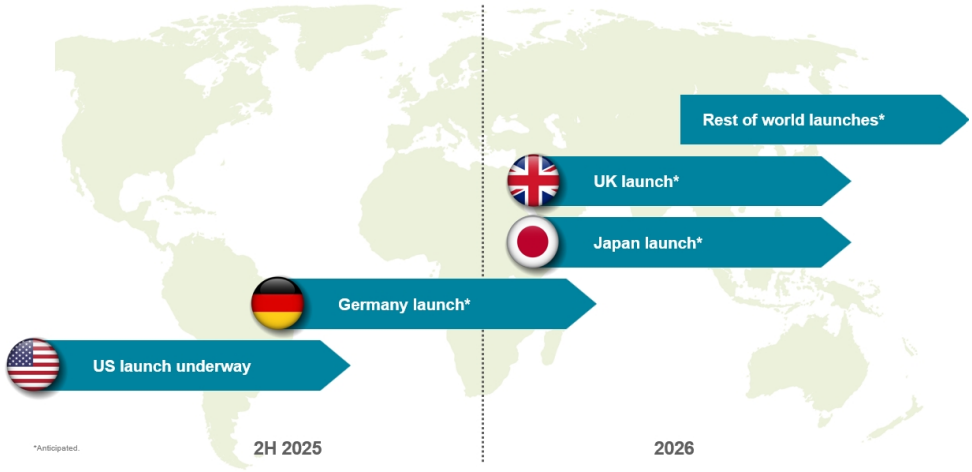
Our Strategy

We are committed to developing better solutions for the unmet needs of patients. The key elements of our strategy include:

- *Position EKTERLY (sebetralstat) to become a foundational therapy for HAE.* We launched EKTERLY (sebetralstat) for the treatment of acute attacks of HAE after receiving FDA approval in July 2025. With clinical experience encompassing over 2,000 attacks spanning all locations and severity, EKTERLY (sebetralstat) is indicated for use at the earliest recognition of an HAE attack for patients 12 years and older. As the first oral on-demand treatment for HAE attacks, we believe EKTERLY (sebetralstat) with its effectiveness as a tablet compared to injectable treatment options, its ability to treat all attacks and to enable early treatment, provides a new and unique opportunity for patients and healthcare providers to revise their approach to HAE disease management. Through our present and future patient and healthcare provider outreach, we anticipate that awareness of EKTERLY's (sebetralstat) utility will create sustained and long-lasting demand.

- *Provide access to sebetralstat globally through focused direct efforts and by entering commercialization agreements in certain locations.* Outside the US, we intend to commercialize sebetralstat with internal sales and marketing capabilities in major markets within Europe and leverage the capabilities of partners to provide market access in other geographies, if approved. For example, in anticipation of receiving a decision on our marketing application in Germany and the UK in the second half of 2025, we are preparing internal sales and marketing teams. Similarly, we have recently announced commercialization partnerships for sebetralstat in Japan, where we anticipate a decision on our NDA in early 2026, and in Canada, through the efforts of our commercial partner.

- *Develop a sustainable pipeline by employing our internal scientific expertise while also planning for growth by evaluating strategic opportunities to in-license or acquire best-in-class assets that complement our core strategy.* Our scientific team has demonstrated the ability to design and formulate multiple drug candidate programs from a broad variety of chemical classes. Our initial focus is specifically on the development of oral plasma kallikrein inhibitors for HAE and Factor XIIa inhibitors for other indications. However, we believe our scientific capabilities also can be applied to develop other therapies for diseases with high unmet need. In addition, we seek to augment our internally developed pipeline projects by selectively and strategically acquiring pipeline assets that will add value to our portfolio. Our management team has decades of deep and expansive strategic expertise building new markets across rare disease, including HAE. We believe that this team, leveraging their experience, strong execution capabilities, and financial discipline, will enable the Company to continue to innovate and grow.



Plasma Kallikrein in HAE

Plasma kallikrein is a serine protease enzyme that is a key mediator of inflammation and edema. The body modulates the downstream inflammatory effects of plasma kallikrein through a circulating inhibitor protein called C1-esterase inhibitor ("C1-INH"). Most patients with HAE have a genetic mutation that leads 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. The majority of the approved therapies in HAE today inhibit plasma kallikrein in some manner.

Hereditary Angioedema

Disease Overview

HAE is a rare and potentially life-threatening genetic condition that occurs in about 1 in 35,000 to 1 in 50,000 people, according to published information from an HAE patient advocacy group. Excessive plasma kallikrein activation that is not sufficiently controlled by C1-INH leads to HAE attacks, which can vary with regard to the affected tissue or organ and severity. HAE attacks include episodes of intense swelling 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. Untreated attacks can be functionally disabling and commonly take days to fully resolve.

Attacks can occur spontaneously although they often are associated with triggers such as anxiety, stress, minor trauma, surgery, or illnesses. 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. Population studies have shown that the mean number of attacks per month for people with HAE is approximately two. Although life-threatening airway swelling is rare, published research suggests at least half of HAE patients have experienced at least one such attack and airway attacks remain a major potential cause of mortality in HAE patients. The severity of attacks is unpredictable and not related to their underlying frequency, and even most patients on long-term prophylaxis continue to experience breakthrough attacks on some basis.

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. The most common cause of HAE is a defect or mutation in the gene responsible for the production of C1-INH. 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.

While HAE most often results from the inheritance of a defective gene from a parent, it is estimated that up to 25% of cases also arise from spontaneous mutations. Patients with C1-INH-related disease are classified as Type 1 or Type 2; Type 1 is the most common form and results in low levels of circulating C1-INH and Type 2 results in production of a low function protein. An additional form of HAE, currently referred to as normal C1-INH HAE, can occur in patients with normal levels of C1-INH for a variety of reasons including mutations in genes for Factor XII, plasminogen or angiopoetin, although in most cases a specific genetic abnormality isn't found. Selective plasma kallikrein inhibitors 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.

HAE Treatment Landscape

There are a number of marketed and development stage therapeutics for HAE, both for prophylaxis to prevent attacks of HAE as well as for the on-demand treatment of acute attacks of HAE. As a result of the lifelong nature of HAE and the challenges related to taking many of the injected therapies, patient surveys consistently indicate an overwhelming desire of patients for an oral on-demand therapy. Prior to the approval of EKTERLY (sebetralstat), all on-demand treatment options approved in the U.S. for HAE require intravenous or subcutaneous administration, which carries a significant treatment burden. Even with the use of long-term prophylaxis as a preventative therapy, most people living with HAE continue to have unpredictable attacks and require ready access to on-demand medication. We believe that a safe and effective oral on-demand agent has the potential to transform treatment for this disease.

EKTERLY (sebetralstat)

Evidence from studies using therapies approved for the treatment of acute HAE attacks shows that earlier treatment has a powerful impact on the efficacy outcomes, and treatment guidelines strongly recommend early treatment of attacks. Despite clear evidence that early treatment markedly reduces attack severity and duration, treatment is often delayed. In one outcome study of 207 HAE attacks, attack duration was 2.75-fold shorter when treatment was administered within one hour of attack onset (6.1 hours versus 16.8 hours ($p<0.001$)), yet treatment was administered more than one hour after attack onset in nearly 60% of attacks, and for 30% of attacks treatment was administered more than five hours after attack onset. We believe this delay in administration is due to many factors including the inconvenience of preparation and administration as well as the discomfort of injectable therapies. An oral therapy has the potential to overcome these limitations and lower the barrier for treatment for patients. We therefore believe that a safe, oral on-demand treatment has the potential to become a preferred alternative for patients currently using injectable treatments, including both acute and prophylactic therapies.

The efficacy and safety of EKTERLY was established by the results from the phase 3 KONFIDENT clinical trial, published in the *New England Journal of Medicine* in May 2024. Based on data from KONFIDENT, together with confirmatory evidence from pharmacokinetic/pharmacodynamic studies, the 600 mg dose of EKTERLY (sebetralstat) was considered by the FDA to be the optimal dose and included in the approved labeling. The KONFIDENT clinical trial met all primary and key secondary endpoints and demonstrated a favorable safety profile. HAE attacks treated with 600 mg of sebetralstat achieved the primary endpoint of beginning of symptom relief significantly faster than placebo (p=0.0013) with a median time to beginning of symptom relief of 1.79 hours (CI 1.33, 2.27) as compared to 6.72 hours with placebo (CI 2.33, >12). Consistent with previous studies, sebetralstat was well-tolerated, with a safety profile similar to placebo. There were no patient withdrawals due to any adverse event and no treatment-related serious adverse events (SAEs) were observed. Treatment-related adverse event rates were 2.2% for 600 mg EKTERLY (sebetralstat) as compared to 4.8% for placebo. Primary and key secondary endpoints were analyzed in a fixed, hierarchical sequence and adjusted for multiplicity. Key secondary endpoints showed:

- Attacks treated with 600mg of EKTERLY (sebetralstat) achieved a significantly faster time to a reduction in attack severity from baseline, compared to placebo (p=0.0032); and
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In August 2024, the EMA validated the submission of our MAA for sebetralstat. This application is currently being reviewed by the EMA's Committee for Medicinal Products for Human Use under the centralized licensing procedure for all 27 Member States of the European Union, as well as the EEA countries Norway, Iceland and Liechtenstein. To enable the broadest possible global availability of sebetralstat, if approved, we intend to engage commercial partners in certain international markets. In September 2024, we announced MAA submissions to the regulatory authorities in the United Kingdom, Switzerland, Australia, and Singapore via the Access Consortium framework for which we have obtained a four-way sharing agreement by the MHRA, Swissmedic, the Therapeutic Goods Administration and Health Sciences Authority. The Access Consortium is designed to maximize regulatory collaboration across countries and support a timely review process. In January 2025, we announced that

Japan's MHLW had granted sebetralstat orphan drug designation, and we also submitted an NDA for sebetralstat to the JPMDA. If approved, sebetralstat would be the first oral on-demand treatment for HAE in Japan.

Sebetralstat received fast track and orphan drug designations from the FDA, orphan drug designation from Japan's MHLW, as well as orphan drug designation and an approved Pediatric Investigational Plan from the EMA. In November 2023, sebetralstat was granted orphan drug status in Switzerland. In February 2024, the MHRA awarded the Innovation Passport for sebetralstat.

Clinical Trials

KONFIDENT-KID

We initiated an open label pediatric clinical trial (KONFIDENT-KID) in June 2024, using an orally disintegrating tablet ("ODT") formulation of sebetralstat developed specifically for pediatric use. The trial will collect safety, pharmacokinetic and efficacy data for up to one year. In March 2025, we announced completion of enrollment in the KONFIDENT-KID trial. If approved, sebetralstat ODT would be the first oral therapy for pediatric patients aged 2 to 11 years old. In addition, sebetralstat has the potential to be the second FDA-approved on-demand therapy of any type in this population.

KONFIDENT-S

In August 2022, we initiated an open label extension study (KONFIDENT-S) to evaluate the long-term safety of sebetralstat for on-demand treatment of HAE attacks in adolescent and adult patients with type I or type II HAE. We began converting adolescent and adult participants in the ongoing KONFIDENT-S study to an ODT formulation in Q4 2024, which may provide people living with HAE with an additional novel option for oral on-demand treatment.

Factor XIIa

We believe our preclinical oral Factor XIIa inhibitor program has the potential to be the first orally delivered Factor XIIa inhibitor for indications across a wide variety of therapeutic areas that are supported by scientific evidence. We are undertaking a strategic review of this program, to evaluate the potential for further progress and indications for future development, including evaluating whether to engage partners in some or all of this development, and we intend to make further decisions on this program following completion of this process.

Commercial Operations

In anticipation of FDA approval for EKTERLY (sebetralstat), we built a commercial operations infrastructure, including, marketing infrastructure, market access capabilities, and a sales field force to reach the allergists and immunologists that account for approximately 90% of all HAE claims in the United States. Following approval of EKTERLY (sebetralstat) by the FDA in July 2025, we began active promotional and other commercial operations in the U.S. We believe that there are significant market opportunities for sebetralstat outside of the United States. In order to capitalize on such opportunities, we may build a commercial operations infrastructure, including, marketing infrastructure, market access capabilities, and a sales field force, where appropriate, and/or to otherwise seek collaborations with other companies. For example, and as described below in further detail, in April 2025, we entered into a License, Supply and Distribution Agreement (the "Kaken Agreement") with Kaken Pharmaceutical, Co., Ltd. ("Kaken") pursuant to which we licensed exclusive commercialization rights in Japan to Kaken for sebetralstat (the "Licensed Product"). In addition, on June 26, 2025, the Company entered into a Licensing Agreement with Pendopharm, a division of Pharmascience, Inc., pursuant to which we licensed the exclusive rights to manage the regulatory approval process and commercialization of sebetralstat in Canada.

License, Supply and Distribution Agreement

Kaken Agreement

In April 2025, we entered into the Kaken Agreement with Kaken pursuant to which we have licensed exclusive commercialization rights in Japan to Kaken for the Licensed Product in exchange for a non-refundable upfront payment of $11.0 million, potential regulatory and sales milestone payments totaling approximately $13.0 million, and effective royalty payments in the mid-twenties that shall be payable for each unit of Licensed Product, which will reflect a percentage of the Japanese National Health Insurance price of the Licensed Product.

We are responsible for obtaining and maintaining all regulatory approvals, performing regulatory submissions for the Licensed Product in Japan and supplying the Licensed Product to Kaken. We retain manufacturing rights for the Licensed Product and are responsible for our own costs associated with the performance of activities under the Kaken Agreement. Kaken received an exclusive license to commercialize the Licensed Products in Japan, including the right to ship, store, and distribute the Licensed Product for such commercialization during the term of the Kaken Agreement. Refer to Note 12, *License, Supply and Distribution Agreement,* for further information.

Competition

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product and 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 marketing our product and 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.

In treating HAE, we expect to face competition from several FDA-approved therapeutics for both prophylactic and on-demand usage. All current on-demand therapies are delivered either intravenously or by subcutaneous injection. Approved therapies include TAKHZYRO®, marketed by Takeda Pharmaceuticals Company Limited ("Takeda") in the U.S. and Europe for the prevention of angioedema attacks in adults and adolescents; FIRAZYR®, marketed by Takeda in the U.S., Europe and certain other geographic territories for the on-demand treatment of angioedema attacks in adult patients; KALBITOR®, an injectable plasma kallikrein inhibitor marketed by Takeda for the on-demand treatment of attacks in adolescent and adult HAE patients; BERINERT®, marketed by CSL Behring for on-demand treatment of abdominal, facial or laryngeal attacks of HAE in adults and adolescents, and HAEGARDA®, also marketed by CSL Behring, for prophylaxis; RUCONEST®, marketed by Pharming Group for the on-demand treatment of angioedema attacks in adult patients; and ORLADEYO®, an oral prophylactic treatment marketed by BioCryst Pharmaceuticals, Inc.; and ANDEMBRY®, marketed by CSL Behring, for prophylaxis, which the FDA approved on June 16, 2025. FIRAZYR became available as a generic drug in 2019 and is sold by multiple companies as generic icatibant for on-demand usage. We are also aware of other companies that are engaged in the clinical development of potential HAE treatments, including Pharvaris GmbH, Intellia Therapeutics, Inc., BioMarin Pharmaceutical Inc., Astria Therapeutics, Inc., ADARx Pharmaceuticals, Inc. and Ionis Pharmaceuticals, Inc.

Intellectual Property

Our success substantially depends on our ability to obtain and maintain patents and other forms of intellectual property rights for our products and product candidates, methods used to manufacture our product candidates and methods for treating patients using our products and 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. Our patent portfolio includes patents and patent applications covering plasma kallikrein inhibitors (the "plasma kallikrein portfolio"), and patent applications covering FXIIa inhibitors (the "FXIIa portfolio").

In the plasma kallikrein portfolio, as of April 30, 2025, we are the owner of, and intend to maintain, eight U.S. patents expiring between 2035 and 2039, absent any extensions, as well as seven pending U.S. patent applications and seven pending U.S. provisional applications. Any patents issuing from the foregoing U.S. patent applications, or patents arising from applications claiming priority from the foregoing U.S. provisional applications, are expected to expire between 2035 and 2045, absent any adjustments or extensions. In the plasma kallikrein portfolio, as of April 30, 2025, we are the owner of, and intend to maintain, approximately 77 pending foreign applications and approximately 374 patents in foreign jurisdictions. Any issued foreign patents, patents issuing from these foreign patent applications, or patents arising from foreign applications claiming priority from U.S. provisional or foreign applications, are expected to expire between 2035 and 2045, absent any adjustments or extensions. In the plasma kallikrein portfolio, as of April 30, 2025, we also are the owner of, and intend to maintain, four pending international applications that, if issued, are expected to expire between 2044 and 2045, absent any adjustments or extensions.

Sebetralstat is an oral plasma kallikrein inhibitor, and is covered by U.S. patents, U.S. patent applications, U.S. provisional applications, and pending international applications, covering composition of matter, methods of treatment, solid form and clinical formulations. The anticipated expiration dates of these patents, patents arising from those applications, or patents arising from applications claiming priority from provisional applications range from 2035 to 2045, absent any adjustments or extensions. Sebetralstat is also covered by EPO patents, European patent applications, and expected European patent applications claiming priority from U.S. provisional applications, covering composition of matter, medical use, solid form and clinical formulations. The anticipated expiration dates of these European patents, European patents arising from applications, or European patents arising from applications claiming priority from U.S. provisional applications range from 2035 to 2045 absent any extensions.

In the FXIIa portfolio, as of April 30, 2025, we are the owner of, and intend to maintain, seven pending U.S. patent applications, one pending U.S. provisional applications, three pending international applications, and approximately nine pending foreign applications in multiple jurisdictions. Any patents issuing from the foregoing applications, or patents arising from applications claiming priority from U.S. provisional applications, in the FXIIa portfolio are expected to expire in between 2039 and 2045, absent any adjustments or extensions.

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 market or intend to market our products and services under various trademarks, and have obtained or are in the process of obtaining registered trademark protection for those trademarks in the U.S. and certain countries outside the U.S. We consider these trademarks to be valuable because of their contribution to the brand identification of our current and future products and services and for protection against counterfeits.

As of April 30, 2025, we are the owner of, and intend to maintain, trademark registrations for “KALVISTA” and separately for the K Design in the U.S., fifteen foreign countries as well as all E.U. member states via an E.U Trade Mark (a unitary right covering all twenty-seven member states of the E.U.) and the katakana transliteration of “KALVISTA” (カルビスタ) in Japan. As of April 30, 2025, we also own pending trademark applications for “KALVISTA” and the K Design in one further foreign country.

We have applied for registration of potential product names for sebetralstat. As of April 30,2025, we are the owner of, and intend to maintain, trademark registrations for the primary candidate name in the U.S., fifteen foreign countries as well as all E.U. member states via an E.U. Trade Mark. As of April 30, 2025, we are the owner of trademark registrations for the secondary candidate name in the U.S., fifteen foreign countries, as well as all E.U. member states via an E.U. Trade Mark. As of April 30, 2025, we own pending trademark applications for both the primary and secondary candidate names in one further foreign country.

As of April 30, 2025, we own pending trademark applications for “KALVISTA CARES” and the KalVista Cares Design in the U.S., which are intended to be used for patient support services.

We also use other forms of protection, such as 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 U.S., at the federal, state and local level, and in other countries and jurisdictions, 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 U.S. 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 U.S., pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act (the "FDC 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 NDAs, 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 U.S. typically involves nonclinical laboratory and animal tests, the submission to the FDA of an investigational new drug application ("IND"), which must become effective before clinical testing may commence, 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 pre-market approval requirements typically take many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. 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 meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; and (iii) under protocols detailing the objectives of the trial and the criteria to be evaluated. Each protocol involving testing on U.S. healthy volunteers or 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 regulations or presents an unacceptable risk to the clinical trial patients. Imposition of a clinical hold may be full or partial. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board ("IRB") for approval. The IRB will also monitor the clinical trial until completed. 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 regulatory approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy volunteers or patients, the product is tested to assess safety, dosage tolerance, metabolism, pharmacokinetics, pharmacological actions, side effects associated with drug exposure, and to obtain early evidence of a treatment effect if possible. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, determine optimal dose and regimen, and to identify common adverse effects and safety risks. If a drug demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain additional information about clinical effects and confirm 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 safety and efficacy of the drug. In rare instances, a single Phase 3 trial may be sufficient when either (1) the trial is a large, multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible or (2) the single trial is supported by confirmatory evidence.

In addition, the manufacturer of an investigational drug in a Phase 2 or Phase 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 to such investigational drug.

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 and distribution of the product may begin in the U.S. The NDA must include the results of all nonclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee unless a waiver applies. Under an approved NDA, the applicant is also subject to an annual program fee. These fees typically increase annually. An NDA for a drug that has been designated as an orphan drug is not subject to an application fee, unless the NDA includes an indication for other than a rare disease or condition. The FDA has 60 days from its receipt of an NDA to determine whether the application will be filed based on the FDA's determination that it is sufficiently complete to permit substantive review. Once the submission is filed, the FDA begins an in-depth review. The FDA has agreed to certain performance goals under the Prescription Drug User Fee Act ("PDUFA") to complete the review of NDAs. Applications for new molecular entities ("NMEs") that are designated for a Standard Review have a PDUFA goal date of ten months after the date the FDA files the NDA; applications for NMEs that are designated for a Priority Review have a PDUFA goal date of six months after the date the FDA files the NDA. An NDA can be designated for Priority Review when the FDA determines the drug 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 reviews may be extended by the FDA for three additional months to consider information deemed by the FDA to constitute a major amendment to the NDA. FDA may not always meet its performance goals under PDUFA.

The FDA may also refer applications for novel drugs, as well as drugs that present difficult questions of safety or efficacy, to be reviewed by an advisory committee—typically a panel that includes clinicians, statisticians and other experts—for review, evaluation and a recommendation as to whether the NDA should be approved. The FDA is not bound by the recommendation of an advisory committee, but generally follows such recommendations.

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with current Good Manufacturing Practices ("cGMP") is satisfactory and the NDA contains data that provide evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and completes any clinical and manufacturing site inspections, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the NDA submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application for approval. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to goals of reviewing such resubmissions in two or six months depending on the type of information included. An approval letter authorizes commercial marketing and distribution of the drug with specific prescribing information for specific indications. A drug may be subject to postmarketing requirements, which are nonclinical studies or clinical trials that are required as a condition of approval, or postmarketing commitments, which are nonclinical studies or clinical trials that the sponsor agrees to conduct. In addition, as a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy ("REMS") to help ensure that the benefits of the drug outweigh the potential risks to patients. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure a product's safe use ("ETASU"). An ETASU can include, but is not limited to, special training or certification for prescribing or dispensing the product, dispensing the product only under certain circumstances, special monitoring, and the use of patient-specific registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, the FDA 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 NDA, including changes in indications, product labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or supplement to an approved NDA, 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 original NDAs.

Orphan Drug Designation

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

Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the drug and its potential orphan disease 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. The first NDA applicant to receive FDA approval for a particular active moiety to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the U.S. for that product in the approved indication.

During the seven-year marketing exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. A product can be considered 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 different drug for the same disease or condition, or the same drug 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.

Fast Track Designation and Priority Review

FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Fast track designation may be granted for products that are intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. Any product submitted to FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review.

Priority review may be granted for products that are intended to treat a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. FDA will attempt to direct additional resources to the evaluation of an application designated for priority review in an effort to facilitate the review.

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 on the website www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of a clinical trial are then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of clinical 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 clinical development programs as well as clinical trial design.

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 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 with orphan product designation.

The Best Pharmaceuticals for Children Act (“BPCA”), provides a six-month extension of any patent or non-patent exclusivity for a drug if certain conditions are met. Conditions for exclusivity include the FDA’s determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

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 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. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities.

Adverse event reporting and submission of periodic safety summary reports is required following FDA approval of an NDA. The FDA also may require nonclinical or clinical postmarketing requirements, REMS, or 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. Sponsors may also agree to conduct nonclinical or clinical postmarketing commitments after approval. In addition, quality control, drug manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects a drug's 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 required regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

The Hatch-Waxman Amendments

Orange Book Listing

Under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch Waxman Amendments, NDA applicants are required to identify to FDA each patent whose claims cover the applicant’s drug or approved method of using the drug. Upon approval of a drug, the applicant must update its listing of patents to the NDA in timely fashion and each of the patents listed in the application for the drug is then published in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book.

Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application (“ANDA”). An ANDA provides for marketing of a drug product that has the same active ingredient(s), strength, route of administration, and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. An approved ANDA product is considered to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved under the ANDA pathway are commonly referred to as “generic equivalents” to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug pursuant to each state’s laws on drug substitution.

The ANDA applicant is required to certify to the FDA concerning any patents identified for the reference listed drug in the Orange Book. Specifically, the applicant must certify to each patent in one of the following ways: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product’s listed patents, or that such patents are invalid, is called a Paragraph IV certification. For patents listed that claim an approved method of use, under certain circumstances the ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents through a Paragraph IV certification, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA-holder and patentee(s) once the ANDA has been accepted for filing by the FDA (referred to as the “notice letter”). The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice letter. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months from the date the notice letter is received, expiration of the patent, the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed, or a decision in the patent case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired. In some instances, an ANDA applicant may receive approval prior to expiration of certain non-patent exclusivity if the applicant seeks, and FDA permits, the omission of such exclusivity-protected information from the ANDA prescribing information.

Exclusivity

Upon NDA approval of a new chemical entity ("NCE") which is a drug that contains no active moiety that has been approved by FDA in any other NDA, that drug receives five years of marketing exclusivity during which FDA cannot receive any ANDA seeking approval of a generic version of that drug unless the application contains a Paragraph IV certification, in which case the application may be submitted one year prior to expiration of the NCE exclusivity. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA for a generic version of the drug may be filed before the expiration of the exclusivity period.

Certain changes to an approved drug, such as the approval of a new indication, the approval of a new strength, and the approval of a new condition of use, are associated with a three-year period of exclusivity from the date of approval during which FDA cannot approve an ANDA for a generic drug that includes the change. In some instances, an ANDA applicant may receive approval prior to expiration of the three-year exclusivity if the applicant seeks, and FDA permits, the omission of such exclusivity-protected information from the ANDA package insert. Orphan designation may extend the period of exclusivity.

Patent Term Extension

The Hatch Waxman Amendments permit a patent term extension as compensation for patent term lost during the FDA regulatory review process. Patent term extension, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. After NDA approval, owners of relevant drug patents may apply for the extension. The allowable patent term extension is calculated as half of the drug's testing phase (the time between IND and NDA submission) and all of the review phase (the time between NDA submission and approval) up to a maximum of five years. The time can be reduced for any time FDA determines that the applicant did not pursue approval with due diligence.

The U.S. Patent and Trademark Office (the "USPTO") in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. However, the USPTO may not grant an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than requested.

The total patent term after the extension may not exceed 14 years, and only one patent can be extended. The application for the extension must be submitted prior to the expiration of the patent, and for patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Other U.S. Healthcare Laws and Compliance Requirements

In the U.S., pharmaceutical and biotechnology company 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 & Medicaid Services ("CMS") other divisions of the U.S. Department of Health and Human Services ("HHS") (e.g., the Office of Inspector General and the Office for Civil Rights), 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 federal 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, recommending or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federally funded healthcare programs. The term remuneration 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/or formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly 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. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. In addition, the statutory exceptions and regulatory safe harbors are subject to change.

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

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

Federal civil and criminal false claims laws, including the federal civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government 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. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the civil False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus generally non-reimbursable, uses and purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes.

HIPAA created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Also, many states 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.

Data privacy and security regulations by both the federal government and the states in which business is conducted may also be applicable. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and its implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. HIPAA requires covered entities to limit the use and disclosure of protected health information to specifically authorized situations, and requires covered entities to implement security measures to protect health information that they maintain in electronic form. Among other things, HITECH made HIPAA's security standards directly applicable to business associates, independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act within the ACA, and its implementing regulations, require that certain manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to the CMS information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, certain advance practices nurses and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. The reported data is made available in searchable form on a public website on an annual basis. Failure to submit required information may result in civil monetary penalties.

Commercial distribution of products requires compliance with state laws that require the registration of manufacturers and wholesale distributors of drugs 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. In addition, 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. Certain local jurisdictions also require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Sales and marketing activities are also potentially subject to federal and state consumer protection and unfair competition laws.

Violation of any of the federal and state healthcare laws described above or any other governmental regulations may result in penalties, including without limitation, significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, imprisonment, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, refusal to enter into government contracts, oversight monitoring, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings.

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 U.S. 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 U.S., 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, as there is no uniform policy of coverage and reimbursement for drug products among third-party payors in the U.S. 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 E.U., 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 U.S. 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.

U.S. Healthcare reform

Healthcare reforms that have been adopted, and that may be adopted in the future, could result in further reductions in coverage and levels of reimbursement for pharmaceutical products, increases in rebates payable under U.S. government rebate programs and additional downward pressure on pharmaceutical product prices.

Several healthcare reform proposals culminated in the enactment of the Inflation Reduction Act ("IRA") in August 2022, which, among other things, allows HHS to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. The negotiated price may not exceed a statutory ceiling price. Only high-expenditure single-source drugs that have been approved for at least seven years (11 years for biologics) are eligible to be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D products in 2023, negotiations began in 2024, and the negotiated maximum fair price for each product has been announced. CMS has selected 15 additional Medicare Part D drugs for negotiated maximum fair pricing in 2027. For 2028, an additional 15 drugs, which may be covered under either Medicare Part B or Part D, will be selected, and for 2029 and subsequent years, 20 Part B or Part D drugs will be selected. A drug or biological product that has an orphan drug designation for only one rare disease or condition will be excluded from the IRA's price negotiation requirements, but will lose that exclusion if it receives designations for more than one rare disease or condition, or if is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. The IRA also imposes rebates on Medicare Part B and Part D drugs whose prices have increased at a rate greater than the rate of inflation, and in November 2024, CMS finalized regulations for these inflation rebates. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. These provisions have been and may continue to be subject to legal challenges. For example, the provisions related to the negotiation of selling prices of high-expenditure single-source drugs and biologics have been challenged in multiple lawsuits brought by pharmaceutical manufacturers. Thus, while it is unclear how the IRA will be implemented, it will likely have a significant impact on the pharmaceutical industry and the pricing of prescription drug products.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and in some cases, designed to encourage importation from other countries and bulk purchasing.

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 U.S. 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 U.S., we are 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 U.S. 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 E.U., 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 E.U. 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 E.U., U.K., and Swiss regulatory systems, we must submit a MAA. The documentation submitted to the FDA in support of an NDA in the U.S. is almost identical to that required in the E.U., U.K., and Switzerland, with the exception of, among other things, country-specific document requirements. For other countries outside of the E.U., U.K. and Switzerland, such as countries in Eastern Europe, the Middle East, 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.

Change in Fiscal Year

On March 13, 2025, the Board approved a change to our fiscal year end from April 30 to December 31. The change in fiscal year is effective for the Company's 2026 fiscal year. We plan to file all required periodic reports under Sections 13 or 15(d) of the Exchange Act, including a transition report on Form 10-K for the eight-month transition period of May 1, 2025 through December 31, 2025. During the transition period, we have elected to file a Quarterly Report on Form 10-Q for the quarter ending July 31, 2025, and then will file quarterly reports based on the new fiscal year beginning with the quarter ending September 30, 2025, pursuant to Rule 15d-10(e)(2) of the Exchange Act.

Human Capital Resources

As of April 30, 2025, we had a total of 270 full-time employees, of whom 171 were located in the U.S., 65 were located in the U.K., and 34 were located in the rest of the world. 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. We believe that our future success largely depends upon our continued ability to attract and retain highly skilled employees.

Corporate Information

Our principal executive offices are located at 55 Cambridge Parkway, Suite 901 East, Cambridge, MA 02142, and our telephone number is (857) 999-0075. Our website address is 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.

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 as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. 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. The information posted on or accessible through these websites are not incorporated into this filing.

Item 1A.

Summary of Risk Factors

An investment in our common stock involves various risks, and prospective investors are urged to carefully consider the matters discussed in the section titled "Risk Factors" prior to making an investment in our common stock. These risks include, but are not limited to, the following:

- 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.
- We may need substantial additional funding to allow us to support through clinical development and commercial launch, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or 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.
- We are heavily dependent on the successful commercialization of EKTERLY (sebetralstat) and the development, regulatory approval, and commercialization of our current and future product candidates.
- We have not yet demonstrated an ability to successfully conduct commercial activities.
- 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.
- The sales, marketing, and distribution of EKTERLY (sebetralstat) or any future approved products may be unsuccessful or less successful than anticipated. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market EKTERLY (sebetralstat) or any future approved products on acceptable terms, we may be unable to successfully commercialize EKTERLY (sebetralstat) or any future approved products.
- We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.
- If we are unable to achieve and maintain third-party payor coverage and adequate levels of reimbursement for EKTERLY (sebetralstat) or any of our other product candidates for which we receive regulatory approval, or any future products we may seek to commercialize, their commercial success may be severely hindered.
- 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.
- If we do not achieve our projected development goals in the timeframes we announce and expect, the commercialization of our products may be delayed 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 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 operations and relationships with healthcare providers, healthcare organizations, customers and third- party payors will be subject to applicable anti-bribery, anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose us to, among other things, enforcement actions, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

- An orphan drug designation by the FDA, EMA, MHRA or JPMDA does not increase the likelihood that our product candidates will receive marketing exclusivity.
- Failure to obtain regulatory approval in international jurisdictions would prevent EKTERLY (sebetralstat) and our other product candidates from being marketed abroad.
- EKTERLY (sebetralstat) and any product candidate for which subsequently we obtain regulatory 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.
- We contract with third parties for the manufacture of EKTERLY (sebetralstat) and our other 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 have entered, and may in the future seek to enter, into collaborations with third parties for the development and commercialization of sebetralstat or our other 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 sebetralstat or our other product candidates.
- 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 future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
- 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.
- Shareholder activism could cause material disruption to our business.
- 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.
- Unstable or unfavorable global market and economic conditions may have adverse consequences on our business, financial condition and stock price.

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. On July 3, 2025, the FDA approved our NDA for EKTERLY (sebetralstat) for the treatment of acute attacks of HAE in adult and pediatric patients aged 12 years and older. In the fiscal years ended April 30, 2025 and 2024, we used net cash of $152.9 million and $89.2 million respectively, in our operating activities substantially all of which related to research and development activities. As of April 30, 2025, our cash and cash equivalents were $131.6 million. We expect our expenses to continue, particularly as we begin commercializing EKTERLY (sebetralstat), continue existing clinical trials and initiate new research and preclinical development efforts. As we begin to commercialize EKTERLY (sebetralstat) and if we obtain regulatory approval of EKTERLY (sebetralstat) in other jurisdictions or indications or for our other product candidates, we expect we will incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of a collaborator. We are devoting substantial resources to the commercial infrastructure for EKTERLY (sebetralstat) and have not yet achieved significant product revenue. We are also devoting substantial resources to the development of our other product candidates. Because of the numerous risks and uncertainties associated with the anticipated commercialization of EKTERLY (sebetralstat) and development of other product candidates, and because the extent to which we may enter into additional collaborations with third parties for any of these activities is unknown, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with the research, development and commercialization. We anticipate that our expenses will increase substantially if and as we:

- establish a commercial infrastructure to support the near-term commercialization of EKTERLY (sebetralstat) and any other product candidates for which we receive regulatory approval, including product sales, medical affairs, marketing, manufacturing and distribution;
- initiate the commercial launch of EKTERLY (sebetralstat) for the treatment of HAE in adult and pediatric patients aged 12 years and older;
- continue clinical development of sebetralstat in other indications as well as our current product candidates in our pipeline;
- 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 regulatory approvals for our product candidates that successfully complete clinical trials;
- maintain, expand and protect our intellectual property portfolio;
- 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 commercialize EKTERLY (sebetralstat) or other products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling those products for which we may obtain regulatory approval, such as EKTERLY (sebetralstat). Even if we succeed in these activities, 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.

We may need substantial additional funding to support us through clinical development and commercial launch, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

Developing and commercializing pharmaceutical products, including conducting preclinical studies and clinical trials and preparing for and executing a commercial launch, is a very time-consuming, expensive and uncertain process that takes years to complete. We expect our expenses to continue, particularly as we commercialize EKTERLY (sebetralstat), continue existing clinical trials and initiate new research and preclinical development efforts. In addition, as we commercialize EKTERLY (sebetralstat) and if we obtain regulatory approval of EKTERLY (sebetralstat) in other jurisdictions or indications or for our other product candidates, we expect we will incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of a collaborator. Furthermore, we continue to incur significant costs associated with operating as a public company.

We believe that our cash and cash equivalents as of April 30, 2025 and the cash that we anticipate generating from expected sales of EKTERLY (sebetralstat) will be sufficient to fund our projected operating expenses and capital expenditure requirements for at least the next 12 months, as well as our anticipated longer-term cash requirements and obligations. Our expectations regarding our short-term and long-term funding requirements are based on assumptions that may prove to be wrong, and we may need additional capital resources to fund our operating plans and capital expenditure requirements.

If our cash, cash equivalents, and cash generated from expected sales of EKTERLY (sebetralstat) are not sufficient to fund our planned expenditures, we will need to finance our cash needs through external sources of funds, which may include equity offerings, debt financings, collaborations, strategic alliances or licensing arrangements. We currently do not have any committed external sources of funds.

If we are unable to generate sufficient funds from expected sales of EKTERLY (sebetralstat) or raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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.

We have entered into a sales agreement with TD Securities (USA) LLC, as sales agent, relating to the issuance and sale of shares of our common stock for an aggregate offering price of up to $100 million under an at-the-market offering program (the “ATM”). No shares of our common stock have been sold under the ATM as of April 30, 2025.

Risks Related to the Development and Commercialization of Our Product Candidates

We are heavily dependent on the successful commercialization of EKTERLY (sebetralstat) in the U.S. and other jurisdictions, where we may obtain regulatory approval, and development, regulatory approval, and commercialization of our other product candidates.

We currently have one product approved for commercial sale, EKTERLY (sebetralstat), which was approved by the U.S. FDA on July 3, 2025 for the treatment of acute attacks of HAE in adult and pediatric patients aged 12 years and older. The success of our business, including our ability to generate revenue from product sales in the future, will primarily depend on the successful commercialization of EKTERLY (sebetralstat) in the U.S. as well as in other jurisdictions, if approved, and the successful development, regulatory approval and commercialization of our other product candidates in one or more jurisdictions. Our ability to generate revenue and achieve profitability depends significantly on our ability, or our current and any future collaborator's ability, to achieve a number of challenging objectives, including:

- timely receipt of regulatory approvals from applicable regulatory authorities for our product candidates for which we successfully complete clinical development;
- successful and timely completion of preclinical and clinical development of our product candidates;
- successfully educating physicians, patients, third party payors and others in the medical community;
- successful commercial launch following any regulatory approval, including leveraging our commercial infrastructure in-house or with one or more collaborators;
- commercial acceptance of EKTERLY (sebetralstat) upon FDA approval and any of our other product candidates by patients, the medical community and third-party payers;
- establishing and maintaining relationships with contract research organizations ("CROs") and clinical sites for the clinical development, both in the U.S. and internationally, of our product candidates;
- making any postmarketing requirements or commitments to applicable regulatory authorities;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for product candidates that we develop, if approved;
- a continued acceptable safety and efficacy profile both prior to and following any regulatory approval of EKTERLY (sebetralstat) and our other product candidates;
- identifying, assessing and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the U.S. and internationally;
- protecting our rights in our intellectual property portfolio;
- defending against third-party interference or infringement claims, if any;
- obtaining favorable terms in any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our existing or acquired product candidates;
- obtaining coverage and adequate reimbursement for customers and patients from government and third-party payers for EKTERLY (sebetralstat) and any other product candidates that we may seek to commercialize;
- addressing any competing therapies and technological and market developments; and

- attracting, hiring and retaining qualified personnel.

Further, we do not have experience commercializing products. We may never be successful in achieving our objectives and, even if we do, may never generate significant revenue that is 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 and we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business, retain key employees and continue our operations.

We obtained regulatory approval from the FDA for EKTERLY (sebetralstat), but have not yet demonstrated an ability to successfully conduct commercial activities.

We received FDA approval for EKTERLY (sebetralstat) for the treatment of acute attacks of HAE in adult and pediatric patients aged 12 years and older on July 3, 2025. Prior to obtaining this approval, our operations were been limited to financing and staffing our company, developing our technology, conducting preclinical research and clinical trials of our product candidates and preparing for a commercial launch. We have not received regulatory approval or commercialized any other product candidates to date and may never do so. We have not yet demonstrated an ability to conduct sales and marketing activities necessary for successful product commercialization. Accordingly, our stockholders should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by biopharmaceutical companies such as ours. Any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to continue to transition from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year.

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 of EKTERLY (sebetralstat).

We received FDA approval for EKTERLY (sebetralstat) for the treatment of acute attacks of HAE in adult and pediatric patients aged 12 years and older in the U.S. on July 3, 2025. Nonetheless, we may fail to gain sufficient market acceptance by physicians, patients, third party payors and others in the medical community necessary for commercial success of EKTERLY (sebetralstat) in the U.S., any other jurisdictions that grant regulatory approval of sebetralstat for the treatment of HAE or any other product candidates. In addition, physicians, patients and third-party payors may prefer other products to ours. If sebetralstat and any other product candidates, if approved, 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 sebetralstat and any other 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 clinical indications for which the product is approved
- changes in the standard of care for the targeted indications for the product;
- the strength of our marketing and distribution support;
- the price at which the product is offered for sale and the availability of third-party coverage and adequate reimbursement, including patient cost-sharing programs such as copays and deductibles;

- the approval of other new products for the same indications;
- the timing of market introduction of our approved products as well as competitive products;
- adverse publicity about the product or favorable publicity about competitive products;
- the ability to develop or partner with third-party collaborators to develop companion diagnostics;
- with respect to any future product candidates, FDA-approved labeling which may include restrictive safety and efficacy data, or may not include aspects of safety and efficacy that we believe are important;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

The development and commercialization of new drug products is highly competitive. We may not be able to successfully convince physicians or patients to switch from existing or new treatments to EKTERLY (sebetralstat) for the treatment of HAE. In treating HAE, we expect to face competition from several FDA-approved therapeutics for both prophylactic and on-demand usage. All current on-demand therapies are delivered either intravenously or by subcutaneous injection. Approved therapies include TAKHZYRO, FIRAZYR; KALBITOR, BERINERT, HAEGARDA, RUCONEST, ORLADEYO, and ANDEMBRY. FIRAZYR became available as a generic drug in 2019 and is sold by multiple companies as generic icatibant for on-demand usage. We are also aware of other companies that are engaged in the clinical development of potential HAE treatments, including Pharvaris GmbH, Intellia Therapeutics, Inc., BioMarin Pharmaceutical Inc., Astria Therapeutics, Inc., ADARx Pharmaceuticals, Inc. and Ionis Pharmaceuticals, Inc. See the risk factor titled "*We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do*" for more information.

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 sebetralstat and any other product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are not successful in commercializing EKTERLY (sebetralstat) and any other product candidates that receive regulatory approval, 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. Our estimates of the potential market opportunities for our products and product candidates are informed by work that is not definitive and future analyses may lead to estimates that are higher or lower than these estimates than those provided at any given time, with respect to addressable patient populations. If our market opportunity is lower than anticipated, our business may suffer.

The sales, marketing, and distribution of EKTERLY (sebetralstat) or any other product candidates, if approved, may be unsuccessful or less successful than anticipated. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market EKTERLY (sebetralstat) or any other product candidates, if approved, on acceptable terms, we may be unable to successfully commercialize EKTERLY (sebetralstat) or any other product candidates.

We recently began commercializing our first product, EKTERLY (sebetralstat), in the U.S. following FDA approval in July 2025. The success of our future commercialization efforts for EKTERLY (sebetralstat) and any other product candidates is subject to the effective execution of our business plan, including, among others, the continued development of our internal sales, marketing, and distribution capabilities. For example, we have established an internal infrastructure as well as a focused sales and distribution infrastructure to market EKTERLY (sebetralstat) in the U.S., and have completed hiring in areas to support commercialization, including sales management, sales representatives, marketing, access and reimbursement, sales support and distribution. There are significant risks involved with establishing our own sales, marketing, and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, provide adequate training to sales and marketing personnel, and effectively manage geographically dispersed sales and marketing teams to generate sufficient demand. Any failure or delay in the development of these capabilities could negatively affect the success of our commercialization efforts and business. For example, the anticipated commercialization of EKTERLY (sebetralstat) may not develop at all, or not as planned or anticipated, which may require us to, among other items, adjust or amend our business plan and incur significant expenses.

Further, because we have chosen to collaborate in certain instances on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, to augment our own sales force and distribution systems, we are

required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration. For example, on April 8, 2025, we entered into the Kaken Agreement, pursuant to which we exclusively licensed commercialization rights to sebetralstat in Japan. If we are unable to enter into other 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 in additional indications or jurisdictions or any such commercialization may experience delays or limitations. In addition, we may have little or no control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. For example, if Kaken is unable to meet its contractual obligations pursuant to the Kaken Agreement, we may be forced to focus our efforts internally to commercialize sebetralstat in Japan, if approved, without the assistance of a commercialization partner or seek another commercialization partner, either of which would result in us incurring greater expenses and could cause a delay in market penetration while we expand our commercial operations or seek an alternative commercialization partner. Such costs may exceed the increased revenues we would receive from direct sebetralstat sales in Japan, at least in the near term. We would also potentially be forced to declare a breach of the agreement with Kaken and seek a termination of the agreement which could result in an extended and uncertain dispute with Kaken, including arbitration or litigation, any of which would be costly. If we are unable to successfully commercialize our approved 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.

Further, in order to continue to commercialize EKTERLY (sebetralstat) or commercialize any other product candidates, if approved, we must continue to build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell and market our product candidates. We may not be successful in accomplishing these required tasks. If our sales, marketing, and distribution capabilities fail, or are otherwise unsuccessful, it would materially adversely impact the commercial launch of EKTERLY (sebetralstat) and impact our ability to generate revenue and harm our business.

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.

In treating HAE, we expect to face competition from several FDA-approved therapeutics for both prophylactic and on-demand usage. All current on-demand therapies are delivered either intravenously or by subcutaneous injection. Approved therapies include TAKHZYRO, marketed by Takeda in the U.S. and Europe for the prevention of angioedema attacks in adults and adolescents; FIRAZYR, marketed by Takeda in the U.S., Europe and certain other geographic territories for the on-demand treatment of angioedema attacks in adult patients; KALBITOR, an injectable plasma kallikrein inhibitor marketed by Takeda for the on-demand treatment of attacks in adolescent and adult HAE patients; BERINERT, marketed by CSL Behring for on-demand treatment of abdominal, facial or laryngeal attacks of HAE in adults and adolescents, and HAEGARDA, also marketed by CSL Behring, for prophylaxis; RUCONEST, marketed by Pharming Group for the on-demand treatment of angioedema attacks in adult patients; ORLADEYO, an oral prophylactic treatment marketed by BioCryst Pharmaceuticals, Inc., and ANDEMBRY, marketed by CSL, for prophylaxis. FIRAZYR became available as a generic drug in 2019 and is sold by multiple companies as generic icatibant for on-demand usage. We are also aware of other companies that are engaged in the clinical development of potential HAE treatments, including Pharvaris GmbH, Intellia Therapeutics, Inc., BioMarin Pharmaceutical Inc., and Ionis Pharmaceuticals, Inc.

Ionis Pharmaceuticals, Inc.'s donidalorsen, an antisense inhibitor of prekallikrein synthesis has also completed Phase 3 development for preventative treatment and has a PDUFA date set for August 21, 2025. Pharvaris is developing two oral treatments, deucrictibant IR (immediate release) and deucrictibant XR (extended release). Deucrictibant is a small molecule inhibitor of B2R. Deucrictibant IR is in Phase 3 development for on-demand treatment. Based on a proof-of-concept Phase 2 trial with deucrictibant IR for preventative treatment, Pharvaris has initiated a Phase 3 trial for deucrictibant XR for preventative treatment.

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 any other product candidates achieve regulatory 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.

If we are unable to achieve and maintain third-party payor coverage and adequate levels of reimbursement for EKTERLY (sebetralstat) or any of our other product candidates for which we receive regulatory approval, or any future products we may seek to commercialize, their commercial success may be severely hindered.

For EKTERLY (sebetralstat) and any of our other product candidates that receive regulatory approval and become available by prescription only, our success will depend on the availability of coverage and adequate reimbursement for our product from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. The availability of coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and private third-party payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. If EKTERLY (sebetralstat) or any of our other product candidates that receive regulatory approval fail to demonstrate attractive efficacy and safety profiles to third-party payors, they may not qualify for coverage and reimbursement. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our prescription-only products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. We cannot be sure that coverage and reimbursement will be available for any product candidate that receives regulatory approval, and any reimbursement that may become available may be decreased or eliminated in the future.

In addition, the market for EKTERLY (sebetralstat), and certain of our product candidates, if approved, will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies.

Obtaining and maintaining reimbursement status is time consuming, costly and uncertain, and there is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the U.S., the principal decisions about reimbursement for new medicines are typically made by the CMS, an agency within HHS, 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, if approved, as there is no body of established practices and precedents for these products.

Although Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs, no uniform policy for coverage and reimbursement for products exists among third party payors in the U.S. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that will require us to provide scientific and clinical support for the use of our products, if approved, to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

Reimbursement agencies in Europe may be more conservative than CMS. Outside the U.S., 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 U.S. 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, if approved. Accordingly, in markets outside the U.S., the reimbursement for our product candidates, if approved, may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenues and profits.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions in both the U.S. and in international markets. Third-party coverage and reimbursement for sebetralstat and any of our product candidates for which we may receive regulatory approval may not be available or adequate in either the U.S. or international markets, which could harm our business, financial condition, operating results, and prospects.

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 and which receive regulatory approval. 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 or difficulties in recruiting new clinical trial participants;
- initiation of investigations by regulators;
- significant costs to defend or settle 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.

Although we maintain product liability insurance coverage, it 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.

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.

The historical failure rate in clinical drug development of product candidates in our industry is high. Before obtaining regulatory 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 our 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 regulatory 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, including our ongoing KONFIDENT-KID and KONFIDENT-S trials of sebetralstat, and we do not know whether future 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 FDA, MHRA, the EMA, or the Japanese Pharmaceuticals and Medical Devices Agency ("JPMDA") 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 regulatory 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 FDA, MHRA, EMA, JPMDA 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;
- delay or failure in data collections in connection with a clinical trial;
- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- 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 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;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- there may be political factors surrounding the approval process, such as government shutdowns or political instability;
- 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 regulatory approval for our product candidates;
- not obtain regulatory approval at all;
- obtain approval for indications, patient populations or doses 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 regulatory approval.

Our product development costs will also increase if we experience delays in testing or regulatory 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 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 many 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 FDA, MHRA, EMA, JPMDA, or a comparable foreign regulatory authority or IRBs, data safety monitoring boards or results from earlier stage or concurrent preclinical and clinical studies, that might require modifications to the protocol;
- decisions by the FDA, MHRA, EMA, JPMDA, 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 timeframes 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. For example, prior to FDA approval on July 3, 2025, on June 13, 2025, the FDA notified us that it would not meet the PDUFA goal date of June 17, 2025 for the regulatory approval of sebetralstat but indicated that it expected to deliver a decision within approximately four weeks. 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.

We are not permitted to commercialize, market, promote or sell any product candidate in the U.S. without obtaining regulatory approval from the FDA. Foreign regulatory authorities, such as the EMA, impose similar requirements. 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. Additional or more severe side effects may be identified for all our programs through further clinical studies or after regulatory approval is received. 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 significantly harm our business, financial condition and prospects.

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 an NDA in the U.S. and by the EMA and similar regulatory authorities outside the U.S. prior to commercialization. We received FDA approval for EKTERLY (sebetralstat) for the treatment of acute attacks of HAE in adult and pediatric patients aged 12 years and older on July 3, 2025. We cannot provide assurance that we will receive regulatory approvals for sebetralstat in other jurisdictions or indications or for our other product candidates.

In order to market any products outside of the U.S., including sebetralstat, we will need to comply with additional onerous but varying regulatory requirements of other countries regarding safety and efficacy on a country-by-country basis. For example, in August 2024, we submitted an MAA for sebetralstat to the European Medicines Agency, which currently is being reviewed by the EMA's Committee for Medicinal Products for Human Use under the centralized licensing procedure for all 27 Member States of the European Union, as well as the EEA countries Norway, Iceland and Liechtenstein. We also have made MAA submissions to the regulatory authorities in the United Kingdom, Switzerland, Australia, and Singapore via the Access Consortium framework for which we have obtained a four-way sharing agreement by the Medicines and Healthcare product Regulatory Agency, Swissmedic, the Therapeutic Goods Administration and Health Sciences Authority. The Access Consortium is designed to maximize regulatory collaboration across countries and support a timely review process. In January 2025, we announced that we submitted a Japanese New Drug Application for sebetralstat to the JPMDA. Approval of EKTERLY (sebetralstat) by the FDA in the U.S. does not ensure approval by comparable regulatory authorities in other countries or jurisdictions nor does it ensure that we will be able to successfully commercialize EKTERLY (sebetralstat) or any other approved products in the U.S. or in other jurisdictions. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Further, successful commercialization in the U.S. does not guarantee successful commercialization in other jurisdictions.

The process of obtaining regulatory approvals, both in the U.S. 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 and therapeutic indications involved. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate. Securing regulatory approval requires the submission of extensive chemistry, manufacturing and preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also usually requires inspection of manufacturing facilities by the regulatory authorities and also audits of the clinical trial sites, data and CROs that have supported KalVista in the clinical development. 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 regulatory approval or prevent or limit commercial use. Regulatory authorities have substantial discretion in the approval process and may refuse to accept an application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies.

Changes in regulatory 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.

For example, the U.K. formally left the E.U. on January 31, 2020, often referred to as Brexit, and the transition period ended on December 31, 2020. Brexit has caused uncertainty in the current regulatory framework in Europe. For instance, Brexit has resulted in the EMA, moving from the U.K. to the Netherlands. The U.K. has now put in place legislation to cover the approval of new medicinal products in the U.K., including designations such as orphan designation, and a pediatric investigational plan. The requirements are similar to those in the E.U. and in many cases have adopted the same requirements. However, there are still adjustments being made to legislation. Any of these adjustments as a result of Brexit could result in significant delays and additional expense to our business. Any of the foregoing factors could have a material adverse effect on our business, results of operations, or financial condition.

Any future regulatory 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.

Our operations and relationships with healthcare providers, healthcare organizations, customers and third- party payors will be subject to applicable anti-bribery, anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose us to, among other things, enforcement actions, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Our current and future arrangements with healthcare providers, healthcare organizations, third-party payors and customers expose us to broadly applicable anti-bribery, fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute any of our product candidates, if approved. Restrictions under applicable federal and state anti-bribery and healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under a federal and state healthcare program such as Medicare and Medicaid. The term remuneration has been broadly interpreted to include anything of value. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal criminal and civil false claims and civil monetary penalties laws, including the federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions against individuals or entities, and the Federal Civil Monetary Penalties Law, which prohibit, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Moreover, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;

- HIPAA and its implementing regulations, which imposes criminal and civil liability, prohibits, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose 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 for or on behalf of a covered entity and their covered subcontractors, 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;

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with certain exceptions, to report annually to CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care professionals (such as physician assistants and certain advance practices nurses), and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members, with the information made publicly available on a searchable website;

- the Foreign Corrupt Practices Act, which prohibits U.S. businesses and their representatives from offering to pay, paying, promising to pay or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business;

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and

- certain state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and drug pricing information, and state and local laws that require the registration of biopharmaceutical sales representatives.

Efforts to ensure that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any such requirements, we may be subject to significant penalties, including 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, any of which could adversely affect our financial results. These risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

An orphan drug designation by the FDA, EMA, MHRA or JPMDA does not increase the likelihood that our product candidates will receive marketing exclusivity.

Regulatory authorities in some jurisdictions, including the U.S. 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 intended to treat a rare disease or condition, which is generally defined as a disease with a prevalence of fewer than 200,000 individuals in the U.S., or if it affects more than 200,000 individuals in the U.S., there is no reasonable expectation that the cost of developing, and making the drug available in the U.S. for such disease will be recovered from sales of the drug.

Generally, if a product with an orphan drug designation in a particular jurisdiction subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the authority in that jurisdiction 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 U.S., ten years in Europe, and ten years in Japan. Orphan drug exclusivity may be lost if the FDA, EMA, MHRA or JPMDA determines that the request for designation was materially defective, the criteria on which the orphan designation was originally issued no longer apply or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. In the E.U. and in Japan, it is necessary to apply for "maintenance" of the orphan drug designation to continue post approval. There is no guarantee that because the product was granted orphan designation during development that this will remain post approval.

The FDA granted orphan drug designation for EKTERLY (sebetralstat) on September 7, 2021. This designation may not effectively protect EKTERLY (sebetralstat) (or other drug products for which we may seek orphan designation) from competition because the designation does not preclude different drugs from being approved for the same condition. Even after an orphan designated drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that it 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 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 regulatory approval.

The FDA granted fast track designation for EKTERLY (sebetralstat) for the treatment of HAE and such designation was approved on July 3, 2025. We may also seek fast track designation for other indications of sebetralstat or for some of our other product candidates. 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 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 though we have received fast track designation for sebetralstat for the treatment of HAE, or even if we receive fast track designation for other indications or for our other product candidates, 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.

Failure to obtain regulatory approval in international jurisdictions would prevent EKTERLY (sebetralstat) and our other product candidates from being marketed abroad.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even though we received FDA approval for EKTERLY (sebetralstat) for the treatment of acute attacks of HAE in adult and pediatric patients aged 12 years and older on July 3, 2025, in order to market and sell our product candidates in the U.K., E.U., Japan and many other jurisdictions outside of the U.S., we or our third-party collaborators must obtain separate regulatory 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 FDA approval. The regulatory approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the U.S., it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We, or our third-party collaborators, may not obtain approvals from regulatory authorities outside the U.S. on a timely basis, if at all. Approval in any one jurisdiction does not ensure approval by regulatory authorities in other countries or jurisdictions, and likewise approval by one regulatory authority outside the U.S. does not ensure approval by regulatory authorities in any other countries or jurisdictions including the U.S. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

Any product candidate for which we obtain regulatory approval, including EKTERLY (sebetralstat) 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.

EKTERLY (sebetralstat) and our other 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 FDA, EMA, MHRA, JPMDA, Swiss and other regulatory authorities. In the U.S., these requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, 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 FDC 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 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 regulatory 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 U.S., U.K., E.U. and Japanese 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 requirements of the U.S., U.K., E.U. and Japan 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 regulatory approval of and commercialize our product candidates and affect the prices we may obtain.

In the U.S. there has been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell EKTERLY (sebetralstat) and any other product candidates for which we obtain regulatory approval.

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 regulatory 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 regulatory approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In addition, in the U.S., there have been and continue to be a number of legislative initiatives to contain healthcare costs, including costs of pharmaceuticals. There has been heightened governmental scrutiny over the manner in which sponsors set prices for their products, which has resulted in several presidential executive orders, Congressional inquiries, and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and Medicaid, and reform government program reimbursement methodologies for drug products.

Several healthcare reform initiatives culminated in the enactment of the IRA in August 2022, which, among other things, allows HHS to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. Only high-expenditure single-source drugs that have been approved for at least seven years (11 years for single-source biologics) are eligible to be selected for negotiation by CMS, with the negotiated price taking effect two years after the selection year. CMS selected 10 high-cost Medicare Part D products in 2023, negotiations began in 2024, and the negotiated maximum fair price for each product has been announced. These negotiations resulted in significant price reductions for the products from their 2023 list prices, ranging from 38 to 79 percent, with an average price reduction of 59.4 percent. The price cap for each of these products, which cannot exceed a statutory ceiling price, will take effect in 2026. Negotiations for Medicare Part B products will begin in 2026 with the negotiated price taking effect in 2028. A drug or biological product that has an orphan drug designation for only one rare disease or condition will be excluded from the IRA's price negotiation requirements, but will lose that exclusion if it receives designations for more than one rare disease or condition, or if is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. The negotiated prices have represented, and will continue to represent, a significant discount from average prices to wholesalers and direct purchasers. The IRA also imposes rebates on Medicare Part D and Part B drugs whose prices have increased at a rate greater than the rate of inflation, and in November 2024, CMS finalized regulations for the Medicare Part B and Part D inflation rebates. In addition, beginning in 2025, the law eliminated the coverage gap under Medicare Part D by significantly lowering the beneficiary maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescription costs for brand drugs below the out-of-pocket limit, and 20% once the out-of-pocket limit has been reached. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including significant civil monetary penalties. These provisions may be subject to legal challenges. For example, the provisions related to the negotiation of selling prices of high-expenditure single-source drugs and biologics have been challenged in multiple lawsuits brought by pharmaceutical manufacturers. Thus, while it is unclear how the IRA will be implemented, it will likely have a significant impact on the pharmaceutical industry and the pricing of EKTERLY (sebetralstat) or any future product candidates, if approved.

On May 12, 2025, an Executive Order was issued that, among other things, required HHS, within 30 days, to establish and communicate to drug manufacturers most-favored-nation ("MFN") price targets designed to bring drug prices for American patients in line with those in comparably developed nations. If significant progress towards MFN pricing is not achieved, the Executive Order requires HHS to propose a rulemaking to implement MFN pricing. It is uncertain what HHS will consider significant progress toward MFN pricing, or when that determination will be made. If HHS issues and finalizes a rule to implement MFN pricing, the rule is likely to mandate reduced prices in the U.S. of drugs, including our drugs, if approved, if they are also sold in comparator countries. Even if we do not market drugs in such countries, we would be indirectly affected if our drugs competed with drugs that were reduced by MFN pricing.

At the state level, legislatures are increasingly enacting laws and implementing regulations designed to control pharmaceutical and biological product pricing, including restrictions or prohibitions on certain marketing practices, reporting of specified categories of remuneration provided to health care practitioners, and reporting and justification of price increases greater than a specified level. In some cases, states have designed programs to encourage importation from other countries and bulk purchasing For example, the FDA released a final rule in September 2020 providing guidance for states to build and submit plans for importing drugs from Canada, and FDA authorized the first such plan in Florida in January 2024, which has been extended until November 2025. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted proposals that are pending review by the FDA.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for pharmaceuticals and other healthcare products and services, which could result in reduced demand for sebetralstat or any future product candidates, if approved, or additional pricing pressures. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize sebetralstat or any future product candidates, if approved.

Governments outside the U.S. tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, particularly the countries of the U.K., E.U. and Japan, 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 regulatory 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 distribution 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.

Disruptions at the FDA, the SEC and other government agencies or comparable regulatory authorities caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, otherwise prevent new products and services from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. In addition, there is substantial uncertainty regarding new initiatives under the new Administration and how these might impact the FDA, its implementation of laws, regulations, policies and guidance and its personnel. Similar initiatives may also be directed toward other government agencies. These initiatives could prevent, limit or delay development and regulatory approval of our product candidates, which would adversely affect our business.

The ability of the FDA or other regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory and policy changes, and other events that may otherwise affect the FDA's or comparable foreign regulatory authorities' ability to perform routine functions. In addition, government funding of the SEC and other government agencies or comparable foreign regulatory authorities on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA or other regulatory authorities may slow the time necessary for new drugs to be reviewed and/or approved, which would adversely affect our business. Changes in FDA staffing could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Moreover, if any legislation, executive orders, or lapses in agency funding impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Similar consequences would also result in the event of another significant shutdown of the federal government. For example, in 2024, the U.S. government was on the verge of a shutdown and has previously shut down several times, and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, or if geopolitical or global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

FDA-regulated industries, such as ours, face uncertainty with regard to the regulatory environment we face as we proceed with research and development and potential future commercialization. Some of these efforts have manifested to date as efforts to reduce the size of the federal government, including large-scale reductions in force at FDA. The loss of key personnel at the FDA, including those in leadership positions, is likely to impact operations at the FDA, which could result in, among other things, delays or limitations on our ability to obtain guidance from the FDA on our product candidates in development, longer review times, and delays in obtaining regulatory approvals for our product candidates. For example, even though we received FDA approval for EKTERLY (sebetralstat) for the treatment of acute attacks of HAE in adult and pediatric patients aged 12 years and older on July 3, 2025, on June 13, 2025, the FDA communicated that it would not meet the PDUFA goal date of June 17, 2025 for our sebetralstat NDA. Moreover, the current administration has recently proposed action to freeze or reduce the budget of the National Institutes of Health ("NIH") as related to its funding for medical research, which could decrease the ability of facilities that rely on NIH funding to enroll and conduct clinical trials or increase the costs to us of conducting clinical trials. There remains general uncertainty regarding future activities. New executive orders, regulations, policies or guidance could be issued or promulgated that adversely affects us or creates a more challenging or costly environment to pursue the development of new therapeutic products. Alternatively, state governments may attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to our operations. If we become negatively impacted by future governmental orders, regulations, policies or guidance, there could be a material adverse effect on us and our business.

Risks Related to Our Dependence on Third Parties

We contract with third parties for the manufacture of EKTERLY (sebetralstat) and our other 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 EKTERLY (sebetralstat) or our other product candidates, and we do not have any direct 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 commercial supply of EKTERLY (sebetralstat) and we do not have backup sources of supply established for our product or product candidates. We review the manufacturing process for sebetralstat and each of our product 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 by us or our collaborators.

Any performance failure on the part of our existing or future manufacturers of drug substance or drug products could delay clinical development or regulatory approval. If current suppliers cannot supply us with our clinical trial or commercial 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.

Even if we choose to self-manufacture, 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, including our ongoing KONFIDENT-KID and KONFIDENT-S trials.

We expect to rely on third-party manufacturers or third-party collaborators for the manufacture of commercial supply of EKTERLY (sebetralstat) and any other product candidates for which our collaborators or we obtain regulatory 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 regulatory 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 U.S. If the FDA determines that our third-party manufacturers are not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may not approve an NDA until the deficiencies are corrected or we replace the manufacturer in our application with a manufacturer that is in compliance. Moreover, 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. In addition, approved products and the facilities at which they are manufactured are required to maintain ongoing compliance with extensive FDA requirements and the requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to cGMP requirements. As such, our third-party manufacturers are subject to continual review and periodic inspections to assess compliance with cGMPs. Furthermore, although we do not have day-to-day control over the operations of our third-party manufacturers, we are responsible for ensuring compliance with applicable laws and regulations, including cGMPs.

In addition, certain Chinese biotechnology companies may become subject to trade restrictions, sanctions, other regulatory requirements, or proposed legislation by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of material to us. For example, there have been legislative proposals that target U.S. government contracts, grants and loans for entities that use equipment and services from certain named Chinese biotechnology companies, and would authorize the U.S. government to name additional Chinese biotechnology companies of concern. If these bills become law, or similar laws are passed, they would have the potential to severely restrict our ability to work with Chinese biotechnology manufacturing companies without losing the ability to contract with, or otherwise receive funding from, the U.S. government. We cannot predict what actions may ultimately be taken with respect to trade relations between the U.S. and China or other countries, what products and services may be subject to such actions or what actions may be taken by China or the other countries in retaliation.

If we are required to change third-party manufacturers for any reason, we will be required to verify that the new third party manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate or product according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of any new third party manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget.

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 EKTERLY (sebetralstat) and our other product candidates or products may adversely affect our future profit margins and our ability to commercialize EKTERLY (sebetralstat) and any other products that receive regulatory 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. The terms of any collaborations may also have impacts on other aspects of our business.

From time to time, we may consider strategic transactions, such as 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 a 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 U.S., 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. Collaborations may also have potential impact on other aspects of our business.

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.

We have entered, and may in the future seek to enter, into collaborations with third parties for the development and commercialization of sebetralstat or our other 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 sebetralstat or our other product candidates that obtain regulatory approval.

In April 2025, we entered into the Kaken Agreement, pursuant to which we have licensed commercialization rights of sebetralstat in Japan, and we may enter into similar agreements in the future for additional geographies. In these and any future collaboration agreements, we expect to have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of sebetralstat or any other 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 may not realize the full potential value of the Kaken Agreement or any future agreement.

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.

Our collaboration with Kaken and any 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;
- 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, we 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.

We rely, and intend to continue to rely, on third parties to support or conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties, fail to comply with applicable regulatory requirements or do not meet expected deadlines, our development programs may be delayed or subject to increased costs or we may be unable to obtain regulatory approval, each of which may have an adverse effect on our business, financial condition, results of operations and prospects.

We do not have the ability to independently conduct all aspects of our clinical trials ourselves. As a result, we are dependent on third parties to conduct our ongoing and planned clinical trials of sebetralstat, including our ongoing KONFIDENT-KID and KONFIDENT-S clinical trials of sebetralstat in patients with HAE, and any future product candidates, as well as potentially preclinical studies of future product candidates. The timing of the initiation and completion of these trials will therefore be partially controlled by such third parties and may result in delays to our development programs. For example, we expect CROs, independent clinical investigators and consultants to play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, these investigators, CROs and other third parties are not our employees, and we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each clinical trial is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the investigators, CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs and other third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the data generated in our clinical trials may be deemed unreliable, and the FDA or other regulators may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA or other regulators will determine that our clinical trials comply with GCPs. In addition, our clinical trials must be conducted with product manufactured under cGMP regulations. Our failure or the failure of third parties on whom we rely to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the regulatory approval process.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. In addition, these third parties may be subject to supply chain or inflationary pressures that limit their ability to achieve anticipated timelines or result in a greater cost to us. For example, we are aware of recurrent shortages of non-human primates available for preclinical studies and although that is not expected to impact our current business, if we begin new product development programs we could be subject to longer development times or difficulty completing necessary research. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise perform in a substandard manner, or terminate their engagements with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If a clinical trial site terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trial site unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible.

In addition, with respect to investigator-sponsored trials that may be conducted, we would not control the design or conduct of these trials, and it is possible that the FDA will not view these investigator-sponsored trials as providing adequate support for future clinical trials or market approval, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results. We expect that such arrangements will provide us certain information rights with respect to the investigator-sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory submissions, resulting from the investigator-sponsored trials. However, we would not have control over the timing and reporting of the data from investigator-sponsored trials, nor would we own the data from the investigator-sponsored trials. If we are unable to confirm or replicate the results from the investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data proves to be inadequate compared to the firsthand knowledge we might have gained had the investigator-sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials

ourselves may be adversely affected. The investigators may design clinical trials with clinical endpoints that are more difficult to achieve, or in other ways that increase the risk of negative clinical trial results compared to clinical trials that we may design on our own. Negative results in investigator-sponsored clinical trials could have a material adverse effect on our efforts to obtain regulatory approval for our product candidates and the public perception of our product candidates. Additionally, the FDA or other regulators may disagree with the sufficiency of our right of reference to the preclinical, manufacturing or clinical data generated by these investigator-sponsored trials, or our interpretation of preclinical, manufacturing or clinical data from these investigator-sponsored trials. If so, the FDA or other regulators may require us to obtain and submit additional preclinical, manufacturing, or clinical data.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors for whom they may also be conducting clinical trials or other pharmaceutical product development activities that could harm our competitive position. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approval for EKTERLY (sebetralstat) and any future product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

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 U.S., the E.U., and other countries with respect to our proprietary technology and products. We seek to protect our proprietary position by filing patent applications in the U.S. and abroad related to our novel technologies and product candidates, including EKTERLY (sebetralstat). 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 U.S. 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 U.S. 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 U.S. patent application prior to the effective date of the relevant provisions of the America Invents Act (i.e. before March 16, 2013) covering our products and product candidates, including EKTERLY (sebetralstat), 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 U.S. 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 E.U., the U.S. 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 EKTERLY (sebetralstat) and other 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 U.S. 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 U.S. 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 EKTERLY (sebetralstat) and our other 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 products or 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, EKTERLY (sebetralstat) and other 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 U.S. 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. The loss of the services of any of our management team, other key employees and other scientific and medical advisors, and our inability to find suitable replacements, could result in a failure to successfully commercialize EKTERLY (sebetralstat), delays in product development and harm our business.

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 expect to continue to increase the size of our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We have grown from 150 employees as of April 30, 2024 to 270 employees as of April 30, 2025, and anticipate continuing to add headcount as we further develop our general and administrative capabilities. 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.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, health epidemics and pandemics, and other natural or man-made disasters or business interruptions, for which we may not have insurance coverage. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process EKTERLY (sebetralstat) and our other product candidates. Our ability to obtain supplies of EKTERLY (sebetralstat) and our other product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. Our operations and financial condition could suffer in the event of a natural or man-made disaster near our headquarters in Cambridge, Massachusetts or our office space in Framingham, Massachusetts and research facilities in Cambridge, Massachusetts; Porton Down, United Kingdom; Salt Lake City, Utah; Zug, Switzerland; Tokyo, Japan; and Dublin, Ireland.

Actual or perceived failure to comply with privacy and data security laws, regulations and standards may cause our business to be materially adversely affected.

We are, and may increasingly become, subject to various laws and regulations, as well as contractual obligations, relating to data privacy and security in the jurisdictions in which we operate. Personal privacy and data security have become significant issues in the U.S., Europe and in many other jurisdictions. The regulatory framework for privacy and security issues worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. We maintain a large quantity of sensitive information, including confidential business information and patient health information in connection with our clinical development regarding the patients enrolled in our clinical trials. Any violations of these rules by us could subject us to civil and criminal penalties and adverse publicity and could harm our ability to initiate and complete clinical trials. We cannot provide assurance that current or future legislation will not prevent us from generating or maintaining personal data or that patients will consent to the use of their personal data (as necessary); either of these circumstances may prevent us from undertaking or publishing essential research and development, manufacturing, and commercialization, which could have a material adverse effect on our business, results of operations, financial condition, and prospects.

The myriad international and U.S. privacy and data breach laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. In many jurisdictions, enforcement actions and consequences for noncompliance are also rising. For instance, companies that violate the European Union's General Data Protection Regulation, including as implemented in the United Kingdom (collectively, the "GDPR"), can face fines of up to the greater of 20 million Euros under the E.U. GDPR / 17.5 million pounds under the U.K. GDPR, or 4% of their worldwide annual revenue, whichever is higher. In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. If there is no lawful manner for us to transfer personal data from the E.U., the U.K., or other jurisdictions to the U.S., or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as the E.U. and/or U.K.) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business.

In addition to government regulation, privacy advocates and industry groups may propose new and different self-regulatory standards that either legally or contractually applies to us. Any inability to adequately address privacy and security concerns, even if unfounded, or comply with applicable privacy and data security laws, regulations and policies, could result in additional cost and liability to us, damage our reputation, and adversely affect our business. Additionally, all of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, distract management or divert resources from other initiatives and projects, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Enforcement actions and investigations by regulatory authorities related to data security incidents and privacy violations continue to increase. Any failure or perceived failure by us (or the third parties with whom we have contracted to process such information) to comply with applicable privacy and data security laws, policies or related contractual obligations, or any compromise of security that results in unauthorized access, use or transmission of, personal user information, could result in a variety of claims against us, including governmental enforcement actions and investigations, class action privacy litigation in certain jurisdictions and proceedings by data protection authorities, potentially amounting to significant compensation or damages liabilities, as well as associated costs, diversion of internal resources, and reputational harm. When such events occur, our reputation may be harmed, we may lose current and potential users and the competitive positions of our brand might be diminished, any or all of which could materially adversely affect our business, operating results, and financial condition. In addition, if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, loss of export privileges, or severe criminal or civil sanctions, all of which may have a material adverse effect on our business, operating results, reputation, and financial condition.

Our business and operations would suffer in the event of system failures, cyberattacks or a deficiency in our cybersecurity.

Our internal computer systems and those of our CROs, third-party manufacturers, collaborators and other 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. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us or our CROs or other contractors or consultants we may utilize to mitigate network security problems, bugs, viruses, worms, cyberattacks, phishing attempts, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. 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, including our ongoing KONFIDENT-KID and KONFIDENT-S 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 or impaired.

In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, if applicable, including HIPAA, as amended by HITECH, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. We would also be exposed to a risk of loss or litigation and potential liability under laws, regulations and contracts that protect the privacy and security of personal information. We would also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, reputation, results of operations, financial condition and prospects. Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. The GDPR and other data protection, privacy and similar national, state/provincial and local laws may restrict the access, use, storage, disclosure and other processing activities concerning patient health information abroad. Compliance efforts will likely be an increasing and substantial cost in the future.

In July 2023, the SEC adopted cybersecurity disclosure rules for public companies that require disclosure regarding cybersecurity risk management (including the board's role in overseeing cybersecurity risks, management's role and expertise in assessing and managing cybersecurity risks and processes for assessing, identifying and managing cybersecurity risks) in annual reports on Form 10-K. These cybersecurity disclosure rules also require the disclosure of material cybersecurity incidents by Form 8-K, within four business days of determining an incident is material.

We also depend on our information technology infrastructure for communications among our personnel, contractors, consultants and vendors. System failures or outages could also compromise our ability to perform these functions in a timely manner, which could harm our ability to conduct business or delay our financial reporting.

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. Factors affecting the market price of our common stock 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 or other significant events for us or our competitors;
- 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, or changes to treatment recommendations or guidelines applicable to treatment;
- 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 EKTERLY (sebetralstat) or any of our other 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 U.S., the U.K. or the E.U.;
- 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;
- general economic and market conditions and overall fluctuations in the U.S. equity markets, including due to rising inflation and interest rates, labor shortages, supply chain issues, and global conflicts such as the war in Ukraine; and
- other events or factors, many of which are beyond our control.

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.

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 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 ("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. Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. Effective April 27, 2020, the SEC adopted amendments to the "accelerated filer" and "large accelerated filer" definitions in Rule 12b-2 under the Securities and Exchange Act of 1934. The amendments exclude from the "accelerated filer" and "large accelerated filer" definitions an issuer that is eligible to be a smaller reporting company and that had annual revenues of less than $100 million in the most recent fiscal year for which audited financial statements are available. We determined that our Company does not meet the accelerated or large accelerated filer definitions as of April 30, 2025. For so long as we remain a smaller reporting company and a non-accelerated filer, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies, including, but not limited to, not being required as a non-accelerated filer to comply with the auditor attestation requirements of Section 404(b). An independent assessment by our independent registered public accounting firm of the effectiveness of internal control over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

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.

In addition, if we lose our status as a "non-accelerated filer," we will be required to have our independent registered public accounting firm attest to the effectiveness of internal control over financial reporting. If our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting once we are an accelerated filer or a large accelerated filer, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our common stock could be negatively affected.

Shareholder Activism Could Cause Material Disruption to Our Business.

Publicly traded companies have increasingly become subject to campaigns by activist investors advocating corporate actions such as actions related to environment, social and governance matters, financial restructuring, increased borrowing, dividends, share repurchases or even sales of assets or the entire company. Responding to proxy contests and other actions by such activist investors or others in the future could be costly and time-consuming, disrupt our operations and divert the attention of our board of directors and senior management from the pursuit of our business strategies, which could adversely affect our results of operations and financial condition.

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.

Under the Tax Cuts and Jobs Act of 2017, ("TCJA"), net operating loss carryforwards ("NOLs") generated in taxable years beginning before January 1, 2018 may be carried forward up to twenty taxable years, and NOLs generated in taxable years beginning after December 31, 2017 will not expire, but will only be available to offset up to 80% of our taxable income in the taxable year (before taking into certain deductions). In addition, 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 NOLs, to offset future taxable income. We have experienced ownership changes in the past that substantially limited our use of the NOLs available to us for U.S. federal income tax purposes and as a result we currently expect that approximately $76.7 million of our NOLs will go unutilized. 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 and there may be periods in which certain states suspend our ability to use our NOLs. Accordingly, we may not be able to utilize a material portion of our NOLs against future taxable income. 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.

General Risk Factors

Unstable or unfavorable global market and economic conditions may have adverse consequences on our business, financial condition and stock price.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Challenging or uncertain economic conditions including those related to global epidemics, pandemic, or contagious diseases, regional geopolitical conflicts, inflation, fluctuation in interest rates and foreign exchange rates, uncertainty with respect to the federal debt ceiling and budget and government shutdowns related thereto, actual or perceived instability in the global banking system, disruptions in supply chains may adversely affect our general business strategy and stock price. In addition, a recession, depression or other sustained adverse market event could materially and adversely affect our business and the value of our common stock.

If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon development plans. There is also a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. In addition, regarding the ongoing conflicts in Ukraine and the Middle East, we do not have any clinical trial sites or operations in the respective conflict zones. However, if the current conflict in the region continues, there is the potential for trial sites in other eastern European countries to slow or stop enrollment, or to be unable to administer our clinical trials.

Changes in tax laws or tax rulings could materially affect our financial position, results of operations and cash flows.

The tax regimes we are subject to or operate under, including income and non-income taxes, are unsettled and may be subject to significant change. Changes in tax laws, regulations, or rulings, or changes in interpretations of existing laws and regulations, could materially affect our financial position and results of operations. For example, the TCJA made broad and complex changes to the Code, including changes to U.S. federal tax rates, additional limitations on the deductibility of interest, both positive and negative changes to the utilization of NOL carryforwards, allowing for the expensing of certain capital expenditures, and putting into effect the migration from a "worldwide" system of taxation to a more territorial system. Under the TCJA, research expenditures incurred by us in taxable years beginning after January 1, 2022 currently are subject to capitalization and amortization over five years in the case of domestic research and fifteen years in the case of foreign research. Future guidance from the IRS with respect to the Tax Act may affect us, and certain aspects of the TCJA could be repealed or modified in future

legislation. The IRA, enacted on August 16, 2022, further amended the U.S. tax code, imposing a 15% minimum tax on "adjusted financial statement income" of certain corporations as well as an 1% excise tax on the repurchase or redemption of stock by certain publicly held corporations, beginning in 2023. In addition, it is uncertain if and to what extent various states will conform to the TCJA, the IRA or any newly enacted federal tax legislation.

As we continue to expand internationally, we will be subject to other jurisdictions around the world with increasingly complex tax laws, the application of which can be uncertain. The amount of taxes we pay in these jurisdictions could increase substantially as a result of changes in the applicable tax principles, including increased tax rates, new tax laws or revised interpretations of existing tax laws and precedents, which could have an adverse impact on our liquidity and results of operations. In addition, the authorities in several jurisdictions could review our tax returns and impose additional tax, interest and penalties, which could have an impact on us and on our results of operations. In addition, many countries in Europe and a number of other countries and organizations, have recently proposed or recommended changes to existing tax laws or have enacted new laws that could significantly increase our tax obligations in the countries where we do or intend to do business or require us to change the manner in which we operate our business.

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 may 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 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 1C. Cybersecurity.

Risk Management & Strategy:

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information with the aim to continually improve security to keep pace with the evolving cyber threat landscape.

Our strategy toward managing cybersecurity risk in our business is informed by and aligned with the core principles and methods outlined within the National Institute of Standards and Technology ("NIST") Cybersecurity Framework, while including elements of the International Organization for Standardization's ISO/IEC 27001 publication and industry best practices. This does not mean that we seek to meet any particular technical standards, specifications, or requirements, only that we intend to use the NIST CSF or ISO 27001, and other resources as guides to help us identify, assess, and manage cybersecurity risks relevant to our business. Inclusive in these frameworks and our program are components for continuous improvement through feedback, self-review and external testing.

Our cybersecurity program leverages people, processes and technology to identify and respond to cybersecurity threats in a timely manner. As part of our cybersecurity program, we maintain various protections designed to safeguard against cyberattacks, including but not limited to firewalls, endpoint detection and response, anti-malware, immutable backups, multi-factor

authentication schemes, data encryption, and security system information event monitoring to detect and respond quickly to any emergent threats. In addition, we periodically conduct intrusion and penetration testing through third parties to evaluate our cybersecurity response capability.

We also maintain a security awareness program with mandatory semi-annual training content and perform automated e-mail based phishing tests. Results of testing help to inform and provide continuous improvement of our security awareness training materials, approaches and strategies. We routinely communicate with employees about the potential for cybersecurity threats, including the latest adversary trends and social engineering techniques, and how to avoid them, and the best use of our established communications channels.

We perform a formal cybersecurity risk assessment each year. As part of our risk assessment, we consider the potential for cybersecurity threats, including but not limited to interruptions, outages and breaches to our operational and financial systems. We have policies, processes, internal controls and tools to assess, identify, and manage material risks from potential cybersecurity threats. We engage third-party service providers, with significant information technology and cybersecurity experience, to assist with designing, implementing and managing our information technology infrastructure and cybersecurity program.

In addition, we engage external third-party information security consultants to periodically conduct information security testing and assessments designed to identify, assess, and manage cybersecurity risks, and to evaluate our overarching information security program and specific incident response procedures. We perform diligence on our vendors and prospective vendors regarding their cybersecurity posture. Although we continue to invest in this diligence regarding our critical vendors, our control over the security posture of our vendors is limited, and there can be no assurance that we can prevent or significantly mitigate the risk of any compromise or failure in the information assets owned or controlled by such vendors.

Governance:

The Vice President of IT is responsible for implementing and maintaining the information security program. The Vice President of IT role is currently held by an individual who has over 20 years of experience in enterprise-level IT operations and management, cybersecurity operations and management and IT/Cyber architecture and strategy. The Vice President of IT reports to our CFO, who together are responsible for coordinating information security risk assessments and overseeing periodic testing of our cybersecurity controls. Our CFO meets with the Audit Committee of our board of directors periodically for the audit committee to provide guidance on the prioritization of risk remediation and ongoing implementation of cybersecurity improvements across our organization.

The Vice President of IT engages with our managed service providers to proactively address emerging threats based on industry reports and respond to any threats and incidents. Our managed service providers also provide continuous support and coverage of our environment. We utilize threat intelligence services from multiple organizations, allowing us to proactively respond to emerging cybersecurity threats.

Our board of directors considers cybersecurity risk part of its risk oversight function and has delegated to the Audit Committee of our board of directors' oversight of cybersecurity and other information technology risks. The Audit Committee oversees management's implementation of our cybersecurity risk management program. The relevant members of management regularly update the Audit Committee with respect to cybersecurity risk, also on an ad-hoc basis as necessary, regarding any material cybersecurity incidents and any incidents with lesser impact potential. The Audit Committee periodically reports to the full board of directors regarding its activities, including those related to cybersecurity.

As of the date of this report, we are not aware of any material risks from cybersecurity threats that have materially affected or are reasonably likely to materially affect the Company, including our business strategy, results of operations, or financial condition. However, we are subject to various cybersecurity risks that may adversely affect our business, financial condition and results of operations. See Item 1A. Risk Factors, "*Our business and operations would suffer in the event of system failures, cyberattacks or a deficiency in our cybersecurity*" for further discussion.

Item 2. Properties.

Details of our principal properties as of April 30, 2025, are provided below:

Location	Function	Square footage	Owned or Leased	Initial Lease Term End Date	Lease Extension Options
Cambridge, MA	Corporate Headquarters	8,300	Leased	2028	None
Framingham, MA	Office Space	32,110	Leased	2035	None
Salt Lake City, Utah	Office Space	6,200	Leased	2032	None
Cambridge, MA	Laboratory facility	500	Leased	2028	Option to renew annually
Porton Down, UK	Laboratory and office space facility	13,400	Leased	2028	None
Dublin, Ireland	Office Space	1,100	Leased	2028	None
Tokyo, Japan	Office Space	237	Leased	2026	None
Zug, Switzerland	Office Space	7,200	Leased	2025	Option to renew annually
Berlin, Germany	Office Space	215	Leased	2026	None

The Company believes that our current and future facilities will be adequate for the foreseeable future. Refer to Note 10, *Leases*, in the Notes to the Consolidated Financial Statements for further details on the Company's leases.

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.

Market Information

Our common stock is traded on the NASDAQ Global Market under the symbol "KALV."

Holders

As of June 18, 2025, there were 17 holders of record of our common stock. The actual number of holders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

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.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. Reserved.

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 within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Exchange Act. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "estimate," or "continue," and similar expressions or variations. These statements are based on the beliefs and assumptions of our management based on information currently available to management, reflecting our current expectations that involve risks and uncertainties. Actual results and the timing of certain events may differ materially from those discussed or implied in these forward-looking statements due to a number of factors, including, but not limited to, those set forth in the section entitled "Risk Factors" and elsewhere in this Annual Report on Form 10-K. You should review the risk factors for a more complete understanding of the risks associated with an investment in our securities. 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. Our fiscal year end is April 30, and references throughout this Annual Report to a given fiscal year are to the twelve months ended on that date.

Management Overview

We are a global biopharmaceutical company dedicated to developing and delivering life-changing oral therapies for individuals affected by rare diseases with significant unmet needs. On July 3, 2025, the FDA approved our NDA for EKTERLY (sebetralstat), a novel, orally delivered, small molecule plasma kallikrein inhibitor, for the treatment of acute attacks of hereditary angioedema ("HAE") in adult and pediatric patients aged 12 years and older. EKTERLY (sebetralstat) is the first and only oral, on-demand therapy for HAE.

The efficacy and safety of EKTERLY was established by the results from the phase 3 KONFIDENT clinical trial, published in the *New England Journal of Medicine* in May 2024. The clinical trial met all primary and key secondary endpoints and demonstrated a favorable safety profile. HAE attacks treated with 600 mg of sebetralstat achieved the primary endpoint of beginning of symptom relief significantly faster than placebo (p=0.0013) with a median time to beginning of symptom relief of 1.79 hours (CI 1.33, 2.27) as compared to 6.72 hours with placebo (CI 2.33, >12). Consistent with previous studies, sebetralstat was well-tolerated, with a safety profile similar to placebo. There were no patient withdrawals due to any adverse event and no treatment-related serious adverse events (SAEs) were observed. Treatment-related adverse event rates were 2.2% for 600 mg EKTERLY (sebetralstat) as compared to 4.8% for placebo. Primary and key secondary endpoints were analyzed in a fixed, hierarchical sequence and adjusted for multiplicity. Key secondary endpoints showed:

- Attacks treated with 600mg of EKTERLY (sebetralstat) achieved a significantly faster time to a reduction in attack severity from baseline, compared to placebo (p=0.0032); and
- Attacks treated with 600mg EKTERLY (sebetralstat) demonstrated a significantly faster time to complete attack resolution as compared to placebo (p<0.0001).

Prior to the approval of EKTERLY (sebetralstat), all on-demand treatment options approved in the U.S. for HAE required intravenous or subcutaneous administration, which carries a significant treatment burden. Even with the use of long-term prophylaxis as a preventative therapy, most people living with HAE continue to have unpredictable attacks and require ready access to on-demand medication. We believe that EKTERLY (sebetralstat) has the potential to fundamentally shift the manner in which HAE is managed, based upon extensive and continuing research conducted with patients, physicians and payers.

Key Updates

In August 2024, the EMA validated the submission of our MAA for sebetralstat. This application is currently being reviewed by the EMA's Committee for Medicinal Products for Human Use under the centralized licensing procedure for all 27 Member States of the European Union, as well as the EEA countries Norway, Iceland and Liechtenstein. In September 2024, we announced MAA submissions to the regulatory authorities in the United Kingdom, Switzerland, Australia, and Singapore via the Access Consortium framework for which we have obtained a four-way sharing agreement by the Medicines and Healthcare product Regulatory Agency, Swissmedic, the Therapeutic Goods Administration and Health Sciences Authority. The Access Consortium is designed to maximize regulatory collaboration across countries and support a timely review process. In January 2025, we announced that Japan's MHLW had granted sebetralstat orphan drug designation, and we also submitted an NDA for

sebetralstat to that agency. To enable the broadest possible global availability of sebetralstat, if approved, we intend to engage commercial partners in certain international markets.

Sebetralstat has received fast track and orphan drug designations from the FDA, orphan drug Designation from Japan's MHLW, as well as orphan drug designation and an approved Pediatric Investigational Plan from the EMA. In November 2023, sebetralstat was granted orphan drug status in Switzerland. In February 2024, the U.K. Medicines and Healthcare products Regulatory Agency ("MHRA") awarded the Innovation Passport for sebetralstat.

In November 2024, we, as guarantor, and KalVista Pharmaceuticals Limited, our wholly owned subsidiary (the "Subsidiary), entered into a Purchase and Sale Agreement the ("PSA") with DRI Healthcare Acquisitions LP (the "Purchaser"), an affiliate of DRI Healthcare Trust, pursuant to which the Subsidiary sold to the Purchaser the right to receive payments from the Subsidiary at a tiered percentage of future worldwide net sales of sebetralstat. Under the terms of the PSA, the Subsidiary received an upfront payment of $100.0 million in exchange for tiered payments on worldwide net sales of sebetralstat, as follows: 5.00% on annual net sales up to and including $500.0 million; 1.10% on annual net sales above $500.0 million and up to and including $750.0 million; and 0.25% on annual net sales above $750.0 million. The Subsidiary is entitled to a potential one-time sales-based milestone payment of $50.0 million if annual global net sales of sebetralstat meet or exceed $550.0 million in any calendar year before January 1, 2031. If sebetralstat is approved prior to October 1, 2025, the Subsidiary has the option to receive a one-time payment of $22.0 million. On July 7, 2025, KalVista Pharmaceuticals Limited, our wholly owned subsidiary, notified DRI it elected to receive the additional payment of $22.0 million in cash following the July 3, 2025 FDA approval of EKTERLY (sebetralstat). If the Subsidiary chooses to receive this optional payment, the royalty rate on net sales up to and including $500 million will increase from 5.00% to 6.00%, and the sales-based milestone amount will increase from $50.0 million to $57.0 million.

In April 2025, KalVista Pharmaceuticals Limited licensed commercialization rights in Japan to Kaken Pharmaceutical, Co., Ltd. for sebetralstat. We received an upfront payment of $11.0 million on June 20, 2025, with an additional payment of up to $11.0 million upon achievement of a regulatory milestone anticipated in early 2026. Beyond these payments, we are eligible for commercial milestone payments, plus royalties based on the Japan National Health Insurance (NHI) price, with the royalty rate as a percentage of sales approximately in the mid-twenties.

Change in fiscal year

On March 13, 2025, the Board approved a change to our fiscal year end from April 30 to December 31. The change in fiscal year is effective for the Company's 2026 fiscal year.

Financial Overview

Revenue

We have not generated any revenue from the sale of products, as we had not yet received approval for commercialization of EKTERLY (sebetralstat) as of April 30, 2025. On July 3, 2025, the FDA approved our NDA for the use of EKTERLY (sebetralstat), a novel, orally delivered, small molecule plasma kallikrein inhibitor, for the treatment of acute attacks of HAE in adult and pediatric patients aged 12 years and older. We do not expect to generate other product revenue unless and until we obtain regulatory approval for, and commercialize, one of our other current or future product candidates.

Research and Development Expenses

Research and development expenses primarily consist of costs associated with our research activities, including the cost to manufacture the commercial drug supply of EKTERLY (sebetralstat) prior to any FDA approval and 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. All research and development costs are expensed as incurred.

Costs for certain research and development activities, such as manufacturing development activities and clinical studies are recognized based on the contracted amounts, as adjusted for the percentage of work completed to date. Payments for these activities are based on the terms of the contractual arrangements, which may differ from the pattern of costs incurred, and are reflected on the consolidated balance sheets as prepaid or accrued expenses. We defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed.

We expect to continue to spend a significant amount of our resources on research and development activities for the foreseeable future as we continue to conduct clinical development 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 regulatory 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 currently estimate with any degree of certainty the costs associated with development of our product candidates. 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 employee-related expenses, including salaries, benefits and equity-based compensation expenses for personnel, costs of establishing a commercial organization to sell, market and distribute our product candidates and costs in executive, finance, legal, medical affairs, information technology, human resources, investor relations, and commercial functions. Other significant general and administrative expenses include facility costs not otherwise included in research and development expenses, legal fees relating to patent and corporate matters and fees for accounting, consulting services, and corporate expenses. We expect general and administrative expense to increase as we continue to invest in building the infrastructure to support the commercialization of EKTERLY (sebetralstat).

Other Income

Other income consists of interest income earned on bank interest and marketable securities, interest expense from the royalty liability, change in fair value of the derivative liability, research and development tax credits from the United Kingdom government's tax incentive programs, realized gains and losses from marketable securities and realized and unrealized exchange rate gains and losses on cash held in foreign currencies and transactions settled in foreign currencies.

Income Taxes

We historically have incurred net losses and have had 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. For tax purposes, we capitalize and subsequently amortize all allowable R&D expenditures over five years for research activities conducted in the U.S. and over fifteen years for research activities conducted outside of the U.S. As a result of the November 2024 PSA and the Kaken Agreement executed in April 2025, the $100.0 million up-front payment and the $11.0 million up-front payment, respectively, were treated as income for tax purposes in the UK under the Research and Development Expenditure Credit scheme. After applying the estimated net operating loss carryforwards and research and development tax credits, we recorded income tax expense of $3.4 million for the year ended April 30, 2025.

Critical Accounting 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 U.S. ("U.S. 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 this Annual Report on Form 10-K, 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:

Liability Related to the Deferred Royalty Obligation

In November 2024, we entered into a royalty financing with DRI to monetize a portion of our future EKTERLY (sebetralstat) royalties in exchange for an upfront payment of $100.0 million. We accounted for the deferred royalty financing arrangement as debt due to it being probable at the time of entering into the arrangement that we would have commercial sales of EKTERLY and our continuing involvement in the future sales of EKTERLY. Under our agreement with DRI, we calculated the liability related to the sale of future royalties, effective interest rate and the related interest expense using our current estimate of anticipated future royalty payments under the arrangement, which we reassess quarterly based on the current net sales forecasts utilizing the prospective method. The amount that DRI will receive under the agreement is based on sales of EKTERLY (sebetralstat), a product candidate that was not commercialized as of year end. As such, the repayment amounts that we estimate related to projections of future sebetralstat revenues contain subjective estimation, which we believe could lead to changes in estimates in the future. If there is a material change in our estimate, we will prospectively adjust the timing and amount of payments due, effective interest rate and the related interest expense.

Under the PSA, the Subsidiary has the option (the "Buy-Back Option") to repurchase future Revenue Participation Rights at any time until December 31, 2026 either (i) in the event of a change of control of the Subsidiary or (ii) in the event that confirmation that payment of the Revenue Participation Rights will not receive certain tax treatment has not been obtained. Additionally, the Purchaser has an option (the "Put Option") to require the Subsidiary to repurchase future Revenue Participation Rights in the event of a change of control of the Subsidiary exercisable until December 31, 2026. The Buy-Back and Put Options are considered embedded derivatives requiring bifurcation as a single compound derivative instrument. The Company estimated the fair value of the derivative liability using a "with-and-without" method. The with-and-without methodology involves valuing the whole instrument on an as-is basis and then valuing the instrument without the individual embedded derivative. The difference between the entire instrument with the embedded derivative compared to the instrument without the embedded derivative is the fair value of the derivative liability. The initial fair value allocated to the derivative liability was recorded against the deferred royalty obligation as a debt discount, which is being amortized in interest expense on the consolidated statement of operations over the expected term using the effective interest method. The embedded derivative is subsequently remeasured at fair value each reporting period.

There are numerous factors, most of which are not within our control, that could materially impact the amount and timing of future royalty payments and could result in changes to our estimate of future royalty payments to DRI. Such factors include, but are not limited to, the expected commercial sales of EKTERLY (sebetralstat), upon FDA approval, competing products or other significant events. These factors and other events or circumstances could result in reduced royalty payments from expected sales of EKTERLY (sebetralstat), which would result in a reduction of our royalty revenue and interest expense over the life of the agreement. Conversely, if sales of EKTERLY (sebetralstat) are more than amounts we estimated, the royalty revenue payments and non-cash interest expense we record would be greater over the life of the arrangement.

Results of Operations

This section of this Annual Report on Form 10-K generally discusses fiscal years 2025 and 2024 items and year-to-year comparisons between fiscal years 2025 and 2024. Discussions of fiscal year 2024 items and year-to-year comparisons between fiscal years 2024 and 2023 that are not included in this Annual Report on Form 10-K can be found in Part II, Item 7 of our Annual Report on Form 10-K for the fiscal year ended April 30, 2024, which was filed with the SEC on July 11, 2024.

Year Ended April 30, 2025 Compared to Year Ended April 30, 2024

The following table sets forth the key components of our results of operations for the years ended April 30, 2025 and 2024:

	Years Ended April 30,		Increase (Decrease)
	2025	2024	
	(in thousands)		
Operating Expenses			
Research and development expenses	71,709	86,167	(14,458)
General and administrative expenses	116,286	54,278	62,008
Other income			
Interest, exchange rate gain and other income	7,943	13,801	(5,858)

Revenue. No revenue was recognized in the years ended April 30, 2025 or 2024.

Research and Development Expenses. Research and development expenses were $71.7 million in the year ended April 30, 2025 compared to $86.2 million in the prior year. The decrease of $14.5 million was primarily due to decreases in R&D spending on sebetralstat and KVD824 of $7.7 million, as the Company's focus shifted to building out the commercialization of sebetralstat pending FDA approval. In addition, the decrease was further driven by a decline in personnel costs of $2.7 million and preclinical and other activities of $3.9 million. The impact of exchange rates on research and development expenses was an increase of approximately $0.9 million compared to the prior year, which is reflected in the figures above.

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

	Years Ended April 30,		Increase (Decrease)	
	2025	2024		
	(in thousands)			
Program-specific costs				
Sebetralstat	$ 29,211	$ 36,544	(7,333)	-20%
KVD824	—	411	(411)	-100%
Unallocated costs				
Personnel	29,481	32,229	(2,748)	-9%
Other R&D	13,017	16,983	(3,966)	-23%
Total	$ 71,709	$ 86,167	$ (14,458)	-17%

We anticipate that these expenses will remain at or slightly below current levels as both the KONFIDENT-S and KONFIDENT-KID trials are ongoing.

Personnel expenses will remain at or slightly below current levels as we prioritize commercial launch efforts.

Other R&D costs decreased primarily due to decreased spending on preclinical activities and a transition to recognizing expense associated with sebetralstat pre-commercial awareness to *General & Administrative Expenses*, as the nature of the expense no longer represented research activities. We anticipate Other R&D costs to remain at current levels as we continue development of the oral Factor XIIa inhibitor program and other preclinical activities.

General and Administrative Expenses. General and administrative expenses were $116.3 million in the year ended April 30, 2025 compared to $54.3 million in the prior fiscal year. The increase of $62.0 million was primarily due to increases of $25.5 million in employee-related expenses primarily from the build out of the commercial and sales organization, $19.2 million in commercial expenses, $8.5 million in EKTERLY (sebetralstat) medical awareness expenses, $3.9 million in professional fees and $4.8 million in other administrative expenses. We anticipate that expenses will increase as we continue to support the commercial launch of EKTERLY.

Other Income. Other income was $7.9 million for the year ended April 30, 2025 compared to $13.8 million in the prior fiscal year. The decrease of $5.8 million was primarily due to a decrease of $3.3 million in income from research and development tax credit as a result of less qualified R&D spending, a $5.8 million increase in interest expense from the Deferred Royalty Obligation and a $1.7 million expense recorded on the change in fair value of the derivative liability. This decrease was partially offset by an increase of $2.5 million in interest income attributable to high average cash and investment balances, and foreign currency exchange rate gains of $2.3 million from transactions denominated in foreign currencies in our foreign subsidiaries and other increases.

Liquidity and Capital Resources

Since inception, we have not generated any revenue from product sales and have incurred losses and cash outflows from operating activities for the years ended April 30, 2025 and 2024. As of April 30, 2025, we had an accumulated deficit of $653.2 million and cash, cash equivalents and marketable securities totaling $220.6 million. We have funded operations primarily through a combination of equity financings, collaborations, strategic partnerships, royalty financings, and licensing arrangements. Our working capital, primarily cash and marketable securities, is anticipated to be sufficient to fund our operations for at least the next twelve months from the date these consolidated financial statements are issued. The Company anticipates cash flows from the sale of EKTERLY.

Sources of Liquidity

In February 2024, we entered into an underwriting agreement with Jefferies LLC, Leerink Partners LLC, Stifel, Nicolaus & Company, Incorporated, and Cantor Fitzgerald & Co., as the representatives of several underwriters to sell an aggregate of 7,016,312 shares of our common stock at a price of $15.25 per share and pre-funded warrants to purchase up to 3,483,688 shares of our common stock at a price of $15.249 per pre-funded warrant (the "February 2024 Offering"). The net proceeds from the February 2024 Offering, after deducting expenses, were approximately $150.1 million. As of April 30, 2025, no pre-funded warrants from the February 2024 Offering have been exercised.

In July 2024, we filed the Registration Statement (as defined below) pursuant to which we may offer and sell securities having an aggregate public offering price of up to $300 million.

In November 2024, we entered into an underwriting agreement with Jefferies LLC, BofA Securities, Inc., TD Securities (USA) LLC and Stifel Nicolaus & Company, Incorporated, as the representatives of several underwriters to sell an aggregate of 5,500,000 shares of our common stock at an offering price of $10.00 per share (the "November 2024 Offering") pursuant to the Registration Statement. The net proceeds from the November 2024 Offering, after deducting expenses, were approximately $51.3 million.

Also in November 2024, we entered into a securities purchase agreement with DRI Healthcare Acquisitions LP to sell an aggregate of 500,000 shares of our common stock at a price of $10.00 per share in a private placement. The net proceeds from the private placement, after deducting placement agent fees and other expenses, were approximately $4.7 million.

Finally, in November 2024 we entered into a royalty purchase agreement with DRI Healthcare Acquisitions LP, an affiliate of DRI Healthcare Trust Royalty Pharma to monetize a portion of our future sebetralstat worldwide net sales. Under the terms of the agreement, we received an upfront payment of $100.0 million in exchange for tiered royalty payments on worldwide net sales of sebetralstat, which is recorded as the Royalty Liability on our Consolidated Balance Sheet.

In April 2025, the Company entered into the Kaken Agreement with Kaken pursuant to which the Company has licensed exclusive commercialization rights in Japan to Kaken for the Licensed Product in exchange for a non-refundable upfront payment of $11.0 million, potential regulatory and sales milestone payments totaling approximately $13.0 million and effective royalty payments in the mid-twenties that shall be payable for each unit of revenue of Licensed Product that the Company supplies, which reflect a percentage of the Japanese National Health Insurance price of the Licensed Product. On June 20, 2025, we received the upfront payment of $11.0 million.

Cash Flows

The following table shows a summary of the net cash flow activity for the years ended April 30, 2025 and 2024:

	Years Ended April 30,	
	2025	2024
	(in thousands)	
Cash flows used in operating activities	$ (152,907)	$ (89,231)
Cash flows (used in) provided by investing activities	91,024	(84,719)
Cash flows provided by financing activities	159,727	150,714
Effect of exchange rate changes on cash	2,639	(1,213)
Net (decrease) increase in cash and cash equivalents	$ 100,483	$ (24,449)

Net cash used in operating activities

Net cash used in operating activities was $152.9 million for the year ended April 30, 2025 and primarily consisted of a net loss of $183.4 million adjusted for stock-based compensation of $12.3 million, an increase of deferred revenue related to the upfront payment of $11.0 million from Kaken, a decrease in the research and development tax credit receivable of $7.3 million, and other changes in net working capital. The research and development tax credit receivable decreased due to the lower tax credit rate which occurred in April 2024 and decreased qualified R&D spending. Net cash used in operating activities was $89.2 million for the year ended April 30, 2024 and primarily consisted of a net loss of $126.6 million adjusted for stock-based compensation of $21.9 million, a decrease in the research and development tax credit receivable of $8.2 million, and other changes in net working capital.

Net cash (used in) provided by investing activities

Net cash provided by investing activities was $91.0 million for the year ended April 30, 2025 and primarily consisted of sales and maturities of marketable securities of $122.5 million offset by purchases of marketable securities of $30.5 million. Net cash used in investing activities was $84.7 million for the year ended April 30, 2024 and primarily consisted of purchases of marketable securities of $189.2 and spend on website development costs of $0.4 million offset by sales and maturities of marketable securities of $105.0 million.

Net cash provided by financing activities

Net cash provided by financing activities was $156.9 million for the year ended April 30, 2025 and consisted of $95.2 million in net proceeds from the Royalty Agreement, $55.9 million from the issuance of common stock and $5.7 million from the issuance of common stock from equity incentive plans. Net cash provided by financing activities was $150.7 million for the year ended April 30, 2024 and primarily consisted of the $150.1 million in net proceeds from the February 2024 Underwritten Offering of common stock and pre-funded warrants.

Recent Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our consolidated financial statements.

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

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed are listed in Item 15 of this Annual Report on Form 10-K 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 Exchange Act of 1934, our management, under the supervision and with the participation of our Chief Executive Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of April 30, 2025. 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, 2025 our Chief Executive Officer has concluded that, as of April 30, 2025, 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, 2025. 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, 2025, 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. Effective April 27, 2020, the SEC adopted amendments to the "accelerated filer" and "large accelerated filer" definitions in Rule 12b-2 under the Exchange Act. The amendments exclude from the accelerated and large accelerated filer definitions an issuer that is eligible to be a smaller reporting company and that had annual revenues of less than $100 million in the most recent fiscal year for which audited financial statements are available. We determined that our Company does not meet the accelerated or large accelerated filer definitions as of April 30, 2025. For as long as we remain a non-accelerated filer, we intend to take advantage of the exemption permitting us not to comply with the requirement under Section 404(b) of the Sarbanes-Oxley Act of 2002 that our independent registered public accounting firm provide an attestation on the management's assessment of 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 year ended April 30, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Insider Trading Arrangements and Policies

During the three months ended April 30, 2025, no director or officer of the Company adopted, modified, or terminated a "Rule 10b5-1 trading agreement; or a "non-Rule 10b5-1 trading agreement' as each term is defined in Item 408(a) of Regulation S-K.

ATM

On July 10, 2025, we entered into a sales agreement (the "Sales Agreement") with TD Securities (USA) LLC ("TD Cowen") under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $100,000,000 (the "ATM Shares"), through TD Cowen as sales agent for the ATM. The ATM Shares offered and sold under the ATM will be issued pursuant to our Registration Statement on Form S-3 filed with the U.S. Securities and Exchange Commission on July 11, 2024 (the "Registration Statement"), the prospectus supplement relating to the ATM filed on July 10, 2025, and any applicable additional prospectus supplement related to the ATM that forms a part of the Registration Statement.

Pursuant to the Sales Agreement, TD Cowen may sell the ATM Shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended. TD Cowen will use its commercially reasonable efforts to place the ATM Shares from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may impose). The Sales Agreement provides that TD Cowen will be entitled to compensation of up to 3.0% of the gross proceeds of the ATM Shares sold through TD Cowen. We will also reimburse TD Cowen for certain expenses incurred in connection with the Sales Agreement, and also have provided TD Cowen with customary indemnification rights. We have no obligation to sell any of the ATM Shares under the Sales Agreement and may at any time suspend solicitation and offers under the Sales Agreement. The ATM will terminate upon the earlier of (i) the sale of the Maximum Amount (as defined in the Sales Agreement) or (ii) the termination of the Sales Agreement according to its terms by either us or TD Cowen. The Sales Agreement contains representations for the benefit of us and TD Cowen and other terms customary for similar agreements.

We currently intend to use the net proceeds from the ATM for general corporate purposes and working capital, including the commercialization of EKTERLY (sebetralstat).

The foregoing description of the Sales Agreement is not complete and is qualified in its entirety by reference to the full text of the Sales Agreement, a copy of which is filed as Exhibit 10.24 to this Annual Report on Form 10-K and is incorporated herein by reference.

This Annual Report on Form 10-K shall not constitute an offer to sell or the solicitation of an offer to buy the securities discussed herein, nor shall there be any offer, solicitation, or sale of the securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

Item 9C. Disclosure Regarding Jurisdictions That Prevent Inspections

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 is set forth in our 2025 Proxy Statement to be filed with the SEC within 120 days of April 30, 2025, and is incorporated by reference into this Annual Report on Form 10-K.

Item 11. Executive Compensation.

The information required by this Item 11 is set forth in our 2025 Proxy Statement to be filed with the SEC within 120 days of April 30, 2025, and is incorporated by reference into this Annual Report on Form 10-K.

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

The information required by this Item 12 is set forth in our 2025 Proxy Statement to be filed with the SEC within 120 days of April 30, 2025, and is incorporated by reference into this Annual Report on Form 10-K.

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

The information required by this Item 13 is set forth in our 2025 Proxy Statement to be filed with the SEC within 120 days of April 30, 2025, and is incorporated by reference into this Annual Report on Form 10-K.

Item 14. Principal Accounting Fees and Services.

The information required by this Item 14 is set forth in our 2025 Proxy Statement to be filed with the SEC within 120 days of April 30, 2025, and is incorporated by reference into this Annual Report on Form 10-K.

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.*

		Incorporated by reference				
Exhibit Number	Description of Document	Form	File No.	Exhibit	Filing Date	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation.	10-Q	001-36830	3.1	December 7, 2023	
3.2	Amended and Restated Bylaws.	8-K	001-36830	3.1	June 14, 2023	
4.1	Form of Common Stock Certificate.	S-1/A	333-201278	4.2	January 23, 2015	
4.2	Description of Registrant's Securities.					X
4.3	Form of Pre-Funded Warrant (February 2024 Offering).	10-Q	001-36830	4.1	March 11, 2024	
5.1	Opinion of Fenwick & West LLP.					X
10.1#	Form of Indemnification Agreement.	S-1	333-201278	10.14	December 29, 2014	
10.2#	Carbylan 2015 Incentive Plan and forms of award agreements.	S-1/A	333-201278	10.3	January 23, 2015	
10.3#	2017 Equity Incentive Plan.	DEF 14A	001-36830	Appendix A	March 2, 2017	
10.4#	2017 Employee Stock Purchase Plan.	DEF 14A	001-36830	Appendix B	March 2, 2017	
10.5#	Forms of Equity Agreements under the 2017 Equity Incentive Plan.	8-K	001-36830	99.1	June 29, 2018	
10.6	Office Lease Agreement by and between the Registrant and 55 Cambridge Parkway, LLC, dated May 30, 2017.	10-K	001-36830	10.12	July 27, 2017	
10.7	Office Lease Agreement by and between the Registrant and OC 990 Corporate Center Associates, LLC dated July 22, 2024.	10-Q	001-36830	10.1	September 5, 2024	
10.8	Underlease by and between the Registrant and Wiltshire Council, dated April 30, 2018.	8-K	001-36830	10.1	May 2, 2018	
10.9#	Enrollment/Change Form under the 2017 Employee Stock Purchase Plan.	S-8	333-237059	99.4	March 10, 2020	
10.10#	Service Agreement dated November 1, 2015, by and between KalVista. Pharmaceuticals Ltd and Dr. Christopher M. Yea.	10-K	001-36830	10.15	July 30, 2018	
10.11#	Amendment, dated January 31, 2019, to the Service Agreement dated November 1, 2015 by and between KalVista Pharmaceuticals Ltd and Dr. Christopher M. Yea.	10-Q	001-36830	10.1	March 14, 2019	
10.12#	Equity Acceleration Letter, dated March 11, 2019 by and between KalVista Pharmaceuticals Ltd and Dr. Christopher M. Yea.	10-Q	001-36830	10.2	March 14, 2019	
10.13#	Amendment, dated June 26, 2019, to the Service Agreement dated November 1, 2015	10-K	001-36830	10.23	July 16, 2019	

	by and between KalVista. Pharmaceuticals Ltd and Dr. Christopher M. Yea.					
10.14#	Amended and Restated Executive Employment Agreement between Registrant and Paul K. Audhya, dated September 9, 2024.	8-K	001-36830	10.3	September 10, 2024	
10.15	First Amendment of Lease, dated November 20, 2020, to the Office Lease Agreement by and between the Registrant and 55 Cambridge Parkway, LLC, dated May 19, 2017.	10-Q	001-36830	10.1	December 10, 2020	
10.16#	Amended and Restated Executive Employment Agreement between the Registrant and Benjamin L. Palleiko, dated September 9, 2024.	8-K	001-36830	10.2	September 10, 2024	
10.17	Amended and Restated 2021 Equity Inducement Plan and forms of agreement.	S-8	333-280579	99.1	June 28, 2024	
10.18	Separation Agreement by and between the Registrant and T. Andrew Crockett, dated March 6, 2024.	10-Q	001-36830	10.2	September 5, 2024	
10.19#	Executive Employment Agreement by and between the Registrant and Brian Piekos, dated September 9, 2024.	8-K	001-36830	10.1	September 10, 2024	
10.20	Securities Purchase Agreement by and between KalVista Pharmaceuticals, Inc. and DRI Healthcare Acquisitions LP, dated November 4, 2024.	8-K	001-36830	1.2	November 4, 2024	
10.21	Purchase and Sale Agreement by and among the Registrant, as guarantor, KalVista Pharmaceuticals Ltd. and DRI Healthcare Acquisitions LP, dated November 4, 2024.	10-Q	001-36830	10.1	March 12, 2025	
10.22	Debenture by and between KalVista Pharmaceuticals Ltd and DRI Healthcare Acquisitions LP, dated November 4, 2024.	10-Q	001-36830	10.2	March 12, 2025	
10.23	License, Supply, and Distribution Agreement between Kaken Pharmaceutical Co., Ltd and KalVista Pharmaceuticals, Ltd, dated April 8, 2025.					X
10.24	Sales Agreement between the Company and TD Securities (USA) LLC, dated July 10, 2025.					X
19.1	Insider Trading Policy.					X
21.1	Subsidiaries of the Registrant.					X
23.1	Consent of Deloitte & Touche LLP.					X
24.1	Power of Attorney. (See signature page hereto.)					X
31.1	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.					X
31.2	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.					X
32.1*	Certification of Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as					X

	adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					
32.2*	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.					X
97.1	Compensation Recovery Policy	10-K	001-36830	97.1	July 11, 2024	
101.INS	Inline XBRL Instance Document - the instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					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.

^ Registrant has omitted schedules and exhibits pursuant to Item 601(a)(5) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of the omitted schedules and exhibits to the SEC 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 Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

KalVista Pharmaceuticals, Inc.

Date: July 10, 2025

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

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Benjamin L. Palleiko and Brian Piekos, 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.

Name	Title	Date
/s/ Benjamin L Palleiko Benjamin L. Palleiko	Chief Executive Officer and Director (Principal Executive)	July 10, 2025
/s/ Brian Piekos Brian Piekos	Chief Financial Officer (Principal Financial and Accounting Officer)	July 10, 2025
/s/ Brian J.G. Pereira Brian J.G. Pereira, M.D.	Director and Chairman	July 10, 2025
/s/ William Fairey William Fairey	Director	July 10, 2025
/s/ Laurence Reid Laurence Reid, Ph.D.	Director	July 10, 2025
/s/ Nancy Stuart Nancy Stuart	Director	July 10, 2025
/s/ Patrick Treanor Patrick Treanor	Director	July 10, 2025
/s/ Edward W. Unkart Edward W. Unkart	Director	July 10, 2025

KALVISTA PHARMACEUTICALS, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows, for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of April 30, 2025 and 2024, 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Deferred Royalty Obligation — Refer to Notes 2 and 11 to the financial statements

Critical Audit Matter Description

On November 4, 2024, the Company, as guarantor, and KalVista Pharmaceuticals Limited, a wholly owned subsidiary of the Company (the “Subsidiary”), entered into a Purchase and Sale Agreement (the “PSA”) with DRI Healthcare Acquisitions LP, an affiliate of DRI Healthcare Trust (“DRI”), for up to $179 million. Under the terms of the PSA, the Subsidiary received an upfront payment of $100.0 million in exchange for tiered royalty payments on worldwide net sales of sebetralstat (“Revenue Participation Rights”). Under the PSA, the Subsidiary has the option (the “Buy-Back Option”) to repurchase future Revenue Participation Rights and DRI has an option (the “Put

Option") to require the Subsidiary to repurchase future Revenue Participation Rights.

The PSA is considered a sale of future revenues and is accounted for as long-term debt (deferred royalty obligation) recorded at amortized cost using the effective interest rate method. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the anticipated life of the arrangement. In addition, the Buy-Back and Put Options are considered embedded derivatives requiring bifurcation as a single compound derivative instrument. The Company estimated the fair value of the derivative liability using a "with-and-without" method.

We identified the accounting treatment for the PSA, which is recorded within the deferred royalty obligation on the balance sheet, as the critical audit matter because of the complexity involved in evaluating (1) the accounting for the deferred royalty obligation as debt and (2) evaluating the existence of and accounting for features embedded in the PSA that must be separated and accounted for as a derivative.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the accounting for the PSA included the following, among others:

- Reading the terms of the PSA.
- Agreeing the $100 million proceeds in the agreement to cash received.
- Evaluating management's assertion that future sales of sebetralstat are within the scope of FASB ASC Topic No. 606, *Revenue from Contracts with Customers*, and the Company has significant continuing involvement in the generation of future cash flows.
- Evaluating management's assertion that the completion of research and development activities, receipt of all required regulatory approvals, and commercialization and future sales were all probable on the date the PSA was entered into.
- Utilizing the assistance of our professionals with specialized knowledge and skills in the relevant technical accounting guidance, we evaluated (1) the classification and presentation of the deferred royalty obligation as debt and (2) the existence of features in the PSA that must be separated and accounted for as a derivative by evaluating the terms against the relevant technical accounting guidance.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
July 10, 2025

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

KALVISTA PHARMACEUTICALS, INC.
Consolidated Balance Sheets
April 30, 2025 and 2024
(in thousands except share and per share amounts)

	2025	2024
Assets		
Current assets:		
Cash and cash equivalents	$ 131,615	$ 31,789
Marketable securities	89,002	178,612
Research and development tax credit receivable	1,383	8,439
Prepaid expenses and other current assets	19,690	6,850
Total current assets	241,690	225,690
Property and equipment, net	1,988	2,227
Right of use assets	5,544	6,920
Other assets	1,548	567
Total assets	$ 250,770	$ 235,404
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,883	$ 9,107
Accrued expenses	27,307	12,398
Lease liability - current portion	1,977	1,302
Deferred revenue	11,000	—
Total current liabilities	45,167	22,807
Long-term liabilities:		
Lease liability - net of current portion	4,330	6,015
Deferred royalty obligation	105,882	—
Total long-term liabilities	110,212	6,015
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, $0.001 par value, 100,000,000 authorized		
Shares issued and outstanding: 49,762,048 and 42,521,975 as of April 30, 2025 and 2024, respectively	50	42
Additional paid-in capital	753,725	679,754
Accumulated deficit	(653,170)	(469,726)
Accumulated other comprehensive loss	(5,214)	(3,488)
Total stockholders' equity	95,391	206,582
Total liabilities and stockholders' equity	$ 250,770	$ 235,404

See notes to consolidated financial statements.

KALVISTA PHARMACEUTICALS, INC.
Consolidated Statements of Operations and Comprehensive Loss
Years Ended April 30, 2025 and 2024
(in thousands, except share and per share amounts)

	2025	2024
Operating expenses:		
Research and development	$ 71,709	$ 86,167
General and administrative	116,286	54,278
Total operating expenses	187,995	140,445
Operating loss	(187,995)	(140,445)
Other income:		
Interest income	6,435	3,896
Interest (expense)	(5,785)	—
Foreign currency exchange gain (loss)	2,481	138
Other income (expenses), net	4,812	9,767
Total other income	7,943	13,801
Loss before income taxes	(180,052)	(126,644)
Income tax (benefit) expense	3,392	—
Net loss	$ (183,444)	$ (126,644)
Other comprehensive (loss) income:		
Foreign currency translation loss	(2,523)	(394)
Unrealized holding gain on marketable securities	2,358	1,291
Reclassification adjustment for realized (gain) loss on available for sale securities included in net loss	(1,561)	(1,325)
Total other comprehensive (loss):	$ (1,726)	$ (428)
Comprehensive loss	$ (185,170)	$ (127,072)
Net loss per share, basic and diluted	$ (3.69)	$ (3.44)
Weighted average common shares outstanding, basic and diluted	49,652,878	36,786,575

See notes to consolidated financial statements.

KALVISTA PHARMACEUTICALS, INC.
Consolidated Statements of Changes in Stockholders' Equity
Years Ended April 30, 2025 and 2024
(in thousands, except share and per share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance at April 30, 2023	34,171,138	$ 34	$ 507,133	$ (343,082)	$ (3,060)	$ 161,025
Exercise of stock options	25,182	—	184	—	—	184
Issuance of stock under employee stock purchase plan	68,677	—	462	—	—	462
Release of restricted and performance stock units	1,058,213	1	(1)	—	—	—
Issuance of common stock, net of issuance costs of $0.5 million	7,016,312	7	96,938	—	—	96,945
Issuance of pre-funded warrants for the purchase of common stock, net of issuance costs	—	—	53,123	—	—	53,123
Cashless exercise of pre-funded warrants	182,453	—	—	—	—	—
Stock-based compensation expense	—	—	21,915	—	—	21,915
Net loss	—	—	—	(126,644)	—	(126,644)
Foreign currency translation loss	—	—	—	—	(394)	(394)
Unrealized holding gain from marketable securities	—	—	—	—	1,291	1,291
Reclassification adjustment for realized gain on marketable securities included in net loss	—	—	—	—	(1,325)	(1,325)
Balance at April 30, 2024	42,521,975	42	679,754	(469,726)	(3,488)	206,582
Exercise of stock options	589,739	1	4,900	—	—	4,901
Issuance of stock under employee stock purchase plan	104,173	—	875	—	—	875
Release of restricted and performance stock units	546,161	1	—	—	—	1
Issuance of common stock, net of issuance costs of $0.5 million	6,000,000	6	55,905	—	—	55,911
Stock-based compensation expense	—	—	12,291	—	—	12,291
Net loss	—	—	—	(183,444)	—	(183,444)
Foreign currency translation loss	—	—	—	—	(2,523)	(2,523)
Unrealized holding gain from marketable securities	—	—	—	—	2,358	2,358
Reclassification adjustment for realized gain on marketable securities included in net loss	—	—	—	—	(1,561)	(1,561)
Balance at April 30, 2025	49,762,048	$ 50	$ 753,725	$ (653,170)	$ (5,214)	$ 95,391

See notes to consolidated financial statements.

KALVISTA PHARMACEUTICALS, INC.
Consolidated Statements of Cash Flows
Years Ended April 30, 2025 and 2024
(in thousands)

	2025	2024
Cash flows from operating activities:		
Net loss	$ (183,444)	$ (126,644)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	941	816
Stock-based compensation expense	12,291	21,915
Realized (gain) loss from sale of marketable securities	(1,561)	(1,325)
Non-cash operating lease expense	370	(12)
Amortization of premium on available for sale securities	14	92
Foreign currency exchange loss (gain)	(4,175)	760
Fair value adjustment to derivative liability	1,750	—
Non-cash interest expense and amortization of issuance costs	5,872	—
Changes in operating assets and liabilities:		
Research and development tax credit receivable	7,251	8,176
Prepaid expenses and other assets	(1,358)	(538)
Other receivables	(10,874)	—
Accounts payable	(4,971)	4,320
Accrued expenses	14,429	3,209
Deferred revenue	10,558	—
Net cash used in operating activities	(152,907)	(89,231)
Cash flows from investing activities:		
Purchases of available for sale securities	(30,571)	(189,231)
Sales and maturities of available for sale securities	122,524	104,955
Acquisition of property and equipment	(434)	(42)
Capitalized website development costs	(495)	(401)
Net cash provided by investing activities	91,024	(84,719)
Cash flows from financing activities:		
Proceeds from the royalty agreement	100,000	—
Issuance costs associated with the royalty agreement	(1,960)	—
Issuance of common stock, net of offering expenses	55,911	96,945
Issuance of pre-funded warrants	—	53,123
Issuance of common stock from equity incentive plans	5,776	646
Net cash provided by financing activities	159,727	150,714
Effect of exchange rate changes on cash and cash equivalents	2,639	(1,213)
Net increase (decrease) in cash and cash equivalents	100,483	(24,449)
Cash and cash equivalents and restricted cash at beginning of year	31,789	56,238
Cash and cash equivalents and restricted cash at end of year	$ 132,272	$ 31,789
Supplemental disclosures of cash flow information:		
Right of use assets obtained in exchange for operating lease liabilities	$ 725	$ 162
Website development costs included in accounts payable	$ —	$ 31

See notes to consolidated financial statements.

KALVISTA PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements

Note 1. Description of Business and Basis of Presentation

KalVista Pharmaceuticals, Inc. ("KalVista" or the "Company") is a commercial stage pharmaceutical company focused on the discovery, development and commercialization of drug therapies for diseases with significant unmet need. The Company has used its capabilities to develop sebetralstat, a novel, orally delivered, small molecule plasma kallikrein inhibitor targeting the disease hereditary angioedema ("HAE").

In July 2025, the U.S. Food and Drug Administration (the "FDA") approved EKTERLY (sebetralstat) for the treatment of acute attacks of HAE in adult and pediatric patients aged 12 years and older. The FDA approval was based on data from the phase 3 KONFIDENT clinical trial, published in the New England Journal of Medicine. Until now, all on-demand treatment options approved in the U.S. required intravenous or subcutaneous administration, which carries a significant treatment burden. Even with the use of long-term prophylaxis as a preventative therapy, most people living with HAE continue to have unpredictable attacks and require ready access to on-demand medication.

The Company's headquarters is currently located in Cambridge, Massachusetts, with additional offices and research activities located in Framingham, Massachusetts; Cambridge, Massachusetts; Porton Down, United Kingdom; Salt Lake City, Utah; Zug, Switzerland; Tokyo, Japan; Berlin, Germany and Dublin, Ireland.

The Company has funded its operations primarily through a combination of equity financings, collaborations, strategic partnerships, royalty financings, and licensing arrangements. As of April 30, 2025, the Company had an accumulated deficit of $653.2 million and cash, cash equivalents and marketable securities totaling $220.6 million. The Company anticipates that it will continue to incur losses for the foreseeable future, and it expects those losses to continue as it begins to commercialize EKTERLY. The Company is subject to risks and uncertainties common to companies in the pharmaceutical industry with development and commercial operations, and it may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect its business. The Company currently anticipates that, based upon its operating plans and existing capital resources, it has sufficient funding to operate for at least the next twelve months.

The Company may seek to finance future cash needs through equity offerings, debt financing, corporate partnerships and product sales.

Change in fiscal year

On March 13, 2025, the Board approved a change to our fiscal year end from April 30 to December 31. The change in fiscal year is effective for the Company's 2026 fiscal year.

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.

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, and as such, the Company has one operating segment. Refer to Note 15, *Segment Information*, for further information.

Use of estimates: The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. Accounting estimates and management judgments reflected in the consolidated financial statements include: the accrual of research and development expenses, stock-based compensation, operating lease liabilities, interest expense on our deferred royalty obligation, and assumptions used to value the embedded derivative in our deferred royalty obligation. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may materially differ from these estimates and assumptions.

Foreign currency: The functional currency of each of the Company's foreign subsidiaries is primarily the local currency of the country in which the subsidiary operates. The Company's asset and liability accounts are translated at the current exchange rate as of the balance sheet date. Revenue and expense accounts are translated at the average exchange rate over the period. Adjustments resulting from the translation of the financial statements of the Company's foreign subsidiaries into U.S. dollars are accumulated as a separate component of stockholders' equity within accumulated other comprehensive income. Gains or losses resulting from transactions denominated in foreign currencies are included in foreign currency losses, net, within the Consolidated Statement of Comprehensive Loss.

Recent Accounting Pronouncements: In November 2024, the Financial Accounting Standards Board ("FASB") issued ASU 2024-03, Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures, which requires public business entities to disclose, on an annual and interim basis, disaggregated information about certain income statement expense line items. The required information includes purchases of inventory, employee compensation, depreciation, intangible asset amortization and depletion. The standard will be effective for the Company beginning with annual financial statements for the fiscal year ending April 30, 2028. The Company has not yet determined the impact of adopting this guidance on its financial statements.

In December 2023, the FASB issued ASU No. 2023-09, Improvements to Income Tax Disclosures, which requires disclosure of disaggregated income taxes paid, prescribes standard categories for the components of the effective tax rate reconciliation, and modifies other income tax-related disclosures. ASU No. 2023-09 is effective for fiscal years beginning after December 15, 2024 and allows for adoption on a prospective basis, with a retrospective option. Early adoption is permitted. The Company does not expect the amendments in this ASU to have a material impact on its consolidated financial statements.

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting – Improvements to Reportable Segment Disclosures, which provides updates to qualitative and quantitative reportable segment disclosure requirements, including enhanced disclosures about significant segment expenses and increased interim disclosure requirements, among others. The new guidance was effective for the Company as of May 1, 2024. The adoption of ASU 2023-7 resulted in additional disclosures but did not have a material impact on its consolidated financial statements (see "*Note 15 - Segment Information*").

The Company does not expect any other recently issued accounting standards to have a material impact to its financial statements or disclosures.

Cash and cash equivalents: Cash and cash equivalents consist of readily available checking and bank deposit accounts and marketable securities. 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 within the next 12 months.

Restricted Cash: Restricted cash consists of deposits held at financial institutions that are used to collateralize irrevocable letters of credit required under the Company's lease agreements. The following table provides a reconciliation of cash and cash equivalents and restricted cash as reported in Other Assets on the consolidated balance sheets to the total of these amounts as reported at the end of the period in the consolidated statements of cash flows (in thousands):

	April 30, 2025	April 30, 2024
Cash and cash equivalents	$ 131,615	$ 31,789
Restricted cash	657	—
Total cash and cash equivalents and restricted cash	$ 132,272	$ 31,789

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:

Asset Classification	Estimated Useful Life
Machinery and equipment	1-5 Years
Furniture and fixtures	1-5 Years
Computer equipment	3-4 Years
Leasehold improvements	15 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.

Leases: The Company determines if an arrangement contains an operating or finance lease at inception and will utilize the short-term lease exception for certain temporary lab and office space arrangements with terms of 12 months or less. As of April 30, 2025, the Company maintained only operating leases. The Company recognizes a right-of-use operating lease asset and associated short- and long-term operating lease liability in the consolidated balance sheets for operating leases greater than one year. The right-of-use assets represent the right to use an underlying asset for the lease term and the lease liabilities represent the obligation to make lease payments arising from the lease arrangement. The Company recognizes the right-of-use operating lease assets and lease liabilities based on the present value of the future minimum lease payments that will be paid over the lease term. The Company determines the lease term at the inception of each lease, and in certain cases the lease term could include renewal options if it is concluded it is reasonably certain the renewal option will be exercised. When a lease option is exercised that was not previously included in the initial lease term, the right-of-use asset and lease liabilities are reassessed for the new lease term.

As the leases do not provide an interest rate implicit in the lease, the Company uses the incremental borrowing rate as the discount rate, based on the information available as of the lease inception date or at the lease option extension date in determining the present value of future payments. The Company recognizes rent expense for the minimum lease payments on a straight-line basis over the expected term of our lease. The Company has elected the practical expedient which allows non-lease components to be combined with the lease components for all existing asset classes and will therefore include any fixed additional rent amounts in its lease payments. Any variable lease payments are excluded from the lease liability and are recognized in the period incurred.

Deferred Royalty Obligation: The Company treats the debt obligation to DRI Healthcare Acquisitions LP, an affiliate of DRI Healthcare Trust ("DRI") discussed further in Note 11, "Purchase and Sale Agreement", as a deferred royalty obligation, amortized using the effective interest rate method over the estimated life of the revenue stream. The Company periodically assesses its expected revenues using internal projections, imputes interest on the carrying value of the deferred royalty obligation, and records interest expense using the imputed effective interest rate. To the extent its estimates of future revenues are greater or less than previous estimates or the estimated timing of such payments is materially different than previous estimates, the Company will account for any such changes by adjusting the effective interest rate on a prospective basis. The assumptions used in determining the expected repayment term of the deferred royalty obligation and amortization period of the issuance costs require that the Company makes estimates that could impact the classification of such costs, as well as the period over which such costs will be amortized.

Embedded Derivative Liability: The Company evaluates all its financial instruments to determine if such instruments contain features that qualify as embedded derivatives per ASC 815, *Derivatives and Hedging* ("ASC 815"). The Purchase and Sale agreement ("PSA") with DRI contains certain features that meet the definition of an embedded derivative requiring bifurcation as a separate compound financial instrument (the "Derivative Liability"). The Derivative Liability was recorded at fair value upon entering into the PSA and is subsequently remeasured to fair value at each reporting period with the corresponding change in fair value recognized in Other Income (Expense) in the consolidated statements of operations. The PSA was initially valued and is remeasured using Monte Carlo simulation models to perform the "with-and-without" method, which involves valuing the PSA with the embedded derivative and then valuing it without the embedded derivative. The Monte Carlo simulation model requires the use of Level 3 unobservable inputs, primarily the amount and timing of expected future revenue, the estimated volatility of these revenues, the discount rate corresponding to the risk of revenue, and the probability of a change

in control. The difference between values is determined to be the estimated fair value of the derivative liability. Bifurcated embedded derivatives are classified with the related host contract in the Company's balance sheet. Refer to Note 3, "Fair Value Measurements" for details regarding the fair value.

Revenue recognition: The Company recognizes revenue from research and development arrangements. In accordance with Accounting Standards Codification ("ASC") 606, "*Revenue from Contracts with Customers*," revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which the Company expects to be entitled to receive in exchange for these goods and services.

Performance obligations promised in a contract are identified based on the goods and services that will be transferred to the customer that are both capable of being distinct, whereby the customer can benefit from the good or service either on its own or together with other available resources, and are distinct in the context of the contract, whereby the transfer of the good or service is separately identifiable from other promises in the contract. To the extent a contract includes multiple promised goods and services, the Company must apply judgment to determine whether promised goods and services are capable of being distinct and distinct in the context of the contract. If these criteria are not met, the promised goods and services are accounted for as a combined performance obligation.

The transaction price is determined based on the consideration to which the Company will be entitled in exchange for transferring goods and services to the customer. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing either the expected value method or the most likely amount method depending on the nature of the variable consideration. Variable consideration is included in the transaction price if, in the Company's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Any estimates, including the effect of the constraint on variable consideration, are evaluated at each reporting period for any changes.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price to each performance obligation on a relative standalone selling price basis unless the transaction price is variable and meets the criteria to be allocated entirely to a performance obligation or to a distinct service that forms part of a single performance obligation. The consideration to be received is allocated among the separate performance obligations based on relative standalone selling prices.

The Company satisfies performance obligations either over time or at a point in time. Revenue is recognized over time if either: (1) the customer simultaneously receives and consumes the benefits provided by the entity's performance, (2) the entity's performance creates or enhances an asset that the customer controls as the asset is created or enhanced or (3) the entity's performance does not create an asset with an alternative use to the entity and the entity has an enforceable right to payment for performance completed to date. If the entity does not satisfy a performance obligation over time, the related performance obligation is satisfied at a point in time by transferring the control of a promised good or service to a customer. ASC 606 requires the Company to select a single revenue recognition method for the performance obligation that faithfully depicts the Company's performance in transferring control of the goods and services. The guidance allows for two methods to measure progress toward complete satisfaction of a performance obligation, depending on the facts and circumstances:

Output methods - recognize revenue on the basis of direct measurements of the value to the customer of the goods or services transferred to date relative to the remaining goods or services promised under the contract (e.g., surveys of performance completed to date, appraisals of results achieved, milestones reached, time elapsed, and units of produced or units delivered); and

Input methods - recognize revenue on the basis of the entity's efforts or inputs to the satisfaction of a performance obligation (e.g., resources consumed, labor hours expended, costs incurred, or time elapsed) relative to the total expected inputs to the satisfaction of that performance obligation.

Licenses of intellectual property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company must consider the nature of the intellectual property to which the customer will have rights (i.e., access at a point in time or benefit of intellectual property enhancements over time). The Company recognizes revenue from non-refundable, up-front fees allocated to the license at a point in time/over the period the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress at each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone payments: At the inception of each arrangement that includes development and regulatory milestone payments for promised goods and services, the Company evaluates the circumstances of whether the milestones will be reached and estimates the amount to be included in the transaction price that will not cause a significant revenue reversal.

Up-front payments: Up-front payments and fees are recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts payable to the Company are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

Contract balances: The Company recognizes a contract asset when the Company transfers goods or services to a customer before the customer pays consideration or before payment is due, excluding any amounts presented as a receivable (i.e., accounts receivable). A contract asset is an entity's right to consideration in exchange for goods or services that the entity has transferred to a customer. The contract liabilities (i.e., deferred revenue) primarily relate to contracts where the Company has received payment but has not yet satisfied the related performance obligations. The advance consideration received from customers for research and development services and/or licenses is a contract liability, recorded as deferred revenue, until the underlying performance obligations are transferred to the customer.

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 to manufacture the commercial drug supply of EKTERLY prior to FDA approval;
- Costs associated with preclinical and development activities;
- Costs associated with regulatory operations.

Costs for certain research and development activities, such as manufacturing development activities and clinical studies are recognized based on the contracted amounts adjusted for the percentage of work completed to date. Payments for these activities are based on the terms of the contractual arrangements, which may differ from the pattern of costs incurred, and are reflected on the consolidated balance sheets as prepaid or accrued expenses. The Company defers and capitalizes non-refundable advance payments made by the Company for research and development activities until the related goods are delivered or the related services are performed.

Income taxes: The Company accounts for income taxes using an asset and liability approach. 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. Forfeitures are recognized as they are incurred.

Net loss per share: Basic net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing net loss by the sum of the weighted average number of common shares and the number of potential dilutive common share equivalents outstanding during the period. Potential dilutive common share equivalents consist of outstanding options, unvested restricted stock units, unvested performance stock units, and shares committed to be purchased under the employee stock purchase plan.

Potential dilutive common share equivalents consist of:

	April 30,	
	2025	2024
Stock options and awards	7,311,578	5,661,896

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

The weighted average number of common shares used in the basic and diluted net loss per common share calculations includes the weighted-average pre-funded warrants outstanding during the period as they are exercisable at any time for nominal cash consideration. There were 3,483,688 pre-funded warrants outstanding at April 30, 2025 and 2024.

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;
- 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 cash equivalents, marketable securities, and derivative liability as of April 30, 2025 were carried at fair value, determined according to the fair value hierarchy. See Note 3, *"Fair Value Measurements"* for further discussion.

Note 3. Fair Value Measurements

The following tables present information about financial assets and liabilities that have been measured at fair value and indicate the fair value hierarchy inputs utilized to determine such fair value as of April 30, 2025 and April 30, 2024 (in thousands):

	Level 1	Level 2	Level 3	Balance at April 30, 2025
Cash equivalents	$ 98,644	$ —	$ —	$ 98,644
Marketable securities:				
Corporate debt securities	—	75,243	—	75,243
U.S. government agency securities	—	13,759	—	13,759
Total financial assets	$ 98,644	$ 89,002	$ —	$ 187,646
Liability:				
Derivative liability	$ —	$ —	$ 6,440	$ 6,440

	Level 1	Level 2	Level 3	Balance at April 30, 2024
Cash equivalents	$ 11,143	$ —	$ —	$ 11,143
Marketable securities:				
Corporate debt securities	—	130,423	—	130,423
U.S. government agency securities	—	48,189	—	48,189
	$ 11,143	$ 178,612	$ —	$ 189,755

The objectives of the Company's investment policy are to ensure the safety and preservation of invested funds, as well as to maintain liquidity sufficient to meet cash flow requirements. The Company invests its excess cash in securities issued by financial institutions, commercial companies, and government agencies that management believes to be of high credit quality in order to limit the amount of its credit exposure. The Company has not realized any material losses from its investments.

The Company classifies all of its debt securities as available-for-sale. Unrealized gains and losses on investments are recognized in accumulated comprehensive loss, unless an unrealized loss is considered to be other than temporary, in which case the unrealized loss is charged to operations. The Company periodically reviews its investments for other than temporary declines in fair value below cost basis and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company believes the individual unrealized losses represent temporary declines primarily resulting from interest rate changes. Realized gains and losses are included in other income in the consolidated statements of operations and comprehensive loss and are determined using the specific identification method with transactions recorded on a trade date basis.

The estimated fair value of the derivative liability as of April 30, 2025 relates to the PSA and was determined using Level 3 inputs. The fair value measurement of the derivative liability is sensitive to changes in the unobservable inputs used to value the financial instrument. Changes in the inputs could result in changes to the fair value of each financial instrument.

The embedded derivative liability associated with the deferred royalty obligation, as discussed further in Note 11, "Purchase and Sale Agreement," is measured at fair value using an option pricing Monte Carlo simulation model and is included as a component of the deferred royalty obligation on the consolidated balance sheet. The embedded derivative liability is subject to remeasurement at the end of each reporting period, with changes in fair value recognized as a component of other income (expense), net. The assumptions used in the option pricing Monte Carlo simulation model incorporates certain Level 3 inputs including: (1) the risk-adjusted discount rate and (2) the probability of a change in control occurring during the term of the instrument.

The Company recorded $4.4 million for the initial fair value of the derivative liability upon the closing of the PSA. The initial fair value allocated to the derivative liability was recorded against the deferred royalty obligation as a debt discount, which is being amortized in interest expense on the consolidated statement of operations over the expected term using the effective interest method. The embedded derivative is subsequently remeasured at fair value each reporting period, with the change in fair value being recorded as a component of other income (expense) on the consolidated statement of operations. During the period from November 4, 2024 through April 30, 2025, the Company recognized $1.7 million as a component of other income (expense), net as the change in fair value for the $6.4 million embedded derivative liability, recorded as a component of the deferred royalty obligation on the consolidated balance sheet, as of April 30, 2025. Refer to Note 11, *"Purchase and Sale Agreement"* for details regarding the valuation methodology related to the embedded derivative and its related inputs.

Marketable Securities

Management evaluated the unrealized losses in available-for-sale ("AFS") debt securities as of April 30, 2025 and 2024 to determine the existence of credit losses considering factors including credit ratings and other relevant information, which may indicate that contractual cash flows are not expected to occur. The results of this evaluation indicated that the unrealized losses on AFS debt securities are primarily attributable to market interest rate increases and not a deterioration in credit quality of the issuers. Based on the analysis, management determined that credit losses did not exist for AFS debt securities in an unrealized loss position as of April 30, 2025 and 2024. It is not considered likely that the Company will be required to sell the investments before full recovery of the amortized cost basis of the AFS debt securities, which may be at maturity. As a result, the Company has not recognized any impairment losses in earnings for the years ended April 30, 2025 and 2024.

Realized gains and losses are included in other income in the consolidated statements of operations and comprehensive loss and are determined using the specific identification method with transactions recorded on a trade date basis. For the years ended April 30, 2025 and 2024, respectively, the Company recorded $1.6 million and $1.3 million in realized gains and losses, respectively on available-for-sale securities, which is included in other income (expense), net on the statements of operations and comprehensive loss.

The following tables summarize the fair value of the Company's investments by type as of April 30, 2025 and 2024 (in thousands):

	April 30, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Corporate debt securities	$ 74,150	$ 1,093	$ -	$ 75,243
Obligations of the U.S. Government and its agencies	13,594	165	—	13,759
Total investments	$ 87,744	$ 1,258	$ -	$ 89,002

	April 30, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Corporate debt securities	$ 130,099	$ 600	$ (276)	$ 130,423
Obligations of the U.S. Government and its agencies	48,228	83	(122)	48,189
Total investments	$ 178,327	$ 683	$ (398)	$ 178,612

The following table summarizes the scheduled maturity for the Company's investments at April 30, 2025 (in thousands):

	April 30, 2025
Maturing in one year or less	$ 57,045
Maturing after one year through two years	26,959
Maturing after two years through four years	4,998
Total investments	$ 89,002

Note 4. Prepaid Expenses and Other Current Assets

At April 30, 2025 and 2024, prepaid expenses and other current assets consisted of (in thousands):

	2025	2024
Kaken receivable (Note 12)	$ 11,000	$ —
Other prepaid expenses	5,125	2,833
Interest and other receivables	1,826	1,409
VAT receivable	932	1,023
Prepaid clinical activities	807	1,585
Total prepaid expenses and other current assets	$ 19,690	$ 6,850

Note 5. Property and Equipment

At April 30, 2025 and 2024, property and equipment consisted of (in thousands):

	2025	2024
Leasehold improvements	$ 3,091	$ 2,859
Laboratory equipment	2,660	2,409
Furniture & fixtures	571	402
Office equipment	413	269
Total property and equipment at cost	6,735	5,939
Less: Accumulated depreciation	(4,747)	(3,712)
Property and equipment, net	$ 1,988	$ 2,227

For the years ended April 30, 2025 and 2024, depreciation expense was $0.9 million and $0.8 million, respectively.

Note 6. Accrued Expenses

At April 30, 2025 and 2024, accrued expenses consisted of (in thousands):

	2025	2024
Accrued compensation	$ 16,123	$ 6,687
Accrued research expense	6,063	3,416
Accrued professional fees	4,315	2,042
Other accrued expenses	806	253
Total accrued expenses	$ 27,307	$ 12,398

Note 7. Stockholder's Equity

Direct Offerings

In April 2024, all pre-funded warrants from a December 2022 Offering were exercised in a cashless exercise, resulting in an issuance of 182,453 shares of common stock. No pre-funded warrants from the December 2022 Offering were outstanding at April 30, 2025 and 2024.

On February 14, 2024, the Company entered into an underwriting agreement with Jefferies LLC, Leerink Partners LLC, Stifel, Nicolaus & Company, Incorporated, and Cantor Fitzgerald & Co., as the representatives of several underwriters to sell an aggregate of 7,016,312 shares of our common stock at price of $15.25 per share and pre-funded warrants to purchase up to 3,483,688 shares of common stock at a price of $15.249 per pre-funded warrant (the "February 2024 Offering"). The purchase price per share of each pre-funded warrant represents the per share offering price for the common stock, less the $0.001 per share exercise price of each pre-funded warrant. The net proceeds from the Offering, after deducting $0.5 million in expenses, were approximately $150.1 million. The pre-funded warrants do not expire and are exercisable at any time after the issuance date. The Company evaluated the pre-funded warrants for liability or equity classification in accordance with the provisions of ASC Topic 480, *Distinguishing Liabilities from Equity*, and determined that equity treatment was appropriate because the

pre-funded warrants did not meet the definition of liability instruments and met the criteria for permanent equity. As of April 30, 2025, no pre-funded warrants from the February 2024 Offering have been exercised.

On November 4, 2024, the Company entered into an underwriting agreement with Jefferies LLC, BofA Securities, Inc., TD Securities (USA) LLC and Stifel Nicolaus & Company, Incorporated, as the representatives of the several underwriters, pursuant to which the Company agreed to issue and sell an aggregate of 5,500,000 shares of its common stock at an offering price of $10.00 per share. The net proceeds from the November 2024 Offering, after deducting estimated expenses, were approximately $51.3 million.

On November 4, 2024, the Company entered into a securities purchase agreement with DRI Healthcare Acquisitions LP, pursuant to which the Company agreed to sell and issue an aggregate of 500,000 shares of Common Stock, at a purchase price of $10.00 per share in a private placement. The net proceeds from the private placement, after deducting placement agent fees and other expenses, were approximately $4.7 million.

Note 8. Stock-Based Compensation

The Company has four plans that provide for equity-based compensation. Two are legacy plans for which no further grants are to be made. As of April 30, 2025, 1,466,813 stock awards remain available for grant under the 2017 Equity Incentive Plan ("2017 Plan"). There are 8,916,060 shares of the Company's common stock that are reserved for issuance upon exercise or settlement of stock options or other awards under these four plans. 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.

In July 2021, the Company approved the 2021 Equity Inducement Plan to reserve 350,000 shares of its common stock to be used exclusively for grants of awards as a material inducement to such individuals' entry into employment with the Company within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules. In June 2023, the Company amended and restated the 2021 Equity Inducement Plan (the "Amendment and Restated 2021 Equity Inducement Plan") to register 500,000 additional shares of its common stock. As of April 30, 2025 there were 234,223 shares remaining available to be issued under the 2021 Inducement Plan.

In June 2024, the Company amended and restated the 2021 Equity Inducement Plan to register 600,000 additional shares of its common stock.

The Company has in place the 2017 Employee Stock Purchase Plan ("ESPP"), under which employees have the option to purchase the Company's common stock at a discount of 15% from the market price during predetermined offering periods each year. There are 1,641,743 shares available for future issuance under the ESPP as of April 30, 2025.

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. The Company determined the expected volatility by using available historical price information. 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:

	2025	2024
Risk-free interest rate	4.21%	4.29%
Expected life of the options	6.25 years	6.25 years
Expected volatility of the underlying stock	79.85%	81.38%
Expected dividend rate	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, 2025	2024
Research and development	$ 4,959	$ 9,305
General and administrative	7,332	12,610
Total stock-based compensation expense	$ 12,291	$ 21,915

A summary of option activity for the year ended April 30, 2025 is presented below:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at May 1, 2024	4,441,641	$ 14.30	5.25	$ 6,505
Options Exercised	(592,247)	8.43		
Options Granted	1,397,750	10.86		
Options Cancelled	(881,192)	18.85		
Outstanding at April 30, 2025	4,365,952	$ 13.08	6.46	$ 12,612
Exercisable at April 30, 2025	2,644,546	$ 14.60	5.10	$ 7,196
Vested and expected to vest at April 30, 2025	4,365,952	$ 13.08	6.46	$ 12,612

The weighted-average grant date fair value of stock options granted during the years ended April 30, 2025 and 2024 was $7.75 and $7.57, respectively. The total intrinsic value (the amount by which the fair market value exceeded the exercise price) of stock options exercised during the years ended April 30, 2025 and 2024 was $2.5 million and $0.1 million, respectively. The total cash received by the Company as a result of employee stock option exercises during the years ended April 30, 2025 and 2024 was $5.0 million and $0.2 million, respectively.

As of April 30, 2025, there was $12.2 million of unrecognized compensation expense related to unvested options, which is expected to be recognized over a weighted-average period of 2.9 years.

Restricted Stock Units

During the fiscal year ended April 30, 2025, the Company granted both executives and employees Restricted Stock Units ("RSUs") from the 2017 Equity Incentive Plan. All RSUs granted are subject to a service condition, and vest over a three or four-year period with equal quarterly vesting.

A summary of activity in connection with RSUs for the year ended April 30, 2025 is as follows:

	Number of Shares Outstanding	Weighted Average Grant Date Fair Value Per Share
RSUs outstanding at April 30, 2024	626,272	10.52
RSUs awarded	2,374,125	9.99
RSUs released	(317,158)	10.15
RSUs forfeited	(72,417)	8.78
RSUs outstanding at April 30, 2025	2,610,822	10.13

As of April 30, 2025, the unrecognized stock-based compensation cost related to the RSUs was $24.8 million, which is expected to be recognized over a weighted-average period of 3.46 years.

Performance Stock Units

A summary of activity in connection with PSUs for the year ended April 30, 2025 is as follows:

	Number of Shares Outstanding	Weighted Average Grant Date Fair Value Per Share
PSUs outstanding at April 30, 2024	541,836	9.87
PSUs awarded	—	—
PSUs released	(229,003)	12.06
PSUs forfeited	(74,583)	7.97
PSUs outstanding at April 30, 2025	238,250	8.36

In January 2023, the Company granted 360,000 PSUs to executives under the 2017 Equity Incentive Plan with a grant date fair value of $6.82. The performance-based metric for the awards is the FDA approval of a New Drug Application for sebetralstat. Upon successful completion of the performance metric, 100% of the PSUs will vest in full. As of April 30, 2025 the Company has not recognized any compensation expense related to these awards as the achievement of the Performance Metric is not yet deemed to be probable. As of April 30, 2025, 182,500 PSUs from this grant have been forfeited and 177,500 shares remain outstanding.

In June 2023, the Company granted 306,667 PSUs to executives under the 2017 Equity Incentive Plan with a grant date fair value of $9.99. The performance-based metric for the awards was the full enrollment for the KVD900-301 clinical trial. This performance metric was certified by the Compensation Committee of the Company's Board of Directors in July 2023, with twelve months of quarterly vesting beginning in August 2023. As of April 30, 2025, $3.0 million of expense from these awards has been recognized, including $0.03 million of expense recognized in the year ended April 30, 2025. As of April 30, 2025, there were no shares outstanding.

In January 2024, the Company granted 306,667 PSUs to seven executives under the 2017 Equity Incentive Plan with a grant date fair value of $12.71. The performance-based metric for the executive awards was the success of the Company’s Phase 3 clinical trial of the sebetralstat program. This performance metric was certified by the Compensation Committee of the Company's Board of Directors in February 2024, with twelve months of quarterly vesting beginning in February 2024. As of the year ended April 30, 2025, the cumulative expense from these awards has been recognized. As of April 30, 2025, there were no shares outstanding.

In January 2024, the Company granted 81,000 PSUs to six non-executives under the 2017 Equity Incentive Plan with a grant date fair value of $12.85. The performance-based metrics for the non-executive awards is the successful NDA filing for sebetralstat program and the FDA approval of the NDA. Upon successful completion of the NDA filing metric, which occurred in June 2024, 25% of the PSUs vested, with the remaining 75% of the PSUs vesting upon successful completion of the NDA approval metric. As of April 30, 2025, the Company has not recognized any of the remaining compensation expense related to these awards as the achievement of the Performance Metrics for the remaining 75% of the PSUs vesting have not yet occurred. As of April 30, 2025, there were 60,750 shares outstanding.

Note 9. Commitments and Contingencies

Commitments

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 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 preclinical studies and clinical trials. The remaining clinical commitments, which have cancellation provisions, totaled $18.1 million as of April 30, 2025.

Drug Manufacturing: The Company’s minimum purchase commitments under the drug manufacturing agreements are $0.6 million as of April 30, 2025, which consist primarily of inventory purchase commitments with our independent drug manufacturers.

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, 2025 and 2024.

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.

Note 10. Leases

The Company maintains leases for the company headquarters, office space and research laboratory space, and as of April 30, 2025, all leases were classified as operating leases. These leases have remaining lease terms ranging from 1 to 10 years, some of which include options to extend or terminate the leases.

Pursuant to the lease in Framingham, signed in July 2024, the Company provided a security deposit in the form of a letter of credit in the amount of $0.7 million, which is classified in our other assets on our consolidated balance sheet.

Total rent expense was $2.7 million and $2.0 million for the years ended April 30, 2025 and 2024, respectively and is reflected in general and administrative expenses and research and development expenses as determined by the underlying activities.

The following table summarizes lease costs included in research and development and general and administrative expense for the years ended April 30, 2025 and 2024 (in thousands):

	2025	2024
Operating lease costs	$ 2,211	$ 1,813
Short-term lease costs	508	114
Variable lease costs	292	238
Total lease costs	$ 3,011	$ 2,165

The following table summarizes the undiscounted payments due under lease liabilities and the present value of those liabilities as of April 30, 2025 (in thousands):

Years ending April 30,	Operating Leases
2026	$ 1,918
2027	1,769
2028	1,725
2029	769
2030	234
Thereafter	430
Total lease payments	6,845
Less: imputed interest	538
Total lease liabilities	6,307
Current lease liabilities	1,977
Long-term lease liabilities	$ 4,330

The following table summarizes the lease term and discount rate as of April 30, 2025 and 2024:

	2025	2024
Weighted-average remaining lease term (years)	3.9	5.0
Weighted-average discount rate	9.0%	9.0%

The following table summarizes the cash paid for amounts included in the measurement of lease liabilities for the years ended April 30, 2025 and 2024 (in thousands):

	2025	2024
Cash paid for amounts included in the measurement of operating lease liabilities	$ 1,765	$ 1,683

Note 11. Purchase and Sale Agreement

Royalty Liability

On November 4, 2024, the Company, as guarantor, and KalVista Pharmaceuticals Limited, a wholly owned subsidiary of the Company (the "Subsidiary"), entered into a PSA with DRI, for up to $179.0 million. Under the terms of the synthetic royalty financing agreement, the Subsidiary received an upfront payment of $100.0 million in exchange for tiered royalty payments on worldwide net sales of sebetralstat, as follows: 5.00% on annual net sales up to and including $500.0 million (the "First Tier Royalty Rate"); 1.10% on annual net sales above $500.0 million and up to and including $750.0 million; and 0.25% on annual net sales above $750.0 million.

Beginning in calendar year 2031, the First Tier Royalty Rate for any calendar year will be determined based on annual net sales of sebetralstat for the prior calendar year: 5.00% if the prior year's annual net sales are at or above $500.0 million or 5.65% if the prior year's annual net sales are below $500.0 million. Additionally, if sebetralstat achieves annual net sales of at least $550.0 million in any calendar year ending before January 1, 2031, the Subsidiary will earn a sales-based milestone payment of $50.0 million.

If sebetralstat is approved prior to October 1, 2025, the Subsidiary will have the option to receive a one-time cash payment of $22.0 million. If the Subsidiary chooses to receive this optional payment, the royalty rate on net sales up to and including $500.0 million will increase from 5.00% to 6.00%, and the sales-based milestone amount will increase from $50.0 million to $57.0 million.

On receipt of the $100.0 million payment from DRI, the Company recorded a deferred royalty obligation of $93.6 million, net of the initial fair value of the bifurcated embedded derivative liability upon execution of the PSA, and debt issuance costs incurred.

The PSA is considered a sale of future revenues and is accounted for as long-term debt recorded at amortized cost using the effective interest rate method. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the anticipated life of the arrangement. During the year ended April 30, 2025, the Company recorded $5.7 million of interest expense related to this arrangement in Interest income (expense), net on the consolidated statement of operations. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including the level of forecasted net sales. The company evaluates the interest rate quarterly based on its current net sales forecasts utilizing the prospective method. A significant increase or decrease in actual or forecasted net sales may materially impact the revenue interest liability, interest expense, other income, and the time period for repayment. The deferred royalty obligation, net of the bifurcated embedded derivative liability, had a net carrying amount of $99.4 million as of April 30, 2025.

The PSA is denominated in US Dollars and was executed with the Company's wholly owned U.K. Subsidiary, whose functional currency is the British Pound. As such, the Company will remeasure the liability each reporting period at current exchange rates and recognize unrealized gains and loss in other income (expense).

Embedded Derivative Liability

Under the PSA, the Subsidiary has the option (the "Buy-Back Option") to repurchase future Revenue Participation Rights at any time until December 31, 2026 either (i) in the event of a change of control of the Subsidiary or (ii) in the event that confirmation that payment of the Revenue Participation Rights will not receive certain tax treatment has not been obtained. Additionally, the Purchaser has an option (the "Put Option") to require the Subsidiary to repurchase future Revenue Participation Rights in the event of a change of control of the Subsidiary exercisable until December 31, 2026. If the Put Option or the Buy-Back Option is exercised terminating the PSA, the required repurchase price is an amount equal to (a) 1.5 multiplied by (b) the Investment Amount, net of the sum of any payments received by the Purchaser prior to such Put Option or Buy-Back Option repurchase date, as applicable.

The Buy-Back and Put Options are considered embedded derivatives requiring bifurcation as a single compound derivative instrument. The Company estimated the fair value of the derivative liability using a "with-and-without" method. The with-and-without methodology involves valuing the whole instrument on an as-is basis and then valuing the instrument without the individual embedded derivative. The difference between the entire instrument with the embedded derivative compared to the instrument without the embedded derivative is the fair value of the derivative liability.

The Company recorded $4.4 million for the initial fair value of the derivative liability upon the closing of the PSA. The initial fair value allocated to the derivative liability was recorded against the deferred royalty obligation as a debt discount, which is being amortized in interest expense on the consolidated statement of operations over the expected term using the effective interest method. The embedded derivative is subsequently remeasured at fair value each reporting period, with the change in fair value being recorded as a component of other income (expense) on the consolidated statement of operations. During the period from November 4, 2024 through April 30, 2025, the Company recognized $1.7 million as a component of other income (expense), net as the change in fair value for the embedded derivative liability as of April 30, 2025. Bifurcated embedded derivatives are classified with the related host contract in the Company's balance sheet. Of the $105.9 million deferred royalty obligation as of April 30, 2025, the embedded derivative had a fair value of $6.4 million.

The estimated probability and timing of underlying events triggering the exercisability of the Buy-Back and Put Options contained in the PSA, forecasted cash flows and the discount rate are significant unobservable inputs used to determine the estimated fair value of the entire instrument with the embedded derivative. Management concluded the buy-back option probability was in the lower quarter tile of possible outcomes. As of inception, the estimated market yield used for the valuation of the derivative liability was 9.15%. As of April 30, 2025, the estimated market yield was 11.82%.

Note 12: License, Supply and Distribution Agreement

Kaken Pharmaceutical Co., Ltd.

In April 2025, the Company entered into the Kaken Agreement with Kaken pursuant to which the Company has licensed exclusive commercialization rights in Japan to Kaken for the Licensed Product in exchange for a non-refundable upfront payment of $11.0 million, received on June 20, 2025, potential regulatory and sales milestone payments totaling approximately $13.0 million and effective royalty payments in the mid-twenties that shall be payable for each unit of revenue of Licensed Product that the Company supplies, which reflect a percentage of the Japanese National Health Insurance price of the Licensed Product.

The Company is responsible for obtaining and maintaining all regulatory approvals, performing regulatory submissions for the Licensed Product in Japan and supplying the Licensed Product to Kaken. The Company retains manufacturing rights for the Licensed Product and is responsible for the Company's own costs associated with the performance of activities under the Kaken Agreement. Kaken received an exclusive license to commercialize the Licensed Product in Japan, including the right to ship, store, and distribute the Licensed Product for such commercialization during the initial 10 year term of the Kaken Agreement.

Under the terms of the Kaken Agreement, Kaken will pay the Company a non-refundable upfront payment of $11.0 million. The obligations have not been met, and as such, the $11.0 million non-refundable upfront payment has been recorded as deferred revenue and accounts receivable, as the payment was not received by the Company as of April 30, 2025.

The potential regulatory and sales milestone payments that the Company is eligible to receive will be recorded if and when they become probable.

Any future potential revenue from units sold to Kaken will be recorded in accordance with ASC 606 "Revenue from Contracts with Customers".

Note 13. Income Taxes

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

	2025	2024
Domestic	$ (91,644)	$ (52,661)
Foreign	(88,408)	(73,983)
Total loss before income taxes	$ (180,052)	$ (126,644)

For the year ended April 30, 2025, the Company recorded $3.4 million of U.S. Federal income tax expense, all of which relates to the current year provision. For the year ended April 30, 2024, the Company did not record any U.S. Federal income tax benefit or expense.

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

	2025	2024
Income tax benefit at U.S. federal statutory rate	21.0%	21.0%
Foreign rate differential	1.8%	2.3%
Nondeductible expenses - UK R&D credit	(0.4)%	(8.3)%
UK Income from Royalty Financing	(15.3)%	—
162(m) permanent adjustment	(0.4)%	(1.9)%
Other	(0.2)%	(0.4)%
GILTI	(7.2)%	
Valuation allowance	(1.3)%	(12.7)%
	(2.0)%	—

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

	2025	2024
Deferred tax assets:		
Net operating loss ("NOL") carryforwards	$ 54,638	$ 50,179
Operating lease liabilities	1,124	1,406
174 capitalization	1,717	2,168
Stock compensation	4,535	3,708
Other	4,170	2,506
Subtotal	66,184	59,967
Less: valuation allowance	(65,064)	(58,537)
Deferred tax assets, net of valuation allowance	1,120	1,430
Deferred tax liabilities:		
Operating lease - Right-of-use assets	(943)	(1,325)
Other	(177)	(105)
Net deferred tax asset	$ —	$ —

Management of the Company has determined it is not more likely than not that the Company will recognize the benefits of net deferred tax assets, the majority of which are NOLs, and has provided a valuation allowance for the full amount of deferred tax assets as of April 30, 2025 and 2024, respectively. During the years ended April 30, 2025 and 2024 the valuation allowance changed by $6.5 million. Realization of deferred tax assets is dependent upon the generation of future taxable income.

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 pre-change net operating loss and tax credit carryforwards, and other tax attributes that can be used to reduce future tax liabilities. The Company determined that ownership changes occurred as a result of public offerings in December 2005, a transaction in November 2016, and public offerings in February 2019 and December 2022. The Company most recently underwent a change of ownership on December 28, 2022. The Company evaluated the 382 position for the period of December 29, 2022 through April 30, 2025 and concluded that the Company did not have any ownership changes during the period of December 29, 2022 to April 30, 2025.

As of April 30, 2025, the Company has available NOL carryforwards for U.S. federal income taxes of $6.0 million generated prior to the Tax Cuts and Jobs Act, that expire in 2036. The Company has an additional $66.0 million in NOL carryforwards generated after the Tax Cuts and Jobs Act that can be carried forward indefinitely. Of the $6 million of NOL expiring in 2036, $3.7 million remains subject to the Section 382 limitation for the change of ownership that occurred on November 21, 2016, and is subject to an annual 382 limitation of $0.3 million, and $2.4 million of NOLs are only subject to a $1.5 million annual limitation. Of the remaining $66 million of indefinite NOL, $23 million is subject to an annual 382 limitation of $1.5 million. The Company also has NOL carryforwards for state income taxes of $142 million that begin to expire in 2036, NOL carryforwards for U.K. income taxes of $140 million that do not expire, and $2 million of NOLs carryforwards in Japan that begin to expire in 2034.

The Company has $111.0 million of NOLs subject to 382 limitation. As a result of these ownership changes, it is estimated that the effect of Section 382 will generally limit the amount of the net operating loss carryforwards that are available to offset future taxable income to approximately $1.5 million, annually. Due to this annual limitation, the company expects $76.7 million of federal NOL to go unutilized.

The company has $1.5 million of R&D credit carryforward subject to 383 limitation. As a result of these ownership changes, it is estimated that the effect of Section 383 will be the limitation of all of these R&D credit carryforwards, with $1.5 million of credit to expire unutilized.

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 files U.S. Federal tax returns, as well as certain state returns. The Company also files returns in the United Kingdom. The Company is subject to U.S. Federal, state, and U.K. income tax examinations by authorities for tax years ending after 2021. There are currently no federal, state, or U.K. audits in process. Tax year 2021 and subsequent years contain matters that could be subject to differing interpretations of the applicable tax laws and regulations as it relates to the amount and or timing of income, deductions, and tax credits. Although the outcome of tax audits is always uncertain, management has analyzed the Company’s tax positions taken for all open tax years and has concluded that no provision for unrecognized tax benefits from uncertain tax positions is required in the Company’s consolidated financial statements for the years ended April 30, 2025 and 2024, respectively.

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. As a result of the November 2024 PSA and the Kaken Agreement executed in April 2025, the $100.0 million up-front payment and the $11.0 million up-front payment, respectively, were treated as income for tax purposes in the UK under the Research and Development Expenditure Credit scheme. After applying the estimated net operating loss carryforwards and research and development tax credits, we recorded income tax expense of $3.4 million for the year ended April 30, 2025 due to an increase in the valuation allowance against our deferred tax assets.

Note 14. Defined Contribution Plans

Employees of the U.S. parent company are eligible to participate in the Company's 401(k) Plan in which employee contributions on a pre-tax basis are supplemented by matching contributions by the Company. Participation in a personal pension plan is available to all non-U.S. based employees of the Company upon commencement of their employment. Employer contributions are made in accordance with local regulations as well as the terms and conditions of the employment contract. Total employer contributions to both plans for the years ended April 30, 2025 and 2024 were $1.9 million and $1.1 million respectively.

Note 15: Segment Information

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision-maker (“CODM”) in deciding how to allocate resources and assess performance. The Company operates in one business segment. The Company’s CODM is its Chief Executive Officer, who reviews financial information presented on a consolidated basis. The CODM’s financial review is focused on the consolidated financial results of the Company which is used as the basis for financial performance assessment and allocation of resources.

The following table presents selected financial information with respect to the Company’s single operating segment for the years ended April 30, 2025 and April 30, 2024 (in thousands):

	Years Ended April 30,	
	2025	2024
Operating Expenses:		
Clinical development	43,166	46,520
Research	19,713	36,074
Regulatory & QA	8,830	3,573
Pre-commercial planning	62,859	18,481
Other G&A	53,427	35,797
Total operating expenses	187,995	140,445
(Loss) income from operations	(187,995)	(140,445)
Interest and other income (expense), net	7,943	13,801
(Loss) income before income taxes	(180,052)	(126,644)
Provision for (benefit from) for income taxes	3,392	-
Net loss	(183,444)	(126,644)

Note 16. Other Income (Expenses), Net

At April 30, 2025 and 2024, other income and expenses consisted of (in thousands):

	2025	2024
R&D tax credit	$ 5,014	$ 8,452
Realized gain on sale of securities	1,561	1,325
Expense from change in fair value of derivative liability	(1,760)	—
Miscellaneous	(3)	(10)
Other income (expenses), net	$ 4,812	$ 9,767

As of April 30, 2025 and 2024 the Company had research and development tax credits receivable totaling $1.4 million and $8.4 million, respectively. This tax credit is related to a tax scheme for small and medium enterprises in the U.K. as well as an R&D expenditure credit system that allows the Company to file a claim for cash credit in proportion to the Company's R&D expenditure for the year. This amount is 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 $5.0 million and $8.5 million related to these programs in the years ended April 30, 2025 and 2024, respectively.

The Company receives tax credits from the U.K. government based on claims made under the Small Medium Enterprise ("SME) research and development tax relief program. Qualifying expenditures largely relate to research and development activities performed by third parties on the Company's behalf, as well as employment costs for research staff and consumables incurred. The research and development tax credits are recognized when the qualifying expenditure has been incurred and there is reasonable assurance that the reimbursement will be received.

Note 17. Subsequent Events

On July 3, 2025, the FDA approved EKTERLY (sebetralstat) for the treatment of acute attacks of HAE in adult and pediatric patients aged 12 years and older.

On July 7, 2025, KalVista Pharmaceuticals Limited, our wholly owned subsidiary, notified DRI it has elected to receive the additional payment of $22.0 million in cash following the July 3, 2025 FDA approval of EKTERLY (sebetralstat).

Exhibit 4.2

DESCRIPTION OF REGISTRANT'S SECURITIES

General

We are authorized to issue 105,000,000 shares of all classes of capital stock, of which 100,000,000 shares are common stock, $0.001 par value per share, and 5,000,000 shares are preferred stock, $0.001 par value per share. The following description summarizes the most important terms of our capital stock. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description, you should refer to our restated certificate of incorporation and restated bylaws, which are included as exhibits to our most recent Annual Report on Form 10-K, and to the applicable provisions of Delaware law.

Common Stock

Voting

Holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and do not have cumulative voting rights. Accordingly, the holders of a majority of the shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election.

Dividends

Subject to preferences that may be applicable to any then-outstanding preferred stock, the holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Fully Paid and Nonassessable

All of our outstanding shares of common stock are fully paid and nonassessable.

Transfer Agent and Registrar

Equiniti Trust Company, LLC is our transfer agent and registrar for the common stock.

The Nasdaq Global Market

Our common stock is listed on The Nasdaq Global Market under the symbol "KALV."

Preferred Stock

Under the terms of our Amended and Restated Certificate of Incorporation, our board of directors have the authority, without further action by our stockholders, to issue up to 5,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The

issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of us and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock on the rights of holders of common stock until the board of directors determines the specific rights attached to that preferred stock.

Anti-Takeover Effects of Provisions of Our Amended and Restated Certificate of Incorporation, Our Bylaws and Delaware Law

Delaware Anti-Takeover Law

We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation's voting stock.

Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions: before the stockholder became interested, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; upon closing of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or at or after the time the stockholder became interested, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may "opt out" of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or bylaws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Our certificate of incorporation and bylaws contain certain provisions that are intended to enhance the likelihood of continuity and stability in the composition of the board of directors and which may have the effect of delaying, deferring or preventing a future takeover or change in control of the company unless such takeover or change in control is approved by the board of directors.

These provisions include:

Classified Board. Our certificate of incorporation provides that our board of directors is divided into three classes of directors, with the classes as nearly equal in number as possible. As a result, approximately one-third of our board of directors are elected each year. The classification of directors has the effect of making it more difficult for stockholders to change the composition of our board. Our bylaws also provide that, subject to any rights of holders of preferred stock to elect additional directors under specified circumstances, the number of directors is fixed exclusively pursuant to a resolution adopted by our board of directors.

Action by Written Consent; Special Meetings of Stockholders. Our certificate of incorporation provides that stockholder action can be taken only at an annual or special meeting of stockholders and cannot be taken by written consent in lieu of a meeting. Our bylaws provide that, subject to any special rights of the holders of any series of preferred stock, and to the requirements of applicable law, special meetings of the stockholders can be called only by or at the direction of the board of directors pursuant to a resolution adopted by a majority of the total number of directors which our board of directors would have if there were no vacancies. Except as described above, stockholders are not permitted to call a special meeting or to require the board of directors to call a special meeting.

Removal of Directors. Our bylaws provide that our directors may be removed only for cause by the affirmative vote of at least 66 2/3% of the voting power of our voting stock, voting together as a single class. This requirement of a supermajority vote to remove directors could enable a minority of our stockholders to prevent a change in the composition of our board.

Advance Notice Procedures. Our bylaws provide for an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to the board of directors. Stockholders at an annual meeting are only be able to consider proposals or nominations specified in the notice of meeting or brought before the

meeting by or at the direction of the board of directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our Secretary timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although the bylaws do not give the board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, the bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of the company.

Super Majority Approval Requirements. The Delaware General Corporation Law generally provides that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws, unless either a corporation's certificate of incorporation or bylaws requires a greater percentage. Our certificate of incorporation and bylaws provide that the affirmative vote of holders of at least 66 2/3% of the total votes eligible to be cast in the election of directors are required to amend, alter, change or repeal certain provisions of the certificate of incorporation and bylaws. This requirement of a supermajority vote to approve amendments to certain provisions of our certificate of incorporation and bylaws could enable a minority of our stockholders to exercise veto power over any such amendments.

Authorized but Unissued Shares. Our authorized but unissued shares of common stock and preferred stock are available for future issuance without stockholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of a majority of our common stock by means of a proxy contest, tender offer, merger or otherwise.

Exclusive Forum. Our certificate of incorporation provides that, to the fullest extent permitted by applicable law, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or (iv) any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our certificate of incorporation described above. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with one or more actions or proceedings described above, a court could find the choice of forum provisions contained in our certificate of incorporation to be inapplicable or unenforceable.

FENWICK

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July 10, 2025

KalVista Pharmaceuticals, Inc.
55 Cambridge Parkway, Suite 901E
Cambridge, MA 02142

Re: Registration Statement on Form S-3

Ladies and Gentlemen:

As counsel to KalVista Pharmaceuticals, Inc., a Delaware corporation (the "***Company***"), we deliver this opinion with respect to certain matters in connection with the offering by the Company, pursuant to that certain Sales Agreement (the "***Sales Agreement***"), dated as of July 10, 2025, by and between the Company and TD Securities (USA) LLC (the "***Sales Agent***") for the sale and issuance, through the Sales Agent, of shares of common stock of the Company, $0.001 par value per share, having an aggregate maximum offering price of up to $100,00,000 (the "***Shares***").

The Shares were registered pursuant to the Registration Statement on Form S-3 (File No. 333-280759) initially filed by the Company with the Securities and Exchange Commission (the "***Commission***") on July 11, 2024 and declared effective on July 19, 2024 (the registration statement at the time it was declared effective, including the documents or portions thereof incorporated by reference therein, as modified or superseded as described therein, and the information deemed to be a part thereof pursuant to Rule 430B under the Securities Act of 1933, as amended (the "***Securities Act***"), the "***Registration Statement***") and the base prospectus dated July 19, 2024 relating to the offering of securities of the Company, which forms a part of, and is substantially in the form included in, the Registration Statement (the "***Base Prospectus***"), as supplemented by the prospectus supplement of the Company relating to the Shares dated July 10, 2025 and filed by the Company with the Commission pursuant to Rule 424(b) of the Securities Act on July 10, 2025 (the "***Sales Agreement Prospectus Supplement***" and, together with the Base Prospectus, including the documents or portions thereof incorporated by reference therein, as modified or superseded as described therein, the "***Prospectus***"). The offering of the Shares by the Company pursuant to the Registration Statement, the Prospectus and the Sales Agreement is referred to herein as the "***Offering***." This opinion is being furnished in connection with the requirements of Item 601(b)(5) of Regulation S-K under the Securities Act, and no opinion is expressed herein as to any matter pertaining to the contents of the Registration Statement or related Prospectus, other than as expressly stated herein with respect to the issue of the Shares.

As to matters of fact relevant to the opinions rendered herein, we have examined such documents, certificates and other instruments which we have deemed necessary or advisable, including a certificate addressed to us and dated the date hereof executed by the Company (the

"***Opinion Certificate***"). We have not undertaken any independent investigation to verify the accuracy of any such information, representations or warranties or to determine the existence or absence of any fact, and no inference as to our knowledge of the existence or absence of any fact should be drawn from our representation of the Company or the rendering of the opinions set forth below. We have not considered parol evidence in connection with any of the agreements or instruments reviewed by us in connection with this letter.

In our examination of documents for purposes of this letter, we have assumed, and express no opinion as to, the genuineness and authenticity of all signatures on original documents, the authenticity and completeness of all documents submitted to us as originals, that each document is what it purports to be, the conformity to originals of all documents submitted to us as copies or facsimile copies, the absence of any termination, modification or waiver of or amendment to any document reviewed by us (other than as has been disclosed to us), the legal competence or capacity of all persons or entities (other than the Company) executing the same and (other than the Company) the due authorization, execution and delivery of all documents by each party thereto. We have also assumed the conformity of the documents filed with the Commission via the Electronic Data Gathering, Analysis and Retrieval System ("***EDGAR***"), except for required EDGAR formatting changes, to physical copies submitted for our examination.

The opinions in this letter are limited to the existing General Corporation Law of the State of Delaware now in effect. We express no opinion with respect to any other laws.

In connection with our opinions expressed below, we have assumed that, (i) at or prior to the time of the delivery of any of the Shares there will not have occurred any change in the law or the facts affecting the validity of the Shares, (ii) the Registration Statement and any amendments (including any necessary post-effective amendments) will be effective under the Securities Act, (iii) at the time of the offer, issuance and sale of any Shares no stop order suspending the Registration Statement's effectiveness will have been issued and remain in effect, (iv) no future amendments will be made to the Company's current certificate of incorporation (as amended from time to time, the "***Certificate of Incorporation***"), or the Company's Amended and Restated Bylaws, as amended (the "***Bylaws***" and, together with the Certificate of Incorporation, the "***Charter Documents***") that would be in conflict with or inconsistent with the Company's right and ability to issue the Shares, (v) at the time of the issuance and sale of the Shares, the Company will be validly existing as a corporation and in good standing under the laws of the State of Delaware; and (vi) at the time of each offer, issuance and sale of any Shares the Company will have a sufficient number of authorized and unissued and unreserved shares of the applicable class or series of its capital stock included in (or purchasable upon exercise or conversion of) the Shares so issued and sold (after taking into account all other outstanding securities of the Company which may require the Company to issue shares of such applicable class or series) to be able to issue all such shares.

We express no opinion regarding the effectiveness of any waiver or stay, extension or of unknown future rights. Further, we express no opinion regarding the effect of provisions relating to indemnification, exculpation or contribution to the extent such provisions may be held unenforceable as contrary to federal or state securities laws or public policy.

Based upon the foregoing, and subject to the qualifications and exceptions contained herein, we are of the opinion that the Shares, when issued, sold and delivered for consideration (of not less than par value per share of Common Stock) in the manner contemplated by the Sales Agreement and the Prospectus and in accordance with the resolutions duly adopted by the Company's Board of Directors (the "***Board***") and to be duly adopted by the placement committee of the Board with respect to the offer, sale and issuance of the Shares, will be validly issued, fully paid and nonassessable.

We consent to the use of this opinion as an exhibit to the Annual Report on Form 10-K to be filed by the Company with the Commission in connection with the offering of the Shares and further consent to all references to us, if any, in the Registration Statement, the Prospectus and any amendments thereto. In giving this consent we do not thereby admit that we come within the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission thereunder.

[Concluding Paragraph Follows on Next Page]

This opinion is intended solely for use in connection with the issuance and sale of the Shares subject to the Registration Statement and is not to be relied upon for any other purpose. In providing this letter, we are opining only as to the specific legal issues expressly set forth above, and no opinion shall be inferred as to any other matter or matters. This opinion is rendered on, and speaks only as of, the date of this letter first written above, is based solely on our understanding of facts in existence as of such date after the aforementioned examination and does not address any potential changes in facts, circumstance or law that may occur after the date of this opinion letter. We assume no obligation to advise you of any fact, circumstance, event or change in the law or the facts that may hereafter be brought to our attention, whether or not such occurrence would affect or modify any of the opinions expressed herein.

Very truly yours,

/s/ Fenwick & West LLP

FENWICK & WEST LLP

Exhibit 10.23

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL

LICENSE, SUPPLY, AND DISTRIBUTION AGREEMENT

BETWEEN

KAKEN PHARMACEUTICAL CO., LTD.

AND

KALVISTA PHARMACEUTICALS, LTD.

Dated April 8, 2025

TABLE OF CONTENTS

Schedules

LICENSE, SUPPLY, AND DISTRIBUTION AGREEMENT

This License, Supply, and Distribution Agreement (this "**Agreement**") is made as of April 8, 2025 (the "**Effective Date**") by and between KalVista Pharmaceuticals, Ltd., a United Kingdom limited company ("**KalVista**"), having a place of business at Porton Science Park, Bybrook Road, Porton Down, Wiltshire, SP4 0BF, United Kingdom, and Kaken Pharmaceutical Co., Ltd., a Japanese corporation organized under the laws of Japan ("**Kaken**"), having a place of business at 28-8, Honkomagome 2-chome, Bunkyo-ku, Tokyo 113-8650, Japan. KalVista and Kaken are referred to in this Agreement individually as a "**Party**" and collectively as the "**Parties**".

Recitals

WHEREAS, KalVista is a biopharmaceutical company engaged in the Development, Manufacture, and Commercialization of medicines for the treatment of rare diseases, including a proprietary compound internally designated as Sebetralstat;

WHEREAS, KalVista Controls certain Know-How and Patent Rights relating to Sebetralstat;

WHEREAS, Kaken is a pharmaceutical company engaged in the Development, Manufacture and Commercialization of pharmaceutical products in the Territory;

WHEREAS, KalVista is seeking a partner to Commercialize the Licensed Product in the Field in the Territory, and Kaken desires to acquire rights to Commercialize the Licensed Product in the Field in the Territory, in each case, upon the terms and conditions set forth herein; and

WHEREAS, KalVista desires to grant to Kaken, and Kaken desires to receive from KalVista, an exclusive right and license under the Licensed Technology to Commercialize the Licensed Product in the Field in the Territory, in each case, upon the terms and conditions set forth herein.

AGREEMENT

NOW, **THEREFORE**, the Parties hereby agree as follows:

Article 1
DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms will have the respective meanings set forth below, whether used in the singular or plural:

1.1. "**Accounting Standards**" means GAAP, JGAAP or IFRS (as applicable to a Party).

1.2. "**Active Ingredient**" means clinically active material that provides pharmacological effect in a pharmaceutical or biologic product (excluding formulation components such as coatings, stabilizers, excipients or solvents, adjuvants, or controlled release technologies).

1.3. "**Additional Development**" has the meaning set forth in Section 4.1.3 (Additional Development).

1.4. "**Affiliates**" of a Person means any other Person that (directly or indirectly) is controlled by, controls, or is under common control with such Person. For the purposes of this definition, the term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") as used with respect to a Person, will mean the possession, directly or

indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise, and "control" will be presumed to exist if either of the following conditions is met: (a) in the case of a corporate entity, direct or indirect ownership of voting securities entitled to cast at least fifty percent (50%) of the votes in the election of directors or (b) in the case of a non-corporate entity, direct or indirect ownership of at least fifty percent (50%) of the equity interests with the power to direct the management and policies of such entity. For all purposes of this Agreement, KalVista will not be an Affiliate of Kaken or any of Kaken's Affiliates.

1.5. "**Agreement**" has the meaning set forth in the Preamble.

1.6. "**Alliance Manager**" has the meaning set forth in Section 7.1 (Alliance Managers).

1.7. "**Anti-Corruption Laws**" means any local and other anti-corruption laws, including the provisions of the United States Foreign Corrupt Practices Act, as amended.

1.8. "**Anti-Social Forces**" means: (a) an organized crime group, a member of an organized crime group, a related company or association of an organized crime group, and any other equivalent person; or (b) a person who, themselves or through the use of Third Parties, conducts a demand with violence, an unreasonable demand beyond its legal entitlement, use of intimidating words or actions, damages the credit, or obstructs the business of the other party by spreading false rumors or by the use of fraudulent, or any other equivalent actions.

1.9. "**Applicable Law**" means collectively all laws, rules, regulations, ordinances, decrees, judicial and administrative orders, notices, and guidelines (and any license, franchise, permit, or similar right granted under any of the foregoing), and any policies and other requirements of any applicable Governmental Authority that govern or otherwise apply to a Party, including all Anti-Corruption Laws.

1.10. "**Approved Labeling**" means, with respect to a Licensed Product: (a) the Regulatory Authority-approved full prescribing information for such Licensed Product; and (b) the Regulatory Authority-approved labels and other written, printed, or graphic materials on any container, wrapper, or any package insert that is used with or for such Licensed Product.

1.11. "**Arising Know-How**" means any Know-How developed or invented during the Term by a Party's or its Affiliates', licensees', or Subcontractors' employees, agents, or independent contractors, or any Persons contractually required to assign or license such Know-How to a Party or any Affiliate of a Party, either alone or jointly with the other Party's or its Affiliates', licensees', or Subcontractors' employees, agents, or independent contractors, or any Persons contractually required to assign or license such Know-How to the other Party or any Affiliate of the other Party, in each case, in the performance of activities under this Agreement or any activities related to the Exploitation of the Licensed Product inside of the Territory.

1.12. "**Arising Patent Right**" means any Patent Right that (a) has a priority date after the Effective Date; and (b) Covers any Invention included in the Arising Know-How.

1.13. "**Business Day**" means a day other than a Saturday, Sunday, or a day on which banking institutions in Boston, Massachusetts (USA) or Tokyo, Japan are required by Applicable Law to remain closed.

1.14. "**Buyers**" has the meaning set forth in Section 1.115 (Net Sales).

1.15. "**Calendar Quarter**" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30, and December 31.

1.16. "**Calendar Year**" means each twelve (12)-month period commencing on January 1.

1.17. "**cGMP**" means all applicable current Good Manufacturing Practices, including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820, (b) European Directive 2003/94/EC and Eudralex 4, (c) the principles detailed in the International Conference on Harmonization's Q7 guidelines, and (d) the equivalent Applicable Law in any relevant country or region, each as may be amended and applicable from time to time.

1.18. "**Change of Control**" means, with respect to a Party, that: (a) any Third Party acquires directly or indirectly the beneficial ownership of any voting security of such Party, or if the percentage ownership of such Third Party in the voting securities of such Party is increased through stock redemption, cancellation, or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing at least fifty percent (50%) of the total voting power of all of the then outstanding voting securities of such Party; (b) a merger, consolidation, recapitalization, or reorganization of such Party is consummated that would result in shareholders or equity holders of such Party immediately prior to such transaction, owning at least fifty percent (50%) of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; or (c) there is a sale or transfer to a Third Party of all or substantially all of such Party's consolidated assets taken as a whole, through one or more related transactions.

1.19. "**Clinical Trial**" means any clinical trial in humans that is conducted in accordance with GCP and is designed to generate data in support or maintenance of a CTA or MAA, or other similar marketing application, whether prior to or after receipt of Regulatory Approval for a pharmaceutical or biologic product.

1.20. "**CMO**" means a contract manufacturing organization.

1.21. "**Commercialization**" means any and all activities directed to the marketing, promotion, distribution, pricing, reimbursement, offering for sale, and sale of a pharmaceutical product and interacting with Regulatory Authorities following receipt of Regulatory Approval in the applicable country or region for such pharmaceutical product regarding the foregoing, including seeking any required Reimbursement Approval, but excluding activities directed to Manufacturing, Development, or Post-Marketing Activities. "**Commercialize**," "**Commercializing**," and "**Commercialized**" will be construed accordingly.

1.22. "**Commercially Reasonable Efforts**" means, with respect to the Exploitation of a Licensed Product by a Party, those efforts and resources [*].

1.23. "**Competitive Product**" means [*].

1.24. "**Confidential Information**" means, subject to Section 9.3 (Exemptions), (a) Know-How and any other technical, scientific, trade, research, manufacturing, business, financial, marketing, product, supplier, intellectual property, and other non-public or proprietary data or information (including unpublished patent applications) that may be disclosed by one Party or its Affiliates to the other Party or its Affiliates pursuant to this Agreement (including information disclosed prior to the Effective Date pursuant to the Nondisclosure Agreement), regardless of whether such information

is specifically marked or designated as confidential and regardless of whether such information is in written, oral, electronic, or other form, and (b) the terms of this Agreement.

1.25. "**Contract MR**" means medical representatives ("**MR**") that belong to a CSO and work by being dispatched by the CSO to Kaken and acting as if they were an MR of Kaken under Kaken's command and control, in accordance with a dispatch contract entered into between the CSO and Kaken.

1.26. "**Control**" or "**Controlled**" means (a) the possession by a Party (whether by ownership, license, or otherwise other than pursuant to this Agreement) of, (i) with respect to any tangible Know-How, the legal authority or right to physical possession of such tangible Know-How, with the right to provide such tangible Know-How to the other Party on the terms set forth herein, or (ii) with respect to Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How, or other intellectual property rights, the legal authority or right to grant a license, sublicense, access, right of reference, or right to use (as applicable) to the other Party under such Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How, or other intellectual property rights on the terms set forth herein, in each case ((i) and (ii)), without breaching or otherwise violating the terms of any arrangement or agreement with a Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, right of reference, right to use, licenses, or sublicense and without being required to make any payment to any Third Party, other than payment obligations related to KalVista In-Licensed Rights in accordance with Section 12.3.3 (Third Party IP Agreements) and (b) with respect to any product, the possession by a Party of the ability (whether by sole or joint ownership, license, or otherwise, other than pursuant to the licenses granted under this Agreement) to grant an exclusive license or sublicense of Patent Rights that Cover such product or proprietary Know-How that is used in connection with the Exploitation of such product. Notwithstanding the foregoing [*].

1.27. "**Cover**" means, with respect to a particular subject matter at issue and a relevant Patent Right, that the manufacture, use, sale, offer for sale, or importation of such subject matter would fall within the scope of one or more claims in such Patent Right.

1.28. "**CPI**" means with respect to KalVista, the Consumer Price Index-Urban Wage Earners and Clerical Workers, U.S. City Average, All Items 1982-84=100, published by the United States Department of Labor, Bureau of Labor Statistics (or its successor equivalent index), in the United States.

1.29. "**CREATE Act**" has the meaning set forth in Section 12.2 (CREATE Act).

1.30. "**CRO**" means a contract research organization.

1.31. "**CSO**" means a contract sales organization.

1.32. "**CTA**" means: (a) with respect to Japan, a common technical document filed with the MHLW; (b) with respect to the U.S., an Investigational New Drug application required pursuant to 21 C.F.R. Part 312; (c) any foreign equivalents as filed with the applicable Regulatory Authorities in other countries or regulatory jurisdictions, as applicable; and (d) all supplements and amendments that may be filed with respect to the foregoing.

1.33. "**Debarred/Excluded**" means any Person becoming debarred or suspended under 21 U.S.C. §335(a) or (b), the subject of a conviction described in Section 306 of the FD&C Act, excluded, or having previously been excluded, from a federal or governmental health care program, debarred

from federal contracting, convicted of or pled *nolo contendere* to any felony, or to any federal or state legal violation (including misdemeanors) relating to prescription drug products or fraud, the subject to OFAC sanctions or on the OFAC list of specially designated nationals, or the subject of any similar sanction of any Governmental Authority in the Territory.

1.34. "**Default**" has the meaning set forth in Section 13.2.2 (Termination for Cause).

1.35. "**Default Notification**" has the meaning set forth in Section 13.2.2 (Termination for Cause).

1.36. "**Development**" means all internal and external research, development, and regulatory activities related to pharmaceutical or biologic products, including (a) research, non-clinical testing, toxicology, testing and studies (including CMC studies), non-clinical and preclinical activities, and Clinical Trials, and (b) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct Clinical Trials and to obtain, support, or maintain Regulatory Approval of a pharmaceutical or biologic product, but excluding activities directed to Manufacturing, Post-Marketing Activities, or Commercialization. Development will include development and regulatory activities for additional forms, formulations, or indications for a pharmaceutical or biologic product after receipt of Regulatory Approval of such product (including label expansion) other than Post-Marketing Activities, including Clinical Trials initiated following the receipt of Regulatory Approval or any Clinical Trial to be conducted after receipt of Regulatory Approval that was mandated by the applicable Regulatory Authority as a condition of such Regulatory Approval with respect to an approved formulation or Indication. "**Develop**," "**Developing**," and "**Developed**" will be construed accordingly.

1.37. "**Disclosing Party**" has the meaning set forth in Section 9.1.1 (Duty of Confidence).

1.38. "**Dispute**" has the meaning set forth in Section 14.1 (Dispute Resolution; General).

1.39. "**Dollar**" means the U.S. dollar, and "$" will be interpreted accordingly.

1.40. "**DRI Agreement**" means the Purchase and Sale Agreement, dated November 4, 2024, by and between KalVista Pharmaceuticals Limited, DRI Healthcare Acquisitions LP, and, solely for the purposes of the Guarantor Provisions (as defined in the DRI Agreement), KalVista Pharmaceuticals, Inc.

1.41. "**Effective Date**" has the meaning set forth in the Preamble.

1.42. "**Excused Reason**" has the meaning set forth in Section 13.2.4 (Cessation of Commercialization).

1.43. "**Executive Officers**" has the meaning set forth in Section 7.4.2 (Decisions of the JSC).

1.44. "**Exploit**" means to make, use, offer to sell, sell, Develop, Manufacture, Commercialize, or otherwise exploit. "**Exploitation**" will be construed accordingly.

1.45. "**FD&C Act**" means the United States Federal Food, Drug and Cosmetic Act, as amended from time to time, together with any rules, regulations, and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.46. "**FDA**" means the United States Food and Drug Administration or any successor entity thereto having essentially the same function.

1.47. "**Field**" means all therapeutic or prophylactic uses for human diseases.

1.48. "**First Commercial Sale**" means, with respect to a Licensed Product or Generic Product (as applicable) in any country, the first sale of such Licensed Product or Generic Product (as applicable) to a Third Party for distribution, use, or consumption in such country after receipt of Regulatory Approvals for such Licensed Product in such country. First Commercial Sale excludes any sale or other distribution of a Licensed Product for use in a Clinical Trial or other Development activity, expanded access programs, compassionate sales or use programs (including named patient programs or single patient programs), or indigent programs, in each case, to the extent that Seller does not invoice or receive amounts therefor.

1.49. "**First NHI Price**" means [*].

1.50. "**FTE**" means the equivalent of the work of one (1) duly qualified employee of KalVista full time for one (1) year (consisting of a total of [*]) carrying out Development or Manufacturing, Post-Marketing Activities, or other scientific or technical work under this Agreement. Overtime and work on weekends, holidays, and the like, in each case, will not be counted with any multiplier (*e.g.*, time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution. The portion of an FTE billable by KalVista for one (1) individual during a given accounting period will be determined by dividing the number of hours worked directly by such individual on the work to be conducted under this Agreement during such accounting period and the number of FTE hours applicable for such accounting period based on [*] per Calendar Year.

1.51. "**FTE Rate**" means the amount for an FTE per Calendar Year, which for the Calendar Year ending on December 31, 2025 will be [*] per FTE, pro-rated for the period beginning on the Effective Date and ending on December 31, 2025. Beginning on January 1, 2026 and on January 1 of each subsequent Calendar Year during the Term, each FTE Rate is subject to annual adjustment by the percentage increase or decrease in the applicable CPI comparing the levels of the applicable CPI as of December 31 of the two (2) most recently completed Calendar Years.

1.52. "**Fully Burdened Manufacturing Cost**" means, [*].

1.53. "**GAAP**" means United States generally accepted accounting principles, consistently applied.

1.54. "**GCP**" means all applicable good clinical practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Trials, including, as applicable (a) as set forth in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) (the "**ICH Guidelines**") and any other guidelines for good clinical practice for trials on medicinal products in the Territory, (b) the Declaration of Helsinki (2013) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (c) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards), and 312 (Investigational New Drug Application), as may be amended from time to time, and (d) the equivalent Applicable Law in the Territory, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

1.55. "**Generic Launch Quarter**" means, with respect to a Generic Product in the Territory by reference to a particular Licensed Product for one (1) or more Indications in the Territory, the Calendar Quarter in which the First Commercial Sale of the applicable Generic Product occurred following receipt of all necessary Regulatory Approvals and Reimbursement Approvals from the applicable Regulatory Authorities to market and sell such Generic Product as a pharmaceutical product for one (1) or more Indications included in the Approved Labeling for such Licensed Product in the Territory.

1.56. "**Generic Product**" means, with respect to a particular Licensed Product in the Territory, a drug product that (a) contains the same Active Ingredient, with the same chemical structure, as the applicable Licensed Product and in the same dosage and route of administration as the applicable Licensed Product; (b) is approved by the PMDA pursuant to an abbreviated new drug application (ANDA) and relies on or receives Regulatory Approval through the use of data included in the Regulatory Submissions for such Licensed Product and is categorized by the applicable Regulatory Authority in the Territory to be bioequivalent to such Licensed Product; (c) has received all necessary Regulatory Approvals and Reimbursement Approvals from such Regulatory Authorities in the Territory to market and sell such product as a pharmaceutical product for any of the Indications included in the Approved Labeling for such Licensed Product; and (d) is sold or marketed for sale in the Territory by a Third Party that has not obtained the rights to market or sell such product as a Sublicensee, or Third Party Distributor of Kaken or any of its Affiliates or Sublicensees with respect to such Licensed Product.

1.57. "**Global Brand Elements**" has the meaning set forth in Section 6.8.1 (Global Brand Elements).

1.58. "**Global Brand Strategy**" has the meaning set forth in Section 6.3 (Marketing Plans).

1.59. "**GLP**" means all applicable good laboratory practice standards, including, as applicable, as set forth in the then-current good laboratory practice standards promulgated or endorsed by the U.S. Food and Drug Administration, as defined in 21 C.F.R. Part 58, and the equivalent Applicable Law in the Territory, each as may be amended and applicable from time to time.

1.60. "**Governmental Authority**" means any federal, national, state, provincial, or local government, or political subdivision thereof, or any multinational organization or any authority, agency, regulatory body, or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, or any court or tribunal (or any department, bureau or division of any of the foregoing, or any governmental arbitrator or arbitral body). Governmental Authorities include all Regulatory Authorities.

1.61. "**GQP**" means Good Quality Practice, which refers to the framework of standards and operational requirements that ensure the quality assurance and proper management of pharmaceutical products, including, as applicable, as set forth in the then-current good quality practice standards promulgated or endorsed by the MHLW, as defined in Ministerial Ordinance No. 136, 2004 (Ministerial Ordinance on Standard for Quality Assurance for Drugs, Quasi-drugs and Cosmetics and Medical Devices), and the equivalent Applicable Laws in the Territory, each as may be amended and applicable from time to time.

1.62. "**HAE**" means hereditary angioedema.

1.63. "**HAE-A**" means the treatment of acute HAE attacks. For the avoidance of doubt, HAE-A does not include long-term prophylaxis for HAE.

1.64. "**IFRS**" means International Financial Reporting Standards, consistently applied.

1.65. "**Indemnified Party**" has the meaning set forth in Section 11.3 (Indemnification Procedure).

1.66. "**Indemnifying Party**" has the meaning set forth in Section 11.3 (Indemnification Procedure).

1.67. "**Indication**" means a separate and distinct disease, disorder, or medical condition [*].

1.68. "**Initial Term**" means, on a Licensed Product-by-Licensed Product basis, the period commencing on the First Commercial Sale of a Licensed Product in the Territory and ending on the latest of (a) the expiration of the last Valid Claim of the Licensed Patent Rights or Joint Arising Patent Rights, including those set forth in Schedule 1.100 (Licensed Patent Rights) as of the Effective Date, Covering the composition of matter or method of use of such Licensed Product or the Manufacture, use, Commercialization, or importation of such Licensed Product in the Territory ((a), the "**Valid Claim Expiration**"); (b) the expiration of any Regulatory Exclusivity for such Licensed Product in the Territory; or (c) the date on which ten (10) years have passed from the First Commercial Sale of the Licensed Product in the Territory.

1.69. "**Initial Term Price**" has the meaning set forth in Section 8.2.2 (After Receipt of the First NHI Price).

1.70. "**Invention**" means any new and useful process, manufacture, or composition of matter, know-how, or other invention that is conceived and first reduced to practice, constructively or actually, by either Party or jointly by the Parties in connection with the performance of activities under this Agreement.

1.71. "**JGAAP**" means Japanese generally accepted accounting principles, consistently applied.

1.72. "**Joint Arising Know-How**" means any Arising Know-How developed or invented jointly by a Party's or its Affiliates', licensees', or Subcontractors' employees, agents, or independent contractors, or any Persons contractually required to assign or license such Arising Know-How to such Party or any Affiliate of such Party, on the one hand, and the other Party's or its Affiliates', licensees', or Subcontractors' employees, agents, or independent contractors, or any Persons contractually required to assign or license such Arising Know-How to such Party or any Affiliate of such Party, on the other hand.

1.73. "**Joint Arising Patent Rights**" means all Arising Patent Rights that Cover Joint Arising Know-How.

1.74. "**Joint Arising Technology**" means the Joint Arising Know-How and the Joint Arising Patent Rights.

1.75. "**JSC**" has the meaning set forth in Section 7.2.1 (Formation and Purpose of JSC).

1.76. "**Kaken**" has the meaning set forth in the Preamble.

1.77. "**Kaken Arising Know-How**" has the meaning set forth in Section 12.1.1 (Ownership).

1.78. "**Kaken Arising Patent Rights**" has the meaning set forth in Section 12.1.1 (Ownership).

1.79. "**Kaken Arising Technology**" means the Kaken Arising Know-How and the Kaken Arising Patent Rights.

1.80. "**Kaken Identified Rights**" has the meaning set forth in Section 12.3.2 (Kaken Identified Rights).

1.81. "**Kaken Indemnitee(s)**" has the meaning set forth in Section 11.2 (Indemnification; By KalVista).

1.82. "**Kaken Know-How**" means all Know-How, other than Joint Arising Know-How, that is (a) Controlled by Kaken or any of its Affiliates as of the Effective Date or during the Term, and (b) necessary or actually used by or on behalf of Kaken to Exploit the Licensed Product, including Kaken Arising Know-How.

1.83. "**Kaken Patent Rights**" means all Patent Rights, other than the Joint Arising Patent Rights, that are (a) Controlled by Kaken or any of its Affiliates as of the Effective Date or during the Term, and (b) necessary (or, with respect to patent applications, would be necessary if such patent applications were to issue as patents) or actually practiced by or on behalf of Kaken to Exploit the Licensed Product, including all Kaken Arising Patent Rights.

1.84. "**Kaken Sublicense or Subcontract Agreement**" has the meaning set forth in Section 2.4 (Terms of Sublicense and Subcontractor Agreements).

1.85. "**Kaken Technology**" means the Kaken Know-How and Kaken Patent Rights.

1.86. "**Kaken Vendors**" means Subcontractors engaged by Kaken to perform any services related to designing and producing promotional materials, programs or other tools, providing a web platform or media for promotion, conducting market research, consulting services, transport or delivery services, or any other services supporting or assisting the Commercialization conducted by Kaken with respect to the Licensed Products.

1.87. "**KalVista**" has the meaning set forth in the Preamble.

1.88. "**KalVista Arising Know-How**" has the meaning set forth in Section 12.1.1 (Ownership).

1.89. "**KalVista Arising Patent Rights**" has the meaning set forth in Section 12.1.1 (Ownership).

1.90. "**KalVista Arising Technology**" has the meaning set forth in Section 12.1.1 (Ownership).

1.91. "**KalVista Identified Rights**" has the meaning set forth in Section 12.3.1 (KalVista Identified Rights).

1.92. "**KalVista Indemnitee(s)**" has the meaning set forth in Section 11.1 (Indemnification; By Kaken).

1.93. "**KalVista In-Licensed Rights**" has the meaning set forth in Section 12.3.3 (Third Party IP Agreements).

1.94. "**KalVista JP**" means KalVista Pharmaceuticals Japan Co., Ltd., with an address of Marunouchi Eiraku Building 26th Floor, 1-4-1 Marunouchi, Chiyoda-ku, 100-0005 Tokyo, Japan as an Affiliate of KalVista.

1.95. "**KalVista Prosecuted Patent Rights**" has the meaning set forth in Section 12.5.1(a) (Right to Prosecute).

1.96. "**Know-How**" means any proprietary information and materials, including records, discoveries, improvements, modifications, processes, techniques, methods, assays, chemical or biological materials, designs, protocols, formulas, data (including physical data, chemical data, toxicology data, animal data, raw data, clinical data, and analytical and quality control data), dosage regimens, control assays, product specifications, marketing, pricing and distribution costs, Inventions, algorithms, technology, forecasts, profiles, strategies, plans, results in any form whatsoever, know-how and trade secrets (in each case, patentable, copyrightable, or otherwise).

1.97. "**Knowledge**" means the actual knowledge, without any inquiry or investigation, of (a) with respect to KalVista, [*], Chief Executive Officer, [*], Chief Development Officer, [*], Chief Financial Officer, [*], Chief Medical Officer, [*], Chief Commercial Officer, [*], Chief Operating Officer, [*], Senior Vice President of Development, [*], Senior Vice President of Regulatory Affairs and Quality Assurance, [*], Senior Vice President of Corporate Development, and [*], General Counsel; and (b) with respect to Kaken, [*], General Manager, Legal Affairs and Intellectual Property.

1.98. "**Licensed Compound**" means Sebetralstat, as further detailed in Schedule 1.98 (Licensed Compound), including [*].

1.99. "**Licensed Know-How**" means all Know-How, including Arising Know-How, that is (a) Controlled by KalVista or any of its Affiliates as of the Effective Date or any time thereafter during the Term; and (b) (i) necessary, (ii) actually used by KalVista or any of its Affiliates; or (iii) otherwise disclosed to Kaken in writing for use in the performance of activities under this Agreement, in each of cases (i)-(iii) above, to Commercialize the Licensed Product in the Field in the Territory.

1.100. "**Licensed Patent Rights**" means all Patent Rights, including any Patent Rights that Cover any Invention jointly developed by or on behalf of each Party in the performance of activities under this Agreement and any other Arising Patent Rights, that are (a) Controlled by KalVista or any of its Affiliates as of the Effective Date or any time thereafter during the Term; and (b) (i) necessary or actually used by KalVista or any of its Affiliates for the Commercialization of the Licensed Product in the Field in the Territory; or (ii) otherwise Cover any Licensed Know-How. Schedule 1.100 (Licensed Patent Rights) includes the Licensed Patent Rights that are owned or exclusively licensed by KalVista in the Territory as of the Effective Date.

1.101. "**Licensed Product**" means any and all pharmaceutical or biologic products containing the [*]. For the avoidance of doubt, a Licensed Product [*].

1.102. "**Licensed Technology**" means Licensed Know-How and Licensed Patent Rights.

1.103. "**Loss of Market Exclusivity**" means a condition where, with respect to a particular Licensed Product in the Territory in the Field: (a) one (1) or more Generic Products are being marketed or sold by a Third Party; and (b) [*] (the "**Supply Price Reduction Trigger**").

1.104. "**Losses**" means damages, debts, obligations, and other liabilities, losses, claims, taxes, interest obligations, deficiencies, judgments, assessments, fines, fees, penalties, or expenses (including amounts paid in settlement, interest, court costs, costs of investigators, reasonable fees and expenses of attorneys, accountants, financial advisors, consultants, and other experts, and other expenses of litigation).

1.105. "**Manufacture**" means activities directed to manufacturing, processing, packaging, labeling, filling, finishing, assembly, shipping, storage, or freight of any pharmaceutical or biologic product (or any components or process steps involving any product or any companion diagnostic), placebo, or comparator agent, as the case may be, including quality assurance and stability testing, characterization testing, quality control release testing of drug substance and drug product, quality assurance batch record review and release of product, process development, qualification, and validation, scale-up, pre-clinical, clinical, and commercial manufacture and analytic development, and product characterization, but excluding activities directed to Development, or Commercialization. "**Manufacturing**" and "**Manufactured**" will be construed accordingly.

1.106. "**Marketing Authorization Application**" or "**MAA**" means any new drug application, biologics license application, or other marketing authorization application, in each case, filed with the applicable Regulatory Authority in a country or other regulatory jurisdiction, which application is required to commercially market or sell a pharmaceutical or biologic product in such country or jurisdiction (and any amendments thereto), including, in the Territory, a new drug application filed with the PMDA and approved by the MHLW.

1.107. "**Marketing Plan**" has the meaning set forth in Section 6.3 (Marketing Plans).

1.108. "**Marketing Year**" means each twelve (12)-month period commencing on April 1.

1.109. "**MHLW**" means the Ministry of Health, Labour, and Welfare, otherwise referred to as "Koro-Sho," or any successor entity thereto having essentially the same function.

1.110. "**Milestone Events**" means Regulatory Milestone Events and Sales Milestone Events.

1.111. "**Milestone Payments**" means Regulatory Milestone Payments and Sales Milestone Payments.

1.112. "**Minimum Sales Default**" has the meaning set forth in Section 13.2.2 (Termination for Cause).

1.113. "**Minimum Sales Target**" has the meaning set forth in Section 6.3 (Marketing Plans).

1.114. "**MR**" has the meaning set forth in Section 1.25 (Contract MR).

1.115. "**Net Sales**" means with respect to a Licensed Product, [*].

1.116. "**New Supply Price**" has the meaning set forth in Section 8.2.4 (Revision of the NHI Price).

1.117. "**NHI Price**" means, with respect to a Licensed Product, [*].

1.118. "**NHI Price Renewal Effective Date**" has the meaning set forth in Section 8.2.4 (Revision of the NHI Price).

1.119. "**Nondisclosure Agreement**" means that certain Mutual Non-Disclosure Agreement, dated June 26, 2023 (as extended on May 9, 2024 and December 27, 2024) by and between KalVista and Kaken.

1.120. "**OFAC**" means the Office of Foreign Assets Control of the United States Department of the Treasury or any successor agency thereto.

1.121. "**Party**" or "**Parties**" has the meaning set forth in the Preamble.

1.122. "**Patent Challenge**" has the meaning set forth in Section 13.2.3 (Termination for Patent Challenge).

1.123. "**Patent Prosecution**" means activities directed to (a) preparing, filing, and prosecuting applications (of all types) for any Patent Right; and (b) maintaining any Patent Right; and (c) defending against any adversarial proceedings relating to the activities described in libs (a) or (b) above such as an opposition, and any equivalent action alleging invalidity or unenforceability.

1.124. "**Patent Rights**" means (a) all patents and patent applications in any country or region, (b) all patent applications filed either from such patents or patent applications or from an application claiming priority from any of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and continued prosecution applications, (c) any and all patents that have issued or in the future issue from the foregoing patent applications, and (d) any and all substitutions, renewals, registrations, confirmations, extensions, or restorations, including revalidations, reissues, and re-examinations (including any supplementary protection certificates and the like) of the foregoing patents or patent applications.

1.125. "**Paying Party**" has the meaning set forth in Section 8.12.2 (Tax Cooperation).

1.126. "**Performance Targets**" has the meaning set forth in Section 6.3 (Marketing Plans).

1.127. "**Person**" means any corporation, limited or general partnership, limited liability company, joint venture, joint stock company, trust, unincorporated association, governmental body, authority, bureau, or agency, or any other entity or body, or an individual.

1.128. "**PMDA**" means the Pharmaceuticals and Medical Devices Agency in Japan or any successor thereto that conducts scientific reviews of marketing authorization applications for pharmaceuticals and monitoring of their post-marketing safety in Japan.

1.129. "**PMD Act**" means the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of August 10, 1960).

1.130. "**Post-Marketing Activities**" means post marketing surveillance, post-marketing studies, observational studies, implementation and management of registries and analysis thereof, in each case, if required by any Regulatory Authority in the Territory to support or maintain Regulatory Approval for a pharmaceutical or biologic product in the Field in the Territory.

1.131. "**Pre-Approval Price**" has the meaning set forth in Section 8.2.1 (Prior to First NHI Price).

1.132. "**Product Infringement**" has the meaning set forth in Section 12.6.1 (Patent Enforcement; Notice).

1.133. "**Product Marks**" has the meaning set forth in Section 6.8.2 (Product Marks in the Territory).

1.134. "**Promotional Materials**" means all written, printed, graphic, electronic, audio, or video matter, including journal advertisements, sales visual aids, leave behind items, formulary binders, reprints, direct mail, direct-to consumer advertising, Internet postings, broadcast advertisements and sales reminder aids (for example, scratch pads, pens and other like items), in each case, created by a Party or on its behalf and used or intended for use in connection with any marketing or promotion of a Licensed Product in the Field to the extent permitted by all Applicable Laws and the terms of all applicable Regulatory Approvals in the Territory.

1.135. "**Public Official**" means (a) any officer, employee or representative of any regional, federal, state, provincial, county or municipal government or government department, agency or other division; (b) any officer, employee or representative of any commercial enterprise that is owned or controlled by a government, including any state-owned or controlled veterinary, laboratory or medical facility; (c) any officer, employee or representative of any public international organization, such as the International Monetary Fund, the United Nations or the World Bank; and (d) any person acting in an official capacity for any government or government entity, enterprise, or organization identified above.

1.136. "**Publication**" has the meaning set forth in Section 9.6 (Publications).

1.137. "**Publication and Communication Strategy**" has the meaning set forth in Section 9.6 (Publications).

1.138. "**PVA**" means the meaning set forth in Section 3.3.2 (Pharmacovigilance (PV) Agreement).

1.139. "**Quality Agreement**" means the quality agreement to be executed with the Supply Agreement.

1.140. "**Receiving Party**" has the meaning set forth in Section 9.1.1 (Duty of Confidence).

1.141. "**Recipient**" has the meaning set forth in Section 8.12.2 (Tax Cooperation).

1.142. "**Regulatory Activities**" has the meaning set forth in Section 3.1.1 (In the Territory).

1.143. "**Regulatory Approval**" means, with respect to a particular country or other regulatory jurisdiction, any approval of an MAA or other approval, product, or establishment license, registration, or authorization of any Regulatory Authority necessary for the commercial marketing or sale of a pharmaceutical or biologic product in such country or other regulatory jurisdiction, excluding, in each case, Reimbursement Approval.

1.144. "**Regulatory Authority**" means any applicable Governmental Authority with jurisdiction or authority over the Development, Manufacture, Commercialization, or other Exploitation (including granting Regulatory Approval or Reimbursement Approval) of pharmaceutical or biologic products in a particular country or other regulatory jurisdiction, including the FDA, PMDA, MHLW, and any corresponding national or regional regulatory authorities.

1.145. "**Regulatory Exclusivity**" means, with respect to a particular Licensed Product in the Field in the Territory, any exclusive data or marketing rights conferred by a Regulatory Authority with respect to such Licensed Product, excluding any rights conferred by or based on any Patent Rights.

1.146. "**Regulatory Milestone Events**" has the meaning set forth in Section 8.3.1 (Regulatory Milestone Events and Payments).

1.147. "**Regulatory Milestone Payment**" has the meaning set forth in Section 8.3.1 (Regulatory Milestone Events and Payments).

1.148. "**Regulatory Submissions**" means any filing, application, or submission with any Regulatory Authority in support of Developing, Manufacturing, or Commercializing a pharmaceutical or biologic product (including to obtain, support, or maintain Regulatory Approval from that Regulatory Authority), and all substantive correspondence or communication with or from the relevant Regulatory Authority, as well as minutes of any substantive meetings, telephone conferences, or discussions with the relevant Regulatory Authority. Regulatory Submissions include all CTAs, MAAs, and other applications for Regulatory Approval and Reimbursement Approvals and each of their equivalents.

1.149. "**Reimbursement Approval**" means an approval, agreement, determination, or other decision by the applicable Governmental Authority that establishes prices charged to end-users for pharmaceutical or biologic products at which a particular pharmaceutical or biologic product will be reimbursed by the Regulatory Authorities or other applicable Governmental Authorities in the Territory, including reimbursement pricing approval by MHLW under the NHI system.

1.150. "**Review Period**" has the meaning set forth in Section 9.6 (Publications).

1.151. "**Revised NHI Price**" has the meaning set forth in Section 8.2.4 (Revision of the NHI Price).

1.152. "**Royalty Monetization Partner**" means [*].

1.153. "**Sales Milestone Event**" has the meaning set forth in Section 8.3.2 (Sales Milestone Events and Payments).

1.154. "**Sales Milestone Payment**" has the meaning set forth in Section 8.3.2 (Sales Milestone Events and Payments).

1.155. "**Seller**" has the meaning set forth in Section 1.115 (Net Sales).

1.156. "**Subcontractor**" means a Third Party contractor engaged by a Party to perform certain obligations or exercise certain rights of such Party under this Agreement on a fee-for-service basis (including CROs, CMOs and CSOs).

1.157. **"Sublicensee"** means a Third Party that has received a license or other right under the Licensed Technology in accordance with Section 2.2 (Sublicensees) but shall not include any Subcontractor.

1.158. "**Supply Agreement**" has the meaning set forth in Section 5.1.1 (Commercial Supply).

1.159. "**Supply Price**" has the meaning set forth in Section 5.1.2 (Supply Price).

1.160. "**Supply Price Reduction Trigger**" has the meaning set forth in Section 1.103 (Loss of Market Exclusivity).

1.161. "**Tax**" or "**Taxes**" means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including any interest thereon), including value add taxes ("**VAT**").

1.162. "**Term**" has the meaning set forth in Section 13.1 (Term).

1.163. "**Termination Date**" has the meaning set forth in Section 13.3.1 (Licenses).

1.164. "**Territory**" means Japan.

1.165. "**Territory Sponsor**" means, with respect to a Clinical Trial for a Licensed Product to be conducted at sites in the Territory, the Party that holds the CTA from the applicable Regulatory Authority in the Territory for such Clinical Trial in its name.

1.166. "**Third Party**" means any Person other than a Party or an Affiliate of a Party.

1.167. "**Third Party Claims**" means collectively, any and all Third Party demands, claims, actions, suits, and proceedings (whether criminal or civil, in contract, tort, or otherwise).

1.168. "**Third Party Distributor**" means any Third Party that purchases Licensed Product from Kaken or its Affiliates, takes title to such Licensed Product, and distributes such Licensed Product directly to customers, but does not Develop or Manufacture any Licensed Product and does not make any royalty, profit-share, or other payment to Kaken or its Affiliates, other than payment for the purchase of Licensed Product for resale.

1.169. "**Third Party IP Agreement**" has the meaning set forth in Section 12.3.3 (Third Party IP Agreements).

1.170. "**True-Up Payment**" has the meaning set forth in Section 8.2.3 (True-Up).

1.171. "**United States**" or "**U.S.**" means the United States of America and its territories and possessions.

1.172. "**Upfront Payment**" has the meaning set forth in Section 8.1 (Upfront Payment).

1.173. "**Valid Claim**" means: (a) a claim of an issued and unexpired patent (as may be extended through supplementary protection certificate or patent term extension or the like) that has not been revoked, held invalid, or unenforceable by a patent office or other Governmental Authority of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period) and which claim has not been disclaimed, denied, or admitted to be invalid or unenforceable through reissue, re-examination, or disclaimer or otherwise; or (b) subject to the proviso, a pending claim of an unissued, pending patent application that has not been pending for more than [*] of such application, *provided* that notwithstanding the foregoing, if such pending claim has been pending for more than [*] (meaning such claim is no longer "Valid Claim") subsequently becomes an issued and unexpired patent, then the claim for such patent shall become a "Valid Claim" again.

1.174. "**Valid Claim Expiration**" has the meaning set forth in Section 1.68 (Initial Term).

1.175. "**VAT**" has the meaning set forth in Section 1.161 (Tax).

1.176. "**VAT Credit**" has the meaning set forth in Section 8.12.5 (VAT Credits).

Article 2
LICENSES

2.1. **License Grants to Kaken**. Subject to the terms of this Agreement, KalVista hereby grants to Kaken an exclusive (subject to KalVista's retained rights set forth in Section 2.6 (Retained Rights)), royalty-bearing license, with the right to grant sublicenses to Sublicensees solely in accordance with Section 2.2 (Sublicensees), under the Licensed Technology to Commercialize the Licensed Products in the Field in the Territory, including the right to ship, store, and freight the Licensed Product for such Commercialization during the Term.

2.2. **Sublicensees.**

2.2.1. **Right to Sublicense.** Kaken shall have the right to grant sublicenses of the rights granted under Section 2.1 (License Grants to Kaken) with respect to the Territory to Sublicensees, other than Subcontractors, only with KalVista's prior written consent. Kaken shall, within thirty (30) days of the execution of an agreement under which Kaken grants any such sublicense, provide KalVista with a copy of such sublicense agreement between Kaken and any Sublicensee, in each case, which agreement may be redacted by Kaken as necessary to protect any sensitive information.

2.3. **Subcontractors.**

2.3.1. **Right to Subcontract**. Subject to the terms of this Agreement, including this Section 2.3.1 (Right to Subcontract), Kaken will have the right to engage one or more Subcontractors to perform Kaken's applicable obligations or exercise Kaken's applicable rights under this Agreement, *provided* that Kaken will not engage any Subcontractors (other than any Contract MR or Kaken Vendors) that are Commercializing a Competitive Product. Prior to the engagement of any Subcontractor (other than any Contract MR) in which Kaken intends to disclose KalVista's Confidential Information to such Subcontractor, Kaken will provide KalVista with notice of and will obtain KalVista's prior written consent, not to be unreasonably withheld, conditioned or delayed, to such proposed Subcontractor. If KalVista has a reasonable concern that the engagement of such Subcontractor will have a material adverse impact on KalVista's or its Affiliates' ability to comply with its obligations under this Agreement in the Territory, including to comply with Applicable Law or other requirements of Regulatory Authorities in the Territory, then KalVista shall inform Kaken thereof no later than [*] after receipt of such notice from Kaken and the Parties will discuss to address KalVista's concern. In the absence of such notice by KalVista within such [*], Kaken may engage such Subcontractor subject to this Section 2.3.1 (Right to Subcontract). For clarity, except as otherwise set forth herein, Kaken may freely engage (a) any Contract MR in any circumstances; and (b) Kaken Vendors solely to the extent Kaken will not disclose KalVista's Confidential Information to such Kaken Vendors. Any termination or expiration of this Agreement will cause Kaken to terminate each agreement with any Subcontractor to the extent such agreement solely relates to the performance of Kaken's applicable obligations or exercise of Kaken's applicable rights under this Agreement.

2.3.2. **Kaken Audits of Subcontractors**. In the event Kaken audits any Subcontractor, Kaken will provide any quality oversight or audit reports from audits that Kaken (or its agent) has conducted on any Subcontractors that Kaken engages to perform its obligations or exercise its rights under this Agreement to the extent such reports are relevant to such Subcontractors' performance of such obligations or exercise of such rights no later than ten (10) Business Days after receiving or preparing, as applicable, any such report.

2.3.3. **Responsibility for Subcontractors**. Kaken will require that all Subcontractors perform the activities that they are engaged to perform in accordance with GLP, cGMP and GCP, as applicable, and otherwise in compliance with this Agreement and Applicable Law in the Territory.

2.4. Terms of Sublicense and Subcontractor Agreements. Each sublicense or subcontractor agreement with a Sublicensee or Subcontractor ("**Kaken Sublicense or Subcontract Agreement**") shall be consistent with the terms and conditions of this Agreement. Notwithstanding the engagement of any Subcontractor or grant of any Sublicense, Kaken will remain primarily liable to KalVista for the performance of all of its obligations under, and Kaken's compliance with, all provisions of this Agreement. Kaken will be fully responsible and liable for any breach of the terms of this Agreement by any of its Subcontractors or Sublicensees to the same extent as if Kaken itself has committed any such breach, and will terminate promptly the agreement with any Subcontractor or Sublicensee if such Subcontractor or Sublicensee, as applicable, materially breaches any of its material obligations under such agreement and does not cure such breach in a timely manner. Without limiting the foregoing, each Kaken Sublicense or Subcontract Agreement shall be in writing and include the following terms and conditions:

(a) the Sublicensee or Subcontractor shall be bound by non-use and non-disclosure obligations no less stringent than those set forth in (i) Article 9 (Confidentiality; Publication), (ii) if applicable, the Milestone Event reporting obligations set forth under Section 8.2 (Milestone Payments), Section 8.11 (Financial Records and Audits), and (iii) the intellectual property provisions set forth in Article 12 (Intellectual Property); *provided* that the duration of such obligations under Article 9 may be limited to a reasonable period agreed between Kaken and such Subcontractor that are equivalent to that agreed in other similar agreements with the Subcontractor;

(b) the Sublicensee or Subcontractor shall not have any right to grant further sublicenses under the Licensed Technology;

(c) the Sublicensee or Subcontractor shall not have any right to prosecute, maintain or enforce any Licensed Patent Rights;

(d) the Sublicensee or Subcontractor shall assign or grant a sublicensable license back to Kaken of all other Know-How and Patent Rights developed, invented, or filed (as applicable) by or on behalf of the Sublicensee or Subcontractor in the performance of activities under each Kaken Sublicense or Subcontract Agreement that are necessary to Exploit the Licensed Product (such that Kaken Controls such Know-How and Patent Rights for the purposes of this Agreement); and

(e) the Sublicensee shall not Exploit any Competitive Product in the Territory independently or for or with any other Third Party.

2.5. **License Grants to KalVista**. Subject to the terms of this Agreement, Kaken hereby grants to KalVista (a) a non-exclusive, perpetual, irrevocable, royalty-free license, with the right to grant sublicenses through multiple tiers, under the Kaken Technology to (i) perform Development and Manufacturing activities for the Licensed Product inside the Territory; and (ii) Exploit the Licensed Product outside of the Territory during the Term; and (b) a non-exclusive, worldwide, perpetual, irrevocable, royalty-free license to use the Kaken Arising Technology as necessary to Exploit Licensed Products.

2.6. **Retained Rights**. Nothing in this Agreement will be interpreted to grant a Party any rights under any intellectual property rights owned or Controlled by the other Party, including Licensed Technology, in each case, that are not expressly granted herein, whether by implication, estoppel, or otherwise. Any rights not expressly granted to Kaken by KalVista under this Agreement are hereby retained by KalVista, including the right (on behalf of itself and its licensees, other than Kaken) to (a) Manufacture the Licensed Product both inside and outside the Territory, (b) perform Development activities for the Licensed Product both inside and outside the Territory, (c) perform KalVista's other obligations and exercise KalVista's rights under this Agreement, and (d) otherwise Exploit the Licensed Product outside of the Territory. Kaken will not practice the Licensed Technology other than as expressly licensed and permitted under this Agreement or otherwise agreed by the Parties in writing.

2.7. **Exclusivity Covenant**. During the applicable period during the Term, Kaken will not, and will ensure that its Affiliates and Sublicensees do not, independently or for, with, or through any Third Party, Commercialize any Competitive Product (or license or otherwise authorize any Third Party to do any of the foregoing) or grant rights to any Third Party rights to Commercialize any Competitive Product, in each case, in the Territory.

Article 3
REGULATORY

3.1. **Regulatory Responsibilities**.

3.1.1. **In the Territory**. Subject to the oversight of the JSC and the terms of this Agreement, during the Term, KalVista will be responsible for and have sole control over and decision-making authority with respect to, [*] seeking, holding, and maintaining all Regulatory Approvals for the Licensed Product in the Territory in its name or the name of a designee, including the filings of all MAAs, applications for Reimbursement Approvals, other Regulatory Submissions, all Post-Marketing Activities, and any other meetings, communications, and correspondence with any Regulatory Authority in the Territory related to the Licensed Product (the "**Regulatory Activities**"). KalVista may perform the Regulatory Activities itself or through any other Third Party designee, *provided* that KalVista will require that such Third Party designee perform the Regulatory Activities that they are engaged to perform in compliance with this Agreement and Applicable Law in the Territory. Notwithstanding the engagement of such Third Party designee, KalVista will remain primarily liable to Kaken for the performance of all of the Regulatory Activities hereunder. KalVista will be fully responsible and liable for any breach of

the terms of this Agreement by such Third Party designee to the same extent as if KalVista itself has committed any such breach.

3.1.2. **Regulatory Assistance**. Each Party will cooperate fully and in a timely manner to assist the other Party in its efforts to prepare and submit any Regulatory Submissions to obtain, support, or maintain Regulatory Approvals and Reimbursement Approval for the Licensed Product in the Territory, including by providing to the other Party all data, records, reports and documentation related to the Licensed Product generated by or on behalf of such Party or its Affiliates (which assistance and data generation must be in accordance with Applicable Law and requirements and standards by the FDA) as well as any necessary samples and materials as provided in Section 12.4 (Data Exchange and Use), in each case, (a) with respect to Kaken, as necessary for Kaken to exercise its rights or perform its obligations under this Agreement, and (b) with respect to KalVista, as necessary for KalVista to exercise its rights or perform its obligations under this Agreement and otherwise to Exploit the Licensed Products outside of the Territory. [*]. If any materials are required to be submitted in any Regulatory Submission only in Japanese, Kaken will have no obligation to translate such materials to English, *provided* that Kaken will, if requested, provide a high level summary of the contents of such data, results, and supporting documentation in English.

3.2. Filings and Correspondence.

3.2.1. **Regulatory Submissions**. Subject to the terms of this Agreement, KalVista will be responsible for the preparation and submission of all Regulatory Submissions for the Licensed Product in the Field in the Territory. KalVista will provide Kaken with an opportunity to review and comment on all Regulatory Submissions to be submitted to any Regulatory Authority in the Territory by or on behalf of KalVista for the Licensed Product in the Field in the Territory. KalVista will consider in good faith and implement, all reasonable comments thereon from Kaken that are provided in a timely manner so as to meet the applicable submission or response deadline for such Regulatory Submission. Kaken will cooperate in order to assist KalVista in its efforts to prepare and submit those Regulatory Submissions that are required to obtain, support, or maintain any Regulatory Approvals or Reimbursement Approvals for the Licensed Product in the Field in the Territory.

3.2.2. **Correspondence with Authorities**. Except as otherwise set forth in this Agreement, and without limiting Section 3.2.1 (Regulatory Submissions), to the extent related to the Licensed Product in the Field in the Territory, promptly following KalVista's receipt, forwarding, or production thereof, KalVista will provide Kaken with (a) access to or copies of all material written or electronic correspondence and communications (other than Regulatory Submissions) received by KalVista or forwarded by KalVista, the Regulatory Authorities in the Territory, and (b) copies of all meeting minutes and summaries of all meetings, conferences, and discussions held by KalVista with the Regulatory Authorities in the Field in the Territory. If such written or electronic correspondence received from any such

Regulatory Authority relates to the prohibition or suspension of the supply of a Licensed Product, or the initiation of any investigation, review, or inquiry by such Regulatory Authority concerning the safety of a Licensed Product, then KalVista will notify Kaken and provide Kaken with copies of such written or electronic correspondence [*].

3.2.3. **Meetings with Regulatory Authorities**. Except as otherwise set forth in this Agreement, KalVista will be responsible for all meetings, conferences, and discussions with Regulatory Authorities or other applicable Governmental Authorities related to the receipt of Regulatory Approval to Commercialize the Licensed Product in the Field in the Territory, including to Manufacture the Licensed Product for Commercialization in the Territory. KalVista will provide Kaken with written notice of any scheduled material meeting, conference, or discussion with a Regulatory Authority or other Governmental Authority in the Territory relating to the Licensed Product in the Field [*].

3.2.4. **Ownership of Regulatory Approvals**. KalVista will have sole control over and decision-making authority with respect to the filing of all MAAs and applications for Reimbursement Approval for the Licensed Product in the Field in the Territory in its name or the name of a Third Party designee, and, subject to the rights granted to Kaken under Section 2.1 (License Grants to Kaken), and as between the Parties, KalVista will own all rights, title, and interests in and to all resulting Regulatory Approvals and Reimbursement Approvals for the Licensed Product in the Field in the Territory and all related Regulatory Submissions. KalVista will promptly inform Kaken [*] of (a) the filing of any MAA for the Licensed Product in the Field in the Territory, and (b) the receipt of any Regulatory Approval or Reimbursement Approval for a Licensed Product in the Field in the Territory.

3.2.5. **Transfer of Ownership of Regulatory Approvals**. Notwithstanding the foregoing, and subject to, and in accordance with, Applicable Law and the requirements of any Regulatory Authority in the Territory, Kaken shall be entitled to request KalVista to transfer to Kaken, [*].

3.3. Adverse Events Reporting.

3.3.1. **Adverse Event Reporting**. [*], the Parties will notify each other in writing of the names and contact information of their respective employees or agents who are responsible for adverse experience reporting.

3.3.2. **Pharmacovigilance (PV) Agreement**. [*], the Parties will enter into a written agreement setting forth worldwide safety and pharmacovigilance procedures for the Parties with respect to the Licensed Product in the Field (the "**PVA**"). Kaken will not market, promote, sell, or otherwise Commercialize the Licensed Product unless and until the Parties enter into the PVA for the Licensed Product. The PVA will describe the obligations of each Party with respect to the coordination of collection, investigation, reporting, and exchange of information among the Parties concerning any adverse event experienced by a subject or patient, and the seriousness

thereof, whether or not determined to be attributable to the Licensed Product, including any such information received by either Party from a Third Party (subject to receipt of any required consents from such Third Party) and will be sufficient to permit each Party and its Affiliates and licensees (as applicable) to comply with its legal obligations with respect thereto, including KalVista's obligations as the owner or holder of Regulatory Approvals and Regulatory Submissions for such Licensed Product in the Territory. The PVA will also detail each Party's responsibilities with respect to the maintenance of a safety database and each Party's responsibilities for recalls and withdrawals of the Licensed Product inside and outside of the Territory. If required by changes in Applicable Law, the Parties will make appropriate updates to the PVA. Each Party will comply with its respective obligations under the PVA and cause its Affiliates to comply with such obligations and, with respect to Kaken, its Sublicensees and Subcontractors to comply with such obligations. Notwithstanding any provision to the contrary set forth in this Agreement or the PVA, KalVista and its Affiliates and licensees will have the right to disclose information related to the safety of the Licensed Product to the extent that such disclosure is required for such Party to comply with its obligations under Applicable Law or the safety requirements of the applicable Regulatory Authorities, *provided* that in each such event, [*] to the extent not prohibited by Applicable Law, KalVista will notify Kaken of such required disclosure and provide a draft of the full details of the disclosure to Kaken [*]. The Parties will cooperate with each other to address any safety-related inquiries or requests for safety assessment by any Regulatory Authority, including providing any necessary data or information in a timely manner. To the extent that there is a conflict between the terms of this Agreement and the terms of the PVA, the terms of the PVA will govern with respect to the subject matter set forth therein.

3.4. **Regulatory Audits**. KalVista or its representatives will be entitled to conduct audits of safety and regulatory systems, procedures, practices, or records of Kaken or its Affiliates relating to the Licensed Product. With respect to any inspection of Kaken or its Affiliates by any Governmental Authority relating to the Licensed Product, Kaken will notify KalVista of such inspection (a) [*]; or (b) [*]. Kaken will promptly provide KalVista with all information related to any such inspection. KalVista will have the right, but not the obligation (unless required by Applicable Law or any Governmental Authority), to be present at any such regulatory inspection. Following any such regulatory inspection related to the Licensed Product in the Territory, Kaken will provide KalVista with (i) an unredacted copy of any findings, notice, or report provided by any Governmental Authority related to such inspection (to the extent related to a Licensed Product) [*], and (ii) a written summary in English of any findings, notice, or report of a Governmental Authority related to such inspection (to the extent related to a Licensed Product) [*]. KalVista will have the final decision-making authority with respect to the content of any responses to Regulatory Authorities or other Governmental Authorities that relate to a Licensed Product in the Field in the Territory and will consider Kaken's reasonable comments to such responses.

3.5. **Notice of Other Actions**. In addition, each Party will promptly notify the other of any information that it receives regarding any threatened or pending action, inspection, or communication by or from a Third Party that would reasonably be expected to materially affect the Development or Commercialization of the Licensed Product in the Field in the Territory.

Article 4
DEVELOPMENT PROGRAM

4.1. **Development**.

4.1.1. **General**. Subject to the oversight of the JSC and the terms of this Agreement, KalVista, [*] unless otherwise agreed in writing by the Parties, will have sole control over and decision-making authority with respect to all Development activities for the Licensed Product inside and outside of the Territory, and Kaken will not perform any Development activities for the Licensed Product.

4.1.2. **Development Diligence Obligations**. Subject to the terms of this Agreement and to Kaken's satisfaction of its obligations hereunder, KalVista will use Commercially Reasonable Efforts to Develop and obtain Regulatory Approval of a Licensed Product in the Territory.

4.1.3. **Additional Development**. If, in order to obtain Regulatory Approval or Reimbursement Approval for the Licensed Product in the Territory, the PMDA or the MHLW requires additional Clinical Trials or other additional Development activities, as compared against KalVista's Development Activities outside of the Territory for the Licensed Product ("**Additional Development**"), then the Parties will discuss, and the JSC will make determinations with respect to, such required activities, including the allocation of costs and expenses reasonably incurred by or on behalf of KalVista in the performance of such Additional Development. For further clarification, unless otherwise agreed by the JSC, KalVista shall be solely responsible for the performance of any of such Additional Development and acknowledges and agrees that Kaken's cooperation in relation to such Additional Development shall be strictly limited to sharing a reasonable part of the costs and expenses reasonably incurred by or on behalf of KalVista as determined by the JSC.

Article 5
MANUFACTURING

5.1. **Supply by KalVista.**

5.1.1. **Commercial Supply**. [*] the Parties will enter into a commercial supply agreement (together with the corresponding Quality Agreement, the "**Supply Agreement**") for the supply to Kaken of filled and finished Licensed Product with all Approved Labeling for the Licensed Product in the Field in the Territory, pursuant to which Kaken will purchase exclusively from KalVista its requirements of the same as necessary for Kaken to Commercialize the Licensed Product in the Field in the Territory. For clarity, KalVista's supply obligation shall be limited to the dosage and

form of the Licensed Product for which Regulatory Approval is received in the Territory. The terms of the Supply Agreement will be consistent with the terms of this Agreement (including the terms of this Article 5 (Manufacturing)) and the terms of other similar supply agreements between KalVista and its CMOs, to the extent applicable to the supply of the Licensed Product in the Field in the Territory for Commercialization purposes.

KalVista will, [*], (a) obtain, maintain, and keep all necessary licenses, approvals, permits, and authorizations required by Applicable Law to supply to Kaken the Licensed Product for use in the Field in the Territory in accordance with the Supply Agreement and Applicable Law, (b) Manufacture and supply to Kaken the Licensed Product in accordance with cGMP, the Supply Agreement, and Applicable Law, and (c) otherwise supply the Licensed Product in accordance with the Supply Agreement.

5.1.2. **Supply Price.** The Supply Agreement will provide that the supply price to be charged to Kaken for Licensed Product in the Territory (for each applicable period, the "**Supply Price**") will be as set forth in Section 8.2 (Supply Price).

5.2. **Product Tracking in the Territory**. Kaken will, [*], maintain adequate records to permit the Parties to trace the distribution, sale, and use of all Licensed Product in the Territory**.**

5.3. **Shortages** As will be more fully set forth in the Supply Agreement, as long as KalVista supplies to Kaken the Licensed Product for use in the Territory, in the event of a shortage of the Licensed Product, KalVista, without prejudice to any remedies and rights granted to Kaken under the Supply Agreement, will allocate available supply of the affected Licensed Product on a *pro rata* basis between Kaken on one hand and KalVista and its other licensees on the other hand, in each case, based on the demand for such Licensed Product in the Territory as compared to demand for such Licensed Product in all countries outside of the Territory.

Article 6
COMMERCIALIZATION

6.1. **Commercialization Responsibilities**. Subject to oversight of the JSC and the other terms of this Agreement and except as otherwise set forth in this Agreement, Kaken, [*], will have sole responsibility with respect to any Commercialization activities for the Licensed Product in the Field in the Territory. Kaken will conduct all Commercialization of the Licensed Product in the Field in the Territory in accordance with the Marketing Plan for such Licensed Product, the terms of this Agreement, and any other written agreement between the Parties with respect to the subject matter set forth herein.

6.2. **Commercialization Diligence Obligations**. Kaken will use Commercially Reasonable Efforts to Commercialize the Licensed Product in the Field in the Territory and to meet the Performance Targets by the applicable date for the achievement thereof set forth in the Marketing Plan.

6.3. **Marketing Plans**. [*]

6.4. **Coordination of Commercialization Activities**. The Parties recognize that each Party may benefit from the coordination of certain Commercialization activities for the Licensed Product inside and outside of the Territory (other than pricing for the Licensed Product inside and outside of the Territory, the responsibilities for which are set forth in Section 6.5 (Pricing; Reimbursement Approvals)). Accordingly, the Parties will coordinate such activities through the JSC where appropriate, which coordination may include communications regarding product positioning.

6.5. **Pricing; Reimbursement Approvals**. KalVista, itself or through a Third Party designee, will have the right to seek Reimbursement Approval and prior to a final pricing determination by Kaken, express its opinion on Kaken's determination of the price of the Licensed Product sold in the Field in the Territory, and Kaken will have the right to determine the price of the Licensed Product sold in the Field in the Territory; including any and all discount and rebate strategies and other economic arrangements relating to the Licensed Product in the Field in the Territory. KalVista, itself or through its designee, will have the right to seek Reimbursement Approval and determine the price of the Licensed Product sold outside of the Territory and in the Territory outside of the Field, including all discount and rebate strategies and other economic arrangements relating to the Licensed Product outside of the Territory and in the Territory outside of the Field, and Kaken will not have the right to direct, control, or approve the price of the Licensed Product sold outside of the Territory or in the Territory outside of the Field. Kaken will provide reasonably requested assistance in connection with obtaining Reimbursement Approval for the Licensed Product in the Field in the Territory, including, if required by Applicable Law, to submit any application for Reimbursement Approval or other Regulatory Submission in Kaken's name as reasonably requested by KalVista. KalVista will keep Kaken timely informed on the status of any application for Reimbursement Approval for the Licensed Product in the Field in the Territory and matters related to market access, discount and rebate strategies, and other pricing related matters for the Licensed Product in the Field in the Territory, including any discussion with any Regulatory Authority or other Governmental Authority with respect thereto.

6.6. **Diversion**. Kaken will not and will ensure that its Affiliates, Subcontractors, and Sublicensees do not, either directly or indirectly, promote, market, distribute, import, sell, or have sold any Licensed Product to any Third Party or to any address or Internet Protocol address or the like outside of the Territory, including via the Internet or mail order. Notwithstanding any provision to the contrary set forth in this Agreement, KalVista will have the right to attend conferences and meetings of congresses inside and outside of the Territory and to promote and market (*i.e.*, raise awareness, generate interest, and encourage sales) the Licensed Product in the Territory to Third Party attendees at such conferences and meetings, subject to this Section 6.6 (Diversion) and compliance with Applicable Law in the Territory, including the PMD Act (including related regulations, ordinances and guidelines), IFPMA code, fair competition code, and JPMA code of practice; *provided* that KalVista will coordinate its presence at any such conference or meeting with Kaken. Kaken will not engage, nor permit its Affiliates to engage, in any advertising or promotional activities relating to the Licensed Product for use directed primarily to customers or other buyers or users of the Licensed Product located in any country or jurisdiction outside of the Territory, or solicit orders from any prospective purchaser located in any country or jurisdiction outside of the Territory. If Kaken or its Affiliates receive any order for any Licensed Product from a prospective purchaser located in a country or jurisdiction outside of the Territory, then Kaken will immediately refer that order to KalVista and will not accept any such orders. Kaken will not, and will cause its Affiliates to not, deliver or tender (or cause to be delivered or tendered) any Licensed Product to Third Parties for use outside of the Territory.

6.7. **Advertising and Promotional Materials**. [*] after the Effective Date and thereafter on a regular basis from time to time, KalVista will provide to Kaken those Promotional Materials, marketing plans, medical presentations, and other communications tools developed by KalVista for the Licensed Products outside the Territory, to be adapted by Kaken for use in the Field in the Territory. [*]. Kaken will not use, and will cause its Affiliates, Sublicensees, and Subcontractors not to use, any Promotional Materials with respect to the Licensed Product that have not been approved in writing by KalVista.

6.8. **Product Trademarks**.

6.8.1. **Global Brand Elements**. Kaken acknowledges that KalVista may decide to develop and adopt certain distinctive colors, logos, images, symbols, and trademarks to be used in connection with the Commercialization of the Licensed Product on a global basis (such branding elements, collectively, the "**Global Brand Elements**"). Subject to the terms and conditions of this Agreement, KalVista will and hereby does grant Kaken the exclusive right to use and have used, in accordance with this Agreement, such Global Brand Elements solely in connection with the Commercialization of the Licensed Product in the Field in the Territory solely in accordance with the terms of this Agreement.

6.8.2. **Product Marks in the Field in the Territory**. Subject to the terms and conditions of this Agreement, KalVista hereby grants Kaken an exclusive, royalty-free license to use and have used, such Product Marks solely in connection with the Commercialization of the Licensed Product in the Field in the Territory during the Term. KalVista will have the right to brand the Licensed Product in the Field in the Territory using those trademarks, logos, and trade names that it determines appropriate for such Licensed Product and that are consistent with KalVista's Global Brand Elements (the "**Product Marks**"); *provided* that, to the extent possible, the Product Marks will be the same as the colors, logos, images, symbols, and trademarks used for Commercialization of the Licensed Product worldwide. Kaken will not use any trademarks of KalVista (including KalVista's corporate name) or any trademark confusingly similar thereto, except as expressly permitted under this Agreement or otherwise, without KalVista's prior written consent. When KalVista intends to change trade names for the Licensed Product sold in the Field in the Territory, KalVista shall promptly inform Kaken to that effect. KalVista shall register the Product Marks in the Field in the Territory and maintain trademark rights therefor and shall be responsible for all filing, prosecution, and defense for such Product Mark before the trademark office in the Territory, in each case, [*].

6.8.3. **Ownership**. KalVista will be the sole and exclusive owner of all Product Marks and Global Brand Elements, including all trademark registrations and applications therefor and all goodwill associated therewith. To the extent Kaken acquires any rights, title, or interests in or to any Product Mark or Global Brand Element (including any trademark registration or application therefore or goodwill associated with any Product Mark), Kaken will assign the same to KalVista in accordance with Section 13.3.4(d) (Assignment and Disclosure).

6.8.4. **Use**. Kaken agrees that it and its Affiliates will Commercialize each of the Licensed Products in the Field in the Territory in a manner consistent with the Global Brand Elements and will, only to the extent applicable with respect to the Product Marks or Global Brand Elements under Applicable Law in the Territory: (a) ensure that all Licensed Products that are being sold by Kaken or its Affiliates or Sublicensees in the Territory bearing the Product Marks and Global Brand Elements are of a high quality and consistent with KalVista's internal quality standards and that are consistent with industry standards for global pharmaceutical and biologic therapeutic products; (b) ensure that each use of the Global Brand Elements and Product Marks by or on behalf of Kaken and its Affiliates is accompanied by an acknowledgement that such Global Brand Elements and Product Marks are owned by KalVista; (c) not use such Global Brand Elements or Product Marks in a way that might prejudice their distinctiveness or validity or the goodwill of KalVista therein and includes the trademark registration symbol ® or ™ as appropriate; (d) not use any trademarks or trade names so resembling any of such Global Brand Elements or Product Marks as to be likely to cause confusion or deception; and (e) place and display the Global Brand Elements and the Product Marks on and in connection with the Licensed Product in a way that acknowledges KalVista's role in discovering the Licensed Product and that such Licensed Product is under license from KalVista. To the extent permitted by Applicable Law, Kaken will include the words "*Discovered and developed by KalVista*" in relevant scientific, medical, and other Licensed Product-related communications, or such other similar text provided by KalVista and reasonably acceptable to Kaken.

6.9. **Sales Reports**. Commencing with the Calendar Quarter during which the First Commercial Sale of a Licensed Product is made in the Territory, within fifteen (15) days after the end of each Calendar Quarter, Kaken will provide KalVista with a report that contains the following information for the applicable Calendar Quarter, on a Licensed Product-by-Licensed Product basis (each, a "**Sales Report** "): (a) the quantity and the amount of Net Sales of each Licensed Product sold by Kaken and its Affiliates in the Territory for each month of such Calendar Quarter, including any deductions used to determine such Net Sales; and (b) the aggregate annual Net Sales of each Licensed Product sold in such Calendar Quarter.

6.10. **Ex-Territory Information**. KalVista will provide updates to the JSC of any material updates related to the Licensed Products that occur outside the Territory, including any sales activity, regulatory statuses or other issues, in each case, to the extent that such updates would reasonably be expected to impact Kaken's Commercialization activities for the Licensed Product in the Field in the Territory.

Article 7
GOVERNANCE

7.1. **Alliance Managers**. Each Party will appoint an individual to act as its alliance manager under this Agreement [*] (each an "**Alliance Manager**"). The Alliance Managers will: (a) serve as the primary points of contact between the Parties for the purpose of providing the other Party with information on the progress of a Party's activities under this Agreement; (b) be responsible for facilitating the flow of information and otherwise promoting communication, coordination, and collaboration between the Parties; (c) facilitate the prompt resolution of any disputes; and (d) attend JSC meetings, in each case, as a non-voting member. An Alliance Manager may also bring any matter to the attention of the JSC if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party will use reasonable efforts to keep an appropriate level of continuity but may replace its Alliance Manager at any time upon written notice to the other Party.

7.2. **Joint Steering Committee**.

7.2.1. **Formation and Purpose of JSC**. [*], the Parties will establish a joint steering committee (the "**JSC**") to monitor and coordinate the Development, Commercialization and Regulatory Activities of the Licensed Product in the Field in the Territory. The JSC will be composed of [*] and who have the appropriate and direct knowledge and expertise and requisite decision-making authority. Each Party may replace any of its representatives on the JSC and appoint a person to fill the vacancy arising from each such replacement. A Party that replaces a representative will notify the other Party at least ten (10) days prior to the next scheduled meeting of the JSC. Both Parties will use reasonable efforts to keep an appropriate level of continuity in representation. Representatives may be represented at any meeting by another person designated by the absent representative. KalVista will designate one of its JSC representatives as one of the co-chairpersons of the JSC and Kaken will designate one of its members as the other co-chairperson of the JSC. Each Party's representatives on the JSC will inform and coordinate within their respective organization to enable each Party to fulfill its obligations as agreed upon between the Parties under this Agreement, including within the timeframes set forth hereunder.

7.2.2. **JSC Roles and Responsibilities**. The responsibilities of the JSC will be to:

[*]

7.2.3. **Meeting Agendas**. Each Party will disclose to the other Party the proposed agenda items along with appropriate information [*]; *provided* that under exigent circumstances requiring JSC input, a Party may provide its agenda items to the other Party within a shorter period of time in advance of a meeting, or may propose that there not be a specific agenda for a particular meeting, so long as such other Party consents to such later addition of such agenda items or the absence of a specific agenda for such JSC meeting.

7.2.4. **Meetings**. The JSC will hold meetings at such times as it elects to do so, but will meet no less than bi-annually, unless otherwise agreed by the Parties. All meetings will be conducted in English unless otherwise agreed by the Parties. The JSC may meet in person or by means of teleconference, Internet conference, videoconference, or other similar communication method; *provided* that at least one meeting each Calendar Year will be conducted in person at a location selected alternatively by KalVista and Kaken or such other location as the Parties may agree. [*]. The Alliance Managers will jointly prepare and circulate minutes for each JSC meeting [*] and will ensure that such minutes are reviewed and approved by their respective companies [*].

7.3. Non-Member Attendance. Each Party may from time to time invite a reasonable number of participants, in addition to its representatives (which may include legal counsel), to attend a meeting of the JSC (in a non-voting capacity), if such participants have expertise that is relevant to the planned agenda for such JSC meeting; *provided* that if either Party intends to have any Third Party (including any consultant) attend such a meeting, then such Party will provide prior written notice to the other Party [*] and will ensure that such Third Party is bound by obligations of confidentiality and non-use at least as stringent as those set forth in Article 9 (Confidentiality; Publication). Notwithstanding any provision to the contrary set forth in this Agreement, if the other Party objects in good faith to the participation of such Third Party in such meeting due to a *bona fide* concern regarding competitively sensitive information that is reasonably likely to be discussed at such meeting *(i.e.*, a consultant that also provides services to a Third Party with a Competitive Product), then such Third Party will not be permitted to participate in such meeting (or the portion thereof during which such competitively sensitive information is reasonably likely to be discussed).

7.4. Decision-Making.

7.4.1. **General Process**. The JSC will only have the powers expressly assigned to it in this Article 7 (Governance) and elsewhere in this Agreement and will not have the authority to: (a) modify or amend the terms of this Agreement; or (b) waive either Party's compliance with the terms of this Agreement. All decisions of the JSC will be made by unanimous vote, with each Party's representatives having one vote (*i.e.*, one vote per Party). No action taken at any meeting of the JSC will be effective unless there is a quorum at such meeting, and at all such meetings, a quorum will be reached [*]. Except as otherwise expressly set forth in this Agreement, the phrase "determine," "designate," "confirm," "approve," or "determine whether to approve" by the JSC and similar phrases used in this Agreement will mean approval in accordance with this Section 7.4 (Decision-Making), including the escalation and tie-breaking provisions herein. For the avoidance of doubt, matters that are specified in Section 7.2.2 (JSC Roles and Responsibilities) to be reviewed and discussed (as opposed to reviewed, discussed, and approved) do not require any agreement or decision by either Party and are not subject to the voting and decision-making procedures set forth in this Section 7.4 (Decision-Making) or in Section 7.5 (Resolution of JSC Disputes).

7.4.2. **Decisions of the JSC**. [*].

7.5. Resolution of JSC Disputes.

7.5.1. **Referral to Executive Officers**. If a Party makes an election under Section 7.4.2 (Decisions of the JSC) to refer a matter on which the JSC cannot reach a consensus decision for resolution by the Executive Officers, which election must be made [*], then the Parties will each submit in writing the respective positions of the Parties to the Executive Officers. The Executive Officers will use good faith efforts to resolve any such matter so referred to them as soon as practicable, and any final decision that the Executive Officers agree to in writing will be conclusive and binding on the Parties.

7.5.2. **Final Decision-Making Authority**. If the Executive Officers are unable to reach agreement on any such matter referred to them [*], then such dispute ("**JSC Dispute**") shall be resolved through the following procedures:

(a) **Expert Opinion**. Except for the matters set forth in Section 7.5.2(b) (Kaken Decisions) or Section 7.5.2(c) (KalVista Decisions), neither Party will have final decision-making authority over any matter within the decision-making authority of the JSC, including the approval of the Performance Targets included in the Marketing Plan. If the JSC is unable to agree on such matter (except for the Minimum Sales Targets, which shall be determined in accordance with Section 6.3 (Marketing Plans)) with the unanimous agreement of the Parties [*], then the Parties will endeavor to agree to engage, at their equal cost, a competent Third Party consulting firm, marketing research company, or other expert (as applicable) (the "**Expert**") to provide its written opinion on the relevant matter (the "**Expert Opinion**"). The Expert shall be an individual with sufficient experience for the relevant matter at issue, who (i) has not worked for or been engaged by either Party or its Affiliates prior to selection of such individual, and (ii) does not own equity or debt in either Party or its Affiliates. [*], the Expert will deliver the Expert Opinion to the Parties, which will be final and binding upon the Parties.

(b) **Kaken Decisions**. Kaken will have final decision-making authority with respect to Kaken's engagement of Subcontractors, except as otherwise set forth under Section 2.3.1 (Right to Subcontract), and all matters for the Licensed Product within the decision-making authority of the JSC that solely relate to the Commercialization of the Licensed Product in the Field in the Territory (including approval of any Marketing Plan or update thereto and the price of the Licensed Product, all discount and rebate strategies and other economic arrangements as described in Section 6.5 (Pricing; Reimbursement Approvals) (other than the approval of any Performance Targets included in any Marketing Plan),) so long as such matter (i) would not be reasonably expected to have any material financial consequence to KalVista or to impact the Exploitation of such Licensed Product outside of the Territory (including safety impacts, regulatory or legal impacts, impacts on any Global Brand Strategy, any Development or Manufacturing activities conducted by or on behalf of KalVista, or any impact on the ownership, prosecution, validity, enforceability, or enforcement of any KalVista Technology), and (ii) is not reasonably likely, in KalVista's reasonable discretion, to give rise to any safety concerns with respect to the Licensed Product.

(c) **KalVista Decisions**. KalVista will have the final decision-making authority on all matters with respect to the Licensed Product within the decision-making authority of the JSC that (i) (A) relate to the Development or Manufacture of the Licensed Product, including with respect to regulatory and pricing strategy for any such Licensed Product, (B) would be reasonably expected to have any material financial consequence to KalVista or to impact the Exploitation of such Licensed Product outside of the Territory (including safety impacts, regulatory or legal impacts, impacts on any Global Brand Strategy, any Development or Manufacturing activities conducted by or on behalf of KalVista, or any impact on the ownership, prosecution, validity, enforceability, or enforcement of any KalVista Technology), or (C) are reasonably likely, in KalVista's reasonable discretion, to give rise to any safety concerns with respect to the Licensed Product; and (ii) relate to the approval of Publications under Section 9.6 (Publications).

7.5.3. Limitations on Decision-Making. Notwithstanding any provision to the contrary set forth in this Agreement, without the other Party's prior written consent, no decision of the JSC or a Party's Executive Officer (in the exercise of a Party's final decision-making authority on any such matters), in each case, may (a) result in a material increase in the other Party's obligations, costs, or expenses under this Agreement, unless, in each case, such actions are reasonably necessary for KalVista to comply with Applicable Law as the Territory Sponsor or as the owner and holder of any Regulatory Submission, Regulatory Approval, or Reimbursement Approval, as applicable, for the Licensed Product, (b) take or decline to take any action that would be reasonably likely to result in a violation of any Applicable Law, the requirements of any Regulatory Authority, or any agreement with any Third Party (including any agreement pursuant to which KalVista Controls any Licensed Technology) or would be reasonably likely to result in the infringement or misappropriation of intellectual property rights of any Third Party, or (c) conflict with this Agreement, any Supply Agreement, any PVA, or any other agreement between the Parties related to the subject matter set forth herein.

7.6. No Harmful Actions. If KalVista believes that Kaken is taking or intends to take any action with respect to the Licensed Product that could have a material adverse impact upon the regulatory status of the Licensed Product outside of the Territory or in the Territory or the global pricing of the Licensed Product, then, in each case, KalVista may bring the matter to the attention of the JSC and the JSC will discuss in good faith a resolution to such concern.

Article 8
PAYMENTS

8.1. Upfront Payment. As consideration for the rights and licenses granted by KalVista to Kaken under this Agreement, [*] after the later of (a) the Effective Date and (b) Kaken's receipt from KalVista of an invoice and all completed tax documents in full compliance with Applicable Laws and regulations reasonably required to be filed with tax authorities in the Territory to reduce or release KalVista's tax liability and reduce or release Kaken's obligation to withhold Taxes under the applicable bilateral income tax treaty for the amount payable to KalVista under this Section 8.1 (Upfront Payment), Kaken will pay to KalVista, by wire transfer of immediately available funds, a non-refundable, non-creditable upfront payment [*] (the "**Upfront Payment**").

8.2. Supply Price.

8.2.1. **Prior to First NHI Price**. Prior to receipt of the First NHI Price, the Supply Price for all Licensed Product supplied by or on behalf of KalVista to Kaken for use in the Territory will be the Fully Burdened Manufacturing Cost of such Licensed Product *plus* [*] (as calculated per three hundred (300) mg dose, the "**Pre-Approval Price**").

8.2.2. **After Receipt of the First NHI Price**. The Supply Price for all Licensed Product supplied by or on behalf of KalVista to Kaken for use in the Territory following receipt of the First NHI Price and thereafter until the expiration of the Initial Term will be as set forth in Table 8.2.2, on a Licensed Product-by-Licensed Product basis, subject to (a) any Revised NHI Price in accordance with Section 8.2.4 (Revision of the NHI Price); and (b) any reductions as further set forth in Section 8.2.6 (Supply Price Reductions) (the "**Initial Term Price**").

Table 8.2.2 INITIAL TERM PRICE

	[*]	**[*]**
Initial Term Price	[*]	[*]
** NHI Prices set forth by the MHLW are inclusive of consumption tax.*		

8.2.3. **True-Up**. [*]. KalVista will have the right to invoice Kaken for the True-Up Payment at any time following receipt of the First NHI Price, and Kaken will pay to KalVista a payment in the amount of the True-Up Payment [*] following receipt of invoice therefor.

8.2.4. **Revision of the NHI Price**. Notwithstanding the final sentence of Section 8.2.2 (After Receipt of the First NHI Price), during the Initial Term and thereafter, in the event of a revision to the NHI Price (the "**Revised NHI Price**"), the Supply Price shall be updated as of the effective date of the revision to the NHI Price ("**NHI Price Renewal Effective Date**") based on the Revised NHI Price using the percentage set forth in Table 8.2.2, in which "First NHI Price" shall be read as "Revised NHI Price" (the "**New Supply Price**"). [*].

8.2.5. **Following Expiration of the Initial Term**. If, prior to the expiration of the Initial Term, Kaken gives notice to KalVista that it wishes for the Term to continue following the expiration of the Initial Term, then (a) the Parties will negotiate in good faith and agree upon a new Supply Price for each Licensed Product supplied following the expiration of the Initial Term, and (b) unless and until the Parties so agree upon a Supply Price for Licensed Product supplied following the expiration of the Initial Term, the Supply Price for all Licensed Product so supplied to Kaken will be reduced by [*] of the Initial Term Price, or if the Supply Price was reduced pursuant to Section 8.2.6 (Supply Price Reductions During the Initial Term), maintain the Supply Price in effect following application of the reduction set forth in such section.

8.2.6. **Supply Price Reductions During Initial Term**.

(a) **Valid Claim Expiration.** Subject to Section 8.2.6(c) (Cumulative Reduction Floor), on a Licensed Product-by-Licensed Product basis, if there is Valid Claim Expiration in the Territory during the Initial Term, then, commencing on Kaken's receipt of the first invoice for the Licensed Product after the date of such Valid Claim Expiration and for all Calendar Quarters thereafter during which any Valid Claim Expiration applies, the Supply Price for Licensed Product to be paid by Kaken to KalVista will be reduced by [*]; *provided* that if such Licensed Product (including any use thereof that is on the approved label in such region or manufacture thereof) subsequently becomes Covered by a Valid Claim of the Licensed Patent Rights or Joint Arising Patent Rights Covering the composition of matter or method of use of such Licensed Product or the Manufacture, use, Commercialization, or importation of such Licensed Product in the Territory prior to either (i) the tenth (10^{th}) anniversary of the date of the First Commercial Sale of such Licensed Product in the Territory; or (ii) the expiration of Regulatory Exclusivity with respect to such Licensed Product, then the Supply Price applicable to Licensed Product supplied by KalVista to Kaken will no longer be subject to the aforementioned reduction beginning at the commencement of the first Calendar Quarter after the date on which the relevant patent issues.

(b) **Loss of Exclusivity Reduction**. Subject to Section 8.2.6(c) (Cumulative Reduction Floor), on a Licensed Product-by-Licensed Product basis, if during any Calendar Quarter during the Initial Term, there is Loss of Market Exclusivity for such Licensed Product in the Territory, then the Supply Price for Licensed Product supplied by KalVista to Kaken for use in the Territory in such Calendar Quarter will be reduced by [*] of the applicable Supply Price that would otherwise be owed, for so long as the Loss of Market Exclusivity continues during the Initial Term for the Licensed Product in the Territory. Kaken will promptly notify KalVista of the occurrence of Loss of Market Exclusivity, which notice will specify the applicable Generic Products and applicable Indication and a calculation result with respect to the Loss of Market Exclusivity.

(c) **Cumulative Reduction Floor**. In no event will the aggregate amount of Supply Price payments due to KalVista for a Licensed Product in the Territory in any given Calendar Quarter during the Initial Term for such Licensed Product in the Territory be reduced to less than [*] of the amount that otherwise would have been due and payable to KalVista in such Calendar Quarter for such Licensed Product in the Territory but for the reductions set forth in Section 8.2.6(a) (Valid Claim Expiration) and Section 8.2.6(b) (Loss of Exclusivity Reduction).

8.3. Milestone Payments.

8.3.1. **Regulatory Milestone Events and Payments**. In the event of the achievement of the regulatory milestone event for the Licensed Product set forth below in Table 8.3.1, [*] after receipt of an invoice from KalVista, Kaken will pay to KalVista a one-time corresponding regulatory milestone payment as set forth below in Table 8.3.1 (the regulatory milestone event set forth in Table 8.3.1, the "**Regulatory Milestone Event**," and the regulatory milestone payment set forth in Table 8.3.1, the "**Regulatory Milestone Payment**").

Table 8.3.1 – REGULATORY MILESTONES	
Milestone Event	***Regulatory Milestone Payment (in U.S. Dollars)***
Receipt of Regulatory Approval from PMDA and Reimbursement Approval from MHLW for the first Licensed Product in the Territory, if the First NHI Price is less than [*] per 300mg dose	[*]
Receipt of Regulatory Approval from PMDA and Reimbursement Approval from MHLW for the first Licensed Product in the Territory, if the First NHI Price is greater than or equal to [*] per 300mg dose	[*]

8.3.2. **Sales Milestone Events and Payments**. In the event of achievement of each sales milestone event for the Licensed Product set forth below in Table 8.3.2, [*] after receipt of an invoice from KalVista to be issued after the end of the relevant Calendar Quarter in which the sales milestone event was achieved, Kaken will pay to KalVista a one-time corresponding sales milestone payment as set forth below in Table 8.3.2 (the sales milestone event set forth in Table 8.3.2, the "**Sales Milestone Event**," and the sales milestone payment set forth in Table 8.3.2, the "**Sales Milestone Payment**"). If in a given Calendar Quarter during the Term more than one of the Sales Milestone Events set forth in Table 8.3.2 below is achieved, then Kaken will pay to KalVista a separate Sales Milestone Payment with respect to each such Sales Milestone Event that is achieved for the first time in such Calendar Quarter.

Table 8.3.2 – SALES MILESTONES	
Milestone Event	***Sales Milestone Payment (in Japanese Yen)***
First Calendar Year in which aggregate annual Net Sales of a Licensed Product in the Territory exceed [*]	[*]
First Calendar Year in which aggregate annual Net Sales of a Licensed Product in the Territory exceed [*]	[*]

8.3.3. **Payment One Time on the First Occurrence of Milestone Event**. Notwithstanding any other provision of this Agreement: (a) each Regulatory Milestone Payment shall be payable one (1) time only on the first occurrence of the applicable Regulatory Milestone Event, regardless

of the number of Licensed Products with respect to which the applicable Regulatory Milestone Event may be achieved; and (b) each Sales Milestone Payment shall be payable one (1) time only on the first occurrence of the applicable Sales Milestone Event.

8.3.4. **Reporting on Milestone Achievement**. Kaken shall provide written notice to KalVista of the occurrence of any Regulatory Milestone Event and any Sales Milestone Event [*].

8.4. **Other Amounts Payable**. With respect to any amounts owed under this Agreement by one Party to the other for which no other invoicing and payment procedure is specified hereunder, [*], each Party will provide an invoice, together with reasonable supporting documentation, to the other Party for such amounts owed in respect of such Calendar Quarter. The owing Party will pay any undisputed amounts [*], and any disputed amounts owed by a Party will be paid [*].

8.5. **No Refunds**. Except as expressly provided herein, all payments under this Agreement will be irrevocable, non-refundable, and non-creditable.

8.6. **Accounting Standards**. If a Party changes its general accounting principles from the then-current standard (*e.g.*, from JGAAP to IFRS) at any time during the Term, then [*], such Party will provide written notice to the other Party of such change.

8.7. **Payments to Third Parties**. Subject to Section 12.3 (Third Party In-Licenses), each Party will be solely responsible for any payments due to Third Parties under any agreement entered into by each Party prior to or after the Effective Date.

8.8. **Currency; Exchange Rate**. All payments to be made by Kaken to KalVista or KalVista to Kaken under this Agreement will be made in Dollars by electronic funds transfer in immediately available funds to a bank account designated in writing by KalVista or Kaken, as applicable. Conversion of Net Sales recorded in local currencies will be converted to Dollars at the exchange rate officially announced by *Mizuho Bank* for the last day of the Calendar Quarter in which the applicable payment obligation became due and payable.

8.9. **Blocked Payments**. If by reason of Applicable Law in any country or region, it becomes impossible or illegal for a Party to transfer, or have transferred on its behalf, payments owed the other Party hereunder, then such Party will promptly notify the other Party of the conditions preventing such transfer and such payments will be deposited in local currency in the relevant country or region to the credit of the other Party in a recognized banking institution designated by the other Party or, if none is designated by the other Party [*], in a recognized banking institution selected by the transferring Party, as the case may be, and identified in a written notice given to the other Party.

8.10. **Late Payments**. Any payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement will bear interest at a rate equal to the lesser of: (a) [*] percentage points above the prime rate as published by *The Wall Street Journal* or any successor thereto on the first day of each Calendar Quarter in which such payments are overdue; or (b) the maximum rate permitted by Applicable Law; in each case, calculated on the number of days such payment is delinquent, compounded monthly.

8.11. **Financial Records and Audits**. Kaken will maintain complete and accurate records in sufficient detail to permit KalVista to determine a Loss of Market Exclusivity, and to confirm the accuracy of the amount of Sales Milestones and other amounts payable under this Agreement. Upon reasonable prior notice, such records will be open during regular business hours for a period of [*] from the creation of individual records for examination by an independent certified public accountant selected by KalVista and reasonably acceptable to Kaken for the sole purpose of verifying the accuracy of the financial reports furnished by Kaken pursuant to this Agreement or of any payments made, or required to be made, by Kaken pursuant to this Agreement; *provided* that such independent accounting firm is subject to written obligations of confidentiality and non-use applicable Kaken's Confidential Information that are at least as stringent as those set forth in Article 9 (Confidentiality; Publication). Such audit will not be (a) performed more frequently than [*] during the Term or once during the [*] period after the expiration or termination of this Agreement or (b) conducted [*] more than [*] after the end of such Calendar Year. Such auditor will not disclose Kaken's Confidential Information to KalVista or to any Third Party, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by Kaken or the amount of payments by Kaken under this Agreement. Kaken will pay any amounts shown to be owed to KalVista but unpaid [*], *plus* interest (as set forth in Section 8.10 (Late Payments)) from the original due date. KalVista will bear the full cost of such audit unless such audit reveals an underpayment by Kaken of more than [*] of the amount actually due for the time period being audited, in which case Kaken will reimburse KalVista for the reasonable audit fees for such examination.

8.12. **Taxes**.

8.12.1. **Taxes on Income**. Except as set forth in this Section 8.12 (Taxes) or Section 8.12.5 (VAT Credits), each Party will be solely responsible for the payment of any and all Taxes levied on account of all payments it receives under this Agreement.

8.12.2. **Tax Cooperation**. The Parties agree to cooperate with one another in accordance with Applicable Law and use reasonable efforts to minimize Tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by each Party to the other Party under this Agreement. To the extent either Party (the "**Paying Party**") is required to deduct and withhold Taxes on any payment to the other Party (the "**Recipient**"), the Paying Party will (a) pay the amount of such Taxes to the proper Governmental Authority in a timely manner, and (b) promptly transmit to the Recipient an official tax certificate or other evidence of such payment sufficient to enable the Recipient to claim such payment of Taxes on the Recipient's applicable tax returns. The Paying Party will provide the Recipient with advance notice prior to withholding any Taxes from payments payable to the Recipient and will provide the Recipient with a commercially reasonable period of time to claim an exemption or reduction in otherwise applicable Taxes. The Recipient will provide the Paying Party any tax forms that may be reasonably necessary in order for the Paying Party to not withhold Tax or to withhold Tax at a reduced rate under an applicable bilateral income tax treaty, to the extent the Paying Party is legally able to do so. The Recipient will use reasonable efforts to provide any such tax forms to the Paying Party in advance of the due date. Each Party will provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Law, of withholding Taxes or similar

obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Paying Party if the Paying Party is the Party bearing such withholding Tax under this Section 8.12 (Taxes). In addition, the Parties will cooperate in accordance with Applicable Law to minimize indirect Taxes (such as VAT, sales tax, consumption tax, and other similar Taxes) in connection with this Agreement. In the event of any inconsistency between this Section 8.12 (Taxes) and Section 8.12.5 (VAT Credits), Section 8.12.5 (VAT Credits) will take precedence.

8.12.3. **Changes in Domicile**. Notwithstanding any provision to the contrary in this Agreement, if the Paying Party assigns, transfers, or otherwise disposes of some or all of its rights and obligations to any Person and if, as a result of such action, the withholding or deduction of Tax required by Applicable Law with respect to payments under this Agreement is increased, then any amount payable to the Recipient under this Agreement will be increased to take into account such withheld Taxes as may be necessary so that, after making all required withholdings (including withholdings on the withheld amounts), the Recipient receives an amount equal to the sum it would have received had no such withholding been made.

8.12.4. **Returns**. All transfer, documentary, sales, use, stamp, registration, and other such Taxes, and any conveyance fees, recording charges, and other fees and charges (including any penalties and interest) incurred in connection with consummation of the transactions contemplated hereby, if any, will be borne and paid by the Paying Party. The Paying Party will prepare and timely file all tax returns required to be filed in respect of any such Taxes. The Parties will reasonably cooperate in accordance with Applicable Law to minimize transfer Taxes in connection with this Agreement.

8.12.5. **VAT Credits**. All payments due to KalVista from Kaken pursuant to this Agreement will be paid without any deduction for any VAT that Kaken may be required to pay to any tax authorities in the Territory. KalVista will use reasonable efforts to assist Kaken to minimize and obtain all available exemptions from such VAT or other taxes, but if applicable, Kaken will pay any such VAT to the proper taxing authorities upon receipt of a valid VAT invoice (where such invoice is required under local VAT laws). If Kaken is required to pay or KalVista is required to report, any such VAT, then Kaken will increase the amount of any and all payments under this Agreement upon which such VAT is due as may be necessary so that after making any payments in respect of any such VAT, KalVista receives an amount equal to the sum that it would have received had no such VAT been required to be paid on such amount. Kaken will promptly provide to KalVista applicable receipts evidencing payment of such VAT and other documentation reasonably requested by Kaken.

Article 9
CONFIDENTIALITY; PUBLICATION

9.1. **Duty of Confidence**. Subject to the other provisions of this Article 9 (Confidentiality; Publication):

9.1.1. except to the extent expressly authorized by this Agreement, all Confidential Information of a Party (the "**Disclosing Party**") will be maintained in confidence and otherwise safeguarded, and not published or otherwise disclosed, by the other Party (the "**Receiving Party**") and its Affiliates for [*];

9.1.2. the Receiving Party will treat all Confidential Information provided by the Disclosing Party with the same degree of care as the Receiving Party uses for its own similar information, but in no event less than a reasonable degree of care;

9.1.3. the Receiving Party may only use any Confidential Information of the Disclosing Party for the purposes of performing its obligations or exercising its rights under this Agreement;

9.1.4. a Receiving Party may disclose Confidential Information of the Disclosing Party to: (a) such Receiving Party's Affiliates, and, to the extent engaged in accordance with this Agreement, Subcontractors and Sublicensees; and (b) employees, directors, officers, agents, contractors, consultants, attorneys, accountants, banks, investors, and advisors of the Receiving Party and its Affiliates, licensees, in each case ((a) and (b)), to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this Agreement; *provided* that such Persons are bound by legally enforceable obligations of confidentiality and non-use with respect to the Disclosing Party's Confidential Information no less stringent than the confidentiality and non-use obligations set forth in this Agreement. Each Party will remain responsible for any failure by its Affiliates, Sublicensees and Subcontractors, and its and its Affiliates', Sublicensees' and Subcontractors' respective employees, directors, officers, agents, consultants, attorneys, accountants, banks, investors, advisors, and contractors, in each case, to treat such Confidential Information as required under this Section 9.1 (Duty of Confidence) (as if such Affiliates, licensees, employees, directors, officers agents, consultants, advisors, attorneys, accountants, banks, investors, and contractors were Parties directly bound to the requirements of this Section 9.1 (Duty of Confidence)); and

9.1.5. each Party will promptly notify the other Party of any misuse or unauthorized disclosure of the other Party's Confidential Information.

9.2. **Confidential Information**. Subject to the provisions of Section 9.3 (Exemptions), the Licensed Know-How, excluding the Joint Arising Know-How, will be the Confidential Information of KalVista. The terms of this Agreement and the Joint Arising Know-How will be the Confidential Information of both Parties. Except as provided in Section 9.4 (Authorized Disclosures) and Section 9.7 (Publicity; Use of Names), neither Party nor its Affiliates may disclose the existence or the terms of this Agreement.

9.3. **Exemptions**. Information of a Disclosing Party will not be Confidential Information of such Disclosing Party to the extent that the Receiving Party can demonstrate through competent evidence that such information:

9.3.1. is known by the Receiving Party or any of its Affiliates without an obligation of confidentiality at the time of its receipt from the Disclosing Party, and not through a prior disclosure by or on behalf of the Disclosing Party, as documented by the Receiving Party's business records;

9.3.2. is generally available to the public before its receipt from the Disclosing Party;

9.3.3. became generally available to the public or otherwise part of the public domain after its disclosure by the Disclosing Party and other than through any act or omission of the Receiving Party or any of its Affiliates or disclosures in breach of this Agreement;

9.3.4. is subsequently disclosed to the Receiving Party or any of its Affiliates without obligation of confidentiality by a Third Party who may rightfully do so and is not under a conflicting obligation of confidentiality to the Disclosing Party; or

9.3.5. is developed by the Receiving Party or any of its Affiliates independently and without use of or reference to any Confidential Information received from the Disclosing Party, as documented by the Receiving Party's business records.

No combination of features or disclosures will be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party.

9.4. **Authorized Disclosures**.

9.4.1. **Permitted Circumstances**. Notwithstanding the obligations set forth in Section 9.1 (Duty of Confidence) and Section 9.6 (Publications), a Party may disclose the other Party's Confidential Information (including this Agreement and the terms herein) to the extent such disclosure is reasonably necessary in the following situations:

(a) (i) the Patent Prosecution of Licensed Patent Rights as contemplated by this Agreement; or (ii) Regulatory Submission and other filings with Governmental Authorities (including Regulatory Authorities), as necessary for the Exploitation of a Licensed Product in accordance with the rights and obligations of the applicable Party under this Agreement;

(b) disclosure of this Agreement, its terms, and the status and results of Exploitation of the Licensed Product to actual or *bona fide* potential investors, acquirors, (sub)licensees, lenders, and other financial or commercial partners (including in connection with any royalty monetization transaction), and their respective attorneys, accountants, banks, investors, and advisors, solely for the purpose of

evaluating or carrying out an actual or potential investment, acquisition, (sub)license, debt transaction, or collaboration; *provided* that, in each such case, on the condition that such Persons are bound by obligations of confidentiality and non-use at least as stringent as those set forth Article 9 (Confidentiality; Publication) or otherwise customary for such type and scope of disclosure any such disclosure is limited to the maximum extent practicable for the particular context in which it is being disclosed;

(c) such disclosure is required to comply with Applicable Law (whether generally or in pursuit of an application for listing of securities) including the United States Securities and Exchange Commission, the rules of the Tokyo Stock Exchange, or equivalent foreign agency or regulatory body, or otherwise required by judicial or administrative process, *provided* that in each such event, as promptly as reasonably practicable and to the extent not prohibited by Applicable Law or judicial or administrative process, such Party will notify the other Party of such required disclosure and provide a draft of the disclosure to the other Party reasonably in advance of such filing or disclosure for the other Party's review and comment. The non-disclosing Party will provide any comments as soon as practicable, and the disclosing Party will consider in good faith any timely comments provided by the non-disclosing Party; *provided* that the disclosing Party may or may not accept such comments in its sole discretion. Confidential Information that is disclosed in order to comply with Applicable Law or by judicial or administrative process pursuant to this Section 9.4.1(c) (Permitted Circumstances), in each case, will remain otherwise subject to the confidentiality and non-use provisions of this Article 9 (Confidentiality; Publication) with respect to the Party disclosing such Confidential Information, and such Party will take all steps reasonably necessary, including seeking of confidential treatment or a protective order for a period of at least ten (10) years (to the extent permitted by Applicable Law or Governmental Authority), to ensure the continued confidential treatment of such Confidential Information, and each Party will be responsible for its own legal and other external costs in connection with any such filing or disclosure pursuant to this Section 9.4.1(c) (Permitted Circumstances);

(d) with respect to KalVista as Disclosing Party, to the extent necessary to comply with the DRI Agreement; *provided* that such Persons to whom KalVista disclosed Kaken's Confidential Information hereunder are bound by obligations of confidentiality and non-use that are at least as stringent as those set forth in this Article 9 (Confidentiality; Publication) and further provided that KalVista shall be liable hereunder for any breach of such obligations by such Persons; or

(e) disclosure pursuant to Section 9.6 (Publications) and Section 9.7 (Publicity; Use of Name).

9.4.2. **Confidential Treatment**. Notwithstanding any provision to the contrary set forth in this Agreement, in each case of a disclosure to be made pursuant to Section 9.4.1(b) or Section 9.4.1(c) (Permitted Circumstances) by Kaken, where some or all of the terms of this Agreement are to be disclosed, Kaken will provide to KalVista a redacted version of the applicable terms of this Agreement to be made in connection with any such disclosure, and Kaken will not disclose or provide any redacted version hereof that has not been approved in writing by KalVista. Subject to the

foregoing, but notwithstanding any other provision to the contrary set forth in this Agreement, if Kaken is required or permitted to make a disclosure of KalVista's Confidential Information pursuant to Section 9.4.1 (Permitted Circumstances), then Kaken will, to the extent not prohibited by Applicable Law or judicial or administrative process, except where impracticable, give reasonable advance notice to KalVista of such proposed disclosure and use reasonable efforts to secure confidential treatment of such information and will only disclose that portion of Confidential Information that is legally required to be disclosed as advised by its legal counsel. In any event, each Party agrees to take all reasonable action to avoid disclosure of Confidential Information of the other Party hereunder.

9.5. **Tax Treatment**. Nothing in Section 9.1 (Duty of Confidence) or 9.4 (Authorized Disclosures) will limit either Party in any way from disclosing to any Third Party such Party's U.S. or foreign income Tax treatment and the U.S. or foreign income Tax structure of the transactions relating to such Party that are based on or derived from this Agreement, or materials of any kind (including opinions or other Tax analyses) relating to such Tax treatment or Tax structure, except to the extent that nondisclosure of such matters is reasonably necessary in order to comply with applicable securities laws.

9.6. **Publications**. Kaken may publicly present or publish any Clinical Trial or Commercialization data, non-clinical or preclinical data, or any associated results, data, or conclusions generated by or on behalf of Kaken pursuant to this Agreement in the Territory (each such proposed presentation or publication, a "**Publication**") solely if such Publication is in accordance with a written global publication and communication strategy with respect to the Licensed Product as reviewed, discussed, and approved by the JSC and updated by the JSC from time to time during the Term (the "**Publication and Communication Strategy**"), and subject to the additional limitations set forth in this Section 9.6 (Publications). If Kaken desires to publicly present or publish a Publication in accordance with the foregoing sentence that is in accordance with the Publication and Communication Strategy, then Kaken will provide KalVista through the JSC with a copy of such proposed Publication [*] prior to the earlier of its presentation or intended submission for publication (such applicable period, the "**Review Period**"). Kaken agrees that Kaken will not submit or present any Publication until (a) KalVista has provided written comments during such Review Period on the material in such Publication, or (b) the applicable Review Period has elapsed without written comments from KalVista, in which case Kaken may proceed and the Publication will be considered approved in its entirety. If Kaken receives written comments from KalVista on any Publication during the applicable Review Period, then Kaken will consider KalVista's comments in good faith and incorporate such comments where appropriate. Notwithstanding any provision to contrary set forth in this Agreement, Kaken will (i) delete any Confidential Information of KalVista that KalVista identifies for deletion, (ii) delete any Clinical Trial data, results, conclusions, or other related information for a Licensed Product, the publication of which KalVista determines, in its sole discretion, would conflict with KalVista's global publication strategy with respect to the Licensed Product, and (iii) delay such Publication for a period [*] to enable KalVista to draft and file one or more patent applications with respect to any subject matter to be made public in such Publication. Kaken agrees to acknowledge the contributions of KalVista and the employees of KalVista, in each case, in all Publications as scientifically appropriate. Kaken will require its Affiliates to comply with the obligations of this Section 9.6 (Publications) as if they were Kaken, and Kaken will be liable for any non-compliance of such Persons.

If KalVista wishes to publicly present or publish a Publication, then KalVista will provide Kaken through the JSC with a copy of such proposed Publication [*] prior to the earlier of (a) its intended presentation; or (b) intended submission for publication (such applicable period, the "**Check Period**") to allow Kaken to review the Publication and request the deletion of any Confidential Information of Kaken. KalVista agrees that KalVista will not submit or present any Publication until (i) Kaken has provided written confirmation of check completion during such Check Period on the material in such Publication; or (ii) the applicable Check Period has elapsed without written notice from Kaken, in which case KalVista may proceed and the Publication will be considered approved in its entirety. If KalVista receives written notice from Kaken that the Publication contains Confidential Information of Kaken during the applicable Check Period, then KalVista will delete any and all Confidential Information of Kaken that Kaken identifies for deletion or delay publication of such Publication for a period not to exceed [*] to allow Kaken to file appropriate patent protections.

9.7. Publicity; Use of Names.

9.7.1. **Press Release**. The Parties have agreed on separate press releases announcing this Agreement, each as set forth on Schedule 9.7.1 (Press Release), to be issued by the applicable Party on such date and time as may be agreed by the Parties. Other than the press releases set forth on Schedule 9.7.1 (Press Release) and the public disclosures permitted by this Section 9.7 (Publicity; Use of Names) and Section 9.4 (Authorized Disclosures), the Parties agree that the portions of any other news release or other public announcement relating to this Agreement or the performance hereunder that would disclose information, other than that which is already in the public domain, and remains true, correct, and current, will first be reviewed and approved by both Parties (with such approval not to be unreasonably withheld). However, the Parties agree that after (a) a disclosure pursuant to Section 9.7 (Publicity; Use of Names) or Section 9.4 (Authorized Disclosures) or (b) the issuance of a press release (including the initial press releases) or other public announcement pursuant to this Section 9.7.1 (Press Release) that has been reviewed and approved by the other Party, the disclosing Party may make subsequent public disclosures reiterating such information without having to obtain the other Party's prior consent and approval so long as the information in such press release or other public announcement remains true, correct, and the most current information with respect to the subject matters set forth therein. Similarly, after a Publication has been made available to the public, each Party may post such Publication or a link to it on its corporate website (or any website managed by such Party in connection with a Clinical Trial for a Licensed Product, as appropriate) without the prior written consent of the other Party, so long as the information in such Publication remains true, correct, and the most current information with respect to the subject matters set forth therein.

9.7.2. **Disclosures by KalVista**. Notwithstanding any provision to the contrary set forth in this Agreement, KalVista has the right to publicly disclose (in written, oral, or other form): (a) the achievement of Milestone Events under this Agreement (including the payment and timing of any such Milestone Event) to the extent required under Applicable Law; (b) any information relating to any Clinical Trial for a Licensed Product, including

the commencement, completion, material data, or key results, whether or not conducted under this Agreement; (c) the achievement of Regulatory Approval or Reimbursement Approval for a Licensed Product in the Territory; or (d) any other information related to the Licensed Products outside of the Territory.

9.7.3. **Use of Names**. [*]. Except as permitted under this Section 9.7 (Publicity; Use of Names) or with the prior express written permission of the other Party, neither Party will use the name, trademark, trade name, or logo of the other Party or its Affiliates or their respective employees in any publicity, promotion, news release, or disclosure relating to this Agreement or its subject matter except as may be required by Applicable Law. Kaken will use the KalVista's corporate name in the form and format provided or otherwise approved by KalVista in all publicity relating to this Agreement, including the initial press release and all subsequent press releases. Kaken will include explanatory text such as "*Discovered and developed by KalVista*" in all publicity, promotion, news releases, or disclosures relating to the Licensed Product, or such other similar text provided by KalVista and reasonably acceptable to Kaken.

9.8. Attorney-Client Privilege. Neither Party is waiving, nor will be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges or the like as a result of disclosing information pursuant to this Agreement, or any of its Confidential Information (including Confidential Information related to pending or threatened litigation) to the Receiving Party, regardless of whether the Disclosing Party has asserted, such privileges and protections. The Parties: (a) share a common legal and commercial interest in such disclosure that is subject to such privileges and protections; (b) are or may become joint defendants in proceedings to which the information covered by such protections and privileges relates; (c) intend that such privileges and protections remain intact should either Party become subject to any actual or threatened proceeding to which the Disclosing Party's Confidential Information covered by such protections and privileges relates; and (d) intend that after the Effective Date both the Receiving Party and the Disclosing Party will have the right to assert such protections and privileges. Notwithstanding any provision to the contrary set forth in this Agreement, nothing in this Section 9.8 (Attorney-Client Privilege) will apply with respect to a Dispute between the Parties (including their respective Affiliates).

Article 10
REPRESENTATIONS, WARRANTIES, AND COVENANTS

10.1. Representations and Warranties of Each Party. Each Party represents and warrants to the other Party as of the Effective Date as follows:

10.1.1. It is a corporation or limited company duly organized, validly existing, and, as applicable, in good standing under the laws of the jurisdiction of its organization, and it has the full right, power and authority to enter into this Agreement and to perform its obligations hereunder.

10.1.2. It has not been Debarred/Excluded and no proceeding that could result it in being Debarred/Excluded is pending, and neither it nor any of its Affiliates has used, in any capacity in the performance of obligations relating to the Licensed Product, any employee, Sublicensee, Subcontractor, consultant, agent, representative, or other Person who has been Debarred/Excluded.

10.1.3. All consents, approvals and authorizations from all Governmental Authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained.

10.1.4. This Agreement has been duly executed by it and is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material Applicable Law or regulation of any court, governmental body, or administrative or other agency having jurisdiction over it.

10.1.5. Neither it nor any of its Affiliates is, at present, (a) an Anti-Social Force; or (b) a person for whom five (5) years have not yet passed since they ceased to be an Anti-Social Force, and it does not have any: (i) relationship by which its management is considered to be controlled by Anti-Social Forces; (ii) relationship by which Anti-Social Forces are considered to be substantially involved in its management; (iii) relationship by which it is considered to unlawfully utilize Anti-Social Forces for the purpose of securing unjust advantage for itself or any third party or of causing damage to any third party; (iv) relationship by which it is considered to offer funds or provide benefits to Anti-Social Forces; or (v) officers or persons that are substantially involved in its management having socially condemnable relationships with Anti-Social Forces.

10.2. Representations and Warranties of KalVista. KalVista represents and warrants to Kaken as of the Effective Date as follows:

10.2.1. It has the right under the Licensed Technology to grant to Kaken the licenses set forth in this Agreement, and it has not granted any license or other right under the Licensed Technology that is inconsistent with the licenses granted to Kaken hereunder and the Licensed Technology is not encumbered by any other lien, option, or encumbrance that is or would be inconsistent with the licenses granted to Kaken hereunder.

10.2.2. With respect to any such Licensed Patent Right identified on Schedule 1.100 (Licensed Patent Rights) as being owned by KalVista, KalVista solely and exclusively owns all rights, title, and interests in and to such Licensed Patent Rights, which are being diligently prosecuted in the respective patent offices in the Territory in accordance with Applicable Law, and have been filed and maintained properly and correctly and all applicable fees have been paid on or before the due date for payment.

10.2.3. All Licensed Patent Rights issued in the Territory as of the Effective Date are, to KalVista's Knowledge, subsisting, valid, in full force and effect and enforceable.

10.2.4. To KalVista's Knowledge as of the Effective Date, the Commercialization of the Licensed Product in the Field in the Territory to be carried out by Kaken in accordance with this Agreement will not infringe any Patent Rights of any Third Party.

10.2.5. Except for the DRI Agreement, neither KalVista nor any of its Affiliates is a party to any agreement with a Third Party pursuant to which KalVista or any of its Affiliates is obligated to pay any amount to a Third Party for the practice or use of any intellectual property rights with respect to KalVista's or its Affiliates' Exploitation of Licensed Products in the Field pursuant to this Agreement.

10.2.6. There is no pending or, to KalVista's Knowledge, threatened (in writing) litigation, adverse actions, suits, proceedings, judgments, orders, decrees or settlements against or owed by KalVista or any of its Affiliates, nor has KalVista received any written notice from any Third Party asserting or alleging that the Exploitation of a Licensed Product prior to the Effective Date in the Field in or for the Territory infringed or misappropriated the intellectual property rights of such Third Party.

10.2.7. To KalVista's Knowledge, no Third Party is infringing or misappropriating (or threatening the same for) any Licensed Technology or Product Marks in the Field in the Territory.

10.2.8. There are no legal claims, judgments, or settlements against or owed by KalVista or any of its Affiliates, or pending or, to KalVista's Knowledge, threatened, legal claims or litigation, in each case, relating to antitrust, anti-competition, or Anti-Corruption Law violations that would impact KalVista's ability to enter into this Agreement or the transactions contemplated herein or to perform its obligations hereunder.

10.2.9. Schedule 1.100 (Licensed Patent Rights) sets forth a true and complete list of all Licensed Patent Rights Covering the Licensed Products in the Field in the Territory that have been issued or that have been applied for and are pending issuance with any Governmental Authority.

10.2.10. All information provided by KalVista during the pre-contractual due diligence, including all information provided in response to due diligence requests in connection with the subject matter of this Agreement, is truthful, and, to KalVista's Knowledge complete and accurate, and KalVista has not failed to disclose to Kaken any fact or circumstance known to KalVista or any of its Affiliates and relating to any of the Licensed Products that would be reasonably material to Kaken in connection with this Agreement or the transactions contemplated herein.

10.2.11. To KalVista's Knowledge, KalVista obtained all necessary assignments from the inventors of all inventorship rights relating to the Licensed Patent Rights, or assignments by operation of Applicable Law, and all such assignments of inventorship rights are valid and enforceable with the applicable inventors having been paid all amounts owing for their inventions as required by Applicable Law or contract.

10.2.12. No Licensed Technology in the Territory is subject to any funding agreement with, or obligation to, any Governmental Authority.

10.2.13. To KalVista's Knowledge, no significant quality or safety issues are or have been identified that would affect the Commercialization of the Licensed Product in the Field in the Territory, and all Licensed Products supplied to Kaken are consistent with industry standards for global pharmaceutical and biologic therapeutic products.

10.2.14. To KalVista's Knowledge, no circumstances that might cause difficulties in the supply of the Licensed Product to Kaken are or have been identified.

10.2.15. To KalVista's Knowledge, neither KalVista nor any of its Affiliates, or its or their directors, officers, employees, distributors, agents, representatives, sales intermediaries, or other Third Parties acting on behalf of KalVista or any of its Affiliates:

(a) has taken any action in violation of any applicable Anti-Corruption Laws; or

(b) has corruptly offered, paid, given, promised to pay or give, or authorized the payment or gift of anything of value, directly or indirectly, to any Public Official, for the purposes of:

(i) influencing any act or decision of any Public Official in his or her official capacity;

(ii) inducing such Public Official to do or omit to do any act in violation of his or her lawful duty;

(iii) securing any improper advantage; or

(iv) inducing such Public Official to use his or her influence with a government, governmental entity, or commercial enterprise owned or controlled by any government (including state-owned or controlled veterinary, laboratory or medical facilities) in obtaining or retaining any business whatsoever.

10.2.16. To KalVista's Knowledge, no Royalty Monetization Partner is at present, (a) Anti-Social Forces or (b) a person for whom five years have not passed since ceasing to be Anti-Social Forces, or have any: (i) relationship by which its management is considered to be controlled by Anti-Social Forces; (ii) relationship by which Anti-Social Forces are considered to be involved substantially in its management; (iii) relationship by which it is considered to unlawfully utilize Anti-Social Forces for the purpose of

securing unjust advantage for itself or any third party or of causing damage to any third party; (iv) relationship by which it is considered to offer funds or provide benefits to Anti-Social Forces; or (v) officers or persons that are substantially involved in its management having socially condemnable relationships with Anti-Social Forces.

10.3. Representations and Warranties of Kaken. Kaken represents and warrants to KalVista as of the Effective Date as follows:

10.3.1. There are no legal claims, judgments, or settlements against or owed by Kaken or any of its Affiliates, or pending or, to Kaken's Knowledge, threatened, legal claims or litigation, in each case, relating to antitrust, anti-competition, or Anti-Corruption Law violations that would impact or have an impact on Kaken's ability to enter into this Agreement or the transactions contemplated herein or to perform its obligations hereunder.

10.3.2. Kaken has sufficient financial wherewithal to (a) perform all of its obligations set forth under this Agreement, and (b) meet all of its obligations that come due in the ordinary course of business.

10.3.3. Kaken has sufficient technical, regulatory, and commercial expertise to perform all of its obligations pursuant to this Agreement, including all Commercialization activities with respect to the Licensed Product in the Field in the Territory as contemplated under this Agreement.

10.3.4. To its Knowledge, neither Kaken nor any of its Affiliates, or its or their directors, officers, employees, distributors, agents, representatives, sales intermediaries, or other Third Parties acting on behalf of Kaken or any of its Affiliates:

(a) has taken any action in violation of any applicable Anti-Corruption Laws; or

(b) has corruptly offered, paid, given, promised to pay or give, or authorized the payment or gift of anything of value, directly or indirectly, to any Public Official, for the purposes of:

(i) influencing any act or decision of any Public Official in his or her official capacity;

(ii) inducing such Public Official to do or omit to do any act in violation of his or her lawful duty;

(iii) securing any improper advantage; or

(iv) inducing such Public Official to use his or her influence with a government, governmental entity, or commercial enterprise owned or controlled by any government (including state-owned or controlled veterinary, laboratory or medical facilities) in obtaining or retaining any business whatsoever.

10.3.5. None of the officers, directors, or employees of Kaken or of any of its Affiliates or agents acting on behalf of Kaken or any of its Affiliates, in each case, that are employed or reside outside the United States, is a Public Official.

10.4. Covenants of KalVista. KalVista covenants to Kaken that:

10.4.1. In the course of performing its obligations or exercising its rights under this Agreement, it will comply with all Applicable Law, and will not employ or engage, and if so employed and engaged, will thereafter terminate any Person who has been Debarred/Excluded (including any Subcontractor), or is the subject of any proceedings that could result in such Person being Debarred/Excluded.

10.4.2. Notwithstanding any provision to the contrary in this Agreement, KalVista agrees as follows:

(a) It will not, in the performance of activities under this Agreement, perform any actions that are prohibited by any Anti-Corruption Laws that may be applicable to one or both Parties.

(b) It will not, in the performance of activities under this Agreement, directly or indirectly, make any payment, or offer or transfer anything of value, or agree or promise to make any payment or offer or transfer anything of value, to a government official or government employee, to any political party or any candidate for political office or to any other Third Party with the purpose of influencing decisions related to either Party or its business in a manner that would violate Anti-Corruption Laws.

(c) It will, [*], verify in writing that to its Knowledge, there have been no violations of Anti-Corruption Laws by it or its Affiliates, or persons employed by or Subcontractors used by it or its Affiliates in the performance of this Agreement, or will provide details of any exception to the foregoing.

(d) It will not (i) license, assign, transfer, or otherwise convey any right, title or interest in, to or under the KalVista Technology; or (ii) otherwise grant any rights under the KalVista Technology, in each case ((i) and (ii)), to any Third Party, in any way that would conflict with the licenses and rights granted to Kaken under this Agreement; *provided* that nothing herein will restrict KalVista from granting a security over its rights under this Agreement with prior written notice to Kaken of any grant of security to the extent related to the licenses granted to Kaken hereunder. KalVista will not grant any security interest over its rights under this Agreement in a manner that imposes or would impose any obligation or burden on Kaken.

(e) It will maintain records (financial and otherwise) and supporting documentation related to the subject matter of this Section 10.4.2 (Covenants of KalVista) in order to document or verify compliance with the provisions of this Section 10.4 (Covenants of KalVista), and upon request of Kaken upon reasonable advance notice, will provide Kaken or its representative with access to such records for purposes of verifying compliance with the provisions of this Section 10.4 (Covenants of KalVista).

10.5. Covenants of Kaken. Kaken covenants to KalVista that:

10.5.1. In the course of performing its obligations or exercising its rights under this Agreement, it will comply with all Applicable Law, and will not employ or engage, and if so employed and engaged, will thereafter terminate any Person who has been Debarred/Excluded (including any Subcontractor), or is the subject of any proceedings that could result in such Person being Debarred/Excluded.

10.5.2. Notwithstanding any provision to the contrary in this Agreement, Kaken agrees as follows:

(a) It will not, in the performance of activities under this Agreement, perform any actions that are prohibited by any Anti-Corruption Laws that may be applicable to one or both Parties.

(b) It will not, in the performance of activities under this Agreement, directly or indirectly, make any payment, or offer or transfer anything of value, or agree or promise to make any payment or offer or transfer anything of value, to a government official or government employee, to any political party or any candidate for political office or to any other Third Party with the purpose of influencing decisions related to either Party or its business in a manner that would violate Anti-Corruption Laws.

(c) It will, [*], verify in writing (in KalVista's format) that to its Knowledge, there have been no violations of Anti-Corruption Laws by it or its Affiliates, or persons employed by or Subcontractors used by it or its Affiliates in the performance of this Agreement, or will provide details of any exception to the foregoing.

(d) It will maintain records (financial and otherwise) and supporting documentation related to the subject matter of this Section 10.5 (Covenants of Kaken) in order to document or verify compliance with the provisions of this Section 10.4 (Covenants of Kaken), and upon request of KalVista upon reasonable advance notice, will provide KalVista or its representative with access to such records for purposes of verifying compliance with the provisions of this Section 10.5 (Covenants of Kaken).

10.6. NO OTHER WARRANTIES. EXCEPT AS EXPRESSLY STATED IN THIS Article 10 (REPRESENTATIONS, WARRANTIES, AND COVENANTS), (A) NO REPRESENTATION, CONDITION, OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF KALVISTA OR KAKEN; AND (B) ALL OTHER CONDITIONS AND WARRANTIES WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE ARE EXPRESSLY EXCLUDED, INCLUDING ANY CONDITIONS AND WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, OR NON-INFRINGEMENT. ANY INFORMATION PROVIDED BY KALVISTA OR ITS AFFILIATES IS MADE AVAILABLE ON AN "AS IS" BASIS WITHOUT WARRANTY WITH RESPECT TO COMPLETENESS, COMPLIANCE WITH REGULATORY STANDARDS OR REGULATIONS, OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER KIND OF WARRANTY WHETHER EXPRESS OR IMPLIED.

10.7. **Compliance with Laws**. Kaken understands and acknowledges that KalVista is subject to regulation by Governmental Authorities in the U.S., including the U.S. Department of Commerce and the U.S. Treasury Department's Office of Foreign Assets Control, both of which regulate the import, export, and diversion of certain products and technology from and to certain countries. Any and all obligations of KalVista to provide the Licensed Product, as well as any other technical information or assistance, and all rights on the part of Kaken to perform its obligations hereunder, will be subject in all respects to such Applicable Law in the U.S. as will from time to time govern the license and delivery of technology and products abroad by persons subject to the jurisdiction of the United States, including regulations promulgated under Executive Order No. 12924 of August 19, 1994 issued pursuant to the President's authority under the International Emergency Economic Powers Act, Title 50 U.S. C., Chapter 35, Section 1701 et seq. and those contained in Title 31, Part 500 of the U.S. Code of Federal Regulations. Kaken will cooperate with KalVista including providing required documentation, in order to comply with any and all Applicable Law in the U.S., Kaken will comply with all Applicable Law in the U.S. governing exports in effect from time to time that are applicable to KalVista as if such laws and regulations were applicable to Kaken. If any rights or obligations hereunder are or become illegal or the subject of sanctions or restrictions, then KalVista will have the right, in its sole discretion, to terminate, without penalty and immediately upon written notice, the provisions of this Agreement which in KalVista's sole discretion relate to such restrictions.

10.8. **Limitation on Claims**. Except in the case of any fraud or intentional misrepresentation by a Party: (a) the representations and warranties of the Parties contained in Section 10.1 (Representations and Warranties of Each Party), Section 10.2 (Representations and Warranties of KalVista), and Section 10.3 (Representations and Warranties of Kaken) will survive until the date that is [*] after the Effective Date, (b) no claim may be made or suit instituted alleging breach or seeking indemnification pursuant to Article 10 (Representations, Warranties, and Covenants) for any breach of, or inaccuracy in, any representation or warranty contained in Section 10.1 (Representations and Warranties of Each Party), Section 10.2 (Representations and Warranties of KalVista), or Section 10.3 (Representations and Warranties of Kaken) unless a written notice is provided to the Indemnifying Party at any time prior to the date that is [*] following the Effective date, and (c) after such [*] period, no Party may bring any claim against the other Party arising from or relating to such other Party's breach of such representations and warranties.

Article 11
INDEMNIFICATION

11.1. **By Kaken**. Kaken will indemnify, defend, and hold harmless KalVista and its Affiliates, and their respective directors, officers, employees, successors, heirs and assigns, and agents (individually and collectively, the "**KalVista Indemnitees**") from and against all Losses incurred in connection with any Third Party Claims to the extent arising from or relating to [*].

11.2. **By KalVista**. KalVista will indemnify, defend, and hold harmless Kaken, its Affiliates, and their directors, officers, employees, successors, heirs and assigns, and agents (individually and collectively, the "**Kaken Indemnitees**") from and against all Losses incurred in connection with any Third Party Claims to the extent from or relating to [*].

11.3. **Indemnification Procedure**. If either Party is seeking indemnification under Section 11.1 (Indemnification; By Kaken) or Section 11.2 (Indemnification; By KalVista) (the "**Indemnified Party**"), then it will inform the other Party (the "**Indemnifying Party**") of the Third Party Claim giving rise to such indemnification obligations within [*] after receiving written notice of the Third Party Claim (it being understood and agreed, however, that the failure or delay by an Indemnified

Party to give such notice of a Third Party Claim will not affect the Indemnifying Party's indemnification obligations hereunder except to the extent the Indemnifying Party will have been actually and materially prejudiced as a result of such failure or delay to give notice). The Indemnifying Party will have the right to assume the defense of any such Third Party Claim for which it is obligated to indemnify the Indemnified Party. [*]. If the Parties cannot agree as to the application of Section 11.1 (Indemnification; By Kaken) or Section 11.2 (Indemnification; By KalVista) as to any Third Party Claim, pending resolution of the Dispute pursuant to Article 14 (Dispute Resolution), then the Parties may conduct separate defenses of such Third Party Claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Section 11.1 (Indemnification; By Kaken) or Section 11.2 (Indemnification; By KalVista), as applicable, upon resolution of the underlying Third Party Claim.

11.4. **Insurance**. Each Party will procure and maintain [*] the last commercial sale of any Licensed Product for which it is responsible, commercial general liability insurance, including coverage for product liability, with coverage limits of not less than [*] per occurrence and [*] in the aggregate. Each Party will provide the other Party with evidence of such insurance promptly following execution by both Parties of this Agreement, upon request, and prior to expiration of any one coverage. Each Party will provide the other Party with written notice [*] to the cancellation or non-renewal of, or material changes in, such insurance. Such insurance will not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 11 (Indemnification).

Article 12
INTELLECTUAL PROPERTY

12.1. **Inventions**.

12.1.1. **Ownership**. As between the Parties, (a) KalVista will solely own all Licensed Technology, all Know-How, other than Joint Arising Know-How, developed or invented during the Term solely by KalVista's or its Affiliates', licensees', or Subcontractors' employees, agents, or independent contractors, or any Persons contractually required to assign or license such Know-How to KalVista or any Affiliate of KalVista in the performance of activities under this Agreement or any activities related to Exploitation of the Licensed Product inside or outside of the Territory ("**KalVista Arising Know-How**") and all Patent Rights that Cover any such Know-How ("**KalVista Arising Patent Rights**" and together with the KalVista Arising Know-How, the "**KalVista Arising Technology**"), (b) Kaken will solely own all Kaken Technology, including all Know-How, other than Joint Arising Know-How, developed or invented during the Term solely by Kaken or its Affiliates', or Subcontractors' employees, agents, or independent contractors, or any Persons contractually required to assign or license such Arising Know-How to Kaken or any Affiliate of Kaken ("**Kaken Arising Know-How**") and all Patent Rights that Cover any such Know-How ("**Kaken Arising Patent Rights**"), and (c) the Parties will jointly own all Joint Arising Technology. Subject only to the rights expressly granted to the other Party under this Agreement, each Party, as between such Party and the other Party, will own all rights, title, and interests in and to any Know-How that is invented, conceived, discovered, created, or otherwise developed by or on behalf of such Party (or its Affiliates) under or in connection with this Agreement, whether or

not patented or patentable, and any and all Patent Rights and other intellectual property rights with respect thereto. All determinations of inventorship under this Agreement will be made in accordance with U.S. patent law.

12.1.2. **Disclosure**. Kaken will promptly disclose to KalVista all Inventions within the Arising Know-How that it develops or invents, whether solely or jointly with others (in any event, prior to the filing of any patent application with respect to such Inventions), including all invention disclosures or other similar documents submitted to Kaken by its or its Affiliates' employees, agents, or independent contractors relating thereto. Kaken will also promptly respond to reasonable requests from KalVista for additional information relating thereto. [*], KalVista will notify Kaken of any Licensed Patent Rights that have come into KalVista's Control during such Calendar Year.

12.1.3. **Practice Under and Other Use of Joint Arising Technology**. Subject to the rights granted under and the restrictions set forth in this Agreement (including the licenses granted under Article 2 (Licenses) and the restrictions set forth in Section 2.72.7 (Exclusivity Covenant)), each Party will be entitled to the free use and enjoyment of all Joint Arising Technology and neither Party will have any obligation to account to the other Party for profits, or to obtain any approval of the other Party to license, assign, or otherwise exploit any Joint Arising Technology by reason of joint ownership thereof. Each Party hereby waives any right it may have under the Applicable Law of any jurisdiction to require any such approval or accounting. To the extent any further consent is required to enable a Party to so license or exploit its interest in the Joint Arising Technology, the other Party will grant consent promptly upon request. Without limitation, each Party will cooperate with the other Party if the Parties determine to apply for U.S. or foreign patent protection for any Joint Arising Technology and will obtain the cooperation of the individual inventors of any such Joint Arising Technology.

12.2. **CREATE Act**. Notwithstanding any provision to the contrary set forth in this Agreement, Kaken may not invoke the Cooperative Research and Technology Enhancement Act, 35 U.S.C. § 102(c) (the "**CREATE Act**") when exercising its rights under this Agreement without the prior written approval of KalVista. If Kaken intends to invoke the CREATE Act, then it will notify KalVista and if agreed by the Parties, then KalVista will cooperate and coordinate its activities with Kaken with respect to any filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in the CREATE Act.

12.3. **Third Party In-Licenses**.

12.3.1. **KalVista Identified Rights**. KalVista will remain solely responsible for the payment of all royalties, license fees, milestone payments, and other payment obligations under all agreements relevant to the Licensed Product entered into by KalVista prior to the Effective Date. [*].

12.3.2. **Kaken Identified Rights**. [*].

12.3.3. **Third Party IP Agreements**. [*].

12.3.4. **Responsibility for Costs**. [*].

12.4. Data Exchange and Use. In addition to its adverse event and safety data reporting obligations set forth in Section 3.3 (Adverse Events Reporting), Kaken will, upon a reasonable request from KalVista, promptly provide to KalVista, as designated by KalVista, in such request, copies of any data and results and all supporting documentation (*e.g.*, protocols, Investigator's Brochures, case report forms, analysis plans) that are reasonably useful for obtaining, supporting, or maintaining Regulatory Approval or any Reimbursement Approval, as applicable, of any Licensed Product outside the Territory Controlled by Kaken that are generated by or on behalf of Kaken or its Affiliates, Sublicensees, or Subcontractors, if applicable, in connection with the performance of any Commercialization activities for each Licensed Product. Kaken will also provide, in English, a high level summary of the contents of such data, results, and supporting documentation. KalVista and its designees will have the right to use and reference such data and results provided by Kaken for the purpose of obtaining, supporting, or maintaining Regulatory Approval or any Reimbursement Approval, as applicable, of any Licensed Product outside of the Territory or in the Territory outside of the Field, without additional consideration.

12.5. Patent Prosecution.

12.5.1. **Licensed Patent Rights**.

(a) **Right to Prosecute**. As between the Parties, KalVista will have the right to control the Patent Prosecution of all Licensed Patent Rights (including the Joint Arising Patent Rights) (the "**KalVista Prosecuted Patent Rights**") throughout the world. Kaken will obtain any necessary assignment documents for KalVista with respect to the Patent Prosecution of such Patent Rights, to render all signatures that will be necessary for such patent filings, and to assist KalVista in all other ways that are reasonably necessary for the issuance of such Patent Rights as well as for the Patent Prosecution of such Patent Rights. [*].

(b) **Review and Consult**. KalVista will consult with Kaken and keep Kaken reasonably informed of the Patent Prosecution of the KalVista Prosecuted Patent Rights in the Territory and will provide Kaken with material correspondence received from any patent authority in the Territory in connection therewith. In addition, KalVista will provide Kaken with drafts of proposed material filings in the Field in the Territory and correspondence to any patent authority in the Territory in connection with the Patent Prosecution of the KalVista Prosecuted Patent Rights in the Territory for Kaken's review and comment prior to the submission of such proposed filings and correspondence. KalVista will consider Kaken's comments on Patent Prosecution in good faith and will incorporate such comments where appropriate and KalVista will take into consideration Kaken's commercial strategy in the Territory relating to the Licensed Product, but will have final decision-making authority under this Section 12.5.1(b) (Review and Consult).

(c) **Abandonment**. If KalVista decides that it is no longer interested in the Patent Prosecution of a particular KalVista Prosecuted Patent Rights in the Territory during the Term, then KalVista will promptly provide written notice to Kaken of such decision [*] before any such KalVista Prosecuted Patent Rights would become abandoned. Kaken may, upon written notice to KalVista, assume the Patent Prosecution of such Patent Right in KalVista's name (or in the joint name

of the Parties in the case of Joint Arising Patent Rights). In such event, [*] of the Patent Prosecution of such Patent Right and may, at its own discretion, cease the Patent Prosecution and abandon such Patent Right without needing to obtain KalVista's consent.

12.5.2. Kaken Patent Rights.

(a) **Right to Prosecute**. As between the Parties, Kaken will have the right to control the Patent Prosecution of all Kaken Patent Rights throughout the world [*].

(b) If Kaken decides that it is no longer interested in the Patent Prosecution of a particular Kaken Patent Right during the Term, then Kaken will promptly provide written notice to KalVista of such decision at least forty-five (45) days before any such Kaken Patent Rights would become abandoned. KalVista may, upon written notice to Kaken, assume the Patent Prosecution of such Kaken Patent Right in Kaken's name [*].

12.5.3. **Cooperation**. Each Party will provide the other Party with all reasonable assistance and cooperation in the Patent Prosecution efforts under this Section 12.5 (Patent Prosecution), including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

12.6. Patent Enforcement.

12.6.1. **Notice**. Each Party will notify the other Party within ten (10) Business Days after becoming aware of any alleged or threatened infringement in the Territory by a Third Party product that is competitive with any Licensed Product of any of the Licensed Patent Rights, and any related declaratory judgment, adversarial Patent Prosecution proceedings, or equivalent action alleging the invalidity, unenforceability, or non-infringement of such Patent Rights (collectively "**Product Infringement**").

12.6.2. **First Right and Step-In for Product Infringement**.

(a) **KalVista First Right**. KalVista will have the first right to bring and control any legal action to enforce KalVista Prosecuted Patent Rights against any Product Infringement in the Territory as it reasonably determines appropriate [*], and KalVista will consider in good faith the interests of Kaken in such enforcement of such Licensed Patent Rights.

(b) **Step-In Rights**. If KalVista (a) decides not to abate the applicable Product Infringement in the Territory or to file an action to abate such Product Infringement in the Territory, (b) fails to do so [*] after a written request from Kaken to do so, or (ii) [*] before the time limit, if any, set forth in the Applicable Laws for the filing of such actions, whichever comes first, or (c) discontinues or decides that it is no longer interested in the prosecution of any such action after filing without abating such infringement, then, in either case, Kaken will have the right to institute, prosecute, and control, or assume in KalVista's name, the enforcement [*], against such Product Infringement in the Territory as it reasonably determines appropriate, which right will be limited to Product Infringements in the Field and,

if required by Applicable Law, KalVista shall permit any action under this Section 12.6 (Patent Enforcement) to be brought in its name, including being joined as a party; *provided* that (i) KalVista does not provide reasonable rationale for not doing so or continuing to do so (including a substantive concern regarding counter-claims by the infringing Third Party), and (ii) Kaken will not enter into any settlement admitting the invalidity of, or otherwise impairing, of any such Patent Rights without the prior written consent of KalVista, such consent not to be unreasonably withheld, conditioned or delayed.

12.6.3. **Cooperation**. At the request of the Party bringing an action related to a Product Infringement, the other Party will, at the expense of such Party bringing the action, provide reasonable assistance in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery, and joining as a party to the action if required by Applicable Law to pursue such action. In the event that Kaken institutes or assume in KalVista's name the enforcement against the applicable Product Infringement after KalVista discontinues or decides that it is no longer interested in the prosecution of an action to abate such Product Infringement pursuant to Section 12.6.2 (First Right and Step-In for Product Infringement), KalVista shall, upon Kaken's request, provide Kaken with all documents and materials related to the action Controlled by KalVista or its Affiliate to the extent permitted by Applicable Law, related to the Licensed Products, and to the extent that providing such information would not compromise any attorney-client privilege.

12.6.4. **Recoveries**. Any recoveries resulting from an enforcement action relating to a claim of Product Infringement in the Territory will be first applied against payment of each Party's costs and expenses in connection therewith. Any such recoveries in excess of such costs and expenses will be split as follows:

(a) In the event that KalVista brings enforcement action pursuant to Section 12.6.2(a) (KalVista First Right), (a) [*] will be paid to KalVista and (b) [*] will be paid to Kaken; and

(b) In the event that Kaken brings or assumes in KalVista's name such enforcement action pursuant to Section 12.6.2(b) (Step-In Rights), (a) [*] will be paid to Kaken; and (b) [*] will be paid to KalVista.

12.7. Infringement of Third Party Rights.

12.7.1. **Notice**. If any Licensed Product used or sold by each Party or its Affiliates becomes the subject of a Third Party's claim or assertion of infringement of a Patent Right or other rights in the Territory that are owned or controlled by such Third Party, then such Party will promptly notify the other Party [*] after receipt of such claim or assertion and will include in such notice a copy of any summons or complaint (or the equivalent thereof) received regarding the foregoing. [*].

12.7.2. **Defense**. [*].

12.8. **Patent Listings**. With respect to patent listings in any patent listing system established by any applicable Regulatory Authority in the Territory during the Term that is similar to the FDA Orange Book, for issued patents for any Licensed Product in the Field, the Parties will agree which patents to list in such patent listing (a) prior to the submission of the first and any subsequent MAA for such Licensed Product in the Field in the Territory to such applicable Regulatory Authority, and (b) [*] after the receipt of the first and any subsequent Regulatory Approval in the Field in the Territory for such Licensed Product from such Regulatory Authority.

12.9. **Patent Term Extensions**. With respect to any system for extending the term of Patent Rights in the Territory established by any applicable Regulatory Authority during the Term that is similar to the patent term extension system in the U.S., KalVista will be solely responsible for making all decisions regarding patent term extensions in the Territory, including supplementary protection certificates and any other extensions that are now or become available in the future, that are applicable to Licensed Patent Rights licensed hereunder and that become available directly as a result of the Regulatory Approval of a Licensed Product in the Territory; *provided* that KalVista will consult with Kaken with respect to such decisions and implement the reasonable comments and concerns of KalVista.

12.10. **Patent Marking**. Except as required to comply with Applicable Law and in such case upon advanced written notice to KalVista, Kaken will not change the labeling or patent markings on Licensed Products as supplied to Kaken or its designee in accordance with this Agreement by KalVista or its Affiliates or CMOs.

Article 13
TERM AND TERMINATION

13.1. **Term**. This Agreement will be effective as of the Effective Date, and will continue in effect, on a Licensed Product-by-Licensed Product basis, until the expiration of the Initial Term; *provided* that this Agreement will automatically renew on a Licensed Product-by-Licensed Product basis for [*], subject to agreement by the Parties on a revised Supply Price for all periods during the Term following the expiration of the Initial Term in accordance with Section 8.2.5 (Following Expiration of the Initial Term), unless Kaken gives KalVista a written notice of its election to terminate the Agreement at least [*] (the "**Term**"). On a Licensed Product-by-Licensed Product basis, upon the expiration of the Initial Term, the license granted to Kaken under Section 2.1 (License Grants to Kaken) will become non-exclusive, fully paid-up, perpetual and irrevocable with respect to such Licensed Product, so long as at such time Kaken has paid to KalVista all amounts due under this Agreement in accordance with the terms hereof and is not at such time in breach of this Agreement.

13.2. **Termination**.

13.2.1. **Termination Without Cause**. Upon [*] prior written notice provided to KalVista, at any time after [*], Kaken may terminate this Agreement in its entirety for convenience and without cause.

13.2.2. **Termination for Cause**. If (a) a Party materially breaches any of its material obligations under this Agreement; or (b) unless otherwise agreed by KalVista in writing, Kaken fails to achieve the Minimum Sales Target for a [*], for (in the case of either (a) or (b) above) any reason other than an Excused Reason (each a "**Default**" and (b) is referred to as the "**Minimum Sales Default**"), then the non-Defaulting Party may deliver notice of such Default to the other Party stating the cause and proposed

remedy ("**Default Notification**"). The Parties stipulate and agree that (i) a material Default of Kaken's obligations set forth under Section 2.7 (Exclusivity Covenant) or Section 6.1 (Commercialization Responsibilities) and (ii) any default under Kaken's payment obligations set forth under Article 7 (Payments), in each case ((i) and (ii)), will be considered a Default under this Agreement for purposes of this Section 13.2.2 (Termination for Cause). For any Default arising from a failure to make a payment set forth in this Agreement, the allegedly Defaulting Party will have [*] from the receipt of the applicable Default Notification to cure such Default. For all Defaults other than a failure to make a payment as set forth in this Agreement, the allegedly Defaulting Party will have [*] from the date of the Default Notification to cure such Default, *provided* that if such Default is not reasonably capable of cure within such [*], but is capable of cure within [*] from the date of such Default Notification, then the Defaulting Party may submit, within [*] of such Default Notification, a reasonable cure plan to remedy such Default as soon as possible and in any event prior to the end of such [*] that is reasonably acceptable to the non-Defaulting Party, and, upon such submission, the [*] cure period will be automatically extended for so long as the Defaulting Party continues to use reasonable efforts to cure such Default in accordance with the cure plan, but for no more than [*]. If the Party receiving notice of Default fails to cure that Default within the applicable period set forth above, then the Party originally delivering the Default Notification may terminate this Agreement effective upon written notice of termination to the other Party. With respect to a Minimum Sales Default, Kaken will have the one-time right, to cure (*i.e.*, to reset to zero) a Minimum Sales Default by paying to KalVista the amount calculated by multiplying the difference between the Minimum Sales Targets for each of [*] and the quantity of the Licensed Product actually sold by Seller during each of [*] by the then-current Supply Price per a Licensed Product within [*] after the receipt of the invoice issued by KalVista on or after the date of the Default Notification. For example, [*] to cure such Minimum Sales Default, which such payment would reset the counting of the consecutive number of Marketing Years for the purposes of the Minimum Sales Default to zero. For clarity, if Kaken exercises the foregoing one-time right to cure a Minimum Sales Default and subsequently commits another Minimum Sales Default, then Kaken may not cure such subsequent Minimum Sales Default and KalVista will have the right to terminate this Agreement in accordance with this Section 13.2.2 (Termination for Cause).

13.2.3. [*]

13.2.4. **Cessation of Commercialization**. Without limiting KalVista's termination remedies under Section 13.2.2 (Termination for Cause), if Kaken and its Affiliates do not conduct any material Commercialization activities with respect to the Licensed Product in the Field in the Territory for a continuous period of longer than [*], and such suspension of activity is not: (a) contemplated in a written agreement of the Parties, (b) a result of Kaken's reasonable response to guidance from or action by a Regulatory Authority in the Territory (such as a clinical hold, or a recall or withdrawal), or (c) solely due to KalVista's misconduct or negligence,

including its failure to supply such Licensed Product in accordance with the terms of the Supply Agreement (each of (a) through (c), an "**Excused Reason**"), then KalVista may, at its election, terminate this Agreement in its entirety upon [*] prior written notice to Kaken.

13.2.5. **Termination for Bankruptcy**. To the extent permitted under Applicable Law, if at any time during the Term, an Event of Bankruptcy (as defined below) relating to either Party (the "**Bankrupt Party**") occurs, the other Party will have, in addition to all other legal and equitable rights and remedies available hereunder, the option to terminate this Agreement upon [*] written notice to the Bankrupt Party. It is agreed and understood that if the other Party does not elect to terminate this Agreement upon the occurrence of an Event of Bankruptcy, except as may otherwise be agreed with the trustee or receiver appointed to manage the affairs of the Bankrupt Party, the other Party will continue to make all payments required of it under this Agreement as if the Event of Bankruptcy had not occurred, then the Bankrupt Party will not have the right to terminate any license granted herein. The term "**Event of Bankruptcy**" means: (a) filing in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Bankrupt Party or of its assets or (b) being served with an involuntary petition against the Bankrupt Party, filed in any insolvency proceeding, and such petition will not be dismissed within [*] after the filing thereof. Without limitation, the Bankrupt Party's rights under this Agreement will include those rights afforded by 11 U.S.C. § 365(n) of the United States Bankruptcy Code (the "**Bankruptcy Code**") and any successor thereto. All payments to be made by Kaken under this Agreement or any ancillary agreement (such as any supply agreement), including the Supply Price, Upfront Payment and Milestone Payments, will be considered "royalties" for purposes of Section 365(n) of the U.S. Bankruptcy Code. If the bankruptcy trustee of a Bankrupt Party as a debtor or debtor-in-possession rejects this Agreement under 11 U.S.C. § 365(n) of the Bankruptcy Code, then the other Party may elect to retain its rights licensed from the Bankrupt Party hereunder (and any other supplementary agreements hereto) for the duration of this Agreement and avail itself of all rights and remedies to the full extent contemplated by this Agreement and 11 U.S.C. § 365(n) of the Bankruptcy Code, and any other Applicable Law.

13.2.6. **Termination for Safety or Regulatory Issues**. In the event that Kaken determines that a safety or regulatory issue exists that materially and adversely affects Commercialization with respect to the Licensed Product in the Field in the Territory, Kaken may, at its election, terminate this Agreement in its entirety or on a Licensed Product-by-Licensed Product basis upon [*] prior written notice to KalVista.

13.2.7. **Full Force and Effect During Notice Period**. This Agreement will remain in full force and effect until the expiration of the applicable termination notice period. For clarity, if Kaken or any of its Affiliates achieve any Milestone Events during the termination notice period, then the corresponding Milestone Payment is accrued and Kaken will remain responsible for the payment of such Milestone Payment even if the due date of such Milestone Payment occur after the effective date of the termination.

13.3. Effect of Termination. Upon the termination (but not expiration) of this Agreement:

13.3.1. **Licenses**. As of the effective date of termination of this Agreement, all licenses and all other rights granted by KalVista to Kaken under the Licensed Technology for the Licensed Product (other than any license(s) that have become fully paid-up, perpetual and irrevocable pursuant to Section 13.1 (Term)) will terminate (other than as reasonably necessary or useful for the performance of activities pursuant to this Section 13.3 (Effects of Termination)) and all sublicenses granted and Subcontractors engaged by Kaken pursuant to Section 2.3 (Subcontractors) with respect to the Licensed Product will also terminate. In the case of termination of this Agreement by Kaken pursuant Section 13.2.2 (Termination for Cause), or Section 13.2.5 (Termination for Bankruptcy), effective upon the effective date of termination of this Agreement ("**Termination Date**"), Kaken will grant to KalVista a worldwide, exclusive, royalty-bearing, and sublicensable (through multiple tiers) license under such Kaken Technology and all other intellectual property owned or Controlled by Kaken as of the Termination Date that are necessary or actually used to Exploit the Licensed Product. In such case, the Parties will negotiate in good faith the terms and conditions of the license, including reasonable consideration. Upon the termination of this Agreement for any other reason, KalVista will have, and Kaken hereby grants to KalVista, effective upon such termination, a worldwide, exclusive, fully-paid, royalty-free, perpetual, irrevocable, and sublicensable (through multiple tiers) license under all Kaken Technology and all other intellectual property owned or Controlled by Kaken as of the Termination Date that are necessary to Exploit the Licensed Product, which license KalVista may practice only in connection with Exploiting the Licensed Product in the Field.

13.3.2. **Assignment of Agreements.** Kaken will assign to KalVista any Third Party IP Agreement pursuant to which Kaken then Controls any Kaken Identified Rights, if permitted under such Third Party IP Agreement (and will use reasonable efforts to seek any consent required from the applicable Third Party in connection with such an assignment). If such Third Party IP Agreement cannot be assigned to KalVista, then upon KalVista's reasonable request, Kaken will maintain such Third Party IP Agreement and KalVista will pay to Kaken [*] of all payments due to the applicable Third Party under any such Third Party IP Agreement in consideration of the sublicense to KalVista and KalVista's Exploitation of such Kaken Identified Rights. If Kaken is unable to sublicense any Kaken Identified Rights to KalVista pursuant to Section 13.3.1 (Effect of Termination; Licenses) without the consent of the Third Party, then Kaken undertakes,

on request from KalVista, to use reasonable efforts to procure such licenses with respect to the Licensed Product on behalf of KalVista to the extent that it is able to do so, and KalVista will pay such fees and agree to be bound by the terms agreed between Kaken and the Third Party licensor.

13.3.3. **Appointment as Exclusive Distributor**.

If Kaken is Commercializing any Licensed Product in the Territory as of the Termination Date, then, at KalVista's election (in its sole discretion), either (a) Kaken will appoint KalVista or its designee as its exclusive distributor of such Licensed Product in the Territory and grant KalVista or its designee the right to appoint sub-distributors, to the extent not prohibited by any written agreement between Kaken or any of its Affiliates and a Third Party; *provided* that KalVista will purchase any and all salable inventory of the Licensed Product held by Kaken or its Affiliates as of the effective date of termination with respect to such Licensed Product at a price equal to the Supply Price paid by Kaken for such Licensed Product, or (b) Kaken will have the continued right to sell the Licensed Product in the Territory from its inventory, and in the case of clause (ii), Kaken's obligations under this Agreement with respect to the Licensed Product that Kaken sells will continue in full force and effect during such period.

13.3.4. **Assignment and Disclosure**. To the extent requested by KalVista following the date that KalVista provides notice of termination of this Agreement, Kaken will promptly upon request (and in any event within [*] after the effective date of termination):

(a) assign and transfer to KalVista or its designee all of Kaken's rights, title, and interests in and to all clinical trial agreements (if any), distribution agreements, confidentiality and other agreements (in each case, to the extent assignable and not cancelled), Kaken Arising Know-How (including commercial information), in each case, relating to the Licensed Product and that are necessary for the Exploitation of the Licensed Product;

(b) assign or amend, as appropriate, any agreements or arrangements with Third Party vendors (including distributors) with respect to the Licensed Product or, to the extent any such Third Party agreement or arrangement is not assignable to KalVista, reasonably cooperate with KalVista to arrange to continue to provide such services for a period of [*] after termination of this Agreement with respect to such Licensed Product to facilitate the orderly transition of all Commercialization and other activities then being performed by or on behalf of Kaken or its Affiliates for the Licensed Product to KalVista or its designee;

(c) disclose to KalVista or its designee all documents, records, and materials related to the Licensed Product that are Controlled by Kaken or its Affiliates or that Kaken is able to obtain using reasonable efforts, and that embody the foregoing to the extent such disclosure does not breach or otherwise violate the terms of any arrangement or agreement with a Third Party;

(d) assign and transfer to KalVista all rights, title, or interests in, to, and under any Product Mark or Global Brand Element (including any trademark registration or application therefore or goodwill associated with any Product Mark); *provided* that KalVista will pay to Kaken the fair market value consideration of such Product Marks and Global Brand Elements; and

(e) assign and transfer to KalVista or its designee all of Kaken's rights, title, and interests in and to any Promotional Materials, training materials, medical education materials, packaging and labeling, and all other literature or other information related to the Licensed Product and copyrights and any registrations for the foregoing.

Unless this Agreement is terminated by Kaken pursuant to Section 13.2.2 (Termination for Cause), Section 13.2.5 (Termination for Bankruptcy) or Section 13.2.6 (Termination for Safety or Regulatory Issues), Kaken will bear the costs and expenses associated with the assignments set forth in this Section 13.3.4 (Assignment and Disclosure). To the extent that any agreement or other asset described in this Section 13.3.4 (Assignment and Disclosure) is not assignable by Kaken, then such agreement or other asset will not be assigned, and upon the request of KalVista, Kaken will take such steps as may be necessary to allow KalVista to obtain and to enjoy the benefits of such agreement or other asset, without additional payment therefor, in the form of a license or other right to the extent Kaken has the right and ability to do so. For clarity, KalVista will have the right to request that Kaken take any or all of the foregoing actions in whole or in part, or with respect to all or any portion of the assets set forth in this Section 13.3.4 (Assignment and Disclosure).

13.3.5. **Know-How Transfer Support**. In furtherance of the assignment of Know-How pursuant to Section 13.3.4 (Assignment and Disclosure), Kaken will, for a period of [*] from the effective date of termination of this Agreement, provide such consultation or other assistance as KalVista may reasonably request to assist KalVista in becoming familiar with such Know-How in order for KalVista to undertake further Exploitation of the Licensed Product, at an hourly rate of [*] plus reasonable out-of-pocket expenses incurred by Kaken or any of its Affiliates, in connection with such consultation or assistance.

13.3.6. **Inventory**. If KalVista elects to request Kaken, or Kaken elects to appoint KalVista or its designee as its exclusive distributor pursuant to Section 13.3.3 (Appointment as Exclusive Distributor), Kaken will transfer to KalVista or its designee some or all inventory of the Licensed Product (including all final product, bulk drug substance, intermediates, works-in-process, formulation materials, reference standards, drug product clinical reserve samples, packaged retention samples, and the like) then in the possession or Control of Kaken or its Affiliates. Unless this Agreement is terminated by Kaken pursuant to Section 13.2.2 (Termination for Cause), Section 13.2.5 (Termination for Bankruptcy) or Section 13.2.6 (Termination for Safety or Regulatory Issues), Kaken will bear the costs and expenses associated with the assignments set forth in this Section 13.3.6 (Inventory).

13.3.7. **Wind Down and Transition**. Kaken will be responsible, [*], for the wind-down of Kaken's and its Affiliates' activities with respect to the Licensed Product; *provided* that in the case of termination of this Agreement by Kaken pursuant to Section 13.2.2 (Termination for Cause) or Section 13.2.6 (Termination for Safety or Regulatory Issues), KalVista will reimburse Kaken for all costs and expenses incurred by or on behalf of Kaken with respect to such wind-down. Subject to Section 13.3.4 (Assignment and Disclosure) and Section 13.3.5 (Know-How Transfer Support), Kaken will, and will cause its Affiliates to, reasonably cooperate with KalVista to facilitate orderly transition of all Commercialization and other activities then being performed by or on behalf of Kaken or its Affiliates for the Licensed Product to KalVista or its designee, including reasonably cooperating with KalVista to transfer all Commercialization and other activities to KalVista or its designee and continuing to perform such activities on KalVista's behalf for a period of [*] after termination of this Agreement with respect to such Licensed Product.

13.3.8. **Return of Confidential Information**. At the Disclosing Party's election, the Receiving Party will return (at Disclosing Party's expense) or destroy all tangible materials comprising, bearing, or containing any Confidential Information of the Disclosing Party relating to the Licensed Product that are in the Receiving Party's or its Affiliates' possession or control and provide written certification of such destruction (except to the extent any information is the Confidential Information of both Parties or to the extent that the Receiving Party has the continuing right to use the Confidential Information under this Agreement); *provided* that the Receiving Party may retain one copy of such Confidential Information for its legal archives. Notwithstanding any provision to the contrary set forth in this Agreement, the Receiving Party will not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information.

13.3.9. **Further Assistance**. For a period of [*] following the termination of this Agreement, Kaken will provide any other assistance or take any other actions, in each case, reasonably requested by KalVista as necessary to transfer to KalVista all Exploitation of the Licensed Product at an hourly rate of [*] plus reasonable out-of-pocket expenses incurred by Kaken or any of its Affiliates, in connection with such assistance or other actions, and will execute all documents as may be reasonably requested by KalVista in order to give effect to this Section 13.3 (Effect of Termination), which will be considered as a part of the wind-down and whose costs will be borne by KalVista or Kaken as set forth under Section 13.3.7 (Wind Down and Transition).

13.3.10. **Alternative Remedy for Termination for Cause**. In the event that Kaken has the right to terminate this Agreement pursuant to Section 13.2.2 (Termination for Cause), then, in lieu of exercising such termination right and upon Kaken's written notice: the amount of any Milestone Payments and the Supply Price applicable to the Licensed Product shall be reduced

by [*]; *provided* that, to the extent Kaken brings an action against KalVista for such material breach and Kaken is awarded damages as a result of such action: (a) the amount of such damages will be reduced by the amount, if any, of any reductions to such Milestone Payments and the Supply Price that Kaken has taken pursuant to this Section 13.3.10 (Alternative Remedy for Termination for Cause) at the time of such damages award; and (b) any reductions to the Milestone Payment and the Supply Price that Kaken is entitled to take pursuant to this Section 13.3.10 (Alternative Remedy for Termination for Cause) following such damages award shall be reduced by the amount, if any, of the awarded damages paid to Kaken as a result of such action.

13.4. **Survival**. Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, the following provisions of this Agreement will survive the expiration or termination of this Agreement: [*].

13.5. **Termination Not Sole Remedy**. Termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding anything to the contrary set forth in this Agreement, all other remedies will remain available except as expressly set forth herein.

Article 14
DISPUTE RESOLUTION

14.1. **General**. The Parties recognize that a dispute may arise relating to this Agreement, including matters that may involve the Affiliates of any Party (a "**Dispute**"). Except as otherwise expressly set forth in this Agreement, any Dispute other than matters subject to resolution under Article 3 (Governance), will be resolved in accordance with this Article 14 (Dispute Resolution).

14.2. **Negotiation; Escalation**. The Parties will negotiate in good faith [*] to settle any Dispute under this Agreement. Any Dispute as to the breach, enforcement, interpretation, or validity of this Agreement will be referred to the Executive Officers for attempted resolution. If the Executive Officers are unable to resolve such Dispute within [*] after such Dispute is referred to them, then, upon the written request of either Party to the other Party, other than a Dispute relating to the scope, validity, enforceability, or infringement of any Patent Rights or trademark rights (which will be submitted for resolution to a court of competent jurisdiction in the country or region in which such Patent Rights or trademark rights were granted or arose), the Dispute will be subject to arbitration process in accordance with Section 14.3 (Arbitration).

14.3. **Arbitration**. [*].

14.4. **Injunctive Relief**. Notwithstanding the foregoing, in the event of an actual or threatened breach hereunder, the aggrieved Party may seek equitable relief (including restraining orders, specific performance or other injunctive relief) in any court or other forum, without first submitting to the dispute resolution procedures set forth in Section 14.2 (Negotiation; Escalation).

14.5. **Confidentiality**. Any and all activities conducted under this Article 14 (Dispute Resolution), including any and all non-public proceedings and decisions under Section 14.3 (Arbitration), will be the Confidential Information of each of the Parties, and will be subject to the terms of Article 9 (Confidentiality; Publication).

Article 15
MISCELLANEOUS

15.1. **Assignment**. This Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the prior written consent of the other Party. Notwithstanding any provision to the contrary set forth in this Agreement, KalVista may assign its rights to receive payments under this Agreement to one or more Royalty Monetization Partners without the consent of Kaken (including as part of a royalty monetization transaction), and either Party may, without consent of the other Party, assign this Agreement and its rights and obligations hereunder (a) in whole or in part to an Affiliate of such Party, or (b) in whole to its successor-in-interest in connection with the sale or other transfer of all or substantially all of its assets to which this Agreement relates, whether in a merger, acquisition, exclusive license, or similar transaction or series of related transactions. Any attempted assignment of this Agreement not in accordance with this Section 15.1 (Assignment) will be null, void, and of no legal effect. Any permitted assignee will assume all assigned obligations of its assignor under this Agreement. The terms of this Agreement will be binding upon, and will inure to the benefit of, the Parties and their respected successors and permitted assigns.

15.2. **LIMITATION OF LIABILITY**. [*], IN EACH CASE, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 15.2 (LIMITATION OF LIABILITY) IS INTENDED TO OR WILL LIMIT OR RESTRICT [*] (A) [*] (B) [*] (C) A CLAIM FOR FRAUD, GROSS NEGLIGENCE, OR WILLFUL MISCONDUCT.

15.3. **Severability**. If any one or more of the provisions contained in this Agreement is held invalid, illegal, or unenforceable in any respect, then the validity, legality, and enforceability of the remaining provisions contained herein will not in any way be affected or impaired thereby, unless the absence of the invalidated provisions adversely affects the substantive rights of the Parties. The Parties will in such an instance use their best efforts to replace the invalid, illegal, or unenforceable provisions with valid, legal, and enforceable provisions that, insofar as practical, implement the purposes of this Agreement.

15.4. **Notices**. All notices that are required or permitted hereunder will be in writing and sufficient if delivered by internationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, and in each case, addressed as follows (with a courtesy copy sent by email, which will not constitute notice):

If to KalVista:

KalVista Pharmaceuticals, Ltd.
Porton Science Park, Bybrook Road, Porton Down, Wiltshire, SP4 0BF, United Kingdom
Attention: [*], Chief Executive Officer

with a copy to:

KalVista Pharmaceuticals, Inc.
55 Cambridge Parkway, Suite 901E Cambridge, MA 02141, USA
Attention: [*], General Counsel
Email: [*]

with a copy to (which will not constitute notice):

Ropes & Gray LLP
800 Boylston Street; Prudential Tower
Boston, MA 02199
Attention: [*]
Email: [*]

If to Kaken:

Kaken Pharmaceutical Co., Ltd.
20th Floor, Bunkyo Green Court
28-8, Honkomagome 2-chome, Bunkyo-ku
Tokyo 113-8650, Japan
Attention: General Manager, Head of Business Development
E-mail: [*]
Tel: [*]

with a copy to:
Atsumi & Sakai
Fukoku Seimei Bldg. (Reception :16th Floor)
2-2, Uchisaiwaicho 2-chome, Chiyoda-ku
Tokyo 100-0011, Japan
Attention: [*]
E-mail: [*]
Tel: [*]

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given: (a) on the Business Day after dispatch if sent by internationally-recognized overnight courier; or (b) on the fifth (5^{th}) Business Day after dispatch if sent by registered or certified mail, postage prepaid, return receipt requested.

15.5. **Governing Law**. This Agreement, including any ancillary agreements, and all claims or causes of action (whether in contract, tort or statute) that may be based upon, arise out of or relate to this Agreement, or the negotiation, execution or performance of this Agreement or the breach thereof (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in or in connection with this Agreement or as an inducement to enter into this Agreement), will be governed by, and enforced in accordance with, the internal laws of the State of New York, including its statutes of limitations without giving effect to the conflicts of law provisions thereunder.

15.6. **Force Majeure**. Both Parties will be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party (other than obligations to make payments hereunder). Such excuse will continue only so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. When the force majeure no longer exists, the affected Party must promptly resume performance. For purposes of this Agreement, force majeure will include conditions beyond the reasonable control of the non-performing Party, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, pandemic, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake,

storm or like catastrophe, failure of plant or machinery and act (or failure to act) of a government of any country or of any Governmental Authority (other than as a result of the non-performing Party's failure to comply with Applicable Law). Notwithstanding any provision to the contrary set forth in this Agreement, a Party will not be excused from making payments owed hereunder because of a force majeure affecting such Party.

15.7. **Entire Agreement; Amendments**. This Agreement, together with the Schedules hereto, contains the entire understanding of the Parties with respect to the licenses granted hereunder. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the licenses granted hereunder are superseded by the terms of this Agreement. The Schedules to this Agreement are incorporated herein by reference and will be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of each Party. The foregoing will not be interpreted as a waiver of any remedies available to either Party or its Affiliates as a result of any breach, prior to the Effective Date, by the other Party or its Affiliates of such Party's or its Affiliate's obligations pursuant to the Nondisclosure Agreement.

15.8. **Headings**. The captions to the several Article**s**, Sections, and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections of this Agreement.

15.9. **Independent Contractors**. It is expressly agreed that KalVista and Kaken will be independent contractors and that the relationship between the two (2) Parties will not constitute a partnership, joint venture or agency. Neither KalVista nor Kaken will have the authority to make any statements, representations, or commitments of any kind, or to take any action that is binding on the other Party without the prior written consent of the other Party.

15.10. **Performance by Affiliates**. Notwithstanding any provision to the contrary set forth in this Agreement, either Party will have the right to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any Affiliate. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance.

15.11. **Waiver**. Any waiver of any provision of this Agreement will be effective only if in writing and signed by KalVista and Kaken. No express or implied waiver by a Party of any default under this Agreement will be a waiver of a future or subsequent default. The failure or delay of any Party in exercising any rights under this Agreement will not constitute a waiver of any such right, and any single or partial exercise of any particular right by any Party will not exhaust the same or constitute a waiver of any other right provided in this Agreement.

15.12. **Waiver of Rule of Construction**. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement will be construed against the drafting Party will not apply.

15.13. **Cumulative Remedies**. No remedy referred to in this Agreement is intended to be exclusive, but each will be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Applicable Law.

15.14. **Business Day Requirements**. If any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a Business Day, then such notice or other action or omission will be deemed to be required to be taken on the next occurring Business Day.

15.15. **Further Actions**. Each Party agrees to execute, acknowledge, and deliver such further instruments, and to do all such other acts, as necessary or appropriate in order to carry out the purposes and intent of this Agreement.

15.16. **Construction**. Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words "include," "includes," and "including" will be deemed to be followed by the phrase "without limitation," (c) the word "will" will be construed to have the same meaning and effect as the word "shall," (d) any definition of or reference to any agreement, instrument, or other document herein will be construed as referring to such agreement, instrument, or other document as from time to time amended, supplemented, or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person will be construed to include the person's successors and assigns, (f) the words "herein," "hereof," and "hereunder" and words of similar import, will each be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Articles, Sections, Schedules, or Exhibits will be construed to refer to Articles, Sections, Schedules, or Exhibits of this Agreement, and references to this Agreement include all Schedules hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent," "approve," or the like will require that such agreement, consent, or approval be specific and in writing, whether by written agreement, letter, approved minutes, or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or Section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or."

15.17. **Language; Translations**. This Agreement is in the English language only, which language will be controlling in all respects, and all versions hereof in any other language will be for accommodation only and will not be binding upon the Parties. All communications and notices to be made or given by one Party to the other pursuant to this Agreement, and any dispute proceeding related to or arising hereunder, will be in the English language. If there is a discrepancy between any translation of this Agreement and any non-English translation of this Agreement, this Agreement will prevail. Upon KalVista's request, Kaken will provide all information, data, documents, and other materials to be provided to KalVista under this Agreement in English;

15.18. **Counterparts**. This Agreement may be executed in counterparts, all of which taken together will be regarded as one and the same instrument. Counterparts may be delivered via electronic mail, including Adobe™ Portable Document Format (PDF) or any electronic signature complying with the U.S. Federal ESIGN Act of 2000, and any counterpart so delivered will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

[Remainder of the Page Intentionally Left Blank; Signature Page Follows]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this License, Supply, and Distribution Agreement to be executed by their respective duly authorized representatives as of the Effective Date.

KalVista Pharmaceuticals, Ltd.

By: /s/ Benjamin L. Palleiko

Name: Benjamin L. Palleiko

Title: Chief Executive Officer

Kaken Pharmaceutical Co. Ltd.

By: /s/ Hiroyuki Horiuchi

Name: Hiroyuki Horiuchi

Title: President and Representative Director

[Signature Page to License, Supply, and Distribution Agreement]

Schedule 1.98

Licensed Compound

[*]

Schedule 1.100

Licensed Patent Rights

[*]

Schedule 6.3

Baseball Arbitration

[*]

Schedule 9.7.1

Press Release

KALVISTA PHARMACEUTICALS, INC.

$100,000,000

COMMON STOCK

SALES AGREEMENT

July 10, 2025

TD Securities (USA) LLC
1 Vanderbilt Avenue
New York, New York 10017

Ladies and Gentlemen:

KalVista Pharmaceuticals, Inc. (the "**Company**"), confirms its agreement (this "**Agreement**") with TD Securities (USA) LLC ("**TD Cowen**"), as follows:

1. Issuance and Sale of Shares. The Company agrees that, from time to time during the term of this Agreement, on the terms and subject to the conditions set forth herein, it may issue and sell through TD Cowen, acting as agent and/or principal, shares (the "**Placement Shares**") of the Company's common stock, par value $0.001 per share (the "**Common Stock**"), having an aggregate offering price of up to $100,000,000 (the "**Maximum Amount**"). Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitation set forth in this Section 1 regarding the aggregate sale price of the Placement Shares issued and sold under this Agreement shall be the sole responsibility of the Company, and TD Cowen shall have no obligation in connection with such compliance. The issuance and sale of Common Stock through TD Cowen will be effected pursuant to the Registration Statement (as defined below) filed by the Company and declared effective by the Securities and Exchange Commission (the "**Commission**"), although nothing in this Agreement shall be construed as requiring the Company to use the Registration Statement (as defined below) to issue the Placement Shares. The Company acknowledges and agrees that sales of Placement Shares under this Agreement may be made through affiliates of TD Cowen, and that TD Cowen may otherwise fulfill its obligations pursuant to this Agreement to or through an affiliated broker-dealer.

The Company has filed, in accordance with the provisions of the Securities Act of 1933, as amended, and the rules and regulations thereunder (collectively, the "**Securities Act**"), with the Commission a registration statement on Form S-3 (File No. 333-280759) (the "**Original Registration Statement**"), including a base prospectus, relating to certain securities, including the Placement Shares, to be issued from time to time by the Company, and which incorporates by reference documents that the Company has filed or will file in accordance with the provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (collectively, the "**Exchange Act**"). The Company has prepared a prospectus supplement specifically relating to the Placement Shares (the "**Prospectus Supplement**") to the base prospectus included as part of the Original Registration Statement. The Company will furnish to

TD Cowen, for use by TD Cowen, copies of the prospectus included as part of such registration statement, as supplemented by the Prospectus Supplement, relating to the Placement Shares. Except where the context otherwise requires, such registration statement, and any post-effective amendment thereto, as amended when it became effective, including all documents filed as part thereof or incorporated by reference therein, and including any information contained in a Prospectus (as defined below) subsequently filed with the Commission pursuant to Rule 424(b) under the Securities Act or deemed to be a part of such registration statement pursuant to Rule 430B or 462(b) of the Securities Act, or any subsequent registration statement on Form S-3 filed pursuant to Rule 415(a)(6) under the Securities Act by the Company with respect to the Placement Shares, is herein called the "**Registration Statement.**" Any registration statement and amendments thereto filed pursuant to Rule 462(b) of the Securities Act and relating to the offering covered by the Registration Statement is herein called a "**Rule 462(b) Registration Statement**" and, after such filing, the "Registration Statement" shall include any Rule 462(b) Registration Statement. The base prospectus, including all documents incorporated therein by reference, included in the Registration Statement, as it may be supplemented by the Prospectus Supplement, in the form in which such prospectus and/or Prospectus Supplement have most recently been filed by the Company with the Commission pursuant to Rule 424(b) under the Securities Act, together with any "issuer free writing prospectus," as defined in Rule 433 under the Securities Act ("**Rule 433**"), relating to the Placement Shares that (i) is consented to by TD Cowen, hereinafter referred to as a "**Permitted Free Writing Prospectus,**" (ii) is required to be filed with the Commission by the Company or (iii) is exempt from filing pursuant to Rule 433(d)(5)(i), in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g), is herein called the "**Prospectus**." Any reference herein to the Registration Statement, the Prospectus or any amendment or supplement thereto shall be deemed to refer to and include the documents incorporated by reference therein, and any reference herein to the terms "amend," "amendment" or "supplement" with respect to the Registration Statement or the Prospectus shall be deemed to refer to and include the filing after the execution hereof of any document with the Commission deemed to be incorporated by reference therein. For purposes of this Agreement, all references to the Registration Statement, the Prospectus or to any amendment or supplement thereto shall be deemed to include any copy filed with the Commission pursuant to the Electronic Data Gathering Analysis and Retrieval System ("**EDGAR**").

2. Placements. Each time that the Company wishes to issue and sell the Placement Shares hereunder (each, a "**Placement**"), it will notify TD Cowen by email notice (or other method mutually agreed to in writing by the parties) (a "**Placement Notice**") containing the parameters in accordance with which it desires the Placement Shares to be sold, which shall at a minimum include the number of Placement Shares to be issued, the time period during which sales are requested to be made, any limitation on the number of Placement Shares that may be sold in any one Trading Day (as defined in Section 3) and any minimum price below which sales may not be made, a form of which containing such minimum sales parameters necessary is attached hereto as **Schedule 1**. The Placement Notice shall originate from any of the individuals from the Company set forth on **Schedule 2** (with a copy to each of the other individuals from the Company listed on such schedule), and shall be addressed to each of the individuals from TD Cowen set forth on **Schedule 2**, as such **Schedule 2** may be amended from time to time. The Placement Notice shall be effective upon receipt by TD Cowen unless and until (i) in accordance with the notice requirements set forth in Section 4, TD Cowen declines to accept the terms contained therein for

any reason, in its sole discretion, (ii) the entire amount of the Placement Shares thereunder have been sold, (iii) in accordance with the notice requirements set forth in Section 4, the Company suspends or terminates the Placement Notice, (iv) the Company issues a subsequent Placement Notice with parameters superseding those on the earlier dated Placement Notice, or (v) this Agreement has been terminated under the provisions of Section 11. The amount of any discount, commission or other compensation to be paid by the Company to TD Cowen in connection with the sale of the Placement Shares shall be calculated in accordance with the terms set forth in **Schedule 3.** It is expressly acknowledged and agreed that neither the Company nor TD Cowen will have any obligation whatsoever with respect to a Placement or any Placement Shares unless and until the Company delivers a Placement Notice to TD Cowen and TD Cowen does not decline such Placement Notice pursuant to the terms set forth above, and then only upon the terms specified therein and herein. In the event of a conflict between the terms of this Agreement and the terms of a Placement Notice, the terms of the Placement Notice will control.

3. Sale of Placement Shares by TD Cowen. Subject to the terms and conditions herein set forth, upon the Company's delivery of a Placement Notice, and unless the sale of the Placement Shares described therein has been declined, suspended, or otherwise terminated in accordance with the terms of this Agreement, TD Cowen, for the period specified in the Placement Notice, will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of the Nasdaq Global Market ("**Nasdaq**") to sell such Placement Shares up to the amount specified, and otherwise in accordance with the terms of such Placement Notice. TD Cowen will provide written confirmation to the Company (including by email correspondence to each of the individuals of the Company set forth on **Schedule 2**, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) no later than the opening of the Trading Day (as defined below) immediately following the Trading Day on which it has made sales of Placement Shares hereunder setting forth the number of Placement Shares sold on such day, the compensation payable by the Company to TD Cowen pursuant to Section 2 with respect to such sales, the volume-weighted average price of the Placement Shares sold, and the Net Proceeds (as defined below) payable to the Company, with an itemization of the deductions made by the Agent (as set forth in Section 5(a)) from the gross proceeds that it receives from such sales. In the event the Company engages TD Cowen for a sale of Placement Shares that would constitute a "block" within the meaning of Rule 10b-18(a)(5) under the Exchange Act (a "**Block Sale**"), the Company will provide TD Cowen, at TD Cowen's request and upon reasonable advance notice to the Company, on or prior to the Settlement Date (as defined below), the opinions of counsel, accountant's letter and officers' certificates set forth in Section 8 hereof, each dated the Settlement Date, and such other documents and information as TD Cowen shall reasonably request. TD Cowen may sell Placement Shares in negotiated transactions, including block trades or Block Sales, or by any method permitted by law deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act, including without limitation sales made through Nasdaq or on any other existing trading market for the Common Stock, or by any other method permitted by law, including but not limited to in privately negotiated transactions. TD Cowen shall not purchase Placement Shares for its own account as principal unless expressly authorized to do so by the Company in a Placement Notice. The Company acknowledges and agrees that (i) there can be no assurance that TD Cowen will be successful in selling Placement Shares, and (ii) TD Cowen will incur no liability or obligation to the Company or any other person or entity if it does not sell Placement Shares for any reason other than a failure by TD Cowen to use its commercially

reasonable efforts consistent with its normal trading and sales practices to sell such Placement Shares as required under this Section 3. For the purposes hereof, "**Trading Day**" means any day on which shares of the Company's Common Stock is purchased and sold on Nasdaq.

Notwithstanding any other provision of this Agreement, the Company shall not offer, sell or deliver, or request the offer or sale, of any Placement Shares pursuant to this Agreement and, by notice to TD Cowen given by telephone (confirmed promptly by email), shall cancel any instructions for the offer or sale of any Placement Shares, and TD Cowen shall not be obligated to offer or sell any Placement Shares, (i) during any period in which the Company is, or could be deemed to be, in possession of material non-public information, or (ii) at any time from and including the date on which the Company shall issue a press release containing, or shall otherwise publicly announce, its earnings, revenues or other results of operations (an "**Earnings Announcement**") through and including the time that the Company files a Quarterly Report on Form 10-Q or an Annual Report on Form 10-K that includes consolidated financial statements as of and for the same period or periods, as the case may be, covered by such Earnings Announcement.

4. Suspension of Sales.

(a) The Company or TD Cowen may, upon notice to the other party in writing (including by email correspondence to each of the individuals of the other party set forth on **Schedule 2**, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) or by telephone (confirmed immediately by verifiable facsimile transmission or email correspondence to each of the individuals of the other party set forth on **Schedule 2**), suspend any sale of Placement Shares (a "**Suspension**"); *provided, however*, that such Suspension shall not affect or impair either party's obligations with respect to any Placement Shares sold hereunder prior to the receipt of such notice. While a Suspension is in effect, any obligation under Sections 7(m), 7(n), 7(o) and 7(p) with respect to the delivery of certificates, opinions, or comfort letters to the Agent, shall be waived. Each of the parties agrees that no such notice under this Section 4 shall be effective against the other unless it is made to one of the individuals named on **Schedule 2** hereto, as such schedule may be amended from time to time.

(b) If either TD Cowen or the Company has reason to believe that the exemptive provisions set forth in Rule 101(c)(1) of Regulation M under the Exchange Act are not satisfied with respect to the Common Stock, it shall promptly notify the other party, and sales of the Placement Shares under this Agreement shall be suspended until that or other exemptive provisions have been satisfied in the judgment of each party.

(c) The Registration Statement was declared effective on July 19, 2024. Notwithstanding any other provision of this Agreement, during any period in which the Registration Statement (including any Rule 462(b) Registration Statement) is no longer effective under the Securities Act, the Company shall promptly notify TD Cowen, the Company shall not request the sale of any Placement Shares, and TD Cowen shall not be obligated to sell or offer to sell any Placement Shares.

5. Settlement.

(a) Settlement of Placement Shares. Unless otherwise specified in the applicable Placement Notice, settlement for sales of Placement Shares will occur on the first (1st) Trading Day following the date on which such sales are made (each, a "**Settlement Date**" and the first such settlement date, the "**First Delivery Date**"). The amount of proceeds to be delivered to the Company on a Settlement Date against receipt of the Placement Shares sold (the "**Net Proceeds**") will be equal to the aggregate sales price received by TD Cowen at which such Placement Shares were sold, after deduction for (i) TD Cowen's commission, discount or other compensation for such sales payable by the Company pursuant to Section 2 hereof, (ii) any other amounts due and payable by the Company to TD Cowen hereunder pursuant to Section 7(g) (Expenses) hereof, and (iii) any transaction fees imposed by any governmental or self-regulatory organization in respect of such sales.

(b) Delivery of Placement Shares. On or before each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Placement Shares being sold by crediting TD Cowen's or its designee's account (provided TD Cowen shall have given the Company written notice of such designee prior to the Settlement Date) at The Depository Trust Company through its Deposit and Withdrawal at Custodian System or by such other means of delivery as may be mutually agreed upon by the parties hereto which in all cases shall be freely tradeable, transferable, registered shares in good deliverable form. On each Settlement Date, TD Cowen will deliver the related Net Proceeds in same day funds to an account designated by the Company on, or prior to, the Settlement Date. The Company agrees that if the Company, or its transfer agent (if applicable), defaults in its obligation to deliver duly authorized Placement Shares on a Settlement Date, the Company agrees that in addition to and in no way limiting the rights and obligations set forth in Section 9(a) (Indemnification and Contribution) hereto, it will (i) hold TD Cowen harmless against any loss, claim, damage, or expense (including reasonable legal fees and expenses), as incurred, arising out of or in connection with such default by the Company and (ii) pay to TD Cowen any commission, discount, or other compensation to which it would otherwise have been entitled absent such default.

6. Representations and Warranties of the Company. The Company represents and warrants to, and agrees with, TD Cowen that as of (i) the date of this Agreement, (ii) each Time of Sale (as defined below), (iii) each Settlement Date, and (iv) each Bring-Down Date (as defined below) (each date included in (i) through (iv), a "**Representation Date**"):

(a) Compliance with Registration Requirements. The Registration Statement was declared effective by the Commission under the Securities Act and any Rule 462(b) Registration Statement will have become effective automatically upon filing under the Securities Act. The Company has complied to the Commission's satisfaction with all requests of the Commission for additional or supplemental information. No stop order suspending the effectiveness of the Registration Statement or any Rule 462(b) Registration Statement is in effect and no proceedings for such purpose have been instituted or are pending or, to the knowledge of the Company, are contemplated or threatened by the Commission. The Company meets the requirements for use of Form S-3 under the Securities Act. The sale of the Placement Shares hereunder meets the requirements of General Instruction I.B.1 of Form S-3. Compliance with any limitation set forth by General Instruction I.B.6 of Form S-3 is the sole responsibility of the Company and TD Cowen shall have no obligation in connection with such compliance.

(b) No Misstatement or Omission. The Prospectus when filed complied and, as amended or supplemented, if applicable, will comply in all material respects with the Securities Act. Each of the Registration Statement, any Rule 462(b) Registration Statement, the Prospectus and any post-effective amendments or supplements thereto, at the time it became effective or its date, as applicable, complied and as of each Representation Date, complied and will comply in all material respects with the Securities Act and did not and, as of each Representation Date, did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. The Prospectus, as amended or supplemented, as of its date, did not and, as of each Representation Date, will not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the two immediately preceding sentences do not apply to statements in or omissions from the Registration Statement, any Rule 462(b) Registration Statement, or any post-effective amendment thereto, or the Prospectus, or any amendments or supplements thereto, made in reliance upon and in conformity with information relating to Agent's Information (as defined below). There are no contracts or other documents required to be described in the Prospectus or to be filed as exhibits to the Registration Statement which have not been described or filed as required. As used herein, "**Time of Sale**" means with respect to each offering of Placement Shares pursuant to this Agreement, the time of TD Cowen's initial entry into contracts with purchasers for the sale of such Placement Shares.

(c) Offering Materials Furnished to TD Cowen. The Company has delivered to TD Cowen one complete copy of the Registration Statement and a copy of each consent and certificate of experts filed as a part thereof, and conformed copies of the Registration Statement (without exhibits) and the Prospectus, as amended or supplemented, in such quantities and at such places as TD Cowen has reasonably requested. The Registration Statement, the Prospectus and any Permitted Free Writing Prospectus (to the extent any such Permitted Free Writing Prospectus was required to be filed with the Commission) delivered to TD Cowen for use in connection with the public offering of the Placement Shares contemplated herein have been and will be identical to the versions of such documents transmitted to the Commission for filing via EDGAR, except to the extent permitted by Regulation S-T.

(d) Not an Ineligible Issuer. At each of (A) the time of filing of the Registration Statement, (B) the time specified in Rules 164 and 433 under the Securities Act and (C) the date hereof, the Company was not and is not an "ineligible issuer," as defined in Rule 405 under the Securities Act.

(e) Distribution of Offering Material By the Company. Prior to the completion of the TD Cowen's distribution of the Placement Shares, the Company has not distributed and will not distribute any offering material in connection with the offering and sale of the Placement Shares other than the Registration Statement or the Prospectus.

(f) The Sales Agreement. This Agreement has been duly authorized, executed and delivered by, and is a valid and binding agreement of, the Company, enforceable in accordance with its terms, except as rights to indemnification hereunder may be limited by applicable law and except as the enforcement hereof may be limited by bankruptcy, insolvency, reorganization moratorium or other similar laws relating to or affecting the rights and remedies of creditors or by general equitable principles.

(g) Authorization of the Placement Shares. The Placement Shares have been duly authorized for issuance and sale pursuant to this Agreement and, when issued and delivered by the Company against payment therefor pursuant to this Agreement, will be validly issued, fully paid and nonassessable, and the issuance and sale of the Placement Shares are not subject to any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase the Placement Shares.

(h) No Applicable Registration or Other Similar Rights. There are no persons with registration or other similar rights to have any equity or debt securities registered for sale under the Registration Statement or included in the offering contemplated by this Agreement, except for such rights as have been duly waived.

(i) No Material Adverse Change. Except as otherwise disclosed in the Prospectus, subsequent to the respective dates as of which information is given in the Prospectus: (i) there has been no material adverse change, or any development that would reasonably be expected to result in a material adverse change, in (A) the condition, financial or otherwise, or in the earnings, business, properties, operations, operating results, assets, liabilities or prospects, whether or not arising from transactions in the ordinary course of business, of the Company and its subsidiaries, considered as one entity or (B) the ability of the Company to consummate the transactions contemplated by this Agreement or perform its obligations hereunder (any such change being referred to herein as a "**Material Adverse Change**"); (ii) the Company and its subsidiaries, considered as one entity, have not incurred any material liability or obligation, indirect, direct or contingent, including without limitation any losses or interference with their business from fire, explosion, flood, earthquakes, accident or other calamity, whether or not covered by insurance, or from any strike, labor dispute or court or governmental action, order or decree, that are material, individually or in the aggregate, to the Company and its subsidiaries, considered as one entity, and have not entered into any transactions not in the ordinary course of business; and (iii) there has not been any material decrease in the capital stock or any material increase in any short-term or long-term indebtedness of the Company or its subsidiaries and there has been no dividend or distribution of any kind declared, paid or made by the Company or, except for dividends paid to the Company or other subsidiaries, by any of the Company's subsidiaries on any class of capital stock, or any repurchase or redemption by the Company or any of its subsidiaries of any class of capital stock.

(j) Independent Accountants. Deloitte & Touche LLP, which have certified the financial statements (which term as used in this Agreement includes the related notes thereto) and supporting schedules filed with the Commission or incorporated by reference as a part of the Registration Statement, and included in the Prospectus, are (i) an independent registered public accounting firm as required by the Securities Act, the Exchange Act, and the rules of the Public Company Accounting Oversight Board ("**PCAOB**"), (ii) in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X under the Securities Act and (iii) registered public accounting firms as defined by the PCAOB whose registration has not been suspended or revoked and who have not requested such registration to be withdrawn.

(k) Financial Statements. The financial statements filed with the Commission as a part of or incorporated by reference in the Registration Statement and the Prospectus present fairly the consolidated financial position of the Company and its subsidiaries as of the dates indicated and the results of their operations, changes in stockholders' equity and cash flows for the periods

specified. The supporting schedules included in or incorporated in the Registration Statement present fairly the information required to be stated therein. Such financial statements and supporting schedules have been prepared in conformity with generally accepted accounting principles as applied in the United States ("**GAAP**") applied on a consistent basis throughout the periods involved, except as may be expressly stated in the related notes thereto. The interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto. No other financial statements or supporting schedules are required to be included in or incorporated in the Registration Statement or the Prospectus. The financial data set forth in or incorporated by reference into each of the Registration Statement and the Prospectus fairly present, in all material respects, the information set forth therein on a basis consistent with that of the audited financial statements contained, incorporated or deemed to be incorporated in the Registration Statement and the Prospectus. All disclosures contained in the Registration Statement and the Prospectus that constitute non-GAAP financial measures (as defined by the rules and regulations under the Securities Act and the Exchange Act) comply with Regulation G under the Exchange Act and Item 10 of Regulation S-K under the Securities Act, as applicable. To the Company's knowledge, no person who has been suspended or barred from being associated with a registered public accounting firm, or who has failed to comply with any sanction pursuant to Rule 5300 promulgated by the PCAOB, has participated in or otherwise aided the preparation of, or audited, the financial statements, supporting schedules or other financial data filed with the Commission as a part of the Registration Statement and the Prospectus.

(l) Company's Accounting System. The Company and each of its subsidiaries make and keep accurate books and records and maintain a system of internal accounting controls designed to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary to permit preparation of the Company's financial statements in conformity with GAAP and to maintain accountability for assets; (iii) access to the Company's assets is permitted only in accordance with management's general or specific authorization; (iv) the recorded accountability for the Company's assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences; and (v) the interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement and the Prospectus fairly presents the information called for in all material respects and is prepared in accordance with the Commission's rules and guidelines applicable thereto.

(m) Disclosure Controls and Procedures; Deficiencies in or Changes to Internal Control Over Financial Reporting. The Company has established and maintains disclosure controls and procedures (as defined in Rules 13a-15 and 15d-15 under the Exchange Act), which (i) are designed to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to the Company's principal executive officer and its principal financial officer by others within those entities; (ii) have been evaluated by management of the Company for effectiveness as of the end of the Company's most recent fiscal quarter; and (iii) are effective in all material respects to perform the functions for which they were established. Since the end of the Company's most recent audited fiscal year, there have been no significant deficiencies or material weakness in the Company's internal control over financial reporting (whether or not remediated) and no change in the Company's internal control over financial

reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. The Company is not aware of any change in its internal control over financial reporting that has occurred during its most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

(n) Compliance with the Sarbanes-Oxley Act. There is and has been no failure on the part of the Company or any of the Company's directors or officers, in their capacities as such, to comply in all material respects with any applicable provision of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith, including Section 402 related to loans and Sections 302 and 906 related to certifications.

(o) Incorporation and Good Standing of the Company. The Company has been duly incorporated and is validly existing as a corporation in good standing under the laws of the jurisdiction of its incorporation and has the corporate power and authority to own, lease and operate its properties and to conduct its business as described in the Registration Statement and the Prospectus and to enter into and perform its obligations under this Agreement. The Company is duly qualified as a foreign corporation to transact business and is in good standing in the Commonwealth of Massachusetts and each other jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure to so qualify or to be in good standing would not reasonably be expected, individually or in the aggregate, to have a material adverse effect on the condition (financial or other), earnings, business, properties, operations, assets, liabilities or prospects of the Company and its subsidiaries, considered as one entity (a "**Material Adverse Effect**").

(p) Subsidiaries. Each of the Company's "subsidiaries" (for purposes of this Agreement, as defined in Rule 405 under the Securities Act) has been duly incorporated or organized, as the case may be, and is validly existing as a corporation, partnership or limited liability company, as applicable, in good standing under the laws of the jurisdiction of its incorporation or organization and has the power and authority (corporate or other) to own, lease and operate its properties and to conduct its business as described in the Registration Statement and the Prospectus. Each of the Company's subsidiaries is duly qualified as a foreign corporation, partnership or limited liability company, as applicable, to transact business and is in good standing in each jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure to so qualify or to be in good standing would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. All of the issued and outstanding capital stock or other equity or ownership interests of each of the Company's subsidiaries have been duly authorized and validly issued, are fully paid and nonassessable and are owned by the Company, directly or through subsidiaries, free and clear of any security interest, mortgage, pledge, lien, encumbrance or adverse claim. The Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed in Exhibit 21 to the Annual Report and incorporated by reference into the Annual Report.

(q) Capitalization and Other Capital Stock Matters. The Common Stock conforms in all material respects to the description thereof contained in the Prospectus. All of the issued and outstanding shares of Common Stock have been duly authorized and validly issued, are fully paid and nonassessable and have been issued in compliance with all federal and state securities laws.

None of the outstanding shares of Common Stock was issued in violation of any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase securities of the Company. There are no authorized or outstanding options, warrants, preemptive rights, rights of first refusal or other rights to purchase, or equity or debt securities convertible into or exchangeable or exercisable for, any capital stock of the Company or any of its subsidiaries other than those described in the Prospectus. The descriptions of the Company's stock option, stock bonus and other stock plans or arrangements, and the options or other rights granted thereunder, set forth in the Registration Statement and the Prospectus accurately and fairly presents in all material respects the information required to be shown with respect to such plans, arrangements, options and rights.

(r) Stock Exchange Listing. The Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act and are listed on Nasdaq, and the Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from Nasdaq, nor has the Company received any notification that the Commission or Nasdaq is contemplating terminating such registration or listing. To the Company's knowledge, it is in compliance with all applicable listing requirements of Nasdaq.

(s) Non-Contravention of Existing Instruments; No Further Authorizations or Approvals Required. Neither the Company nor any of its subsidiaries is in violation of its charter or by-laws, partnership agreement or operating agreement or similar organizational documents, as applicable, or is in default (or, with the giving of notice or lapse of time, would be in default) ("**Default**") under any indenture, loan, credit agreement, note, lease, license agreement, contract, franchise or other instrument (including, without limitation, any pledge agreement, security agreement, mortgage or other instrument or agreement evidencing, guaranteeing, securing or relating to indebtedness) to which the Company or any of its subsidiaries is a party or by which it or any of them may be bound, or to which any of their respective properties or assets are subject (each, an "**Existing Instrument**"), except for such Defaults as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. The Company's execution, delivery and performance of this Agreement, and consummation of the transactions contemplated hereby and the fulfillment of the terms hereof or thereof and by the Registration Statement and the Prospectus and the issuance and sale of the Placement Shares (i) have been duly authorized by all necessary corporate action and will not result in any violation of the provisions of the charter or by-laws, partnership agreement or operating agreement or similar organizational documents, as applicable, of the Company or any subsidiary (ii) will not conflict with or constitute a breach of, or Default or a Debt Repayment Triggering Event (as defined below) under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company or any of its subsidiaries pursuant to, or require the consent of any other party to, any Existing Instrument and (iii) will not result in any violation of any law, administrative regulation or administrative or court decree applicable to the Company or any of its subsidiaries, except for such conflicts, breaches, Defaults, Debt Repayment Triggering Event, liens, charges, encumbrances or violations specified in clauses (ii) and (iii) as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. To the Company's knowledge, no consent, approval, authorization or other order of, or registration or filing with, any court or other governmental or regulatory authority or agency, is required for the Company's execution, delivery and performance of this Agreement and consummation of the transactions contemplated hereby and by the Registration Statement and the Prospectus, except such as have been obtained or made

by the Company and are in full force and effect under the Securities Act and such as may be required under applicable state securities or blue sky laws or the Financial Industry Regulatory Authority ("**FINRA**"). As used herein, a "**Debt Repayment Triggering Event**" means any event or condition which gives, or with the giving of notice or lapse of time would give, the holder of any note, debenture or other evidence of indebtedness (or any person acting on such holder's behalf) the right to require the repurchase, redemption or repayment of all or a portion of such indebtedness by the Company or any of its subsidiaries.

(t) Compliance with Laws. The Company and its subsidiaries have been and are in compliance with all applicable laws, rules and regulations, except where failure to be so in compliance would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.

(u) Compliance with Health Care Laws. The Company has operated at all relevant times and currently is in compliance with all applicable health care laws, rules and regulations, including, without limitation, (i) the Federal, Food, Drug and Cosmetic Act (21 U.S.C. §§ 301 et seq.) and the Public Health Service Act (42 U.S.C. §201 et seq.); (ii) all applicable federal, state, local and all applicable foreign healthcare related fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)), the U.S. Physician Payments Sunshine Act (42 U.S.C. § 1320a-7h), the civil False Claims Act (31 U.S.C. §§ 3729 et seq.), the criminal False Claims Law (42 U.S.C. § 1320a-7b(a)), all criminal laws relating to healthcare fraud and abuse, including but not limited to 18 U.S.C. Sections 286 and 287, the healthcare fraud criminal provisions under the U.S. Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**") (42 U.S.C. Section 1320d et seq.), the exclusion laws (42 U.S.C. § 1320a-7), and the civil monetary penalties law (42 U.S.C. § 1320a-7a); (iii) any applicable provisions of HIPAA, as amended by the Health Information Technology for Economic Clinical Health Act (42 U.S.C. Section 17921 et seq.); (iv) the regulations promulgated pursuant to such laws; (v) any and all any and all other applicable health care laws, rules, and regulations applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, advertising, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product manufactured, distributed, or under development by the Company, and (vi) any other similar local, state, federal, or foreign laws (collectively, the "**Health Care Laws**"), except where failure to be so in compliance would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. Neither the Company, nor, to the Company's knowledge, any of its officers, directors, employees or agents have engaged in activities which are, as applicable, cause for false claims liability, civil penalties, or mandatory or permissive exclusion from Medicare, Medicaid, or any other state or federal healthcare program. The Company has not received written notice or other correspondence of any claim, action, suit, audit, survey, proceeding, hearing, enforcement, investigation, arbitration or other action from any court or arbitrator or governmental or regulatory authority or third party alleging that any product operation or activity is in violation of any Health Care Laws, and, to the Company's knowledge, no such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action is threatened. The Company is not a party to and does not have any ongoing reporting obligations pursuant to any corporate integrity agreement, deferred prosecution agreement, monitoring agreement, consent decree, settlement order, plan of correction or similar agreement imposed by any governmental or regulatory authority. Additionally, neither the Company, nor any of its employees, officers, directors, employees or agents, has been excluded, suspended or debarred

from participation in any U.S. state or federal health care program or human clinical research or is subject to a governmental inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in debarment, suspension, or exclusion. The Company has filed, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Health Care Laws, and all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and accurate on the date filed in all material respects (or were corrected or supplemented by a subsequent submission);

(v) No Material Actions or Proceedings. There is no action, suit, proceeding, inquiry or investigation brought by or before any legal or governmental entity now pending or, to the knowledge of the Company, threatened, against or affecting the Company or any of its subsidiaries, which would reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect or materially and adversely affect the consummation of the transactions contemplated by this Agreement or the performance by the Company of its obligations hereunder; and the aggregate of all pending legal or governmental proceedings to which the Company or any such subsidiary is a party or of which any of their respective properties or assets is the subject, including ordinary routine litigation incidental to the business, if determined adversely to the Company, would not reasonably be expected to have a Material Adverse Effect. No material labor dispute with the employees of the Company or any of its subsidiaries, or with the employees of any principal supplier, manufacturer, customer or contractor of the Company, exists or, to the knowledge of the Company, is threatened or imminent, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its or any subsidiary's principal suppliers, manufacturers, customers or contractors, which, in either case, would result in a Material Adverse Effect.

(w) Intellectual Property Rights. The Company and its subsidiaries own, or have obtained valid and enforceable licenses for, the inventions, patent applications, patents, trademarks, trade names, service names, copyrights, trade secrets and other intellectual property described in the Registration Statement and the Prospectus as being owned or licensed by them or which are necessary for the conduct of their respective businesses as currently conducted or as currently proposed to be conducted (collectively, "**Intellectual Property**"). To the Company's knowledge: (i) there are no third parties who have rights to any Intellectual Property, except for customary reversionary rights of third-party licensors with respect to Intellectual Property that is disclosed in the Registration Statement and the Prospectus as licensed to the Company or one or more of its subsidiaries; and (ii) there is no infringement by third parties of any Intellectual Property. There is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others: (A) challenging the Company's or any of its subsidiaries' rights in or to any Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; (B) challenging the validity, enforceability or scope of any Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; or (C) asserting that the Company or any of its subsidiaries infringes or otherwise violates, or would, upon the commercialization of any product or service described in the Registration Statement or the Prospectus as under development, infringe or violate, any patent, trademark, trade name, service name, copyright, trade secret or other proprietary rights of others, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim. The Company and its

subsidiaries have complied with the terms of each agreement pursuant to which Intellectual Property has been licensed to the Company or any subsidiary, and all such agreements are in full force and effect. The product candidates described in the Registration Statement and the Prospectus as under development by the Company or any subsidiary fall within the scope of the claims of one or more patents owned by, or exclusively licensed to, the Company or any subsidiary.

(x) All Necessary Permits, etc. The Company and its subsidiaries possess such valid and current material certificates, authorizations or permits required by state, federal or foreign regulatory agencies or bodies to conduct their respective businesses as currently conducted and as described in the Registration Statement or the Prospectus ("**Permits**"). Neither the Company nor any of its subsidiaries is in violation of, or in default under, any of the Permits or has received any notice of proceedings relating to the revocation or modification of, or non-compliance with, any such Permit.

(y) Title to Properties. The Company and its subsidiaries have good and marketable title to all of the real and personal property and other assets reflected as owned in the financial statements referred to in Section 6(i) above (or elsewhere in the Registration Statement or the Prospectus), in each case free and clear of any security interests, mortgages, liens, encumbrances, equities, adverse claims and other defects except as would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Effect. The real property, improvements, equipment and personal property held under lease by the Company or any of its subsidiaries are held under valid and enforceable leases, with such exceptions as are not material and do not materially interfere with the use made or proposed to be made of such real property, improvements, equipment or personal property by the Company or such subsidiary.

(z) Tax Law Compliance. The Company and its subsidiaries have filed all necessary federal, state and foreign income and franchise tax returns or have properly requested extensions thereof and have paid all taxes required to be paid by any of them and, if due and payable, any related or similar assessment, fine or penalty levied against any of them except as may be being contested in good faith and by appropriate proceedings. The Company has made adequate charges, accruals and reserves in the applicable financial statements referred to in Section 6(i) above in respect of all federal, state and foreign income and franchise taxes for all periods as to which the tax liability of the Company or any of its subsidiaries has not been finally determined.

(aa) Stock Transfer Taxes. All stock transfer or other taxes (other than income taxes) which are required to be paid by the Company in connection with the sale and transfer of the Placement Shares to be sold hereunder will be, or will have been, fully paid by the Company and all laws imposing such taxes will be or will have been fully complied with in all material respects.

(bb) Insurance. Each of the Company and its subsidiaries are insured by recognized, financially sound and reputable institutions with policies in such amounts and with such deductibles and covering such risks as are, in the reasonable judgment of the Company, generally deemed adequate and customary for their businesses including, but not limited to, policies covering real and personal property owned or leased by the Company and its subsidiaries against theft, damage, destruction, acts of vandalism and earthquakes and policies covering the Company and its subsidiaries for product liability claims and clinical trial liability claims. The Company has no reason to believe that it or any of its subsidiaries will not be able (i) to renew its existing insurance coverage as and when such policies expire or (ii) to obtain comparable coverage from similar

institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not reasonably be expected to have a Material Adverse Effect. Neither the Company nor any of its subsidiaries has been denied any insurance coverage which it has sought or for which it has applied.

(cc) Compliance with Environmental Laws. Except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect: (i) neither the Company nor any of its subsidiaries is in violation of any federal, state, local or foreign statute, law, rule, regulation, ordinance, code, policy or rule of common law or any judicial or administrative interpretation thereof, including any judicial or administrative order, consent, decree or judgment, relating to pollution or protection of human health, the environment (including, without limitation, ambient air, surface water, groundwater, land surface or subsurface strata) or wildlife, including, without limitation, laws and regulations relating to the release or threatened release of chemicals, pollutants, contaminants, wastes, toxic substances, hazardous substances, petroleum or petroleum products (collectively, "**Hazardous Materials**") or to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials (collectively, "**Environmental Laws**"); (ii) the Company and its subsidiaries have all permits, authorizations and approvals required under any applicable Environmental Laws and are each in compliance with their requirements; (iii) there are no pending or, to the Company's knowledge, threatened administrative, regulatory or judicial actions, suits, demands, demand letters, claims, liens, notices of noncompliance or violation, investigation or proceedings relating to any Environmental Law against the Company or any of its subsidiaries; and (iv) to the Company's knowledge, there are no events or circumstances that would reasonably be expected to form the basis of an order for clean-up or remediation, or an action, suit or proceeding by any private party or governmental body or agency, against or affecting the Company or any of its subsidiaries relating to Hazardous Materials or any Environmental Laws.

(dd) ERISA Compliance. The Company and its subsidiaries and any "employee benefit plan" (as defined under the Employee Retirement Income Security Act of 1974, as amended, and the regulations and published interpretations thereunder (collectively, "**ERISA**")) established or maintained by the Company, its subsidiaries or their "ERISA Affiliates" (as defined below) are in compliance in all material respects with ERISA. "**ERISA Affiliate**" means, with respect to the Company or any of its subsidiaries, any member of any group of organizations described in Sections 414(b), (c), (m) or (o) of the Internal Revenue Code of 1986, as amended, and the regulations and published interpretations thereunder (the "**Code**") of which the Company or such subsidiary is a member. No "reportable event" (as defined under ERISA) has occurred or is reasonably expected to occur with respect to any "employee benefit plan" established or maintained by the Company, its subsidiaries or any of their ERISA Affiliates. No "employee benefit plan" established or maintained by the Company, its subsidiaries or any of their ERISA Affiliates, if such "employee benefit plan" were terminated, would have any "amount of unfunded benefit liabilities" (as defined under ERISA). Neither the Company, its subsidiaries nor any of their ERISA Affiliates has incurred or reasonably expects to incur any liability under (i) Title IV of ERISA with respect to termination of, or withdrawal from, any "employee benefit plan" or (ii) Sections 412, 4971, 4975 or 4980B of the Code. Each employee benefit plan established or maintained by the Company, its subsidiaries or any of their ERISA Affiliates that is intended to be qualified under Section 401(a) of the Code is so qualified and nothing has occurred, whether by action or failure to act, which would cause the loss of such qualification.

(ee) Company Not an "Investment Company." The Company is not, and will not be, either after receipt of payment for the Placement Shares or after the application of the proceeds therefrom as described under "Use of Proceeds" in the Registration Statement or the Prospectus, required to register as an "investment company" under the Investment Company Act of 1940, as amended (the **"Investment Company Act**").

(ff) No Price Stabilization or Manipulation; Compliance with Regulation M. Neither the Company nor any of its subsidiaries has taken, directly or indirectly, without giving any effect to the activities by TD Cowen, any action designed to or that would reasonably be expected to cause or result in stabilization or manipulation of the price of the Common Stock or of any "reference security" (as defined in Rule 100 of Regulation M under the Exchange Act ("**Regulation M**")) with respect to the Common Stock, whether to facilitate the sale or resale of the Placement Shares or otherwise, and has taken no action which would directly or indirectly violate Regulation M.

(gg) Related-Party Transactions. There are no business relationships or related-party transactions involving the Company or any of its subsidiaries or any other person required to be described in the Registration Statement or the Prospectus that have not been described as required.

(hh) Broker-Dealer Status; FINRA Matters. The Company is not required to register as a "broker" or "dealer" in accordance with the provisions of the Exchange Act and does not, directly or indirectly through one or more intermediaries, control or have any other association with (within the meaning of Article I of the By-laws of FINRA) any member firm of FINRA. No relationship, direct or indirect, exists between or among the Company, on the one hand, and the directors, officers or stockholders of the Company, on the other hand, which is required by the rules of FINRA to be described in the Registration Statement and the Prospectus which is not so described. All of the information (including, but not limited to, information regarding affiliations, security ownership and trading activity) provided to the TD Cowen or to counsel for TD Cowen by the Company, and, to the Company's knowledge, its counsel, its officers and directors and certain holders of any securities (debt or equity) or warrants, options or rights to acquire any securities of the Company in connection with the offering of the Placement Shares is true, complete, correct and compliant in all material respects with FINRA's rules and any letters, filings or other supplemental information provided to FINRA by the Company, and, to the Company's knowledge, its counsel, its officers and directors and certain holders of any securities (debt or equity) or options to acquire any securities of the Company pursuant to FINRA Rules or NASD Conduct Rules is true, complete and correct in all material respects.

(ii) Statistical and Market-Related Data. All statistical, demographic and market-related data included in the Registration Statement or the Prospectus are based on or derived from sources that the Company believes, after reasonable inquiry, to be reliable and accurate in all material respects. To the extent required, the Company has obtained the written consent to the use of such data from such sources.

(jj) No Unlawful Contributions or Other Payments. Neither the Company nor any of its subsidiaries nor, to the Company's knowledge, any employee or agent of the Company or any subsidiary, has made any contribution or other payment to any official of, or candidate for, any federal, state or foreign office in violation of any applicable law or of the character required to be disclosed in the Registration Statement or the Prospectus.

(kk) Anti-Corruption and Anti-Bribery Laws. Neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, any director, officer, agent, employee, affiliate or other person acting on behalf of the Company or any of its subsidiaries has, in the course of its actions for, or on behalf of, the Company or any of its subsidiaries (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expenses relating to political activity; (ii) made any direct or indirect unlawful payment to any domestic government official, "foreign official" (as defined in the U.S. Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (collectively, the "**FCPA**")) or employee from corporate funds; (iii) violated or is in violation of any provision of the FCPA or any applicable non-U.S. anti-bribery statute or regulation; or (iv) made any unlawful bribe, rebate, payoff, influence payment, kickback or other unlawful payment to any domestic government official, such foreign official or employee; and the Company and its subsidiaries and, to the knowledge of the Company, the Company's affiliates have conducted their respective businesses in compliance with the FCPA and have instituted and maintain policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith.

(ll) Money Laundering Laws. The operations of the Company and its subsidiaries are, and have been conducted at all times, in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all applicable jurisdictions, the rules and regulations thereunder and any related or similar applicable rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "**Money Laundering Laws**") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(mm) Sanctions. Neither the Company nor any of its subsidiaries, directors, officers, or employees, nor, to the knowledge of the Company, after due inquiry, any agent, affiliate or other person acting on behalf of the Company or any of its subsidiaries is currently the subject or the target of any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury ("**OFAC**") or the U.S. Department of State, the United Nations Security Council, the European Union, His Majesty's Treasury of the United Kingdom, or other relevant sanctions authority (collectively, "**Sanctions**"); nor is the Company or any of its subsidiaries located, organized or resident in a country or territory that is the subject or the target of Sanctions, including, without limitation, the so-called Donetsk People's Republic, the so-called Luhansk People's Republic, the Crimea region and the non-government controlled areas of the Zaporizhzhia and Kerson Regions of Ukraine (or any other Covered Region of Ukraine identified pursuant to Executive Order 14065), Cuba, Iran, North Korea and Syria (each, a "**Sanctioned Country**"); and the Company will not directly or indirectly use the proceeds of this offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, or any joint venture partner or other person or entity, for the purpose of financing the activities of or business with any person, or in any country or territory, that at the time of such financing, is the subject or the target of Sanctions or in any other manner that will result in a violation by any person (including any person participating in the transaction whether as underwriter, advisor, investor or otherwise) of applicable Sanctions. Since April 24, 2019, the Company and its subsidiaries have not knowingly engaged in and are not now knowingly engaged in any dealings or transactions with any person

that at the time of the dealing or transaction is or was the subject or the target of Sanctions or with any Sanctioned Country.

(nn) Brokers. Except pursuant to this Agreement, there is no broker, finder or other party that is entitled to receive from the Company any brokerage or finder's fee or other fee or commission as a result of any transactions contemplated by this Agreement.

(oo) Forward-Looking Statements. Each financial or operational projection or other "forward-looking statement" (as defined by Section 27A of the Securities Act or Section 21E of the Exchange Act) contained in the Registration Statement or the Prospectus (i) was so included by the Company in good faith and with reasonable basis after due consideration by the Company of the underlying assumptions, estimates and other applicable facts and circumstances and (ii) is accompanied by meaningful cautionary statements identifying those factors that could cause actual results to differ materially from those in such forward-looking statement. No such statement was made with the knowledge of an executive officer or director of the Company that it was false or misleading.

(pp) Cybersecurity. The Company and its subsidiaries' information technology assets and equipment, computers, systems, networks, hardware, software, websites, applications, and databases (collectively, "**IT Systems**") are adequate for, and operate and perform in all material respects as required in connection with the operation of the business of the Company and its subsidiaries as currently conducted, and, to the Company's knowledge, are free and clear of all material bugs, errors, defects, Trojan horses, time bombs, malware and other corruptants. The Company and its subsidiaries have implemented and maintained commercially reasonable physical, technical and administrative controls, policies, procedures, and safeguards to maintain and protect their material confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and data, including "Personal Data," used in connection with their businesses. "**Personal Data**" means (i) a natural person's name, street address, telephone number, e-mail address, photograph, social security number or tax identification number, driver's license number, passport number, credit card number, bank information, or customer or account number; (ii) any information which would qualify as "personally identifying information" under the Federal Trade Commission Act, as amended; (iii) "personal data" as defined by GDPR (as defined below); (iv) any information which would qualify as "protected health information" under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (collectively, "**HIPAA**"); and (v) any other piece of information that allows the identification of such natural person, or his or her family, or permits the collection or analysis of any data related to an identified person's health or sexual orientation. There have been no breaches, violations, outages or unauthorized uses of or accesses to same, except for those that have been remedied without material cost or liability or the duty to notify any other person, nor any incidents under internal review or investigations relating to the same. The Company and its subsidiaries are presently in material compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Personal Data and to the protection of such IT Systems and Personal Data from unauthorized use, access, misappropriation or modification.

(qq) Compliance with Data Privacy Laws. The Company and its subsidiaries are, and at all prior times were, to the knowledge of the Company, in material compliance with all applicable state and federal data privacy and security laws and regulations, including, without limitation, HIPAA, and the Company and its subsidiaries have taken commercially reasonable actions to prepare to comply with, and since May 25, 2018, have been and currently are in compliance with, the European Union General Data Protection Regulation ("**GDPR**") (EU 2016/679) (together with HIPAA, the "**Privacy Laws**"). To ensure compliance with the Privacy Laws, the Company and its subsidiaries have in place, comply with, and take appropriate steps reasonably designed to ensure compliance in all material respects with their policies and procedures relating to data privacy and security and the collection, storage, use, disclosure, handling, and analysis of Personal Data (the "**Policies**"). The Company and its subsidiaries have at all times made all disclosures to users or customers required by applicable laws and regulatory rules or requirements, and none of such disclosures made or contained in any Policy have, to the knowledge of the Company, been inaccurate or in violation of any applicable laws and regulatory rules or requirements in any material respect. The Company further certifies that neither it nor any subsidiary: (i) has received notice of any actual or potential liability under or relating to, or actual or potential violation of, any of the Privacy Laws, and has no knowledge of any event or condition that would reasonably be expected to result in any such notice; (ii) is currently conducting or paying for, in whole or in part, any investigation, remediation, or other corrective action pursuant to any Privacy Law; or (iii) is a party to any order, decree, or agreement that imposes any obligation or liability under any Privacy Law.

(rr) No Outstanding Loans or Other Extensions of Credit. The Company does not have any outstanding extension of credit, in the form of a personal loan, to or for any director or executive officer (or equivalent thereof) of the Company except for such extensions of credit as are expressly permitted by Section 13(k) of the Exchange Act.

(ss) No Reliance. The Company has not relied upon TD Cowen or legal counsel for TD Cowen for any legal, tax or accounting advice in connection with the offering and sale of the Placement Shares.

(tt) Exchange Act Compliance. The documents incorporated or deemed to be incorporated by reference in the Prospectus, at the time they were or hereafter are filed with the Commission, complied and will comply in all material respects with the requirements of the Exchange Act, and, when read together with the other information in the Prospectus, at the Settlement Dates, will not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(uu) Clinical Data and Regulatory Compliance. The nonclinical studies and clinical trials (collectively, "**Studies**") that are described in, or the results of which are described or referred to in, the Registration Statement or the Prospectus were and, if still pending, are being conducted in all material respects in accordance with the protocols, procedures and controls designed and approved for such Studies and with standard medical and scientific research procedures; each description of the results of such Studies is accurate and complete in all material respects and fairly presents the data derived from such Studies, and the Company and its subsidiaries have no knowledge of any other studies the results of which are inconsistent with, or otherwise call into

question, the results described or referred to in the Registration Statement or the Prospectus; the Company and its subsidiaries are and have been in compliance with all statutes, laws, ordinances, rules and regulations applicable to the operation and business of the Company and its subsidiaries including, but not limited to those for the ownership, testing, development, manufacture, packaging, processing, use, labeling, storage, or disposal of any product manufactured by or on behalf of the Company, including without limitation, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq., and the amendments thereto (the "**Applicable Laws**"). The Company and its subsidiaries have made all such filings and obtained all such approvals as may be required by the U.S. Food and Drug Administration ("**FDA**") and from any other federal, state, local or foreign regulatory authority with jurisdiction over the products being developed by the Company and its subsidiaries (collectively, the "**Regulatory Agencies**"); neither the Company nor any of its subsidiaries has received any notice of, or correspondence from, any Regulatory Agency requiring the termination, suspension or modification of any clinical trials that are described or referred to in the Registration Statement or the Prospectus; and the Company and its subsidiaries have each operated and currently are in compliance in all material respects with all applicable laws, rules, and regulations of the Regulatory Agencies. The Company and its subsidiaries, are and have been in compliance with all statutes, laws, ordinances, rules and regulations applicable to the operation and business of the Company and its subsidiaries including, but not limited to those for the ownership, testing, development, manufacture, packaging, processing, use, labeling, storage, or disposal of any product manufactured by or on behalf of the Company, including without limitation, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq., the amendments thereto and the regulations promulgated thereunder, in all material respects. Neither the Company nor its subsidiaries have received any written notice of adverse finding, warning letter or other written correspondence or notice from the FDA or any other governmental entity alleging or asserting noncompliance with any Applicable Laws; the Company has not received written notice of any ongoing claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any governmental entity or third party alleging that any product, operation or activity is in violation of any Applicable Laws or has any knowledge that any such governmental entity or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding, nor, to the best of the Company's knowledge, has there been any noncompliance with or violation of any Applicable Laws by the Company or its subsidiaries that could reasonably be expected to require the issuance of any such written notice or result in an investigation, corrective action, or enforcement action by the FDA or similar governmental entity; neither the Company nor its subsidiaries has received written notice that any governmental entity has taken, is taking or intends to take action to limit, suspend, modify or revoke any permits or has any knowledge that any such governmental entity has threatened or is considering such action; and the Company and its subsidiaries have filed, obtained, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any applicable laws and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete, correct and not misleading on the date filed (or were corrected or supplemented by a subsequent submission), in all material respects. Neither the Company, its subsidiaries and, to the Company's knowledge, any of its directors, officers, employees or agents, has made, or caused the making of, any false statements on, or material omissions from, any other records or documentation prepared or maintained to comply with the requirements of the FDA or any other governmental entity.

(vv) No Contract Terminations. Neither the Company nor any of its subsidiaries has sent or received any communication regarding termination of, or intent not to renew, any of the contracts or agreements referred to or described in the Prospectus or any Permitted Free Writing Prospectus, or referred to or described in, or filed as an exhibit to, the Registration Statement, or any document incorporated by reference therein, and no such termination or non-renewal has been threatened by the Company or any of its subsidiaries or, to the Company's knowledge, any other party to any such contract or agreement, which threat of termination or non-renewal has not been rescinded as of the date hereof.

(ww) No Rights to Purchase Preferred Stock. The issuance and sale of the Placement Shares as contemplated hereby will not cause any holder of any shares of capital stock, securities convertible into or exchangeable or exercisable for capital stock or options, warrants or other rights to purchase capital stock or any other securities of the Company to have any right to acquire any shares of preferred stock of the Company.

(xx) Dividend Restrictions. No subsidiary of the Company is prohibited or restricted, directly or indirectly, from paying dividends to the Company, or from making any other distribution with respect to such subsidiary's equity securities or from repaying to the Company or any other subsidiary of the Company any amounts that may from time to time become due under any loans or advances to such subsidiary from the Company or from transferring any property or assets to the Company or to any other subsidiary.

(yy) Lending Relationship. Except as disclosed in the Registration Statement and the Prospectus, the Company (i) does not have any material lending or other relationship with any bank or lending affiliate of TD Cowen and (ii) does not intend to use any of the proceeds from the sale of the Placement Shares to repay any outstanding debt owed to any affiliate of TD Cowen.

(zz) FINRA Exemption. The Company qualifies as an "experienced issuer" (within the meaning of FINRA Conduct Rule 5110(j)(6)) for purposes of the exemption from filing under FINRA Conduct Rule 5110(h)(1)(C).

(aaa) Other At The Market Sales Agreements. The Company is not a party to any agreement with an agent or underwriter for any other "at the market" offering.

(bbb) Actively Traded Security. The Common Stock is an "actively traded security exempted from the requirements of Rule 101 of Regulation M under the Exchange Act by subsection (c)(1) of such rule.

(ccc) Outbound Investment Security Program. Neither the Company nor any of its subsidiaries is a "covered foreign person", as that term is defined in 31 C.F.R. §850.209. Neither the Company nor any of its subsidiaries currently engages, or has plans to engage, directly or indirectly, in a "covered activity", as that term is defined in in 31 C.F.R. § 850.208 ("Covered Activity"). The Company does not have any joint ventures that engages in or plans to engage in any Covered Activity. The Company also does not, directly or indirectly, hold a board seat on, have a voting or equity interest in, or have any contractual power to direct or cause the direction of the management or policies of any person or persons that engages or plans to engage in any Covered Activity.

The Company acknowledges that TD Cowen and, for purposes of the opinions to be delivered pursuant to Section 7 hereof, counsel to the Company and counsel to TD Cowen, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

7. Covenants of the Company. The Company covenants and agrees with TD Cowen that:

(a) Registration Statement Amendments. After the date of this Agreement and during any period in which a Prospectus relating to any Placement Shares is required to be delivered by TD Cowen under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), (i) the Company will notify TD Cowen promptly of the time when any subsequent amendment to the Registration Statement, other than documents incorporated by reference, has been filed with the Commission and/or has become effective or any subsequent supplement to the Prospectus has been filed and of any request by the Commission for any amendment or supplement to the Registration Statement or Prospectus or for additional information, (ii) the Company will prepare and file with the Commission, promptly upon TD Cowen's request, any amendments or supplements to the Registration Statement or Prospectus that, in TD Cowen's reasonable opinion, may be necessary or advisable in connection with the distribution of the Placement Shares by TD Cowen (*provided, however*, that the failure of TD Cowen to make such request shall not relieve the Company of any obligation or liability hereunder, or affect TD Cowen's right to rely on the representations and warranties made by the Company in this Agreement and *provided*, *further*, that the only remedy TD Cowen shall have with respect to the failure to make such filing (other than TD Cowen's rights under Section 9 hereof) shall be to cease making sales under this Agreement until such amendment or supplement is filed); (iii) the Company will not file any amendment or supplement to the Registration Statement or Prospectus, other than documents incorporated by reference, relating to the Placement Shares or a security convertible into the Placement Shares unless a copy thereof has been submitted to TD Cowen within a reasonable period of time before the filing and TD Cowen has not reasonably objected thereto (*provided, however*, that the failure of TD Cowen to make such objection shall not relieve the Company of any obligation or liability hereunder, or affect TD Cowen's right to rely on the representations and warranties made by the Company in this Agreement and *provided*, *further*, that the only remedy TD Cowen shall have with respect to the failure to make such filing (other than TD Cowen's rights under Section 9 hereof) shall be to cease making sales under this Agreement until such amendment or supplement is filed) and the Company will furnish to TD Cowen at the time of filing thereof a copy of any document that upon filing is deemed to be incorporated by reference into the Registration Statement or Prospectus, except for those documents available via EDGAR; (iv) the Company will cause each amendment or supplement to the Prospectus, other than documents incorporated by reference, to be filed with the Commission as required pursuant to the applicable paragraph of Rule 424(b) of the Securities Act, and (v) prior to the termination of this Agreement, the Company will notify TD Cowen if at any time the Registration Statement shall no longer be effective as a result of the passage of time pursuant to Rule 415 under the Securities Act or otherwise.

(b) Notice of Commission Stop Orders. The Company will advise TD Cowen, promptly after it receives notice or obtains knowledge thereof, of the issuance or threatened issuance by the Commission of any stop order suspending the effectiveness of the Registration

Statement, of the suspension of the qualification of the Placement Shares for offering or sale in any jurisdiction, or of the initiation or threatening of any proceeding for any such purpose; and it will promptly use its commercially reasonable efforts to prevent the issuance of any stop order or to obtain its withdrawal if such a stop order should be issued.

(c) Delivery of Prospectus; Subsequent Changes. During any period in which a Prospectus relating to the Placement Shares is required to be delivered by TD Cowen under the Securities Act with respect to a pending sale of the Placement Shares, (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), the Company will comply with all requirements imposed upon it by the Securities Act, as from time to time in force, and to file on or before their respective due dates all reports and any definitive proxy or information statements required to be filed by the Company with the Commission pursuant to Sections 13(a), 13(c), 14, 15(d) or any other provision of or under the Exchange Act. If during such period any event occurs as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances then existing, not misleading, or if during such period it is necessary to amend or supplement the Registration Statement or Prospectus to comply with the Securities Act, the Company will promptly notify TD Cowen to suspend the offering of Placement Shares during such period and the Company will promptly amend or supplement the Registration Statement or Prospectus (at the expense of the Company) so as to correct such statement or omission or effect such compliance.

(d) Listing of Placement Shares. During any period in which the Prospectus relating to the Placement Shares is required to be delivered by TD Cowen under the Securities Act with respect to a pending sale of the Placement Shares (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), the Company will use its commercially reasonable efforts to cause the Placement Shares to be listed on Nasdaq and to qualify the Placement Shares for sale under the securities laws of such jurisdictions as TD Cowen reasonably designates and to continue such qualifications in effect so long as required for the distribution of the Placement Shares; *provided, however,* that the Company shall not be required in connection therewith to qualify as a foreign corporation or dealer in securities or file a general consent to service of process in any jurisdiction.

(e) Delivery of Registration Statement and Prospectus. The Company will furnish to TD Cowen and its counsel (at the expense of the Company) copies of the Registration Statement, the Prospectus (including all documents incorporated by reference therein) and all amendments and supplements to the Registration Statement or Prospectus that are filed with the Commission during any period in which a Prospectus relating to the Placement Shares is required to be delivered under the Securities Act (including all documents filed with the Commission during such period that are deemed to be incorporated by reference therein), in each case as soon as reasonably practicable and in such quantities as TD Cowen may from time to time reasonably request and, at TD Cowen's request, will also furnish copies of the Prospectus to each exchange or market on which sales of the Placement Shares may be made; *provided, however,* that the Company shall not be required to furnish any document (other than the Prospectus) to TD Cowen to the extent such document is available on EDGAR.

(f) Earnings Statement. The Company will make generally available to its security holders as soon as practicable, but in any event not later than 15 months after the end of

the Company's current fiscal quarter, an earnings statement covering a 12-month period that satisfies the provisions of Section 11(a) and Rule 158 of the Securities Act.

(g) Expenses. The Company, whether or not the transactions contemplated hereunder are consummated or this Agreement is terminated, in accordance with the provisions of Section 11 hereunder, will pay the following expenses all incident to the performance of its obligations hereunder, including, but not limited to, expenses relating to (i) the preparation, printing and filing of the Registration Statement and each amendment and supplement thereto, of each Prospectus and of each amendment and supplement thereto, (ii) the preparation, issuance and delivery of the Placement Shares, (iii) the qualification of the Placement Shares under securities laws in accordance with the provisions of Section 7(d) of this Agreement, including filing fees (provided, however, that any fees or disbursements of counsel for TD Cowen in connection therewith shall be paid by TD Cowen except as set forth in (vii) below), (iv) the printing and delivery to TD Cowen of copies of the Prospectus and any amendments or supplements thereto, and of this Agreement, (v) the fees and expenses incurred in connection with the listing or qualification of the Placement Shares for trading on Nasdaq, (vi) the filing fees and expenses, if any, of the Commission, (vii) the filing fees and associated legal expenses of TD Cowen's outside counsel for filings with the FINRA Corporate Financing Department, such legal expense reimbursement not to exceed $15,000 and, (viii) the reasonable fees and disbursements of TD Cowen's counsel; provided, however, the reimbursement obligations in clauses (vii) and (viii) shall not exceed, in the aggregate, (A) $75,000 in connection with the execution of this Agreement and (B) $25,000 in connection with each Bring-Down Date (as defined below) on which the Company is required to provide a certificate pursuant to Section 7(m).

(h) Use of Proceeds. The Company will use the Net Proceeds as described in the Prospectus in the section entitled "Use of Proceeds."

(i) Notice of Other Sales. During the pendency of any Placement Notice given hereunder, and for 5 trading days following the termination of any Placement Notice given hereunder, the Company shall provide TD Cowen notice as promptly as reasonably possible before it offers to sell, contracts to sell, sells, grants any option to sell or otherwise disposes of any shares of Common Stock (other than Placement Shares offered pursuant to the provisions of this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire Common Stock; *provided*, that such notice shall not be required in connection with the (i) issuance, grant or sale of Common Stock, options to purchase shares of Common Stock or Common Stock issuable upon the exercise of options or other equity awards pursuant to any stock option, stock bonus or other stock plan or arrangement described in the Prospectus, (ii) the issuance of securities in connection with an acquisition, merger or sale or purchase of assets, or other business combinations, (iii) the issuance of Common Stock, securities convertible into or exercisable for Common Stock or other securities offered and sold in a privately negotiated transaction to vendors, customers, strategic partners or other investors conducted or in connection with a transaction that includes a commercial relationship (including joint ventures, marketing or distribution arrangements, collaboration agreements or intellectual property license agreements) in a manner so as not to be integrated with the offering of the Placement Shares hereby, (iv) the issuance or sale of Common Stock pursuant to any dividend reinvestment plan that the Company may adopt from time to time provided the implementation of such is disclosed to TD

Cowen in advance or (v) any shares of Common Stock issuable upon the exchange, conversion or redemption of securities or the exercise of warrants, options or other rights in effect or outstanding.

(j) Change of Circumstances. The Company will, at any time during a fiscal quarter in which the Company intends to tender a Placement Notice or sell Placement Shares, advise TD Cowen promptly after it shall have received notice or obtained knowledge thereof, of any information or fact that would alter or affect in any material respect any opinion, certificate, letter or other document provided to TD Cowen pursuant to this Agreement.

(k) Due Diligence Cooperation. The Company will cooperate with any reasonable due diligence review conducted by TD Cowen or its agents in connection with the transactions contemplated hereby, including, without limitation, providing information and making available documents and senior corporate officers, during regular business hours and at the Company's principal offices, as TD Cowen may reasonably request.

(l) Required Filings Relating to Placement of Placement Shares. The Company agrees that on such dates as the Securities Act shall require, the Company will (i) file a prospectus supplement with the Commission under the applicable paragraph of Rule 424(b) under the Securities Act (each and every filing under Rule 424(b), a "**Filing Date**"), and (ii) deliver such number of copies of each such prospectus supplement to each exchange or market on which such sales were effected as may be required by the rules or regulations of such exchange or market. The Company shall disclose in its quarterly reports on Form 10-Q and in its annual report on Form 10-K, the number of the Placement Shares sold through TD Cowen under this Agreement and the Net Proceeds to the Company from the sale of the Placement Shares, pursuant to this Agreement during the relevant quarter or, in the case of an Annual Report on Form 10-K, during the fiscal year covered by such Annual Report and the fourth quarter of such fiscal year.

(m) Bring-Down Dates; Certificate. On or prior to the First Delivery Date and each time (i) the Company files the Prospectus relating to the Placement Shares or amends or supplements the Registration Statement (other than a prospectus supplement relating solely to an offering of securities other than Placement Shares) or the Prospectus relating to the Placement Shares (other than a prospectus supplement filed in accordance with Section 7(l) of this Agreement) by means of a post-effective amendment, sticker, or supplement but not by means of incorporation of document(s) by reference to the Registration Statement or the Prospectus relating to the Placement Shares; (ii) the Company files an annual report on Form 10-K under the Exchange Act; (iii) the Company files its quarterly reports on Form 10-Q under the Exchange Act; or (iv) the Company files a report on Form 8-K containing amended financial information (other than an earnings release, information "furnished" pursuant to Items 2.02 or 7.01 of Form 8-K or to provide disclosure pursuant to Item 8.01 of Form 8-K relating to the reclassification of certain properties as discontinued operations in accordance with Statement of Financial Accounting Standards No. 144) under the Exchange Act (each date of filing of one or more of the documents referred to in clauses (i) through (iv) shall be a **"Bring-Down Date"**); the Company shall furnish TD Cowen (but in the case of clause (iv) above only if TD Cowen reasonably determines that the information contained in such Form 8-K is material) with a certificate, in the form attached hereto as Exhibit 7(m) within one (1) Trading Day of any Bring-Down Date if requested by TD Cowen. The requirement to provide a certificate under this Section 7(m) shall be waived for any Bring-Down Date occurring at a time at which no Placement Notice is pending or a Suspension is in effect, which waiver shall continue until the earlier to occur of the date the Company delivers a Placement

Notice hereunder (which for such calendar quarter shall be considered a Bring-Down Date) and the next occurring Bring-Down Date; *provided*, *however*, that such waiver shall not apply for any Bring-Down Date on which the Company files its annual report on Form 10-K. Notwithstanding the foregoing, if the Company subsequently decides to sell Placement Shares following a Bring-Down Date when the Company relied on such waiver and did not provide TD Cowen with a certificate under this Section 7(m), then before the Company delivers the Placement Notice or TD Cowen sells any Placement Shares, the Company shall provide TD Cowen with a certificate, in the form attached hereto as Exhibit 7(m), dated the date of the Placement Notice.

(n) Legal Opinion. On or prior to the First Delivery Date and within one (1) Trading Day of each Bring-Down Date with respect to which the Company is obligated to deliver a certificate in the form attached hereto as Exhibit 7(m) for which no waiver is applicable, the Company shall cause to be furnished to TD Cowen a written opinion of Fenwick & West LLP ("**Company Counsel**") and written opinion of Carpmaels & Ransford LLP, intellectual property counsel to the Company ("**Company IP Counsel**"), or other counsel satisfactory to TD Cowen, in form and substance satisfactory to TD Cowen and its counsel, dated the date that the opinion is required to be delivered; *provided*, *however*, the Company shall be required to furnish to Agent no more than one opinion from each of Company Counsel and Company IP Counsel hereunder per calendar quarter; *provided*, *further,* that in lieu of such opinions for subsequent Bring-Down Dates, Company Counsel and Company IP Counsel, as applicable, may furnish TD Cowen with a letter (a "**Reliance Letter**") to the effect that TD Cowen may rely on a prior opinion delivered under this Section 7(n) to the same extent as if it were dated the date of such letter (except that statements in such prior opinion shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented at such Bring-Down Date).

(o) Comfort Letter. On or prior to the First Delivery Date and within one (1) Trading Day of each Bring-Down Date with respect to which the Company is obligated to deliver a certificate in the form attached hereto as Exhibit 7(m) for which no waiver is applicable, the Company shall cause its independent accountants to furnish TD Cowen letters (the "**Comfort Letters**"), dated the date the Comfort Letter is delivered, in form and substance satisfactory to TD Cowen, (i) confirming that they are an independent registered public accounting firm within the meaning of the Securities Act and the PCAOB, (ii) stating, as of such date, the conclusions and findings of such firm with respect to the financial information and other matters ordinarily covered by accountants' "comfort letters" to TD Cowen in connection with registered public offerings (the first such letter, the **"Initial Comfort Letter"**) and (iii) updating the Initial Comfort Letter with any information that would have been included in the Initial Comfort Letter had it been given on such date and modified as necessary to relate to the Registration Statement and the Prospectus, as amended and supplemented to the date of such letter.

(p) Chief Financial Officer's Certificate. If applicable, on or prior to the First Delivery Date and within one (1) Trading Day of each Bring-Down Date with respect to which the Company is obligated to deliver a certificate in the form attached hereto as Exhibit 7(m) for which no waiver is applicable, the Company shall have delivered to TD Cowen a certificate executed by the Chief Financial Officer of the Company ("**CFO Certificate**"), dated as of such date, in form and substance satisfactory to TD Cowen.

(q) Market Activities. The Company will not, directly or indirectly, (i) take any action designed to cause or result in, or that constitutes or might reasonably be expected to constitute, the

stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Placement Shares or (ii) sell, bid for, or purchase the Common Stock to be issued and sold pursuant to this Agreement, or pay anyone any compensation for soliciting purchases of the Placement Shares other than TD Cowen; provided, however, that the Company may bid for and purchase shares of its common stock in accordance with Rule 10b-18 under the Exchange Act.

(r) Investment Company Act. The Company will conduct its affairs in such a manner so as to reasonably ensure that neither it nor its subsidiaries will be or become, at any time prior to the termination of this Agreement, required to register as an "investment company," as such term is defined in the Investment Company Act, assuming no change in the Commission's current interpretation as to entities that are not considered an investment company.

(s) No Offer to Sell. Other than a Permitted Free Writing Prospectus, neither TD Cowen nor the Company (including its agents and representatives, other than TD Cowen in its capacity as such) will make, use, prepare, authorize, approve or refer to any written communication (as defined in Rule 405 under the Securities Act), required to be filed with the Commission, that constitutes an offer to sell or solicitation of an offer to buy Common Stock hereunder.

(t) Sarbanes-Oxley Act. The Company and its subsidiaries will use their best efforts to comply with all effective applicable provisions of the Sarbanes-Oxley Act.

(u) Affirmation. Each Placement Notice delivered by the Company to TD Cowen shall be deemed to be (i) an affirmation that the representations, warranties and agreements of the Company herein contained and contained in any certificate delivered to TD Cowen pursuant hereto are true and correct at the time of delivery of such Placement Notice, and (ii) an undertaking that such representations, warranties and agreements will be true and correct on any applicable Time of Sale and Settlement Date, as though made at and as of each such time (it being understood that such representations, warranties and agreements shall relate to the Registration Statement and the Prospectus as amended and supplemented to the time of such Placement Notice acceptance).

(v) Renewal. If immediately prior to the third anniversary (the "**Renewal Deadline**") of the initial effective date of the Registration Statement, the aggregate gross sales price of Placement Shares sold by the Company is less than the Maximum Amount and this Agreement has not expired or been terminated, the Company will, prior to the Renewal Deadline, file, if it has not already done so and is eligible to do so, a new shelf registration statement relating to the Placement Shares, in a form satisfactory to TD Cowen, and, if not automatically effective, will use its commercially reasonable efforts to cause such registration statement to be declared effective within 60 days after the Renewal Deadline. The Company will take all other action necessary or appropriate to permit the issuance and sale of the Placement Shares to continue as contemplated in the expired registration statement relating to the Placement Shares. References herein to the Registration Statement shall include such new shelf registration statement.

8. Conditions to TD Cowen's Obligations. The obligations of TD Cowen hereunder with respect to a Placement Notice will be subject to the continuing accuracy and completeness of the representations and warranties made by the Company herein, to the due performance by the Company of its obligations hereunder and thereunder, to the completion by TD Cowen of a due

diligence review satisfactory to TD Cowen in its reasonable judgment, and to the continuing satisfaction (or waiver by TD Cowen in its sole discretion) of the following additional conditions:

(a) Registration Statement Effective. The Registration Statement shall be effective and shall be available for (i) all sales of Placement Shares issued pursuant to all prior Placement Notices and (ii) the sale of all Placement Shares contemplated to be issued pursuant to any Placement Notice.

(b) No Material Notices. None of the following events shall have occurred and be continuing: (i) receipt by the Company or any of its subsidiaries of any request for additional information from the Commission or any other federal or state governmental authority during the period of effectiveness of the Registration Statement, the response to which would require any post-effective amendments or supplements to the Registration Statement or the Prospectus; (ii) the issuance by the Commission or any other federal or state governmental authority of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for that purpose; (iii) receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Placement Shares for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; or (iv) the occurrence of any event that makes any material statement made in the Registration Statement or the Prospectus or any material document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires the making of any changes in the Registration Statement, related Prospectus or such documents so that, in the case of the Registration Statement, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading and, that in the case of the Prospectus, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(c) No Misstatement or Material Omission. TD Cowen shall not have advised the Company that the Registration Statement or Prospectus, or any amendment or supplement thereto, contains an untrue statement of fact that in TD Cowen's reasonable opinion is material, or omits to state a fact that in TD Cowen's opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.

(d) Material Changes. Except as contemplated in the Prospectus, or disclosed in the Company's reports filed with the Commission, there shall not have been any material adverse change, on a consolidated basis, in the authorized capital stock of the Company or any Material Adverse Change or any development that could reasonably be expected to result in a Material Adverse Change, or any downgrading in or withdrawal of the rating assigned to any of the Company's securities (other than asset backed securities) by any rating organization or a public announcement by any rating organization that it has under surveillance or review its rating of any of the Company's securities (other than asset backed securities), the effect of which, in the case of any such action by a rating organization described above, in the reasonable judgment of TD Cowen (without relieving the Company of any obligation or liability it may otherwise have), is so material as to make it impracticable or inadvisable to proceed with the offering of the Placement Shares on the terms and in the manner contemplated in the Prospectus.

(e) Company Counsel Legal Opinion. TD Cowen shall have received the opinions of Company Counsel and Company IP Counsel required to be delivered pursuant to Section 7(n) on or before the date on which such delivery of such opinion is required pursuant to Section 7(n).

(f) TD Cowen Counsel Legal Opinion. TD Cowen shall have received from Goodwin Procter LLP, counsel for TD Cowen, such opinion or opinions, on or before the date on which the delivery of the Company Counsel legal opinion is required pursuant to Section 7(n), with respect to such matters as TD Cowen may reasonably require, and the Company shall have furnished to such counsel such documents as they request for enabling them to pass upon such matters.

(g) Comfort Letter. TD Cowen shall have received the Comfort Letter required to be delivered pursuant to Section 7(o) on or before the date on which such delivery of such Comfort Letter is required pursuant to Section 7(o).

(h) Representation Certificate. TD Cowen shall have received the certificate required to be delivered pursuant to Section 7(m) on or before the date on which delivery of such certificate is required pursuant to Section 7(m).

(i) Secretary's Certificate. On or prior to the First Delivery Date, TD Cowen shall have received a certificate, signed on behalf of the Company by its corporate secretary, in form and substance satisfactory to TD Cowen and its counsel.

(j) CFO Certificate. If applicable, TD Cowen shall have received the CFO Certificate required to be delivered pursuant to Section 7(p) on or before the date on which delivery of such certificate is required pursuant to Section 7(p).

(k) No Suspension. Trading in the Common Stock shall not have been suspended on Nasdaq.

(l) Other Materials. On each date on which the Company is required to deliver a certificate pursuant to Section 7(m), the Company shall have furnished to TD Cowen such appropriate further information, certificates and documents as TD Cowen may have reasonably requested. All such opinions, certificates, letters and other documents shall have been in compliance with the provisions hereof. The Company will furnish TD Cowen with such conformed copies of such opinions, certificates, letters and other documents as TD Cowen shall have reasonably requested.

(m) Securities Act Filings Made. All filings with the Commission required by Rule 424 under the Securities Act to have been filed prior to the issuance of any Placement Notice hereunder shall have been made within the applicable time period prescribed for such filing by Rule 424.

(n) Approval for Listing. The Placement Shares shall either have been (i) approved for listing on Nasdaq, subject only to notice of issuance, or (ii) the Company shall have filed an application for listing of the Placement Shares on Nasdaq at, or prior to, the issuance of any Placement Notice.

(o) No Termination Event. There shall not have occurred any event that would permit TD Cowen to terminate this Agreement pursuant to Section 11(a).

9. Indemnification and Contribution.

(a) Company Indemnification. The Company agrees to indemnify and hold harmless TD Cowen, its affiliates and each of their respective directors, officers, partners, employees and agents of TD Cowen and each person, if any, who controls TD Cowen within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act from and against any and all losses, claims, liabilities, expenses and damages (including, but not limited to, any and all reasonable investigative and documented legal fees and other expenses incurred in connection with, and any and all amounts paid in settlement (in accordance with Section 9(c)) of, any action, suit or proceeding between any of the indemnified parties and any indemnifying parties or between any indemnified party and any third party, or otherwise, or any claim asserted), as and when incurred, to which TD Cowen, or any such person, may become subject under the Securities Act, the Exchange Act or other federal or state statutory law or regulation, at common law or otherwise, insofar as such losses, claims, liabilities, expenses or damages arise out of or are based, directly or indirectly, upon (x) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement or the Prospectus or any amendment or supplement to the Registration Statement or the Prospectus or in any free writing prospectus or based on written information furnished by or on behalf of the Company filed in any jurisdiction in order to qualify the Common Stock under the securities laws thereof or filed with the Commission or (y) the omission or alleged omission to state in any such document a material fact required to be stated in it or necessary to make the statements in it not misleading; *provided*, *however*, that this indemnity agreement shall not apply to the extent that such loss, claim, liability, expense or damage arises from the sale of the Placement Shares pursuant to this Agreement and is caused directly or indirectly by an untrue statement or omission made in reliance upon and in conformity with solely Agent's Information. "Agent's Information" means, solely, the following information in the Prospectus: the third sentence of the ninth paragraph under the caption "Plan of Distribution" in the Prospectus. This indemnity agreement will be in addition to any liability that the Company might otherwise have.

(b) TD Cowen Indemnification. TD Cowen agrees to indemnify and hold harmless the Company and its directors and each officer of the Company that signed the Registration Statement, and each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act any and all loss, liability, claim, damage and expense described in the indemnity contained in Section 9(a), as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions, made in the Registration Statement (or any amendments thereto) or the Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with the Agent's Information.

(c) Procedure. Any party that proposes to assert the right to be indemnified under this Section 9 will, promptly after receipt of notice of commencement of any action against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section 9, notify each such indemnifying party of the commencement of such action, enclosing a copy of all papers served, but the omission so to notify such indemnifying party will not relieve the indemnifying party from (i) any liability that it might have to any indemnified party otherwise than under this Section 9 and (ii) any liability that it may have to any indemnified party under the

foregoing provision of this Section 9 unless, and only to the extent that, such omission results in the forfeiture of substantive rights or defenses by the indemnifying party. If any such action is brought against any indemnified party and it notifies the indemnifying party of its commencement, the indemnifying party will be entitled to participate in and, to the extent that it elects by delivering written notice to the indemnified party promptly after receiving notice of the commencement of the action from the indemnified party, jointly with any other indemnifying party similarly notified, to assume the defense of the action, with counsel reasonably satisfactory to the indemnified party, and after notice from the indemnifying party to the indemnified party of its election to assume the defense, the indemnifying party will not be liable to the indemnified party for any legal or other expenses except as provided below and except for the reasonable costs of investigation subsequently incurred by the indemnified party in connection with the defense. The indemnified party will have the right to employ its own counsel in any such action, but the fees, expenses and other charges of such counsel will be at the expense of such indemnified party unless (1) the employment of counsel by the indemnified party has been authorized in writing by the indemnifying party, (2) the indemnified party has reasonably concluded (based on advice of counsel) that there may be legal defenses available to it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (3) a conflict or potential conflict exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party will not have the right to direct the defense of such action on behalf of the indemnified party) or (4) the indemnifying party has not in fact employed counsel to assume the defense of such action within a reasonable time after receiving notice of the commencement of the action, in each of which cases the reasonable and documented out of pocket fees, disbursements and other charges of counsel will be at the expense of the indemnifying party or parties. It is understood that the indemnifying party or parties shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable and documented out of pocket fees, disbursements and other charges of more than one separate firm admitted to practice in such jurisdiction at any one time for all such indemnified party or parties. All such fees, disbursements and other charges will be reimbursed by the indemnifying party promptly as they are incurred. An indemnifying party will not, in any event, be liable for any settlement of any action or claim effected without its written consent. No indemnifying party shall, without the prior written consent of each indemnified party, settle or compromise or consent to the entry of any judgment in any pending or threatened claim, action or proceeding relating to the matters contemplated by this Section 9 (whether or not any indemnified party is a party thereto), unless such settlement, compromise or consent includes an unconditional release of each indemnified party from all liability arising or that may arise out of such claim, action or proceeding.

(d) Contribution. In order to provide for just and equitable contribution in circumstances in which the indemnification provided for in the foregoing paragraphs of this Section 9 is applicable in accordance with its terms but for any reason is held to be unavailable from the Company or TD Cowen, the Company and TD Cowen will contribute to the total losses, claims, liabilities, expenses and damages (including any investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted, but after deducting any contribution received by the Company from persons other than TD Cowen, such as persons who control the Company within the meaning of the Securities Act, officers of the Company who signed the Registration Statement and directors of the Company, who also may be liable for contribution) to which the Company and TD Cowen

may be subject in such proportion as shall be appropriate to reflect the relative benefits received by the Company on the one hand and TD Cowen on the other. The relative benefits received by the Company on the one hand and TD Cowen on the other hand shall be deemed to be in the same proportion as the total Net Proceeds from the sale of the Placement Shares (before deducting expenses) received by the Company bear to the total compensation received by TD Cowen from the sale of Placement Shares on behalf of the Company. If, but only if, the allocation provided by the foregoing sentence is not permitted by applicable law, the allocation of contribution shall be made in such proportion as is appropriate to reflect not only the relative benefits referred to in the foregoing sentence but also the relative fault of the Company, on the one hand, and TD Cowen, on the other, with respect to the statements or omission that resulted in such loss, claim, liability, expense or damage, or action in respect thereof, as well as any other relevant equitable considerations with respect to such offering. Such relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or TD Cowen, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and TD Cowen agree that it would not be just and equitable if contributions pursuant to this Section 9(d) were to be determined by pro rata allocation or by any other method of allocation that does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, liability, expense, or damage, or action in respect thereof, referred to above in this Section 9(d) shall be deemed to include, for the purpose of this Section 9(d), any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim to the extent consistent with Section 9(c) hereof. Notwithstanding the foregoing provisions of this Section 9(d), TD Cowen shall not be required to contribute any amount in excess of the commissions received by it under this Agreement and no person found guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 9(d), any person who controls a party to this Agreement within the meaning of the Securities Act, and any officers, directors, partners, employees or agents of TD Cowen, will have the same rights to contribution as that party, and each officer of the Company who signed the Registration Statement will have the same rights to contribution as the Company, subject in each case to the provisions hereof. Any party entitled to contribution, promptly after receipt of notice of commencement of any action against such party in respect of which a claim for contribution may be made under this Section 9(d), will notify any such party or parties from whom contribution may be sought, but the omission to so notify will not relieve that party or parties from whom contribution may be sought from any other obligation it or they may have under this Section 9(d) except to the extent that the failure to so notify such other party materially prejudiced the substantive rights or defenses of the party from whom contribution is sought. Except for a settlement entered into pursuant to the last sentence of Section 9(c) hereof, no party will be liable for contribution with respect to any action or claim settled without its written consent if such consent is required pursuant to Section 9(c) hereof.

10. Representations and Agreements to Survive Delivery. The indemnity and contribution agreements contained in Section 9 of this Agreement and all representations and warranties of the Company herein or in certificates delivered pursuant hereto shall survive, as of their respective dates, regardless of (i) any investigation made by or on behalf of TD Cowen, any controlling persons, or the Company (or any of their respective officers, directors or controlling

persons), (ii) delivery and acceptance of the Placement Shares and payment therefor or (iii) any termination of this Agreement.

11. Termination.

(a) TD Cowen shall have the right by giving notice to the Company as hereinafter specified at any time to terminate this Agreement if (i) any Material Adverse Change, or any development that could reasonably be expected to result in a Material Adverse Change has occurred that, in the reasonable judgment of TD Cowen, may materially impair the ability of TD Cowen to sell the Placement Shares hereunder, (ii) the Company shall have failed, refused or been unable to perform any agreement on its part to be performed hereunder, or (iii) any other condition of TD Cowen's obligations hereunder is not fulfilled, or (iv), any suspension or limitation of trading in the Placement Shares or in securities generally on Nasdaq shall have occurred. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g) (Expenses), Section 9 (Indemnification and Contribution), Section 10 (Representations and Agreements to Survive Delivery), Section 16 (Applicable Law; Consent to Jurisdiction) and Section 17 (Waiver of Jury Trial) hereof shall remain in full force and effect notwithstanding such termination. If TD Cowen elects to terminate this Agreement as provided in this Section 11(a), TD Cowen shall provide the required notice as specified in Section 12 (Notices).

(b) The Company shall have the right, by giving ten (10) days' notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g), Section 9, Section 10, Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination.

(c) TD Cowen shall have the right, by giving ten (10) days' notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g), Section 9, Section 10, Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination.

(d) Unless earlier terminated pursuant to this Section 11, this Agreement shall automatically terminate upon the issuance and sale of all of the Placement Shares through TD Cowen on the terms and subject to the conditions set forth herein; *provided* that the provisions of Section 7(g), Section 9, Section 10, Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination.

(e) This Agreement shall remain in full force and effect unless terminated pursuant to Sections 11(a), (b), (c), or (d) above or otherwise by mutual agreement of the parties; *provided, however,* that any such termination by mutual agreement shall in all cases be deemed to provide that Section 7(g), Section 9, Section 10, Section 16 and Section 17 shall remain in full force and effect.

(f) Any termination of this Agreement shall be effective on the date specified in such notice of termination; *provided, however,* that such termination shall not be effective until the close of business on the date of receipt of such notice by TD Cowen or the Company, as the

case may be. If such termination shall occur prior to the Settlement Date for any sale of Placement Shares, such Placement Shares shall settle in accordance with the provisions of this Agreement.

12. Notices. All notices or other communications required or permitted to be given by any party to any other party pursuant to the terms of this Agreement shall be in writing, unless otherwise specified in this Agreement, and if sent to TD Cowen, shall be delivered to TD Cowen at TD Securities (USA) LLC, 1 Vanderbilt Avenue, New York, NY 10017, fax no. 646-562-1130, Attention: Head of Equity Capital Markets, email: CIBLegal@tdsecurities.com, with a copy (which shall not constitute notice) to Goodwin Procter LLP, attention: Benjamin Marsh, email:BenjaminMarsh@goodwinlaw.com; or if sent to the Company, shall be delivered to KalVista Pharmaceuticals, Inc., 55 Cambridge Parkway, Suite 901E, Cambridge, Massachusetts 02142, attention: Chief Executive Officer, email: blp@kalvista.com, with a copy (which shall not constitute notice) to Fenwick & West LLP, attention: Julia Forbess, email: jforbess@fenwick.com. Each party to this Agreement may change such address for notices by sending to the parties to this Agreement written notice of a new address for such purpose. Each such notice or other communication shall be deemed given (i) when delivered personally or by verifiable facsimile transmission (with an original to follow) on or before 4:30 p.m., New York City time, on a Business Day (as defined below), or, if such day is not a Business Day on the next succeeding Business Day, (ii) on the next Business Day after timely delivery to a nationally-recognized overnight courier and (iii) on the Business Day actually received if deposited in the U.S. mail (certified or registered mail, return receipt requested, postage prepaid). For purposes of this Agreement, "**Business Day**" shall mean any day on which the Nasdaq and commercial banks in the City of New York are open for business.

13. Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the Company and TD Cowen and their respective successors and the affiliates, controlling persons, officers and directors referred to in Section 9 hereof. References to any of the parties contained in this Agreement shall be deemed to include the successors and permitted assigns of such party. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement. Neither party may assign its rights or obligations under this Agreement without the prior written consent of the other party; *provided*, *however*, that TD Cowen may assign its rights and obligations hereunder to an affiliate of TD Cowen without obtaining the Company's consent.

14. Adjustments for Share Splits. The parties acknowledge and agree that all share-related numbers contained in this Agreement shall be adjusted to take into account any share split, share dividend or similar event effected with respect to the Common Stock.

15. Entire Agreement; Amendment; Severability. This Agreement (including all schedules and exhibits attached hereto and Placement Notices issued pursuant hereto) constitutes the entire agreement and supersedes all other prior and contemporaneous agreements and undertakings, both written and oral, among the parties hereto with regard to the subject matter hereof. Neither this Agreement nor any term hereof may be amended except pursuant to a written instrument executed by the Company and TD Cowen. In the event that any one or more of the provisions contained herein, or the application thereof in any circumstance, is held invalid, illegal or unenforceable as written by a court of competent jurisdiction, then such provision shall be given

full force and effect to the fullest possible extent that it is valid, legal and enforceable, and the remainder of the terms and provisions herein shall be construed as if such invalid, illegal or unenforceable term or provision was not contained herein, but only to the extent that giving effect to such provision and the remainder of the terms and provisions hereof shall be in accordance with the intent of the parties as reflected in this Agreement.

16. Applicable Law; Consent to Jurisdiction. This Agreement shall be governed by, and construed in accordance with, the internal laws of the State of New York without regard to the principles of conflicts of laws. Each party hereby irrevocably submits to the non-exclusive jurisdiction of the state and federal courts sitting in the City of New York, borough of Manhattan, for the adjudication of any dispute hereunder or in connection with any transaction contemplated hereby, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof (certified or registered mail, return receipt requested) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law.

17. Waiver of Jury Trial. The Company and TD Cowen each hereby irrevocably waives any right it may have to a trial by jury in respect of any claim based upon or arising out of this Agreement or any transaction contemplated hereby.

18. Absence of Fiduciary Relationship. The Company acknowledges and agrees that:

(a) TD Cowen has been retained solely to act as an arm's length contractual counterparty to the Company in connection with the sale of the Placement Shares contemplated hereby and that no fiduciary, advisory or agency relationship between the Company and TD Cowen has been created in respect of any of the transactions contemplated by this Agreement, irrespective of whether TD Cowen has advised or is advising the Company on other matters;

(b) the Company is capable of evaluating and understanding and understands and accepts the terms, risks and conditions of the transactions contemplated by this Agreement;

(c) the Company has been advised that TD Cowen and its affiliates are engaged in a broad range of transactions which may involve interests that differ from those of the Company and that TD Cowen has no obligation to disclose such interests and transactions to the Company by virtue of any fiduciary, advisory or agency relationship; and

(d) the Company waives, to the fullest extent permitted by law, any claims it may have against TD Cowen, for breach of fiduciary duty or alleged breach of fiduciary duty and agrees that TD Cowen shall have no liability (whether direct or indirect) to the Company in respect of such a fiduciary claim or to any person asserting a fiduciary duty claim on behalf of or in right of the Company, including stockholders, partners, employees or creditors of the Company.

19. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Delivery of an executed Agreement by one party to the other may be made by facsimile or other electronic transmission (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com or www.echosign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

20. Recognition of the U.S. Special Resolution Regimes.

(a) In the event that TD Cowen is a Covered Entity and becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from TD Cowen of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.

(b) In the event that TD Cowen is a Covered Entity and TD Cowen or a BHC Act Affiliate of TD Cowen becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against TD Cowen are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

(c) For purposes of this Section 20; (a) "**BHC Act Affiliate**" has the meaning assigned to the term "affiliate" in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k), (b) "**Covered Entity**" means any of the following: (i) a "covered entity" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b); (ii) a "covered bank" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b); or (iii) a "covered FSI" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b), (c) "**Default Right**" has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable, and (d) "**U.S. Special Resolution Regime**" means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

[Remainder of Page Intentionally Blank]

If the foregoing correctly sets forth the understanding between the Company and TD Cowen, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement between the Company and TD Cowen.

Very truly yours,

TD SECURITIES (USA) LLC

By: /s/ Michael Murphy
Name: Michael Murphy
Title: Managing Director

ACCEPTED as of the date first-above written:

KALVISTA PHARMACEUTICALS, INC.

By: /s/ Benjamin Palleiko
Name: Benjamin L. Palleiko
Title: Chief Executive Officer

SCHEDULE 1

FORM OF PLACEMENT NOTICE

From: [ ]
Cc: [ ]
To: [ ]
Subject: TD Cowen At the Market Offering—Placement Notice

Gentlemen:

Pursuant to the terms and subject to the conditions contained in the Sales Agreement between KalVista Pharmaceuticals, Inc. (the "Company"), and TD Securities (USA) LLC ("TD Cowen") dated July 10, 2025 (the "Agreement"), I hereby request on behalf of the Company that TD Cowen sell up to [ ] shares of the Company's common stock, par value 0.001 per share, at a minimum market price of $_____ per share. Sales should begin on [DATE][the date of this Notice] and shall continue until [DATE] [all shares are sold].

SCHEDULE 2

Notice Parties

Company

Ben Palleiko	Chief Executive Officer
Brian Piekos	Chief Financial Officer

TD Cowen

Michael J. Murphy	Managing Director
William Follis	Managing Director
Adriano Pierroz	Director
Megan Sanford	Analyst

SCHEDULE 3

Compensation

TD Cowen shall be paid compensation equal up to 3.0% of the gross proceeds from the sales of Common Stock pursuant to the terms of this Agreement.

Exhibit 7(m)

OFFICER CERTIFICATE

The undersigned, the duly qualified and elected _____, of KalVista Pharmaceuticals, Inc. ("**Company**"), a Delaware corporation, does hereby certify in such capacity and on behalf of the Company, pursuant to Section 7(m) of the Sales Agreement dated July 10, 2025 (the "**Sales Agreement**") between the Company and TD Securities (USA) LLC, that to the best of the knowledge of the undersigned.

(i) The representations and warranties of the Company in Section 6 of the Sales Agreement (A) to the extent such representations and warranties are subject to qualifications and exceptions contained therein relating to materiality or Material Adverse Change, are true and correct on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof, except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date, and (B) to the extent such representations and warranties are not subject to any qualifications or exceptions, are true and correct in all material respects as of the date hereof as if made on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date; and

(ii) The Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied pursuant to the Sales Agreement at or prior to the date hereof.

By:_____
Name:
Title:

Date:_____

KALVISTA PHARMACEUTICALS, INC.

INSIDER TRADING POLICY

As adopted March 2025

I. PURPOSE

It is illegal for any employee, officer or director of KalVista Pharmaceuticals, Inc. (the "***Company***") to trade in the securities of the Company while in the possession of material nonpublic information about the Company. It is also illegal for any employee, officer or director of the Company to give material nonpublic information to others who may trade on the basis of that information.

In order to comply with federal and state securities laws governing (i) trading in Company securities while in the possession of material nonpublic information concerning the Company and (ii) tipping or disclosing material nonpublic information to any outside person, and in order to prevent the appearance of improper trading or tipping, the Company has adopted this Insider Trading Policy (this "***Policy***") for all of its employees, officers and directors, members of their immediate families and others living in their households, and venture capital funds and other entities (such as trusts and corporations) over which such employees, officers or directors have or share voting or investment control.

II. SCOPE

A. This Policy covers all employees, officers and directors of the Company, as well as their immediate family members, people sharing their households and anyone subject to their influence or control. Employees, officers and directors are responsible for ensuring compliance by their immediate families and affiliated or associated entities. An "***immediate family member***" under this Policy means any child, stepchild, parent, stepparent, spouse, domestic partner, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law of a security holder, and includes any person (other than a tenant or employee) sharing the household of that person. All of these individuals and entities are referred to in this policy collectively as "***Insiders***."

B. This Policy applies to any and all transactions in the Company's securities, including shares of its Common Stock and options to purchase Common Stock (as described in more detail in Section VI.E below), however acquired, and any other type of securities that the Company may issue, such as shares of preferred stock, convertible debentures, warrants and exchange-traded options or other derivative securities.

C. This Policy will be delivered to all employees, officers and directors upon its adoption by the Company, and to all new employees, officers and directors at the start of their employment or relationship with the Company. Upon first receiving a copy of this Policy or any revised versions, each employee, officer or director must sign a certification that he or she has received a copy and agrees to comply with the terms of this Policy. This certification and agreement will constitute consent for the Company to impose sanctions for violation of this Policy and to issue any necessary stop-transfer orders to the Company's transfer agent to enforce compliance with this Policy. As discussed in Section VII.B, sanctions for individuals may include demotion or other disciplinary actions, up to and including termination of employment, if the Company has a reasonable basis to conclude that this Policy has been violated. Section 16 Insiders, as defined below, may be required to certify compliance with this Policy on an annual basis.

D. This Policy allows for trades by Insiders (as defined below) made in compliance with Rule 10b5-1 ("***Rule 10b5-1***") promulgated by the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), subject to the approval of the General Counsel.

E. The Company may change these procedures or adopt such other procedures in the future as the Company considers appropriate in order to carry out the purposes of this Policy.

III. SECTION 16 INSIDERS; ACCESS PERSONS

A. ***Section 16 Insiders***. The Company has designated those persons listed on Exhibit A attached hereto as the officers (as defined in Rule 16a-1(f) of the Exchange Act) and directors who are subject to the reporting provisions and trading restrictions of Section 16 of the Exchange Act and the underlying rules and regulations promulgated by the Securities and Exchange Commission ("***SEC***"). Each such person, and each entity affiliated or associated with any such officer or director (other than venture capital funds affiliated with a director), is referred to herein as a "***Section 16 Insider***." Section 16 Insiders must obtain prior approval of all trades in Company securities from the General Counsel in accordance with the procedures set forth in Section VI.D below. The Company will amend Exhibit A from time to time as necessary to reflect the addition and the resignation or departure of Section 16 Insiders.

B. ***Access Persons.*** The Company has designated those persons listed on Exhibit A attached hereto as the persons who have regular access to material nonpublic information in the normal course of their duties for the Company (other than Section 16 Insiders); each person listed on Exhibit A is referred to herein as an "***Access Person***." Access Persons must obtain prior approval of all trades in Company securities from the General Counsel in accordance with the procedures set forth in Section VI.D below. The Company will amend Exhibit A from time to time as necessary to reflect the addition and the resignation, departure or change of status of Access Persons.

IV. INSIDER TRADING GENERAL COUNSEL DUTIES

The General Counsel will review and either approve or prohibit all proposed trades by Section 16 Insiders or Access Persons in accordance with the procedures set forth in Section VI.D below, except that with respect to proposed trades by the General Counsel, any proposed trades must be approved by the Company's Chief Executive Officer. In addition to the trading approval duties described in Section VI.D below, the duties of the General Counsel will include the following:

A. Administering and interpreting this Policy and monitoring and enforcing compliance with all the provisions and procedures set forth in this Policy.

B. Responding to all inquiries relating to this Policy and its procedures.

C. Designating and announcing special trading blackout periods during which no designated Section 16 Insider, Access Person or certain other Insiders may trade in Company securities.

D. Providing copies of this Policy and other appropriate materials to all current and new Insiders, and such other persons who the General Counsel determines may have access to material nonpublic information concerning the Company.

E. Revising this Policy as necessary to reflect changes in federal or state insider trading laws and regulations, subject to approval by the Company's Board of Directors or a duly authorized committee thereof.

F. Maintaining the accuracy of the list of Section 16 Insiders as attached on Exhibit A and the list of Access Persons as attached on Exhibit A and updating such lists periodically as necessary to reflect additions or deletions.

The General Counsel may designate one or more individuals who may perform the General Counsel's duties in the event that the General Counsel is unable or unavailable to perform such duties.

V. DEFINITION OF "MATERIAL NONPUBLIC INFORMATION"

A. "Material" Information

Information about the Company is "material" if it would be expected to affect the investment or voting decisions of a reasonable stockholder or investor, or if the disclosure of the information would be expected to alter significantly the total mix of the information in the marketplace about the Company. In simple terms, material information is any type of information that could reasonably be expected to affect the market price of the Company's securities. Both positive and negative information may be material. While it is not possible to identify all information that would be deemed "material," the following types of information ordinarily would be considered material:

- financial performance, such as quarterly and year-end earnings, and significant changes in financial performance or liquidity, as well as cash balance, burn and runway;
- significant communications to or from regulatory agencies, or other significant regulatory developments;
- new product launches or the introduction of new business strategies;
- the status of the Company's progress toward achieving significant Company goals;
- results of studies and clinical trials or other significant development milestones;
- potential material mergers and acquisitions or material sales of Company assets or subsidiaries;
- important pipeline expansion;

- significant cybersecurity incidents or data breaches;
- stock splits, public or private securities/debt offerings, or changes in Company dividend policies or amounts;
- significant changes in senior management or the Company's Board of Directors;
- significant developments regarding the Company's products, technology or business operations;
- new major contracts, customers, distributors or suppliers, or the loss of a major customer; and
- initiation of a significant lawsuit or regulatory inquiries or developments in existing litigation or inquiries.

B. "Nonpublic" Information

Material information is "nonpublic" if it has not been widely disseminated to the public, for example, through major newswire services, national news services, pre-announced webcasts or financial news services. For the purposes of this Policy, information will be considered public, i.e., no longer "nonpublic," after the second full trading day following the Company's widespread public release of the information.

C. Consult the General Counsel for Guidance

Insiders who are unsure whether the information that they possess is material or nonpublic must consult the General Counsel for guidance before trading in any Company securities.

VI. STATEMENT OF COMPANY POLICY AND PROCEDURES

A. Prohibited Activities

1. No Insider may trade in Company securities while possessing material nonpublic information concerning the Company (except as permitted by Section VI.C). It does not matter that there may exist a justifiable reason for a purchase or sale apart from the nonpublic information; if the Insider has material nonpublic information, the prohibition still applies.

2. No Insider may trade in Company securities outside of the applicable "trading windows" described in Section VI.B below and no Insider may trade in the Company securities during any special trading blackout periods designated by the General Counsel that are applicable to such Insider (except as permitted by Section VI.C).

3. No Section 16 Insider or Access Person may trade in Company securities unless the trade has been approved by the General Counsel in accordance with the procedures set forth in Section VI.D below (except as permitted by Section VI.C).

4. The General Counsel may not trade in Company securities unless the trade has been approved by the Company's Chief Executive Officer in accordance with the procedures set forth in Section VI.D below (except as permitted by Section VI.C).

5. No Insider may disclose material nonpublic information concerning the Company to any outside person (including family members, analysts, individual investors and members of the investment community and news media), unless required as part of the regular duties of such employee, director or officer for the Company or authorized by the General Counsel. In any instance in which such information is disclosed to outsiders, the Company will take such steps as are necessary to preserve the confidentiality of the information, including requiring the outsider to agree in writing to comply with the terms of this Policy and/or sign a confidentiality agreement. All inquiries from outsiders regarding material nonpublic information about the Company must be forwarded to the General Counsel.

6. No Insider may give trading advice of any kind about the Company to anyone while possessing material nonpublic information about the Company, except that Insiders should advise others not to trade if doing so might violate the law or this Policy. The Company strongly discourages all employees, officers or directors from giving trading advice concerning the Company to third parties even when the employees, officers and directors do not possess material nonpublic information about the Company.

7. No Insider may engage in hedging or monetization transactions, sell, or trade in any interest or position relating to the future price of Company securities, such as a put option, a call option, or a short sale (including a short sale "against the box").

8. No Insider may (a) trade in the securities of any other public company while possessing material nonpublic information concerning that company obtained in the course of service as an employee, officer or director, (b) "tip" or disclose such material nonpublic information concerning any other public company to anyone, or (c) give trading advice of any kind to anyone concerning any other public company while possessing such material nonpublic information about that company.

9. No Insider may purchase Company securities on margin, borrow against any account in which Company securities are held, or pledge Company securities as collateral for a loan, except that such employee, officer, or director may pledge Company securities as collateral for a loan (not including margin debt) if they can clearly demonstrate the financial capacity to repay the loan without resort to the pledged securities. Any Insider wishing to pledge Company securities as collateral for a loan must submit a request for pre-clearance to the General Counsel at least two weeks prior to the proposed execution of documents evidencing the proposed pledge.

10. Except as permitted by Section VI.C, no Insider may make a gift or other transfer without consideration of Company securities during a period when that Insider is not permitted to trade.

11. No Insider may participate, in any manner other than passive observation, in any of the investment or stock-related Internet "chat" rooms, blogs, social media sites or message boards relating to the Company.

12. No entity over which an Insider has or shares voting or investment control may distribute securities of the Company to its limited partners, general partners or stockholders during a period when the Insider is not permitted to trade, unless the limited partners, general partners or stockholders of that entity have agreed in writing to hold the securities until the trading window described in Section VI.B below is first open.

13. It is the Company's policy to disclose material information concerning the Company to the public only in accordance with its Corporate Communications Policy in order to avoid inappropriate publicity and to ensure that all such information is communicated in a way that is reasonably designed to provide broad, non-exclusionary distribution of information to the public. All inquiries or calls from the press, investors and financial analysts should be referred to a designated Company spokesperson. Please see the Company's Corporate Communications Policy for details.

B. Trading Windows and Blackout Periods

1. ***Trading Windows for Section 16 Insiders and Access Persons.*** Subject to the exceptions described in Section VI.C below, after obtaining trading approval from the General Counsel in accordance with the procedures set forth in Section VI.D below, Section 16 Insiders and Access Persons listed on Exhibit A, attached hereto, may trade in Company securities only during the period beginning after the second full trading day following the Company's widespread public release of quarterly or year-end earnings, and ending at the close of trading on the last day of the last month of the then-current quarter, as long as they are not in possession of material nonpublic information or subject to any special trading blackout period.

2. ***Trading Windows for Affiliated Venture Capital Funds.*** Venture capital funds affiliated with a director may trade in Company securities only during the period beginning after the second full trading day following the Company's widespread public release of quarterly or year-end earnings, and ending at the close of trading on the 15th day of the last month of the then-current quarter, as long as they are not in possession of material nonpublic information or subject to any special trading blackout period.

3. ***No Trading During Trading Windows While in the Possession of Material Nonpublic Information.*** No Insider possessing material nonpublic information concerning the Company may trade in Company securities even during applicable trading windows, except as permitted by Section VI.C. Persons possessing such information may trade during a trading window only after the second full trading day following the Company's widespread public release of the information.

4. ***No Trading During Blackout Periods.*** The General Counsel may designate special trading blackout periods that apply to particular individuals or groups of persons for such time as is determined by the General Counsel. No Insider may trade in Company securities outside of the applicable trading windows or during any special blackout periods that the General Counsel may designate that applies to such Insider,

except as permitted by Section VI.C. No Insider subject to a special trading blackout period may disclose to anyone not subject to the special trading blackout period that a special trading blackout period has been designated or that one previously was in place because that is also confidential information.

C. Exception for Transfers Pursuant to Rule 10b5-1 Plans

1. The Company allows Insiders to trade in Company securities while in possession of material nonpublic information, outside of a trading window or during a special trading blackout period, pursuant to a written plan for selling or purchasing a predetermined number of shares that is entered into while an Insider is not in possession of material non- public information as contemplated in Rule 10b5-1 (a, "***Rule 10b5-1 Plan***") that is approved in writing by email by the General Counsel.

D. Procedures for Approving Trades

1. ***Section 16 Insiders and Access Persons.*** No Section 16 Insider or Access Person may trade in Company securities (except as permitted by Section VI.C), until:

a) The person trading has notified the General Counsel in writing via email of the amount and nature of the proposed trade(s);

b) The person trading has certified to the General Counsel in writing via email no earlier than two business days prior to the proposed trade(s) that:

(1) such person is not in possession of material nonpublic information concerning the Company and, to such person's knowledge, such person will not be in possession of material nonpublic information concerning the Company on the date of the proposed trade; and

(2) the proposed trade(s) do not violate the trading restrictions of Section 16 of the Exchange Act, Rule 144 of the Securities Act (if applicable) or any other securities laws; and

c) The General Counsel has approved the trade(s) and has certified such approval in writing via email, except as provided in paragraph 2 of this subsection.

d) The person must notify the General Counsel promptly in writing of any changes to the certification in (b) prior to the proposed trade.

2. ***Rule 10b5-1 Plans.*** No trades shall be treated as having been made pursuant to a Rule 10b5-1 Plan under this Policy unless:

a) The Rule 10b5-1 Plan complies with the requirements of Rule 10b5-1 and this policy;

b) The person establishing the Rule 10b5-1 Plan has certified to the General Counsel in writing via email no earlier than two business days prior to the date that the Rule 10b5-1 Plan is formally adopted (and shall not have withdrawn such certification prior to such adoption) that as of such date and as of the adoption date of the 10b5-1 Plan, that:

(1) such person is not, and to their knowledge, will not be aware of material nonpublic information concerning the Company,

(2) all such trades to be made pursuant to Rule 10b5-1 Plan will be made in accordance with applicable SEC rules,

(3) such person is adopting the 10b5-1 Plan in good faith and not as part of a plan or scheme to evade the prohibitions of Section 10(b) of the Exchange Act and Rule 10b-5 of the Exchange Act, and

(4) such person will act in good faith with respect to the 10b5-1 Plan throughout its duration;

c) Such person adopting the 10b5-1 Plan must notify the General Counsel promptly via email and withdraw the certification if any changes of circumstances prior to the adoption date of the 10b5-1 Plan have or will render such certification to be inaccurate as of that time;

d) The first trade under the 10b5-1 Plan does not occur (i) for a Section 16 Insider: until the later of (A) ninety (90) days after adoption of the 10b5-1 Plan and (B) two (2) business days following the disclosure of the Company's financial results in a Form 10-Q or Form 10-K for the completed fiscal quarter in which the 10b5-1 Plan was adopted that discloses the Company's financial results (but not to exceed 120 days following the adoption of the 10b5-1 Plan); and (ii) for persons other than Section 16 Insiders: thirty (30) days after adoption of the 10b5-1 Plan, in each case, following our General Counsel's approval of the 10b5-1 Plan. These waiting periods are collectively referred to as the "***Cooling-Off Period***";

e) The 10b5-1 Plan is not a single-trade 10b5-1 Plan adopted during the 12-month period immediately following such person's adoption of another single-trade 10b5-1 Plan, subject to the exceptions noted in Rule 10b5-1, which are provided for in the Appendix;

f) The 10b5-1 Plan is adopted during a trading window and not during any blackout period; and

g) A person may have no more than one 10b5-1 Plan adopted at any point in time (i.e., multiple concurrent or overlapping plans are prohibited), subject to the exceptions noted in Rule 10b5-1, which are provided in the Appendix. One of these exceptions is for plans authorizing certain "sell-to-cover" transactions.

3. ***Modification of a Rule 10b5-1 Plan***. Once an approved Rule 10b5-1 Plan is in place, approval from the General Counsel is necessary to make certain changes to it. Modifying or changing the amount, price, or timing of the purchase or sale of our securities underlying the Rule 10b5-1 Plan (or a modification or change to a written formula or algorithm, or computer program that affects the amount, price, or timing of the purchase or sale of such securities) (any such modification or change, a "***Plan Modification***") will be deemed to be the same as terminating the existing Rule 10b5-1 Plan and entering into a new Rule 10b5-1 Plan. As a result, the approval process for a Plan Modification is the same as the approval process for initially establishing a Rule 10b5-1 Plan, including being subject to a new Cooling-Off Period. The Company discourages employees, officers or directors from making multiple Plan Modifications, as that may give the appearance that such person is trading on material non-public information under the guise of that plan. Plan Modifications can only be made during a trading window and not during any blackout period and only when such person is not in possession of material non-public information. For other modifications to a 10b5-1 Plan, the General Counsel must be notified of such modification in writing at least two business days prior to the modification and such modification must be approved by the General Counsel.

4. ***Termination of a Rule 10b5-1 Plan***. Once an approved 10b5-1 Plan is in place, approval from the General Counsel will be necessary to terminate it.

5. ***No Other Trading Arrangements.*** Insiders are not allowed to enter into "non-Rule 10b5-1 trading arrangements" (as defined in Regulation S-K Item 408(c)) unless otherwise approved in advance by the General Counsel.

6. ***No Obligation to Approve Trades.*** The existence of the foregoing approval procedures does not in any way obligate the General Counsel to approve any trades requested by an Insider of the Company or to approve any Rule 10b5-1 Plan. The General Counsel may reject any trading requests or Rule 10b5-1 Plans at his or her sole reasonable discretion. Approval of a Rule 10b5-1 Plan by the General Counsel shall not be considered a determination by the Company or the General Counsel that the Rule 10b5-1 Plan satisfies the requirements of Rule 10b5-1.

E. Employee Stock Purchase and Equity Incentive Plans

1. ***Employee Stock Purchase Plan***. The trading prohibitions and restrictions set forth in this Policy do not apply to periodic wage withholding contributions by the Company or employees to the Company's Employee Stock Purchase Plan that is used to purchase Company securities pursuant to the employees' advance instructions. However, no officers may alter their instructions regarding the level of withholding or purchase by the officer of Company securities under such plan while in the possession of material

nonpublic information. Any sale of securities acquired under such plan is subject to the prohibitions and restrictions of this Policy.

2. ***Stock Option Plans****.* The trading prohibitions and restrictions set forth in this Policy do not apply to the exercise of stock options granted under our equity incentive plans for cash or by delivering to the Company previously owned Company stock or through a net exercise of a stock option that is permitted by the Company's equity incentive plans and that does not involve a sale of shares in the open market. The trading prohibitions and restrictions set forth in this Policy also do not apply to the payment of taxes in connection with exercising stock options granted under our equity incentive plans pursuant to net withholding arrangements approved by the Company for the payment of taxes upon the exercise of stock options and that does not involve a sale of shares in the open market. However, the sale of any shares issued on the exercise of Company-granted stock options, as well as any cashless exercise of Company-granted stock options in which stock is sold on the open market to pay the exercise price or taxes (i.e., "same-day sales") are subject to trading restrictions under this Policy.

3. ***RSUs***. The trading prohibitions and restrictions set forth in this Policy do not apply to the settlement of RSUs pursuant to a net settlement or a "sale to cover" for non-discretionary, automatic tax withholdings initiated and approved by the Company for the payment of taxes upon the vesting of RSUs.

F. Priority of Statutory or Regulatory Trading Restrictions

The trading prohibitions and restrictions set forth in this Policy will be superseded by any greater prohibitions or restrictions prescribed by federal or state securities laws and regulations, e.g., contractual restrictions on the sale of securities, short- swing trading by Section 16 Insiders or restrictions on the sale of securities subject to Rule 144 under the Securities Act. Any Insider who is uncertain whether other prohibitions or restrictions apply should ask the General Counsel.

VII. POTENTIAL CIVIL, CRIMINAL AND DISCIPLINARY SANCTIONS

A. Civil and Criminal Penalties

The consequences of prohibited insider trading or tipping can be severe. Persons violating insider trading or tipping rules may be required to disgorge the profit made or the loss avoided by trading, pay the loss suffered by the persons who purchased securities from or sold securities to the insider tippee, pay civil penalties, pay a criminal penalty serve a jail term. The Company and/or the supervisors of the person violating the rules may also be required to pay major civil or criminal penalties and could under certain circumstances be subject to private lawsuits by contemporaneous traders for damages suffered as a result of illegal insider trading or tipping by persons under the Company's control.

B. Company Discipline

Violation of this Policy or federal or state insider trading or tipping laws by any (i) employee or officer may subject such employee or officer to disciplinary action by the Company, up to and including termination for cause, and (ii) director may subject such director to dismissal proceedings. A violation of this Policy is not necessarily the same as a violation of law. In fact, for the reasons indicated above, this Policy is intended to be broader than the law. The Company reserves the right to determine, in its own discretion and on the basis of the information available to it, whether this Policy has been violated. The Company may determine that specific conduct violates this Policy, whether or not the conduct also violates the law. It is not necessary for the Company to await the filing or conclusion of a civil or criminal action against the alleged violator before taking disciplinary action.

C. Reporting of Violations

Any Insider who violates this Policy or any federal or state laws governing insider trading or tipping, or knows of any such violation by any other Insider, must report the violation immediately to the General Counsel, Chief Financial Officer or the Chief Executive Officer, or through the procedures outlined in the Company's Whistleblower and Complaint Policy. Upon learning of any such violation, the General Counsel or the Chief Executive Officer, in consultation with the Company's legal counsel, will determine whether the Company should release any material nonpublic information, or whether the Company should report the violation to the SEC or other appropriate governmental authority.

VIII. INQUIRIES

Please direct all inquiries regarding any of the provisions or procedures of this Policy to the General Counsel.

IX. CHANGES TO THE POLICY; EFFECTIVE DATE

A. Policy Modifications or Waivers

The Company's Board of Directors reserves the right in its sole discretion to modify or grant waivers to this policy. Any amendments or waivers may be publicly disclosed if required by applicable laws, rules and regulations. For the avoidance of doubt, unless explicitly stated by the Board of Directors, any waiver, amendment or modification of the policy by the Board of Directors shall not be considered a waiver of the Company's Code of Conduct and Ethics.

B. Effective Date

The effective date of this policy is March 17, 2025. The amendments to this policy will not apply to any existing Rule 10b5-1 Plan that was entered into prior to March 17, 2025.

APPENDIX

Exceptions to the Multiple, Overlapping 10b5-1 Plan Restriction

Such exceptions are:

- An eligible "sell-to-cover" 10b5-1 Plan where such plan authorizes an agent to sell only such securities as are necessary to satisfy tax withholding obligations arising exclusively from the vesting of a compensatory award, such as restricted stock or stock appreciation rights, and the Insider does not otherwise exercise control over the timing of such sales. For the avoidance of doubt, this exception does not extend to sales incident to the exercise of option awards.

- A series of separate contracts with different broker-dealers or other agents acting on behalf of the person (other than the Company) to execute trades thereunder may be treated as a single 10b5-1 Plan, provided that the individual constituent contracts with each broker-dealer or other agent, when taken together as a whole, meet all of the applicable conditions of and remain collectively subject to the provisions of Rule 10b5-1, including that a modification of any individual contract acts as modification of the whole 10b5-1 Plan, as defined in Rule 10b5-1(c)(1)(iv). The substitution of a broker-dealer or other agent acting on behalf of the person (other than the Company) for another broker-dealer that is executing trades pursuant to a 10b5-1 Plan shall not be a "Plan Modification" as long as the purchase or sales instructions applicable to the substitute and substituted broker are identical with respect to the prices of securities to be purchased or sold, dates of the purchases or sales to be executed, and amount of securities to be purchased or sold.

- One later-commencing 10b5-1 Plan for purchases or sales of any securities of the Company on the open market under which trading is not authorized to begin until after all trades under the earlier-commencing 10b5-1 Plan are completed or expired without execution. However, the first trade under such later-commencing 10b5-1 Plan must be scheduled after the "Effective Cooling-Off Period," or the Cooling-Off Period that would be applicable to the later-commencing 10b5-1 Plan if the date of adoption of the later- commencing 10b5-1 Plan were deemed to be the date of termination of the earlier- commencing 10b5-1 Plan.

Exceptions to the Single-Trade 10b5-1 Plan Restriction

There is an exception for eligible "sell-to-cover" 10b5-1 Plans where the plan authorizes an agent to sell only such securities as are necessary to satisfy tax withholding obligations arising exclusively from the vesting of a compensatory award, such as restricted stock or stock appreciation rights, and the Insider does not otherwise exercise control over the timing of such sales.

EXHIBIT A

KALVISTA PHARMACEUTICALS, INC.

Section 16 Insider

(*As of March 2025*)

Exhibit 21.1

List of Subsidiaries of KalVista Pharmaceuticals, Inc.

Name of Subsidiary	Jurisdiction of Incorporation or Organization
KalVista Pharmaceuticals Limited (UK)	England and Wales
KalVista Securities Holding Corporation	Massachusetts
KalVista Pharmaceuticals (Ireland) Limited	Ireland
KalVista Pharmaceuticals Switzerland GmbH	Switzerland
KalVista Pharmaceuticals Japan K.K.	Japan
KalVista Pharmaceuticals Germany GmbH	Germany

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-280759 on Form S-3 and Registration Statement Nos. 333-203721, 333-215184, 333-216032, 333-217008, 333-226442, 333-230279, 333-237059, 333-254178, 333-257871, 333-263431, 333-269174, 333-272777, 333-276444, 333-280579 and 333-284321 on Form S-8 of our report dated July 10, 2025, relating to the financial statements of KalVista Pharmaceuticals, Inc. appearing in this Annual Report on Form 10-K for the year ended April 30, 2025.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
July 10, 2025

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) OR 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 Rules 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 10, 2025

By: /s/ Benjamin L Palleiko
Benjamin L Palleiko
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Brian Piekos, 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 Rules 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 10, 2025

By: /s/ Brian Piekos
Brian Piekos
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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 Executive Officer of KalVista Pharmaceuticals, Inc. (the "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, 2025 (the "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, as amended; and
- the information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company for the periods presented therein.

Date: July 10, 2025

By: /s/ Benjamin L Palleiko
Benjamin L. Palleiko
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

I, Brian Piekos, Chief Financial Officer of KalVista Pharmaceuticals, Inc. (the "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, 2025 (the "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, as amended; and
- the information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company for the periods presented therein.

Date: July 10, 2025

By: /s/ Brian Piekos
Brian Piekos
Chief Financial Officer
(Principal Financial and Accounting Officer)